Competition and Regulation in India 2023

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Regulatory Deficit in Access to Equitable Healthcare

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Foreword

India Competition and Regulation Report (ICRR) 2023 delves deep into the theme of "Regulatory Deficit in Access to Equitable Healthcare." It talks about the critical discourse that addresses the pressing challenges faced by our healthcare sector in ensuring equitable access to quality services.

The ICRR 2023 delves into the intricate dynamics of the regulatory framework governing healthcare in India, aiming to analyse existing gaps and deficiencies while seeking avenues for reform that will pave the way for a more inclusive and accessible healthcare ecosystem. This report aims to identify regulatory deficits and propose innovative solutions that promote competition while safeguarding the interests of patients and healthcare providers alike.

Access to healthcare is a fundamental right and an essential aspect of human dignity. The COVID-19 pandemic has cast a harsh spotlight on the inequities in healthcare access, underscoring the urgency of addressing the regulatory deficits that perpetuate these disparities. In India, as in many other countries, these deficits manifest as a complex interplay of market dynamics, regulatory frameworks, affordability challenges and geographical barriers. Fostering competition in healthcare markets can be a potent force for positive change. By encouraging market dynamics that prioritise affordability, quality, and innovation we can pave the way.

The Competition Commission of India (CCl) recognises the need to address regulatory deficits perpetuating healthcare access disparities. The CCl has observed that information asymmetry in the pharmaceutical/healthcare sector significantly restricts consumer choice, leading to industry practices that choke competition. CCl has consistently worked in the direction of infusing competition in this sector.

We must recognise that fostering competition in healthcare markets can be a potent force for positive change. By encouraging market dynamics that prioritise affordability, quality and innovation, we can pave the way for improved access to healthcare services. However, we also acknowledge that competition alone cannot address all the challenges we face.

It is crucial to strike a harmonious balance between competition and regulation, recognising that these are not opposing forces but complementary tools in our quest for equitable healthcare. Effective regulation can ensure that competition works to the advantage of the patients, safeguarding their interests and promoting a healthcare ecosystem that is fair, efficient and accessible.

In conclusion, the pursuit of equitable healthcare access is a shared responsibility that transcends borders, ideologies and professions. It is a cause that unites us in our commitment to the well-being of all individuals, regardless of their socioeconomic status or geographic location. Let us take inspiration and work collaboratively to bridge the regulatory deficit, ensuring that equitable healthcare becomes a reality for every citizen.

New Delhi
November 30, 2023

Ravneet Kaur
Chairperson
Competition Commission of India

Preface

Over the past years, the world has grappled with an unprecedented health crisis, the likes of which have never been witnessed before. The COVID-19 pandemic and its evolving variants have not only had profound effects on individuals but have also significantly influenced various economic sectors. Global healthcare systems played a crucial role in monitoring and responding to the pandemic, striving to minimise its adverse consequences. Furthermore, this crisis served as a wake-up call for policymakers and regulatory bodies. With millions of lives tragically lost, the pandemic had immeasurable consequences for the working-class population.

The healthcare industry faces a multitude of regulatory and competition challenges in its current form. These challenges have significant implications for the accessibility, affordability, and quality of healthcare services.

One of the key steps in addressing the regulatory challenges is their identification, and assessment of their impact. Regulatory challenges of deficits are egregious to universal and equitable access to healthcare. Access to equitable healthcare not only includes availability but also access both physical and financial, and equality in quality of services. In addition to welcoming the healthcare reforms that the pandemic forced upon us, it is essential that any progress is not lost and innovation comes forth in our next steps. For this, a collaboration between all relevant stakeholders including policymakers, regulators, industry players and most importantly consumers to find solutions is desirable.

CUTS and CIRC have been publishing India Competition and Regulation Reports (ICRRs) every second year since 2007 and I have been closely involved in the process of their preparation. These reports have been raising major issues concerned with competition and the regulatory environment in India.

The ICRR 2023, in its ninth edition, covers 22 chapters. Upholding tradition, the initial two chapters provide an 'overview' and a 'perception survey on regulation and competitive scenarios in the country.' The subsequent chapters delve into significant subjects, showcasing perspectives from domain experts, thereby undertaking a scholarly examination of the regulatory landscape and competitive dynamics.

The upcoming ICRR 2023 edition, albeit a comprehensive one is focussed on addressing modern regulatory and competition challenges within the healthcare

sector. It delves into various aspects of the healthcare industry, including healthcare services, pharmaceuticals, medical devices, pathology, medical education, medical insurance, global healthcare issues like equitable vaccine access, and preventive healthcare measures such as food and road safety, among others.

The report's gaze extends to crucial facets such as mental healthcare, medical waste management, and the imperative discourse on mitigating API import dependence. From the latent potential of medical tourism to the pandemic's resounding call for equitable drug access, this anthology serves as a guiding beacon through the labyrinth of healthcare regulations.

The chapters of ICRR 2023 cover a diverse range of critical issues in the healthcare sector. These include barriers to entry, encompassing both regulatory and non-regulatory challenges that hinder market access. The examination of anti-competitive practices, such as cartels and collusions, sheds light on unfair market behaviours. Additionally, the abuse of market dominance and the implications of mergers and acquisitions are explored.

Regulatory conflicts and overlaps, essential for effective governance, have also been covered. Safeguarding consumer rights and ensuring data privacy in the digital healthcare landscape will be paramount, along with strategies to promote innovation and discussions on achieving optimal regulation. The primary objective is to identify and analyse current regulatory and competition issues that impede healthcare access and provide recommendations to address these concerns effectively.

Similar to previous editions, ICRRs have consistently brought attention to contemporary regulatory and competition concerns in India. Just as in the past, I anticipate that ICRR 2023 will provide valuable policy insights that contribute to the development of a sustainable, accessible and equitable healthcare system in India and to the goal of making India a developed nation.

New Delhi
November 2023

Nitin Desai
Former Under Secretary,
United Nations (UN) &
Distinguished Fellow, CUTS International

Editor's Note

Ensuring quality healthcare for citizens has been high on the government's agenda, particularly during and after the pandemic. Both the Central and state governments in India are making efforts to move in the direction of achieving universal health coverage and delivering affordable quality healthcare services to all. Though the Indian healthcare network is among the largest in the world, the high out-of-pocket expenditures are still a concern, mainly for the poorer sector.

While more investments in modernising the health infrastructure and improvements in health systems are being continuously reiterated, the role of regulations and competition in enhancing access to affordable healthcare has not been much talked about. The present edition of the India Competition and Regulation Report (ICRR) on the theme "Regulatory Deficit in Access to Equitable Healthcare" endeavours to fill this gap.

The ICRR series, a flagship biennial publication of CUTS International and the CUTS Institute for Regulation & Competition (CIRC) since 2007, has served as an invaluable compendium of policy-relevant research, shedding light on the state of competition and regulation in India, encompassing various sectors and contemporary cross-cutting issues.

The present edition of ICRR delves into regulatory or competition aspects to various facets of healthcare, including healthcare services, pharmaceuticals, medical devices, pathology, medical education, medical insurance, global issues like TRIPs waiver, and preventative healthcare issues like road safety and food safety. These topics encompass the broad spectrum of healthcare and insights into the regulatory frameworks that govern them.

To address regulatory issues in various segments of healthcare, for the first time a deviation has been made as far as the number of chapters are concerned. As against eight to ten chapters in earlier versions, this edition has a total of 22 chapters, thus, requiring a very diverse expertise.

Our commitment to providing this very comprehensive and insightful report required the active participation of several domain experts from shaping the chapter outlines to contributing chapters to providing reviews and comments. Their contributions have been invaluable in shaping this edition and ensuring that the report offers well-rounded perspectives on the multifaceted challenges and opportunities within the healthcare sector in India.

First, we are extremely grateful to the National Reference Group (NRG) members, who deliberated at length to finalise the ICRR chapters covering various segments of healthcare. We are grateful to Nitin Desai, Indu Bhushan, Dipika Jain, Darren Punnen, Milind Antani, Santosh Mehrotra, Ajay Shankar, Sanjay Mitra, Amir Ullah Khan, Saleema Razvi, Rupa Chanda, Archana Jatkar, Alok V. Kulkarni, Neeraj Jain, Sabine Kapasi, Nitya Nanda, Sunil Nandraj, Rama Baru and Chandrakant Lahariya.

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We are grateful to Ravneet Kaur for writing the Foreword and Nitin Desai for writing the Preface.

With this, we proudly present to you this edition of ICRR, dedicated to the theme *Regulatory Deficit in Access to Equitable Healthcare*. We hope you will find this edition as interesting as the earlier editions of ICRRs (available at: https://cuts-ccier.org/icrr-2021/).

We would appreciate receiving your comments at: ccier@cuts.org or ujk@cuts.org.

Jaipur

Pradeep S Mehta
and Ujjwal Kumar
CUTS International

Abbreviations

ABDM:	Ayushman Bharat Digital Mission
ABHA:	Ayushman Bharat Health Account
ABS:	Anti-lock Braking Systems
AGCM:	Autorità Garante della Concorrenza e del Mercato
AGMARK:	Agricultural Marketing Standard
AIIMS:	All-India Institute of Medical Sciences
AIOCD:	All India Organisation of Chemists and Druggists
AKCDA:	All Kerala Chemists & Druggists Association
ALS:	Advanced Life Support
APIs:	Active Pharmaceutical Ingredients
ARI:	Apollo Radiology International
AWSS:	Anganwadi Services Scheme
BITs:	Bilateral Investment Treaties
BLS:	Basic Life Support
BMW:	Bio-medical Waste
BNVSAP:	Bharat New Vehicle Safety Assessment Programme
BoG:	Board of Governors
BOT:	Build-Operate-Transfer
CAC:	Central Advisory Committee
CAG:	Comptroller and Auditor General
CBMWTF:	Common Bio-Medical Waste Treatment Facility
CCI:	Competition Commission of India
CDA:	Cyclohexane Diacetic Acid
CDSCO:	Central Drugs Control Standards Organisation
CE:	Clinical Establishment
CEPI:	Coalition for Epidemic Preparedness Innovations
CERC:	Clinical Establishment Regulatory Commission
CEs:	Clinical Establishments
CGHS:	Central Government Health Scheme
CHOs:	Community Health Officers

CMVR:	Central Motor Vehicles Rules
CNNS:	Comprehensive National Nutrition Survey
CPCB:	Central Pollution Control Board
CPD:	Continuous Professional Development
CRSs:	Child Restraint Systems
CSIR:	Council of Scientific and Industrial Research
CVDs:	Cardiovascular Disease
CVITA:	COVID-19 Vaccine Investment and Trade Agreement
D&C:	Drug and Cosmetics
DALYs:	Disability-Adjusted Life Years
DBFOM:	Design-Build-Finance-Operate-Maintain
DIET:	District Institutes of Education and Training,
DIs:	Drug Intermediates
DISHA:	Digital Information Security in Healthcare Act
DO:	Designated Officer
DPCO:	Drug Price Control Order
DPDPB:	Digital Personal Data Protection Bill
DSM:	Diagnostic and Statistical Manual
DVA:	Domestic Value Addition
ECHS:	Ex-servicemen Contributory Health Scheme
ECT:	Electroconvulsive Therapy
EHRs:	Electronic Health Records
EMS:	Emergency Medical Services
e-PHI:	e-Personal Health Information
ESIC:	Employees' State Insurance Corporation
EU:	European Union
FBO:	Food Business Operator
FDI:	Foreign Direct Investment
FNE:	Fiscalía Nacional Económica
FoSCoRIS:	Food Safety Compliance via a Regular Inspection and Sampling System
FoSCoS:	Food Safety and Compliance System
FPOs:	Farmers Producer Organisations
FRAND:	Fair, Reasonable and Non-Discriminatory
FRCS:	Fellowship of the Royal College of Surgeons
FSO:	Food Safety Officer
FSS Act:	Food Safety and Standards Act, 2006,
FSSAI:	Food Safety and Standards Authority of India

FSTaC	FSSAI's Flagship Food Safety Training and Certification
FTAs:	Foreign Tourist Arrivals
FTC:	Federal Trade Commission
GDP:	Gross Domestic Product
GHI:	Global Hunger Index
Global NCAP:	Global New Car Assessment Programme
GoI:	Government of India
GSK:	GlaxoSmithKline
GSPA-PHI:	Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property
GVK:	Gunapati Venkata Krishna
HCFs	Healthcare Facilities
HCOs:	Healthcare Organisations
HDMP:	Health Data Management Policy
HSW:	Hospital Solid Waste
HWCs:	Health and Wellness Centers
ICDS:	Integrated Child Development Services
ICMR:	Indian Council for Medical Research
IDSP:	Integrated Disease Surveillance Project
IP:	Intellectual Property
IPHS:	Indian Public Health Standards
IRDAI:	Insurance Regulatory and Development Authority of India
ISPE:	International Society of Pharmaceutical Engineering
ISRO:	Indian Space Research Organisation
ISSNIP:	ICDS Systems Strengthening & Nutrition Improvement Programme
IT:	Information Technology
JCI:	Joint Commission International
KPME:	Karnataka Private Medical Establishment
KSMs:	Key Starting Materials
LMICs:	Low and Middle-Income Countries
MC12:	Ministerial Conference of the WTO
MCI:	Medical Council of India
MDM:	Mid-Day Meal
MDR:	Medical Device Rules
MHCA:	Mental Healthcare Act

MHEs:	Mental Health Establishments
MHRB:	Mental Health Review Boards
MoHFW:	Ministry of Health and Family Welfare
MoRTH:	Ministry of Road Transport and Highways
MoUs:	Memorandum of Understanding
MPP:	Medicines Patent Pool
MRA:	Mutual Recognition Agreement
MRCP:	Membership of the Royal College of Physicians
MSF:	Médecins Sans Frontières
MTI:	Medical Tourism Index
MVA:	Motor Vehicles Act
MWCD:	Ministry of Women & Child Development
NABH:	National Accreditation Board for Hospitals & Healthcare Providers
NABL:	National Accreditation Board For Testing and Calibration Laboratories
NAC:	National Ambulance Code
NCDs:	Non-Communicable Diseases
NDHB:	National Digital Health Blueprint
NDHM:	National Digital Health Mission
NDRC:	National Development and Reform Commission
NEET-UG:	National Eligibility cum Entrance Test- Undergraduate
NEP:	National Education Policy
NETF:	National Educational Technology Forum
NFSA:	National Food Security Act
NHA:	National Health Account
NHAI:	National Highways Authority of India
NHM:	National Health Mission
NHP:	National Health Policy
NHS:	National Health Stack
NIMHANS:	National Institute of Mental Health and Neurosciences
NIN:	National Institute of Nutrition
NIPCCID:	National Institute of Public Cooperation and Child Development
NITI:	National Institution for Transforming India
NLEM:	National List of Essential Medicines
NMC:	National Medical Commission
NoC:	No Objection Certificate
NP-NSPE:	National Programme of Nutritional Support to Primary Education

NPPA:	National Pharmaceutical Pricing Authority
NRSB:	National Road Safety Board
OBC:	Other Backward Classes
OEMs:	Original Equipment Manufacturers
ONCONET:	National Cancer Network
OPDs:	Outpatient Departments
PEE:	Personal Protective Equipment
PHCs:	Primary Health Centres
PL:	Pathological Laboratories
PLI:	Production Linked Incentive
PMJAY:	Pradhan Mantri Jan Aarogya Yojana
PMMVY:	Pradhan Mantri Matru Vandana Yojana
PPPs:	Public Private Partnerships
PSEs:	Public Sector Enterprises
PwMI:	Persons with Mental Illness
R&D:	Research and Development
RDAs:	Recommended Dietary Allowances
RGJAY:	Rajiv Gandhi Jeevandayee Arogya Yojana
RIE:	Regional Institutes of Education
RSBY:	Rashtriya Swasthya Bima Yojana
RTA:	Regional Transport Authority
RTAs:	Regional Trade Agreements
RUCO:	Repurpose Used Cooking Oil
S&T:	Science & Technology
SAG:	Scheme for Adolescent Girls
SC:	Scheduled Castes
SDG:	Sustainable Development Goal
SEDGs:	Socio-Economically Disadvantaged Groups
SEPs:	Standard Essential Patents
SFAs:	State Food Authorities
SHCs:	Sub-Health Centres
SHGs:	Self-Help Groups
SMHA:	State Mental Health Authorities
SMS:	Sample Management Systems
SOPs:	Standard Operating Procedures
ST:	Schedule Tribes

STA:	State Transport Authority
STC:	Special Training Centres
TDFC:	Tribunal for the Defense of Free Competition
THI:	Trade and Health Initiative
TIFAC:	Technology Information, Forecasting And Assessment Council
TMR:	Trade Margin Rationalisation
TPG:	Telemedicine Practice Guidelines
TRIPs:	Trade-Related Aspects of Intellectual Property Rights
UHC:	Universal Health Coverage
UHID:	Universal Health Identifier
UN:	United Nations
UNCRPD:	United Nations Convention on the Rights of Persons with Disabilities
USFDA:	US Food and Drug Administration
UTs:	Union Territories
VLTS:	Vehicle Location Tracking and Emergency Alerts System
VRUs:	Vulnerable Road Users
WCD:	Women and Child Development
WHO:	World Health Organisation
WIPO:	World Intellectual Property Organisation
WTO:	World Trade Organisation

CHAPTER 1

An Overview

India's Present Macroeconomic Status

India, a rapidly advancing economic powerhouse and a prominent player in the Global South, stands at the forefront of shaping the future of global trade. In the fiscal year 2022, India showcased a robust recovery from the pandemic, positioning itself to retrace the pre-pandemic growth trajectory. As the nation enters fiscal year 2023, it continues its upward trajectory, propelled by a notable surge in exports.[1] This economic resurgence aligns with India's ambitious vision of becoming a developed nation, encapsulated in the "Viksit Bharat" initiative, with the target set for the year 2047.

The country's economic momentum gained significant traction, particularly as China, a key global player, experienced a slowdown in its post-pandemic recovery. India's strategic positioning and resilience are contributing factors to its emergence as a pivotal force in the evolving landscape of international trade. This trajectory underscores India's commitment to sustained economic growth, growing at 6.5-7.0 percent in this financial year.[2]

The country witnessed GDP growth of 6.0 percent to 6.8 percent in 2023-24 and is ranked 62 amongst 74 emerging economies in the inclusive development index (IDI), as reported by the World Economic Forum. Figure 1.1 presents a snapshot of the Indian economy that vividly establishes its robustness and stability.

India's economic landscape showcased resilience amidst escalating global uncertainties. Factors such as the rising inflation of the Russia-Ukraine conflict, the depreciation of the rupee, and the potential impacts of monetary tightening posed challenges to global economic stability. In this context, India's ability to navigate these challenges and sustain its growth trajectory was indicative of its adept response to the complex and dynamic global economic environment. The nation's progress towards resilient economic growth serves as a testament to its adaptability and strategic approach in the face of multifaceted challenges. Figure 1.2 presents a snapshot of India's resilient economic growth.

Figure 1.1: Indian Economy- A snapshot [3]

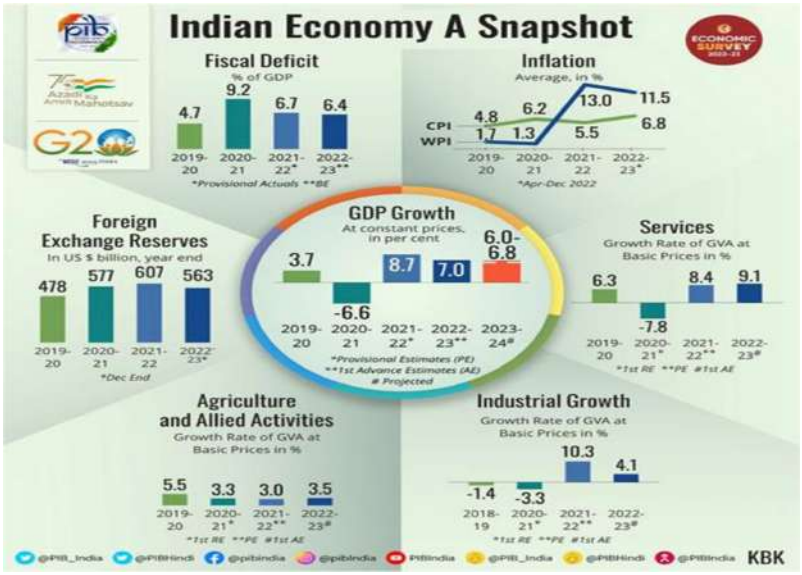
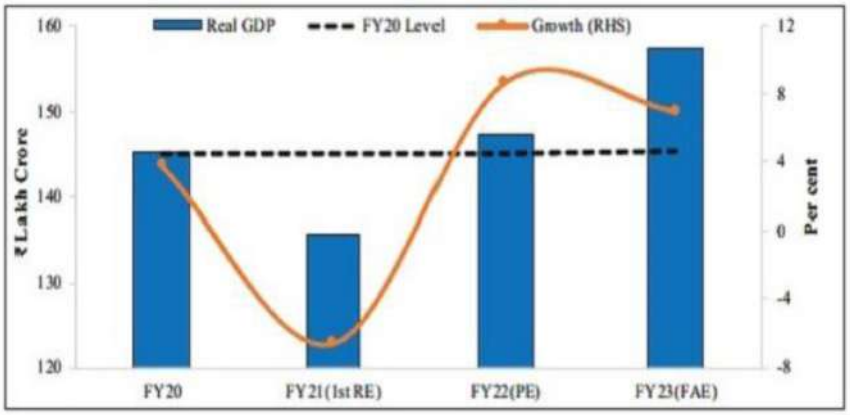


Figure 1.2: Resilient Nature of India's Economic Growth[4]



Despite India's comparatively swift recovery from the pandemic, outperforming many nations in the Global South, the year 2022 saw the country securing the 132nd position in the Human Development Index. This ranking underscores the considerable distance India still needs to cover on the path of development.

As far as healthcare is concerned, despite possessing an expansive healthcare infrastructure, the pandemic wreaked havoc by disrupting the delivery of essential healthcare services in India. This crisis accentuated notable disparities in the quality of healthcare facilities, both between rural and urban areas and among public and private healthcare providers. Furthermore, though there has been some decrease in out-of-pocket expenditure, it remains quite high reflecting the growing financial burden on individuals for healthcare services. This emphasises the critical necessity for focused interventions aimed at mitigating healthcare disparities and improving overall health outcomes throughout the nation.[5]

Healthcare Status in India

India boasts one of the world's most extensive healthcare networks, showcasing significant advancements in its health-related metrics over the years. Figure 1.3 provides a comparative analysis between the National Family Health Survey (NFHS) 5 and 4 reports, shedding light on India's strategic trajectory in enhancing the nation's health indicators.

Figure 1.3: Improvement in Health-related Indicators [6]

	NFHS-4 (2015-16)	NFHS-5 (2019-21)
Households with any usual member covered under a health insurance/ financing scheme (per cent)	28.7	↑ 41.0
Total fertility rate (children per woman)	2.2	↓ 2.0
Current Use of Family Planning Method- Any Method (per cent)	53.5	↑ 66.7
Mothers who had at least 4 antenatal care visits (per cent)	51.2	↑ 58.1
Institutional births (per cent)	78.9	↑ 88.6
Neonatal mortality rate (per 1000 live births)	29.5	↓ 24.9
Infant mortality rate (per 1000 live births)	40.7	↓ 35.2
Under-five mortality rate (per 1000 live births)	49.7	↓ 41.9
Children age 12-23 months fully vaccinated based on information from either vaccination card or mother's recall (per cent)	62.0	↑ 76.4
Children under age 6 months exclusively breastfed (per cent)	54.9	↑ 63.7
Children under 5 years who are stunted (height-for-age) (per cent)	38.4	↓ 35.5
Children under 5 years who are wasted (weight-for-height) (per cent)	21.0	↓ 19.3
Children under 5 years who are underweight (weight-for-age) (per cent)	35.8	↓ 32.1
Children under 5 years who are overweight (weight-for-height) (per cent)	2.1	↑ 3.4
Women who are overweight or obese (BMI≥25.0 kg/m^2) (per cent)	20.6	↑ 24.0
Men who are overweight or obese (BMI≥25.0 kg/m^2) (per cent)	18.9	↑ 22.9
Women age 15-24 years who use hygienic methods of protection during their menstrual period (per cent)	57.6	↑ 77.3

Moreover, there has been an increase in the government's expenditure on public healthcare and social security for universal health coverage, as reported by the National Health Account. Figure 1.4 showcases the increase of 1.3 percent in the government's expenditure towards public healthcare and social security for universal healthcare in the country's total GDP for FY19. There has been an increase of 9.6 percent in the government's expenditure towards social security which includes social health insurance schemes like Pradhan Mantri Jan Arogya Yojana and medical reimbursements made to government employees.

Therefore, we can say that citizens of the country are better equipped and better provided with healthcare services. It has been noted that the out-of-pocket expenditure has decreased to 48.2 percent from 64.2 percent in FY19. This is a result of a few major initiatives undertaken by the Indian government from FY2014 to FY2022 (see Figure 1.5).

Figure 1.4: Government's Health Expenditure and Out-of-Pocket Expenditure as Percentage of Total Health Expenditure[7]

Figure 1.5: Major Initiatives from 2014 to 2022 for Overall Better Health[8]

Despite such massive improvements, India still grapples with the challenge of delivering accessible and high-quality healthcare services to most of its citizens, despite its burgeoning economy. The strain on the Indian healthcare system became glaringly apparent during the global pandemic, exposing vulnerabilities and obstacles in the current health delivery framework. This underscored the imperative for the Indian government to prioritise the provision of healthcare services that are not only affordable but also of exemplary quality to meet the evolving needs of its populace.

Apart from the emphasis on health infrastructure, there is also a need to review regulatory frameworks governing various segments of healthcare. This is particularly important since the private sector plays a crucial role in meeting public health demands.

An Overview of the 2023 Report

This edition of ICCR with the theme "The Regulatory Deficit in Access to Equitable Healthcare" looks into several regulatory and competition aspects in the healthcare and pharmaceutical sectors. It delves into the pertinent issues relating to distinct areas of healthcare, i.e., hospitals, pharmaceuticals, telemedicine, biomedical waste, mental health, e-pharmacy, and digital health. The report's focus on this theme aligns with the crucial need to identify and address the gap in the regulatory framework in all the abovementioned areas associated with the healthcare sector to ensure fair, equitable, accessible quality healthcare in India. The following paragraphs provide an overview of this edition of ICRR.

Chapter 2: Perception and Awareness Reporting
The next chapter (i.e., Chapter 2) is a regular feature depicting survey-based perception and awareness about competition and regulatory issues among Indian consumers and businesses. For this edition, the focus of the survey has been India's healthcare and pharmaceutical sectors. The survey comprises 1,200 respondents distributed across 6 regions and 12 states, ensuring equitable representation and distribution. The survey results provide a comprehensive view of healthcare accessibility, digital services, and stakeholder awareness. Various parameters, such as access to healthcare services, awareness of schemes, opinions on unethical practices, telemedicine, medical insurance, and awareness of regulatory issues, have been explored in chapter two.

Chapter 3: Competition Issues in the Healthcare and Pharmaceutical Sectors
This chapter introduces various competition concerns prevalent in the healthcare and pharmaceutical sectors. It illustrates, using real cases, both *ex-ante* competition policy approach and *ex-post* competition enforcement to deal with such competition concerns.

Chapter 4: Public-Private Partnership Model in the Healthcare Services Sector

This chapter explores the role of public-private partnerships (PPPs) in India's healthcare sector. It begins by emphasising the significance of PPPs in addressing complex healthcare challenges and the unique characteristics of the healthcare landscape. The status of India's healthcare sector is analysed, revealing gaps in funding and workforce. The chapter identifies specific segments of healthcare suitable for PPP models, including hospital infrastructure, diagnostic services, medical technology, health insurance, and primary care. Case studies illustrate successful PPP implementations in various countries. The chapter concludes by addressing challenges in PPP implementation, emphasising the need for robust governance, legal frameworks, and stakeholder engagement for successful healthcare transformation through PPPs.

Chapter 5: Regulatory Framework and Investment in Hospitals and Pharmaceutical Sectors

This chapter explores the relationship between regulatory framework and investments in hospitals and pharmaceuticals in India. It highlights the underlying infrastructural challenges due to a lack of adequate investments and barriers such as a low level of health insurance affecting foreign direct investment in hospitals and then explores the possibility of eliminating these barriers. Furthermore, it delineates the key elements that define optimal regulation in the sector.

Chapter 6: Evolving Policy and Regulatory Landscape for Digital Health in India: A Narrative Review

This chapter delves into the regulatory landscape of digital health in India, exploring the transformative potential of technological advancements against the backdrop of a fragile public health system prevailing in the country. It highlights the disconnect between the aspirational disease discourse surrounding digital health and the practical challenges hindering its effective implementation. Despite ambitious programs like the Ayushman Bharat Digital Mission, the chapter emphasises the pressing issues of weak infrastructure, inadequate human resources, low public health spending and a deficient legal framework for data protection. The narrative analysis calls for a comprehensive understanding of ground realities to bridge the gap between policy objectives and people's needs, urging policymakers to prioritise addressing fundamental healthcare deficiencies by leveraging digital innovations.

Chapter 7: Telemedicine – Regulation and Promotion

This chapter addresses the need for the integration of telemedicine into health systems to reduce inequality and obstacles to accessing quality healthcare in India. The pandemic highlighted the urgent need for telemedicine

in India, as it became an important tool for providing healthcare services remotely. It talks about the dire need to make telemedicine a legal process in India, assesses the existing telemedicine practice guidelines, and dissects the regulatory challenges associated with it to get an idea of the regulatory and policy measures necessary to unlock the complete potential of telemedicine. The chapter also dwells on the legal, technological, privacy, and data usage challenges related to the integration of telemedicine into the health system and comes up with suggestions like improvements in regulatory clarity, certainty, and policy predictability that are necessary for this integration.

Chapter 8: The E-Pharmacy Conundrum: Regulatory Challenges and the Ripple Effects on Market Competition

This chapter addresses the regulatory and competition concerns surrounding e-pharmacy and its impact on investment and growth of the sector. It talks about common challenges like the need for a clean and authorised process to review patients' prescriptions and concerns related to maintaining price parity through contractual clauses, as well as horizontal mergers leading to the lessening of competition in the e-pharmacy space. The chapter discusses the uncertain regulatory environment, including conflicting high court judgements, and recommends an optimal regulation for e-pharmacy.

Chapter 9: Regulation of Mental Healthcare

This chapter addresses the critical issue of mental health in India, where millions need care but few seek it. The background highlights the impact of the COVID-19 pandemic on mental health, emphasising challenges such as stress and limited access to services. Mental health services, provided by public, private, and non-profit sectors, face various shortcomings, including inadequate infrastructure. The chapter delves into the regulatory framework, focusing on the Mental Healthcare Act (2017) and its impact on patient rights, establishments, and suicide decriminalisation. Implementation challenges are discussed, revealing poor progress and the need for increased resources. The chapter concludes by urging comprehensive efforts for effective mental healthcare.

Chapter 10: Regulation of Medical Waste Management

This chapter deals with the current status of biomedical waste generation, national strategies to tackle it, and then provides precautionary measures to avoid future disasters. It draws attention to the significant problems India is facing due to the improper management of medical waste. The chapter dissects the Bio-Medical Waste Management Rules (BMW), 2016 and the several amendments to it to find the regulatory gaps. It also draws attention to newer technologies for the proper disposal of waste, along with the scope of improvement to the current situation. Additionally, the chapter also talks about the need for stricter enforcement of the BMW rules and

suggests that an inclusive approach involving all stakeholders is necessary to effectively address this issue.

Chapter 11: Domestic Production of APIs in India

The chapter traces the trajectory of India's pharmaceutical industry, evolving from import dependence to global self-reliance. It examines the challenges posed by globalisation and China-centric supply chains, prompting the introduction of the Product Linked Incentive (PLI) Scheme. The chapter analyses the rise and decline of the Indian Active Pharmaceutical Ingredient (API) sector due to factors like import liberalisation and reduced tariffs. The chapter advocates for a nuanced understanding of import dependence, investor confidence, Micro, Small and Medium-sized Enterprises (MSMEs) inclusion, and Public Sector Enterprise (PSE) involvement to foster self-reliance. In summary, the chapter emphasises the crucial role of a unified policy approach in fostering successful industrial development within India's pharmaceutical sector.

Chapter 12: Pricing and Availability of Medical Devices

This chapter addresses the pricing and availability of medical devices for accessible and affordable healthcare systems across the country, examining the legalities of price regulation, and also traces the evolution of price control mechanisms. It further examines the Trade Margin Rationalisation (TMR) approach opted for by the National Pharmaceutical Pricing Authority (NPPA) to fix the prices for the public interest. The chapter evaluates the impact of price control on medical devices and the risks associated with the same and proposes a coherent pricing regulation.

Chapter 13: Regulation of Pathological Laboratories in India

This chapter provides an overview of the regulation of Pathological Laboratories in India under the Clinical Establishments (Registration and Regulation) Act (CE Act) of 2010. The chapter examines different aspects of the Act while noting that its implementation is still in its nascent stage. While 16 States and Union Territories have adopted the central enactment, others have either their laws or are yet to adopt any. The chapter explores state-level developments, with examples from Telangana and West Bengal, highlighting the challenges and regulatory actions taken. The role of the National Accreditation Board for Testing and Calibration Laboratories (NABL) is discussed, emphasising its voluntary accreditation process. The chapter concludes by addressing the growing importance of regulating Point-Of-Care Testing (POCT) and the need for a comprehensive regulatory framework.

Chapter 14: Unlocking the Potential of Medical Tourism in India

This chapter delves into the potential and the barriers to medical tourism destined for India. The country offers cost-effective high-quality medical services, attracting global patients. Despite strengths like quality, affordability

and presence of skilled professionals, regulatory issues such as lack of international recognition, insurance portability, and redressal mechanisms pose hurdles to its potential growth. The chapter also talks about ways to address these barriers and challenges. Collaborative efforts and international engagements are the keys to unlocking India's full medical tourism potential.

Chapter 15: TRIPs Waiver and Equitable Access to COVID-19 Drugs
This chapter critically analyses the TRIPs waiver proposal by India and South Africa and the proposal by the EU. It deliberates whether the intellectual property protection mandated by TRIPs posed a substantial barrier to expanding manufacturing and ensuring fair access to COVID-19 vaccines, medications, and other technologies. It also brings the issue of the transfer of know-how, which is necessary for the manufacturing of modern vaccines. The paper proposes a better synergy between governments, regulators, businesses, and civil society to address global health inequality.

Chapter 16: Regulatory Issues in Medical Education in India
The chapter presents an analysis of the regulatory challenges confronting medical education in India, addressing the critical shortage of doctors and the need for increased educational opportunities. It scrutinises the historical evolution of regulations, emphasising key milestones and the recent transition from the Medical Council of India (MCI) to the National Medical Commission (NMC). The analysis encompasses the National Education Policy 2020, financial support for students, online education, and the impact of the Russia-Ukraine issue on medical education. The chapter proposes solutions, advocating for infrastructure status, fee rationalisation, and the independence of the NMC to revitalise medical education and meet the urgent healthcare needs of the nation.

Chapter 17: The Design and Regulation of Health Insurance in India
This chapter gives an overview of the status of health insurance coverage among the population and its impact on access to healthcare. It discusses the need for redesigning health insurance contracts in India by proposing a pathway of reform that envisions the adoption of managed care models of health insurance regulated through the regulatory system of managed competition. Long-term recommendations for regulatory reform to move towards a system that delivers both financial protection and good quality healthcare have also been proposed.

Chapter 18: Road Safety in India: A Public Health Challenge
The chapter provides an extensive overview of the road safety scenario in India, emphasising the rapid growth of the road network and the increasing number of vehicles. It highlights the negative consequences, including a rise in road crashes, injuries, and fatalities, attributing them to factors such as

poor road design, weak enforcement of safety laws, and inadequate vehicle safety standards. The significance of the Motor Vehicles Act of 1988, particularly its amendment in 2019, in addressing these challenges is discussed, along with the public health implications of road accidents. The chapter concludes with recommendations to strengthen regulatory frameworks, enhance road safety measures, and promote public awareness.

Chapter 19: Ambulance Services in India- Are the Sirens Loud Enough!
This chapter unveils critical issues afflicting India's ambulance services amid one of the highest global road traffic fatality rates. Unveiling stark realities, it exposes deficiencies in equipment (90 percent) and personnel training (95 percent), emphasising a substantial gap in emergency care. The heightened demand during the COVID-19 pandemic underscores the crucial need for comprehensive attention to this vital domain. Analysing ambulance types, service providers, and their availability, the chapter highlights data disparities, emphasising the absence of a unified national database. In conclusion, it stresses regulatory deficiencies, urging urgent reforms to overcome service challenges and address regulatory gaps.

Chapter 20: Food Safety for Health and Wellbeing - Addressing the Challenges of Regulatory System
This chapter delves into the critical importance of food safety for public health, emphasising the need for a robust regulatory system. It explores global challenges, citing WHO data on foodborne illnesses, and underscores the evolving concept of "Farm to Fork." The chapter scrutinises emerging health challenges in India, including the rise of ultra-processed foods, street food concerns, and profit-driven unsafe food practices. It assesses the current state of food safety in India, highlighting issues of adulteration and lapses in the existing regulatory system. The Food Safety and Standards Act, 2006, is examined, detailing key provisions and regulatory perspectives. The chapter concludes with insights into new initiatives by FSSAI and recommendations for strengthening food safety regulations in India.

Chapter 21: Nutrition Status in India through the Regulatory Lens
This chapter deliberates upon the critical issue of nutrition security in India, examining it from various perspectives and highlighting the role of regulatory bodies. It emphasises the interconnectedness of food safety and nutrition, citing global challenges such as the COVID-19 pandemic, climate change, and inequality. The chapter details the prevalence of hunger and food insecurity, addressing the complex challenge of triple-burden malnutrition in India. It discusses the status of health in India, official figures, and initiatives like the National Nutrition Mission (POSHAN ABHIYAAN) and Mission Poshan 2.0. The role of the Food Safety and Standards Authority of India (FSSAI) is explored, along with challenges and potential solutions through food regulations. The chapter underscores the need for a coordinated approach involving various stakeholders to tackle malnutrition effectively.

Endnotes

1 Government of India and Department of Economic Affairs, n.d.

2 *Ibid*

3 Ministry of Finance and Press Information Bureau 2023

4 Supra Note 1

5 Kapoor et al. 2023, #

6 Economic Survey of India-2022-23, n.d.

7 *Ibid*

8 *Ibid*

CHAPTER 2

Perception and Awareness Reporting

Introduction

The perception and awareness survey on competition and regulatory scenarios in India is conducted biennially by CUTS International for the ICRRs. This year the survey is conducted to gauge the level of awareness of the consumer and business segments on competition and regulation issues in the healthcare and pharmaceutical sectors of India.

The consumer survey covered 12 states representing all regions in India, which included Assam and Tripura in the North-East, Bihar and West Bengal in the East, Delhi and Punjab in the North, Chhattisgarh and Madhya Pradesh in the Central, Gujarat and Maharashtra in the West, and Kerala and Telangana in the South. A total of 1,200 respondents were distributed among the six regions. The parameters under consideration for the survey were access to healthcare services, the respondent's awareness of and opinion on healthcare schemes, unethical practices in the healthcare sector, telemedicine, medical insurance and awareness of competition and regulatory issues.

The respondents of the business segment comprised different categories of healthcare service providers. The business segment included a sample of 310 respondents that was covered across 6 regions and 12 states. Equal representation of the target population was ensured from each region. The variables under consideration for the survey were: ease of doing business and their awareness and opinions about various regulatory regimes.

Perception and Awareness among Consumers in India

Data and Survey Design

The statistical analysis was based on the data gathered from the pan-India survey. A stratified random sampling technique was chosen for a better representation of the population. This method was explicitly used because it often improves the representation of the sample by reducing sampling errors.

The survey was conducted taking two states each from six selected regions of the country to assess the regulatory deficit in accessing healthcare as perceived by service recipients.

The sample size of 1200 consisted of a nearly equal distribution of male (57.6 percent) and female (42.4 percent) respondents, aged 18-60. The majority fell within the 30-45 age range (46.8 percent). Monthly family income mostly ranged from ₹5,000 to ₹20,000, with the ₹10,000 to ₹20,000 group dominating (44.9 percent). All respondents were literate, with only a small percentage (3.1 percent) reported as illiterate. Education levels varied from below primary to graduate, with a relatively high proportion having completed secondary and higher secondary education.

Figure 2.1: Gender Distribution

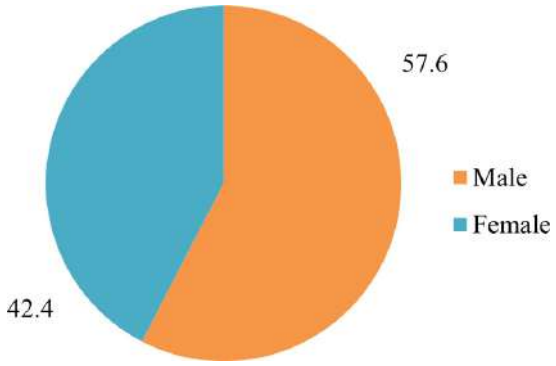


Figure 2.2: Economic Profile

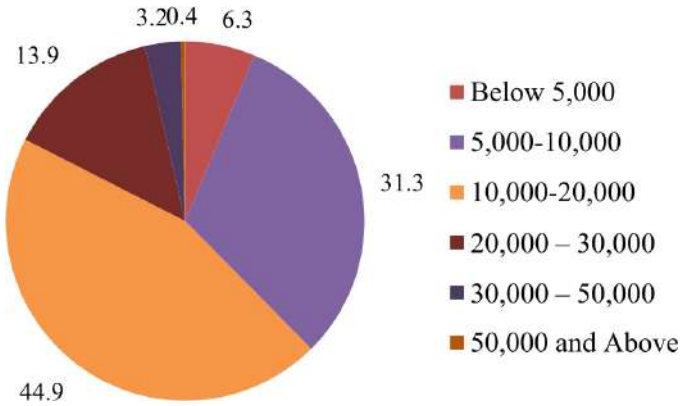
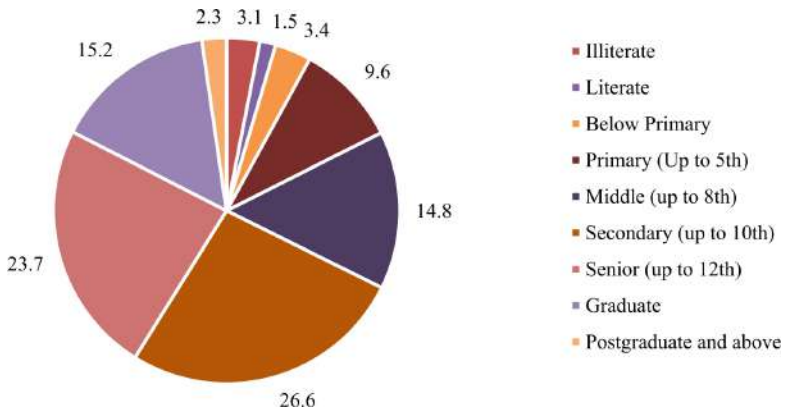


Figure 2.3: Education Profile



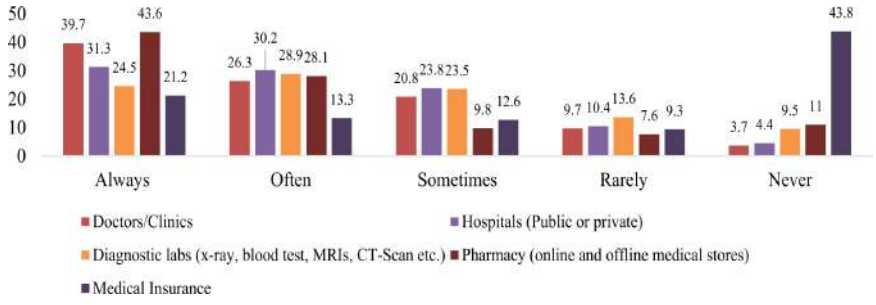
Analysis of Survey Findings/Results

Healthcare Services

Accessibility of Healthcare Services

In general, the survey revealed that the majority of healthcare services were readily accessible to respondents, except medical insurance. A significant proportion of respondents demonstrated limited awareness regarding medical insurance.

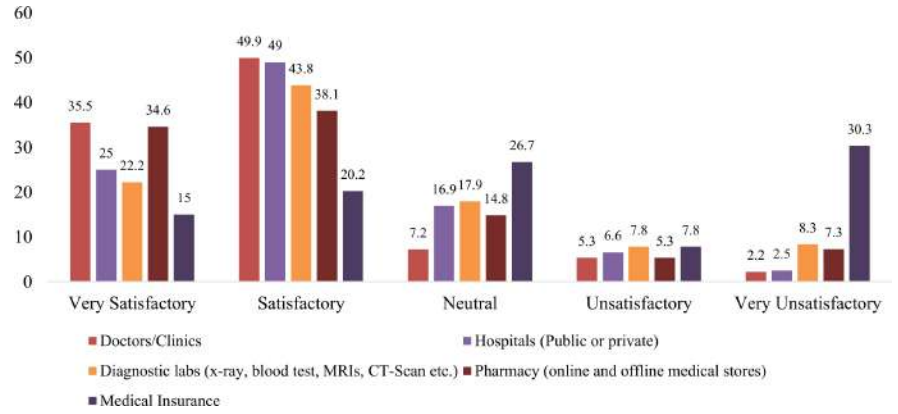
Figure 2.4: Availability of Healthcare Services



Quality of Healthcare Services

The majority of the respondents found the doctors/clinics, hospitals, diagnostic centres, etc. satisfactory or very satisfactory. At the same time, the level of satisfaction related to the medical insurance services was found on the lower side.

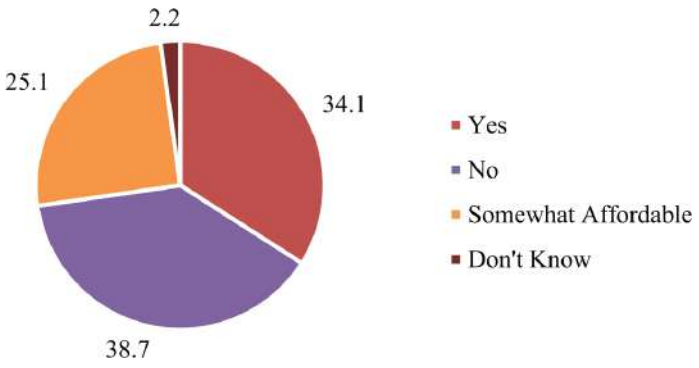
Figure 2.5: Quality of Healthcare Services



Affordability of Healthcare Services

When asked about the affordability of the healthcare services available in the market majority of the respondent mentioned that the services ranges from affordable to somewhat affordable. When looking at it from an economic perspective, the majority of the respondents belonging to an income group between ₹30,000-50,000 (47.4 percent) found it affordable followed by families earning below 5,000 (40.8 percent).

Figure 2.6: Affordability of Healthcare Services



Awareness and Opinion on Healthcare schemes

When asked about various promotional schemes provided by different health service providers, a lack of awareness of such programmes is evidenced throughout except for Delhi (76 percent). When asked about providers of subsidiary healthcare schemes, respondents primarily identified pharmaceutical stores, followed by healthcare clinics/hospitals and pathological laboratories. This highlights a gap in respondents' understanding of healthcare service schemes. Many believed that the discounts on medicines offered by pharmacies were part of a larger scheme.

Upon assessing consumer opinions on prevailing promotional schemes *(https://pib.gov.in/pressreleaseshare.aspx?prid=1576128)*, the majority expressed satisfaction (highly satisfied - 22 percent, somewhat satisfied - 47.7 percent) citing positive perceptions of consumer benefits, quality, and pricing. Beneficiaries in Punjab, Telangana, and West Bengal were notably highly satisfied with consumer benefits and fair pricing. Gujarat respondents were generally satisfied, while Chhattisgarh had a mixed response. Dissatisfaction with service quality was prominent in Chhattisgarh (41.2 percent), Gujarat (9.6 percent), Kerala (5 percent), Madhya Pradesh (4.2 percent), and Maharashtra (34.2 percent).

Figure 2.7: Consumer Awareness of Various Promotional Schemes

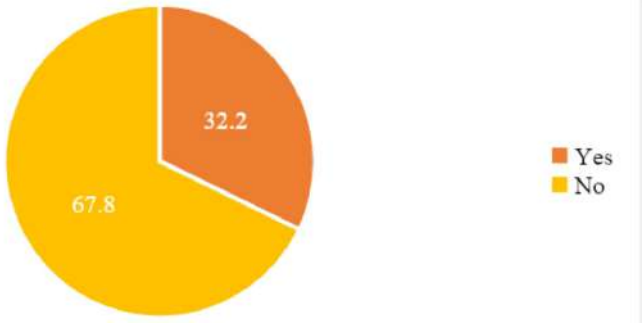


Figure 2.8: Consumer Awareness of Promotional Service Providers

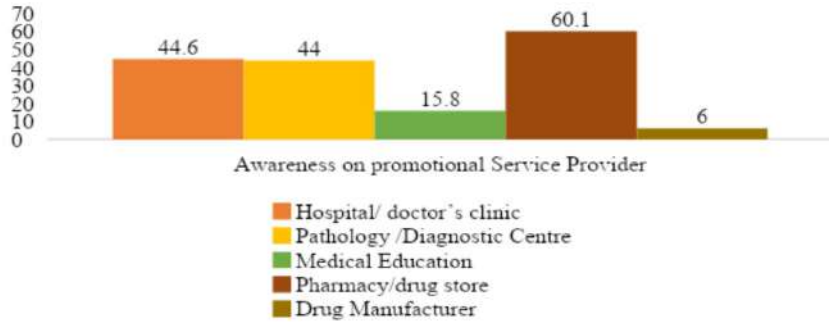
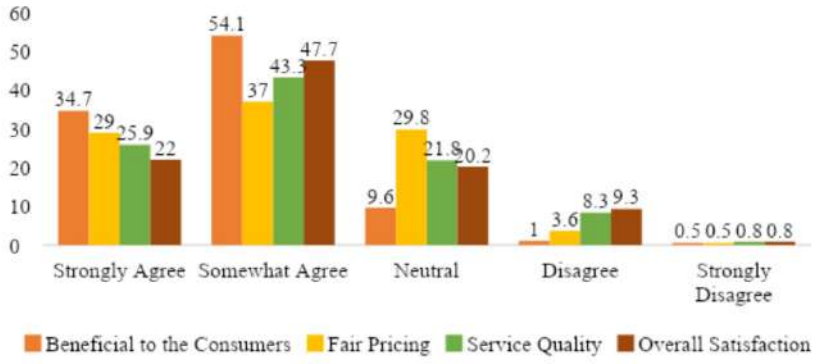


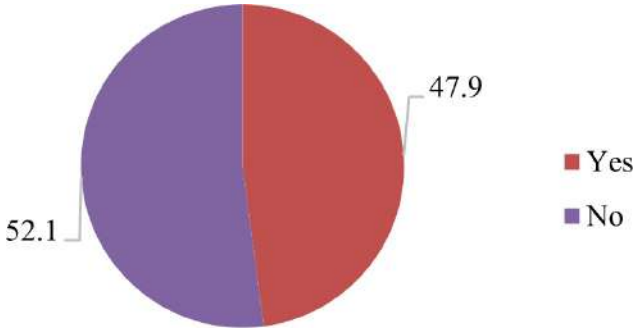
Figure 2.9: Consumer Opinion on Promotional Schemes in the Market



Consumers on Tied Selling

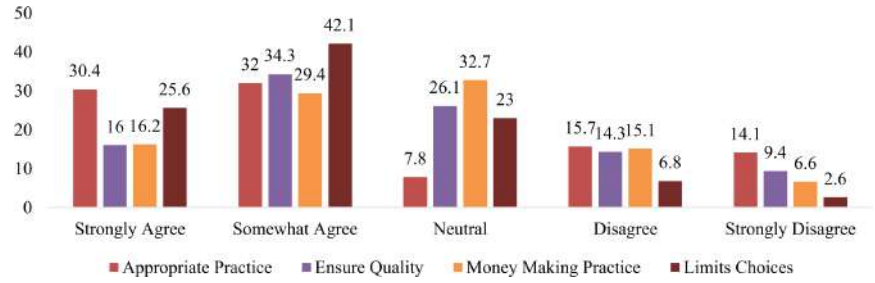
While enquired about the **tied selling** practices provided by various healthcare units, a gap was evidenced among the respondents on awareness of such practices in the market. Only 47.9 percent reported that they are aware of tied selling across the targeted geography. Considering the widespread practice in the market, awareness identified was found to be on the lower side.

Figure 2.10: Consumer Awareness of Tied Selling Practices



To know more about people's perception of tied selling practices, people holding knowledge on the same were asked about their opinion on different aspects like appropriateness, quality, limitations on choices etc. The majority of the respondents firmly believe that the practice is appropriate as well as necessary for ensuring quality and no way a means for making money even though it limits the choices of the consumers.

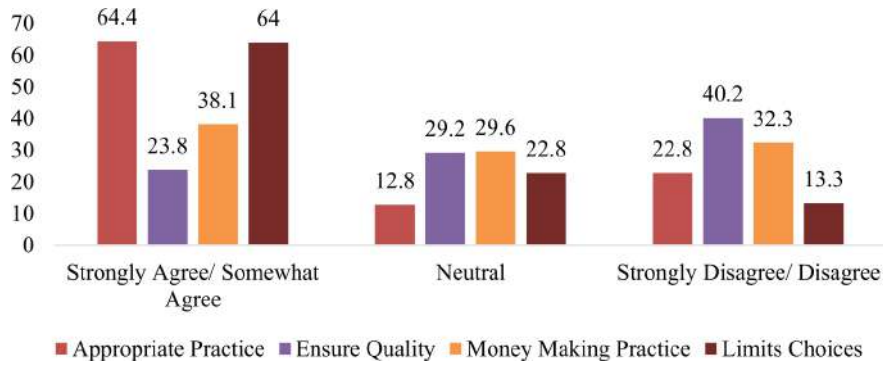
Figure 2.11: Consumer Opinion of Tied Selling Practices



Consumers on Prescription in Brand Name

When consumers were asked about their perceptions related to the brand selling practices in the market where doctors prescribe medicines on the brand name instead of generic names, a mixed response was received from the consumers, where the majority agreed on the appropriateness, but the same also reported limitations in choices due to the practice.

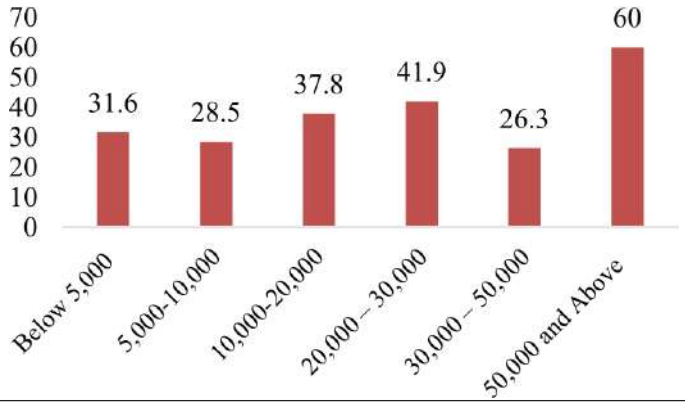
Figure 2.12: Consumer Opinion Related to Brand Selling



Consumers on Telemedicine

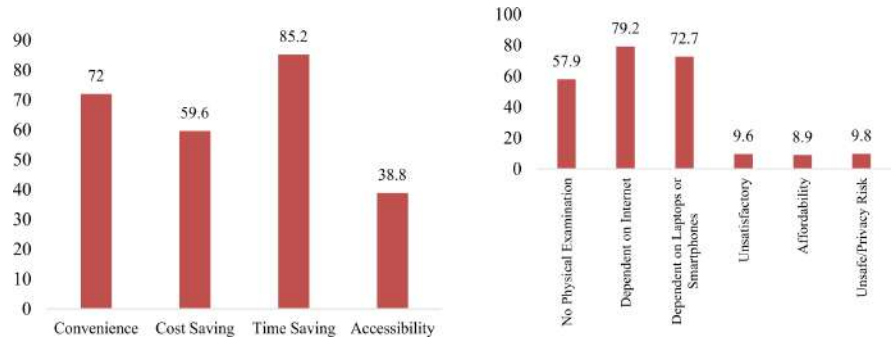
When asked about telemedicine services, only about 34.8% of the respondents reported awareness with Delhi, Kerala and Bihar being the major contributors to the overall awareness received under the study. Awareness was evidenced as low as under 10% in some states like Telangana and Gujarat. Again, the majority of the awareness was found among the higher income groups with income groups where about 60 percent, 41.9 percent and 37.8 of the respondents interviewed from income group 50,000 and above, and 10,000 to 30,000 respectively reported awareness of telemedicinal services.

Figure 2.13: Consumer Awareness of Tele-medicine



When respondents were asked about the benefits and challenges related to the use of telemedicine. As for the benefits concerned, the majority of the respondents reported that telemedicine was convenient (72 percent), cost savings (59.6 percent) and time savings (85.2 percent) in most cases. Common challenges on the other hand found to be lack of physical examination (57.9 percent), dependency on the internet (79.2 percent) and laptop or smartphone (72.7 percent).

Figure 2.14: Benefits and Challenges of Tele-medicine



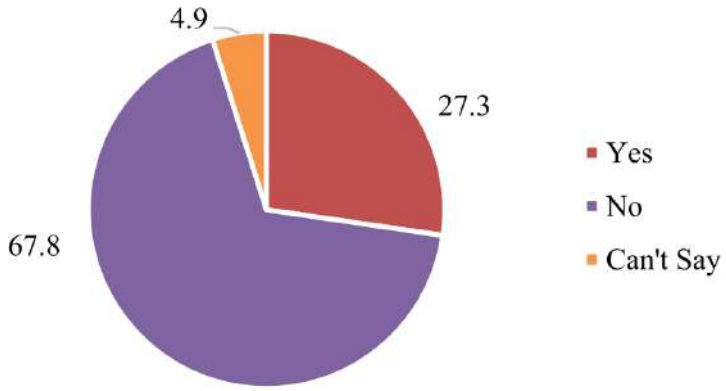
Awareness and Opinion on Medical Insurance

Awareness, access, and utilisation of medical insurance were found to be a struggling factor for a very long time across rural and urban sectors, regardless of the socio-economic profile of the consumers. Despite the need for increased coverage of health insurance to achieve Universal Health Coverage, Awareness and knowledge of health insurance lack time. As per

the NITI Aayog report published in 2021, lack of awareness, identification & outreach, adverse & preferred selection and affordability have been identified as the key challenges in the path of achieving increased awareness among the general population.

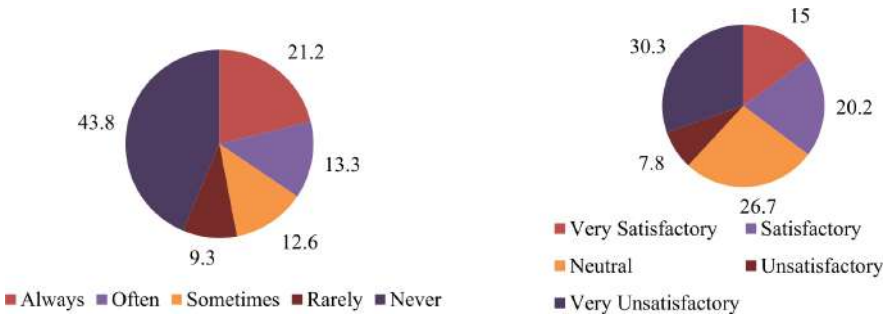
A similar situation is captured in this study where the availability of medical insurance was found to be minimal across the states regardless of the socio-economic profile of the respondents.

Figure 2.15: Use of Medical Insurance



Similarly, knowledge and awareness of the accessibility of medical insurance were found minimal across states with a majority of the respondents reporting never accessible (43.8 percent). Quality on the other hand was reported to be very unsatisfactory (30.3 percent) followed by neutral (26.7 percent).

Figure 2.16: Accessibility and Quality of Medical Insurance



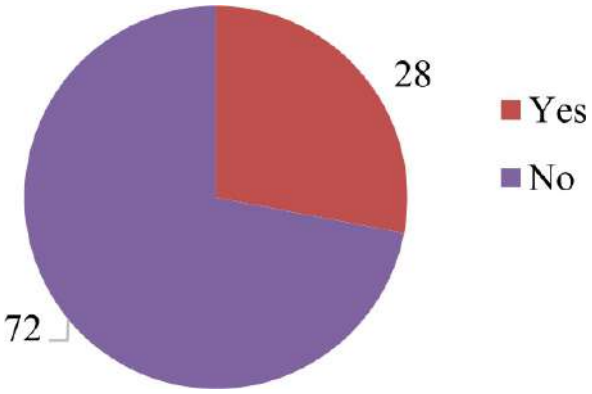
Awareness of Regulatory Framework and Market Competition

Consumer Grievance Redressal

The Government of India has enhanced regulatory measures to streamline the consumer grievance mechanism across various sectors. As per guidelines for establishing grievance redressal and health helpline by the Ministry of Health and Family Welfare (MoHFW), authorities/nodal officers at the appropriate level (State/District/Block/Facility) have to resolve all the grievances generated in the facility within seven days. This has been put in place to ensure the quality of healthcare services made available to the general population of the country. However, the knowledge and awareness of such a facility were found to be minimal among the targeted population.

When asked about the public grievance redressal mechanism in the healthcare sector, only about 28 percent of the respondents expressed their awareness of such mechanisms. The majority of the respondents from Bihar and Delhi were aware of the grievance redressal mechanism. Additionally, there was a positive correlation between respondent's education levels and awareness of the grievance redressal mechanism, highlighting a significant communication gap in generating public awareness by the MoHFW in this area.

Figure 2.17: Awareness of Grievance Redressal Mechanism



The respondents who indicated awareness of public grievance mechanisms in the health sector were questioned about their usage and opinions on the existing mechanisms in India. The utilisation of these services was notably low, standing at 25.6 percent among those aware. The users were distributed across income groups, with 26 percent, 28 percent, 29 percent, 16 percent, and 1 percent belonging to income brackets below ₹5,000, ₹5,000-10,000, ₹10,000-20,000, ₹20,000-30,000, and ₹30,000-50,000, respectively.

Figure 2.18: Use of Grievance Redressal Mechanism

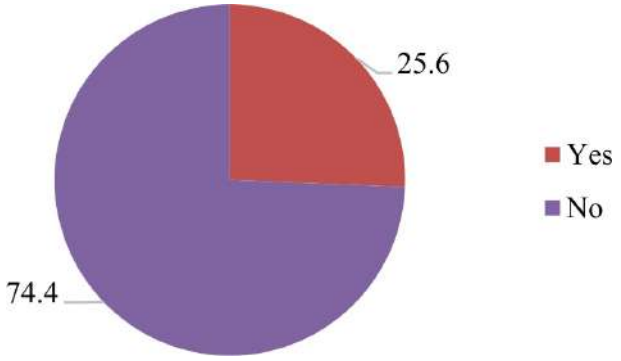
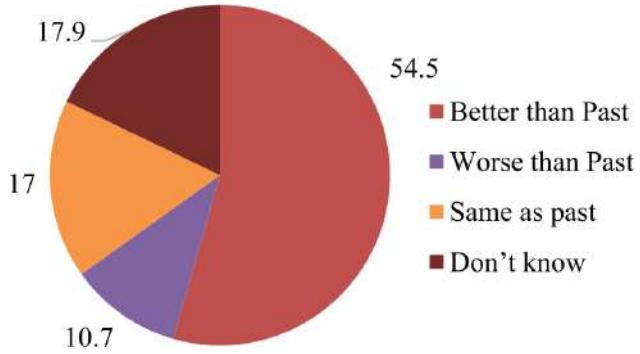


Figure 2.19: Opinion on Grievance Redressal Mechanism

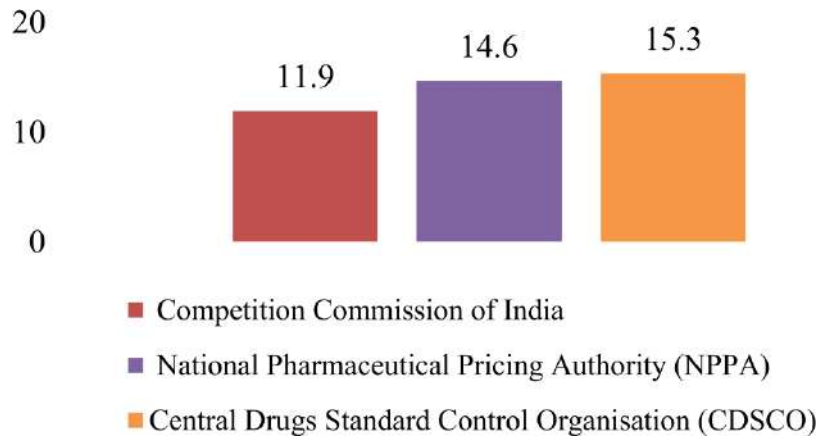


The Competition Commission of India (CCI)

Upon enquiry, very few of the respondents were found aware of the regulation in the healthcare industry. Only (11.9 percent), (14.6 percent) and (15.3 percent) of respondents expressed their awareness of the Competition Commission of India, National Pharmaceutical Pricing Authority (NPPA) and Central Drug Standard Control Organisation (CDSCO).

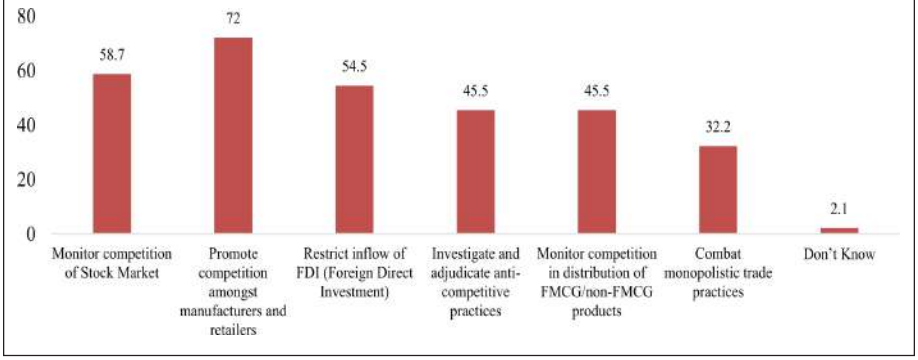
The overall objective of CCI is to prevent practices that harm the competition. It promotes and sustains competition in markets, protects the interests of consumers and ensures freedom of trade. Considering these facts, a healthy percentage of respondents who are aware of CCI have a broad understanding of CCI and its functions in the market. However, there is ample scope for campaigning towards knowledge enhancement for greater awareness among the citizens.

Figure 2.20: Consumer Awareness of Various Regulators



We have judged the respondent's knowledge of the functionality of CCI through six indicators as presented in Figure 2.21. Over (50 percent) of the respondents identified monitoring competition in the stock market, promotion of competition amongst manufacturers and retailers and restricting the inflow of Foreign Direct Investment (FDI) as the primary roles of CCI, while respondents ranging between (30 percent) to (46 percent) reported investigation and adjudication of anti-competitive practices, monitoring competition in the distribution of Fast Moving Consumer Goods (FMCG)/non-FMCG products and combat against monopolistic trade practices as the key roles of the commission.

Figure 2.21: Purpose of CCI

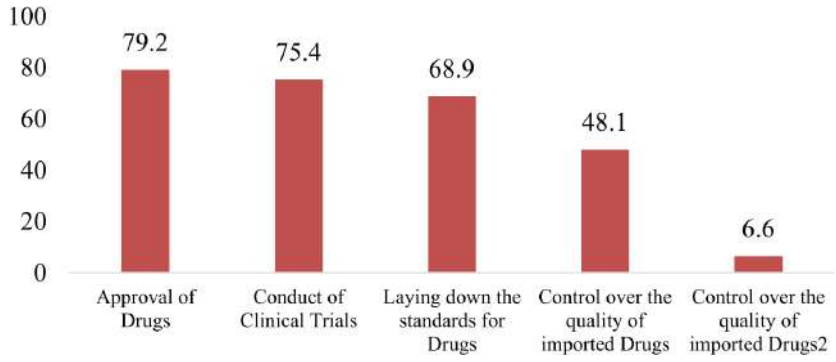


Central Drug Standard Control Organisation (CDSCO)

The CDSCO has been entrusted to regulate the quality of medicine through the approval of drugs, laying down guidelines for the conduct of clinical trials, and standards for drugs, amongst others, to safeguard and enhance public health and safety.

The respondents who were aware of CDSCO were asked about its purpose in India. The majority of the respondents reported approval of drugs (79.2 percent), followed by the conduct of clinical trials (75.4 percent) and laying down the standards for drugs (68.9 percent) as the key purposes of CDSCO.

Figure 2.22: Functions of CDSCO



National Pharmaceutical Pricing Authority (NPPA)

The NPPA was established in 1995 to *inter alia* fix or revise the prices of controlled bulk drugs and to enforce prices and availability of medicines in the country, to make them more affordable to the common citizens.

On asking questions related to the purpose of NPPA, the majority of the people having knowledge reported monitoring and ensuring the availability of drugs (77.7 percent), followed by control prices of essential drugs (72 percent), study pricing of drugs/formulations (65.7 percent) as the key purposes of NPPA that comes under the Drugs (Prices Control) Order, 1995, adhered and ensured by NPPA.

Furthermore, the respondents were asked for their opinion on the need for price control of essential drugs in the market and their reasons. The majority of the respondents were in support of the need for control over the essential drugs in the market (70 percent). Upon probing on the reason for such perception, the majority of them identified "affordability" (53.2 percent) followed by "stopping monopoly (49.3%), "restricting abnormally high prices by pharma companies" (36.2 percent) and "Restricts influence of doctors and retailers" (35.5 percent) as the key factors.

Figure 2.23: Awareness of NPPA

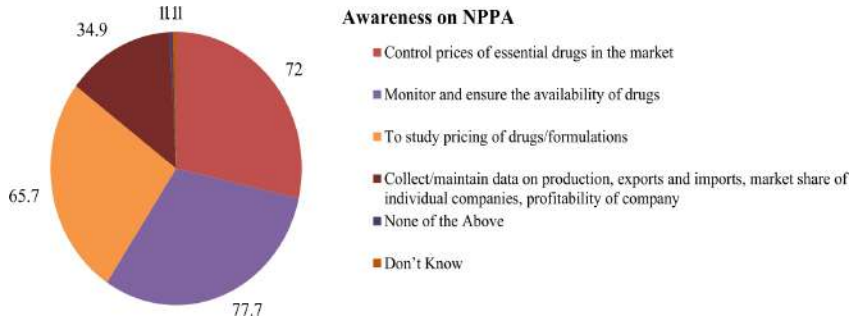
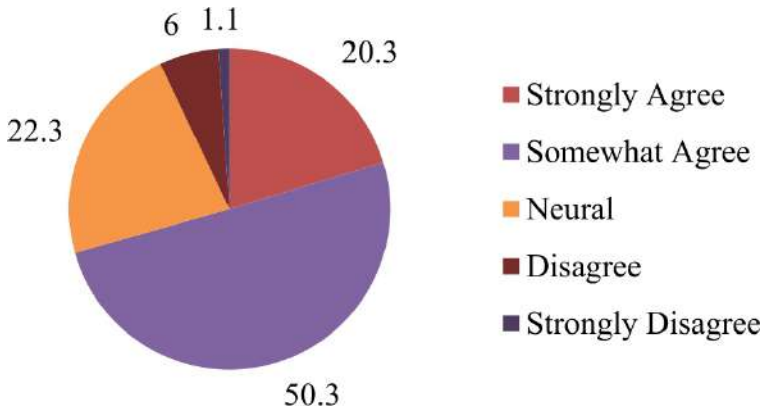


Figure 2.24: Need for Controlling Price of Essential Drugs

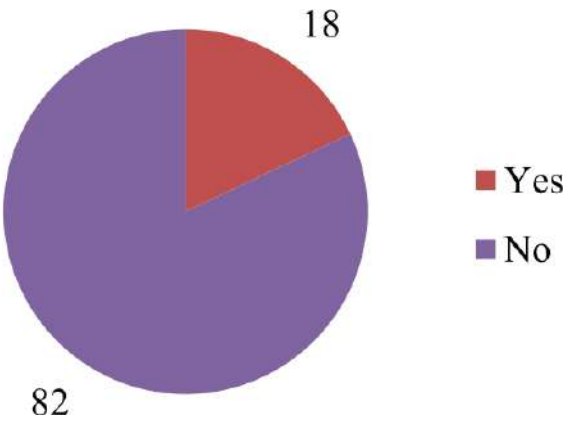


National Medical Commission (NMC)

National Medical Commission is the successor of the Medical Commission of India replaced by the National Medical Commission Act, 2019. The role of the NMC is to look after medical education, availability of healthcare persons like doctors, and paramedics, accessibility to healthcare, medical research, medical college establishment & approval, records medical facility list, addresses public grievance, set ethical standards etc.

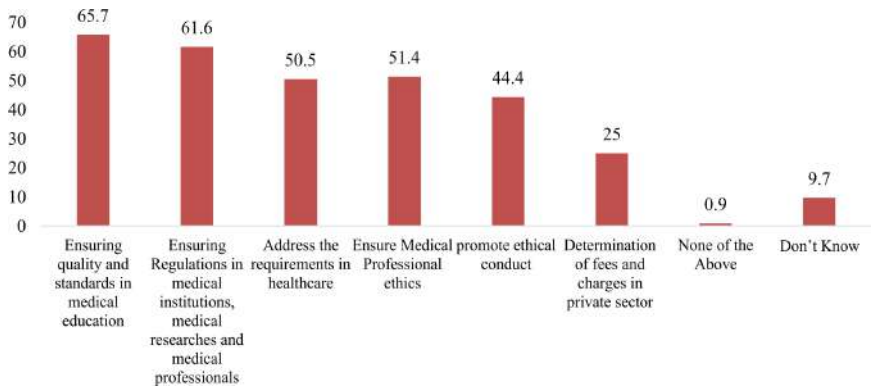
Sadly, only about 18 percent were able to report awareness, while a striking percentage of the respondents were unaware of NMC.

Figure 2.25: Awareness of NMC



Further analysis shows that most of the respondents aware of NMC could identify maintenance of medical education (65.7 percent), regulation of medical institutions (61.6 percent), addressing requirements of human resources (50.4 percent) and implementation of code of ethics (51.4 percent) as the key role of NMC in the country.

Figure 2.26: Purpose of NMC



Quality of Regulation

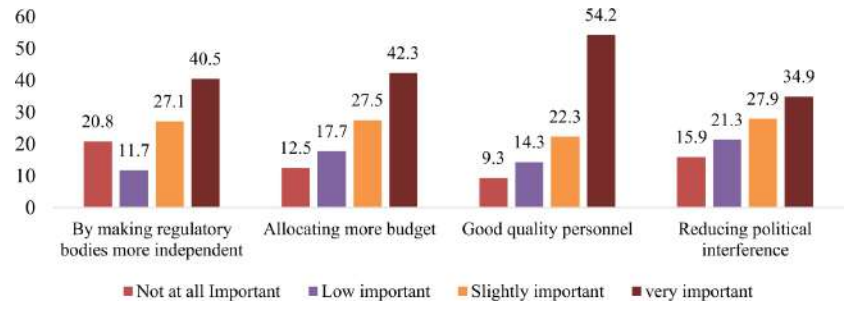
As the regulatory mechanism is ever-evolving to ensure the quality and affordability of healthcare services in the country, the stakeholders enquired about the concurrent quality of the regulatory mechanism and its efficiency. As a result, the majority of the respondents reported marginal satisfaction with the existing mechanism, indicating a need for strengthening and proper implementation of regulation across all levels.

Table 2.1: Quality of Regulation for Healthcare in India

States	Excellent	Good	Satisfactory	Poor	Very Poor
Assam	1	15	43	41	0
Bihar	5	8	49	37	1
Chhattisgarh	0	8	73	19	0
Delhi	0	1	61	38	0
Gujarat	1	7	60	26	6
Kerala	3	9	68	19	1
Madhya Pradesh	5	1	39	25	30
Maharashtra	0	18	48	34	0
Punjab	24	21	14	41	0
Telangana	0	19	66	15	0
Tripura	4	16	45	35	0
West Bengal	0	10	41	42	7
Overall	**3.6**	**11.1**	**50.6**	**31**	**3.8**

Stakeholders were followed up for their suggestions for improving the quality of regulation. The importance of Good quality personnel was prioritised by the majority of the respondents (54.2 percent) followed by the requirement of more budget (42.3 percent) and independency of the regulatory bodies (40.5 percent). The requirement of reduced political influence in the health system (34.9 percent) was found least important by the respondents in the study.

Figure 2.27: Changes Required for Improvement in Quality of Regulation



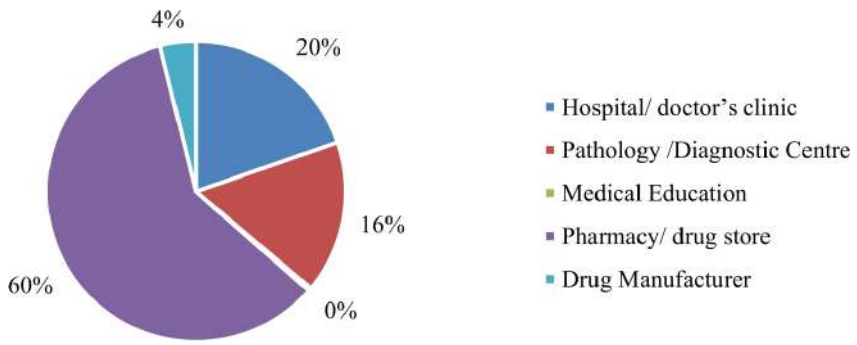
Perception and Awareness among Businesses in India

Data and Survey Design

The statistical analysis was based on the data gathered from structured questionnaires administered to a random stratified sample across various states in India. This method was chosen specifically since it often improves the representation of the sample by reducing sampling errors. The sample contained a total of 310 respondents spread across six regions and 12 states. Equal representation of the target population was ensured from each region.

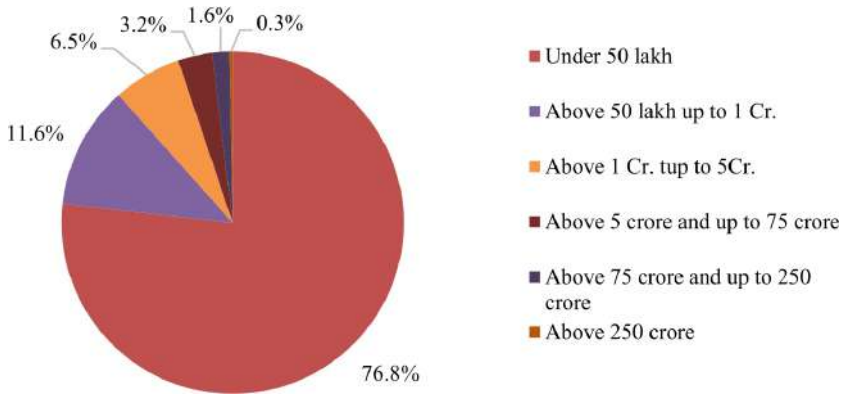
In addition to the above, a minimum of 10 drug manufacturers were covered under the study to provide us with a holistic understanding of the awareness among all primary players in the market. The sample consisted of pharmacy/ drug stores (60 percent), followed by hospital doctor's clinics (20 percent) and pathology/diagnostic centres (16 percent). Drug Manufacturers contributed about (4 percent) of the total sample.

Figure 2.28: Background of Businesses



About (80 percent) of the stakeholders that participated in the study represented an annual turnover of under ₹50 lakhs, followed by an annual income of ₹50 lakh to ₹1 crore (12 percent), ₹1 crore to ₹5 crore (6.5 percent) and remaining 5 percent above ₹5 crore.

Figure 2.29: Annual Income

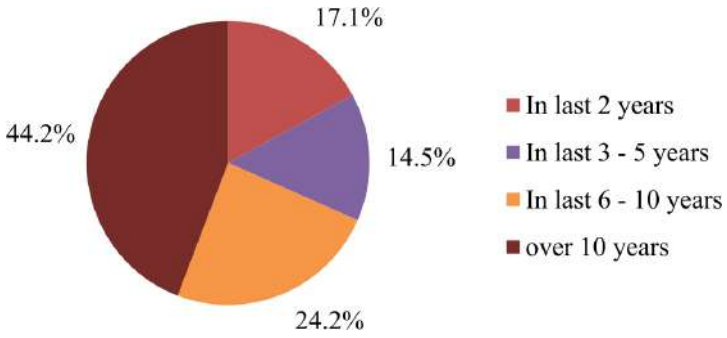


Analysis of Survey Findings/Results

Ease of Doing Business

Respondents were asked to mention their years of operation. Nearly half of the business segments were more than 10 years old, while 17 percent were very young, nearly 15 percent of the respondents belonged between 3-5 years of age, and 24 percent belonged 6 to 10 years.

Figure 2.30: Business Inauguration



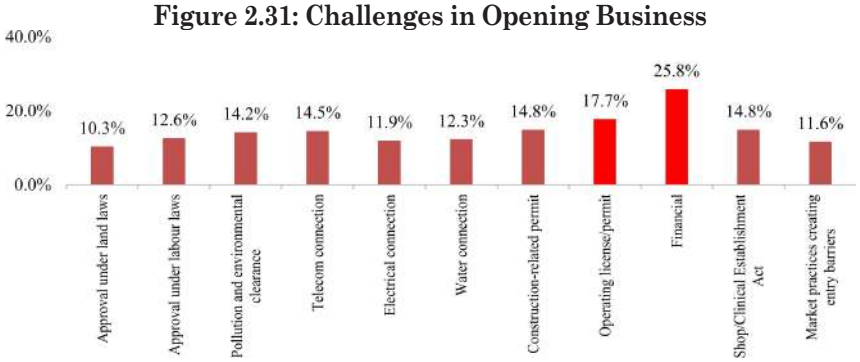
Asked about their experience in starting their business, nearly half of the (51 percent) stakeholders found some kind of challenges in starting their business. Above half of the pathology/diagnostic centre (58.8 percent) as well as pharmacy/drug stores (50.8 percent) reported some kind of challenge in opening their business, followed by a significant 47.5 percent of hospitals/ clinics. Overall, half of the respondents found no challenges in running their

businesses. However, a relatively large proportion of respondents felt financial and licence/permit-related issues are creating challenges.

Most of the drug manufacturers faced financial-related challenges, while 29 percent) of pathology centres, 26 percent of hospitals/doctors' clinics, and 22 percent of pharmacies faced a similar challenge. Over 20 percent of pathological centres and hospitals/doctor's clinics also reported registration under the Clinical Establishment Act as the second most pressing challenge followed by operating permits and pollution and environment clearance.

The following table (Table 2.2) gives a picture of the kinds of current challenges that businesses face. The trend is encouraging from the EODB perspective, though there is significant scope for improvement.

Figure 2.31: Challenges in Opening Business



Awareness and Opinion on Drug Price Control

Business owners were relatively less aware of NPPA as compared to consumers. Awareness was found to be on the higher side in the case of drug manufacturers (91.7 percent), pharmacy/drug stores (52.4 percent), and medical education centres (100 percent), while nearly (50 percent) of doctors and pathology /diagnostic centres also have awareness of the Act.

Figure 2.32: Awareness of NPPA

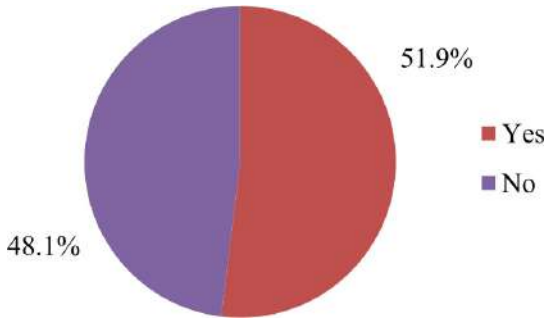


Table 2.2: Challenges Faced in Opening Business Over Time

	In the last 2 years	In the last 3 - 5 years	In the last 6 - 10 years	over 10 years
Experience in starting your Business				
Approval under land laws				
No obstacle at all	32.1	60.0	69.2	50.0
Manageable	39.3	30.0	20.5	29.4
Cumber-some	17.9	10.0	7.7	10.3
Very cumber-some	10.7	0.0	0.0	10.3
Can't Say/Don't know	0.0	0.0	2.6	0.0
Approval under labour laws				
No obstacle at all	21.4	50.0	64.1	50.0
Manageable	35.7	30.0	25.6	23.5
Cumber-some	25.0	15.0	10.3	16.2
Very cumber-some	3.6	0.0	0.0	5.9
Can't Say/Don't know	14.3	5.0	0.0	4.4
Pollution and environmental clearance				
No obstacle at all	17.9	30.0	56.4	51.5
Manageable	42.9	30.0	17.9	27.9
Cumber-some	17.9	35.0	15.4	8.8
Very cumber-some	10.7	0.0	7.7	8.8
Can't Say/Don't know	10.7	5.0	2.6	2.9
Telecom connection				
No obstacle at all	35.7	25.0	56.4	58.8
Manageable	28.6	35.0	17.9	16.2
Cumber-some	17.9	35.0	25.6	16.2
Very cumber-some	0.0	0.0	0.0	5.9
Can't Say/Don't know	17.9	5.0	0.0	2.9
Electrical connection				
No obstacle at all	25.0	30.0	61.5	54.4
Manageable	60.7	45.0	17.9	27.9
Cumber-some	10.7	25.0	15.4	10.3
Very cumber-some	3.6	0.0	5.1	5.9
Can't Say/Don't know	0.0	0.0	0.0	1.5
Water connection				
No obstacle at all	17.9	50.0	53.8	54.4
Manageable	39.3	35.0	20.5	25.0

	In the last 2 years	In the last 3 - 5 years	In the last 6 - 10 years	over 10 years
Cumber-some	25.0	10.0	17.9	13.2
Very cumber-some	7.1	0.0	2.6	5.9
Can't Say/Don't know	10.7	5.0	5.1	1.5
Construction-related permit				
No obstacle at all	32.1	45.0	61.5	48.5
Manageable	35.7	50.0	20.5	32.4
Cumber-some	28.6	5.0	15.4	13.2
Very cumber-some	3.6	0.0	0.0	5.9
Can't Say/Don't know	0.0	0.0	2.6	0.0
Operating license/permit				
No obstacle at all	32.1	40.0	38.5	44.1
Manageable	32.1	25.0	30.8	25.0
Cumber-some	17.9	25.0	17.9	13.2
Very cumber-some	14.3	5.0	10.3	11.8
Can't Say/Don't know	3.6	5.0	2.6	5.9
Financial				
No obstacle at all	25.0	20.0	28.2	36.8
Manageable	35.7	40.0	41.0	26.5
Cumber-some	25.0	25.0	15.4	17.6
Very cumber-some	14.3	15.0	10.3	14.7
Can't Say/Don't know	0.0	0.0	5.1	4.4
Shop/Clinical Establishment Act				
No obstacle at all	14.3	40.0	38.5	44.1
Manageable	50.0	45.0	38.5	27.9
Cumber-some	14.3	15.0	17.9	17.6
Very cumber-some	14.3	0.0	2.6	7.4
Can't Say/Don't know	7.1	0.0	2.6	2.9
Market practices creating entry barriers				
No obstacle at all	39.3	60.0	56.4	42.6
Manageable	28.6	20.0	23.1	38.2
Cumber-some	10.7	20.0	12.8	11.8
Very cumber-some	10.7	0.0	7.7	4.4
Can't Say/Don't know	10.7	0.0	0.0	2.9

When followed up on the purpose of NPPA, stakeholders reporting their awareness of NPPA identified price control over essential drugs (75.2 percent), ensuring availability of drugs (83.2 percent) and pricing of drugs/formulations (74.5 percent) as the key purposes.

Stakeholders were asked about their opinions related to the importance of price control of essential drugs. Where the majority were in support of drug price control (68 percent), a significant portion of the stakeholders did not hold any opinion related to the matter (27.1 percent). "Avoiding monopoly" and "ensuring affordability" were identified as the key reasons by the stakeholders.

Figure 2.33: Awareness of the Role of NPPA

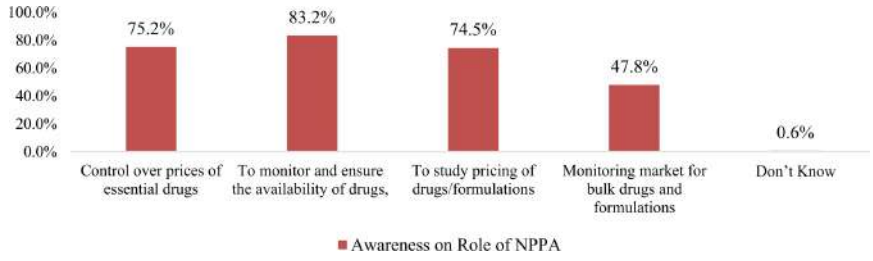
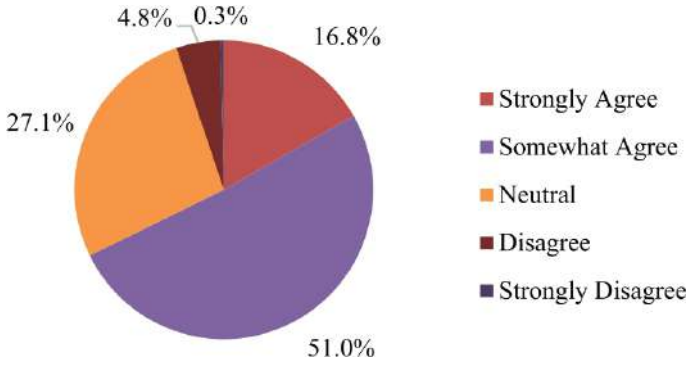
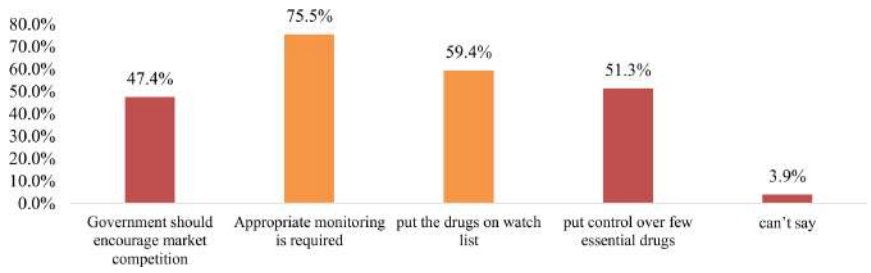


Figure 2.34: Importance of Drug Price Control



When suggestions were sought from the respondents on drug price control, a significant segment of the stakeholders believed that appropriate monitoring (75.5 percent) and putting drugs on the watchlist (59.4 percent) was essential.

Figure 2.35: Suggestion Related to Drug Price Control



Awareness and Opinion on CCI

The awareness level about the Competition Commission of India (CCI) among businesses remains on the lower side (34.5 percent). When asked about the purpose of CCI, around 67 percent, 50 percent and 50 percent were able to identify the promotion of competition, investigation & adjudication of anti-competitive practices and monitoring of the stock market respectively as the key purpose of CCI. A significant portion of them also reported monitoring of FDI inflow (45 percent) and monitoring competition of FMCG and Non-FMCG markets (43 percent).

Figure 2.36: Awareness of CCI

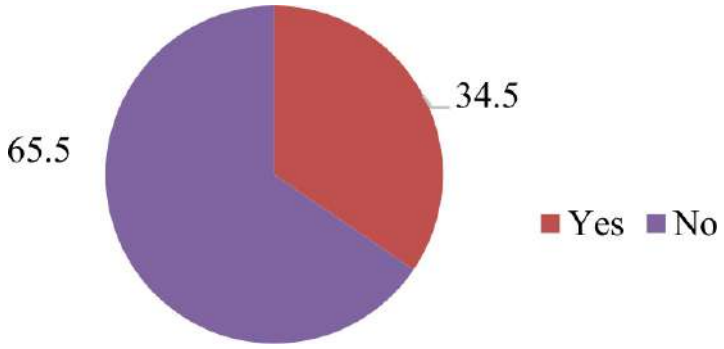
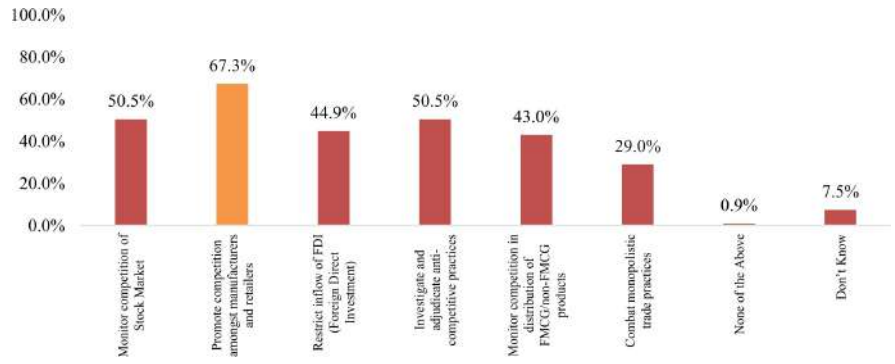


Figure 2.37: Purpose of CCI



The majority of stakeholders thought that practices, like tied selling and prescriptions in brand names, are quite prevalent in the market.

Table 2.3: Opinion of Various Market Practices

	Strongly Agree	Somewhat Agree	Neutral	Disagree	Strongly Disagree
Opinion related to Tied Selling					
Appropriateness of the practice	40	26	16	8	10
This helps ensure quality	54	22	12	2	10
This is just a means to make easy money	10	12	46	26	6
This limits the choice of consumers	18	46	28	8	0
Opinions related to promotional schemes run by health service providers					
Appropriateness of the practice	47.3	29.5	10.7	9.8	2.7
This helps ensure quality	39.3	25.9	23.2	8	3.6
This is just a means to make easy money	31.3	34.8	27.7	4.5	1.8
This limits the choice of consumers	33	35.7	24.1	5.4	1.8
Opinion related to brand selling by doctors					
Appropriateness of the practice	41.1	30.4	12.5	5.4	10.7
This helps ensure quality	41.1	27.7	18.8	7.1	5.4
This is just a means to make easy money	17	8	51.8	11.6	11.6
This limits the choice of consumers	36.6	25	26.8	8	3.6

Awareness and Opinion on CDSCO

The stakeholders were asked about the awareness of regulations that are established on safeguarding the standard of drugs in the Indian market and their purpose. Only about half of the key stakeholders dealing with the services are aware of the Central Drug Standard Control Organisation, while considering the drug manufacturers, nearly all the drug manufacturers know CDSCO.

Among those aware of CDSCO, about 81 percent, 75 percent, 74 percent and 55 percent respectively reported approval of drugs, clinical trials, laying down drug standards and quality control of imported drugs as the key role of CDSCO.

Table 2.4: Awareness of Central Drugs Standard Control Organisation (CDSCO)

	Hospital/ doctor's clinic	Pathology/ Diagnostic Centre	Medical Education	Pharmacy/ drugstore	Drug Manufacturer	Overall
Yes	47.5	41.2	100	49.7	100	46.8
No	52.5	58.8	0	50.3	0	50.0

Table 2.5: Awareness of Purpose of CDSCO

	Approval of Drugs	Conduct of Clinical Trials	Laying down the Standards for Drugs	Control over the quality of imported Drugs	None of the Above	Don't Know
Hospital/doctor's clinic	75.9	82.8	72.4	48.3	0.0	0.0
Pathology /Diagnostic Centre	85.7	85.7	76.2	61.9	4.8	4.8
Medical Education	100.0	100.0	100.0	100.0	0.0	0.0
Pharmacy/drugstore	80.4	70.7	70.7	54.3	1.1	5.4
Drug Manufacturer	91.7	66.7	100.0	66.7	0.0	0.0
Overall	**81.3**	**74.8**	**74.2**	**55.5**	**1.3**	**3.9**
**Multiple Responses*						

Awareness of the National Medical Commission (NMC)

Unlike the consumer segment, the majority of the business segment was aware of the NMC, but that only made up 53.5 percent of the total respondents. Considering the functioning industry, knowledge among the respondents was still on the lower side which needs to be enriched through awareness campaigns.

Further analysis shows that the respondents reporting awareness of NMC could identify quality and standards of medical education (70.5 percent), regulation on medical institutions (65.1 percent), addressing requirements in healthcare (62.7 percent) and ensuring professional ethics (53 percent) as the key role of NMC. Other roles identified by the respondents were the promotion of ethical conduct (53 percent) and the determination of fees in the private sector.

Figure 2.38: Awareness of NMC

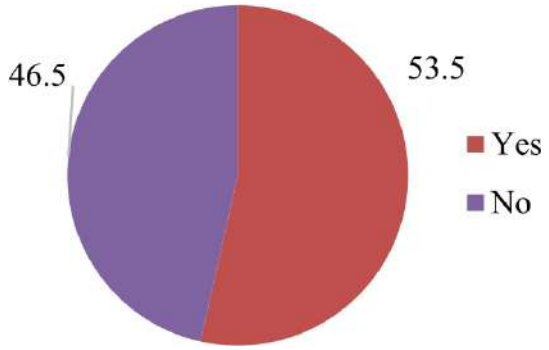
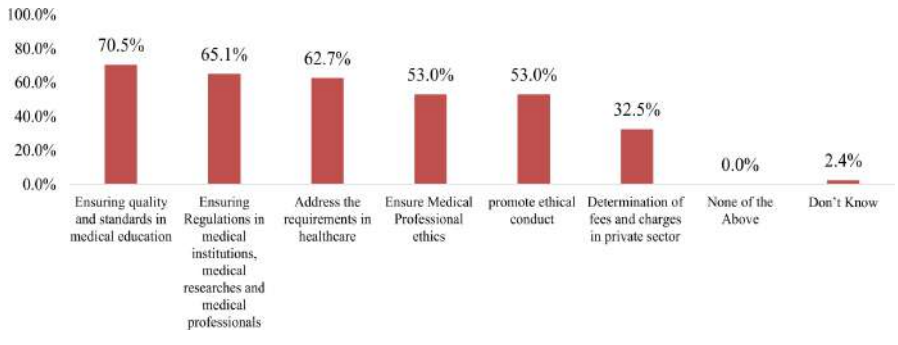


Figure 2.39: Awareness of Functions of NMC



Awareness and Opinion on Bio-medical Waste Management (BMWM)

Stakeholders covered under the study are majorly equipped with the knowledge of BMWM across sectors. Though the awareness of the BMWM system, its guidelines and segregation process are found on the high side, however, there is a gap in the service providers' knowledge.

Table 2.6: Awareness on BMWM

	Awareness of Biomedical Waste Management System	Awareness of Guidelines under BMWM	Awareness of the Segregation Process of BMWM
Hospital/doctor's clinic	73.8	65.6	67.2
Pathology/ Diagnostic Centre	86.3	84.3	86.3
Overall	79.5	74.1	75.9

Table 2.7: Opinion of BMWM Practices in Healthcare Units

	Adherence to Colour coding of different BMW as per Guideline	Adherence to BMW storage facility at healthcare centre as per Guideline	Adherence to guidelines for Deep pit burials	Availability of BMW protective kits
Opinion on BMWM practices in large healthcare units				
Strongly Agree	59.6	55.1	51.7	51.7
Somewhat Agree	33.7	29.2	28.1	31.5
Neutral	4.5	11.2	13.5	12.4
Disagree	1.1	2.2	5.6	2.2
Strongly Disagree	1.1	2.2	1.1	2.2
Opinion on BMWM practices in small healthcare units				
Strongly Agree	55.1	50.6	48.3	49.4
Somewhat Agree	40.4	30.3	33.7	31.5
Neutral	4.5	13.5	15.7	18
Disagree	0	3.4	2.2	1.1
Strongly Disagree	0	2.2	0	0

Respondents reporting awareness of BMWM were followed up with a series of questions related to the prevalent practices among different scales of healthcare units. Almost all the respondents expressed their positive perception related to BMWM practice in large and small healthcare units, while the availability of protective kits for the BMW handlers was found to be on the lower side.

Opinion on the Clinical Establishment Act

The respondents strongly agree with the requirement of the CE Act, 2010 for ensuring standards (60.8 percent), quality (60.8 percent), affordability (56.9 percent) and availability (45.1 percent), to ensure proper healthcare (56.8 percent).

Table 2.8: Opinion of Clinical Establishment Act, 2010

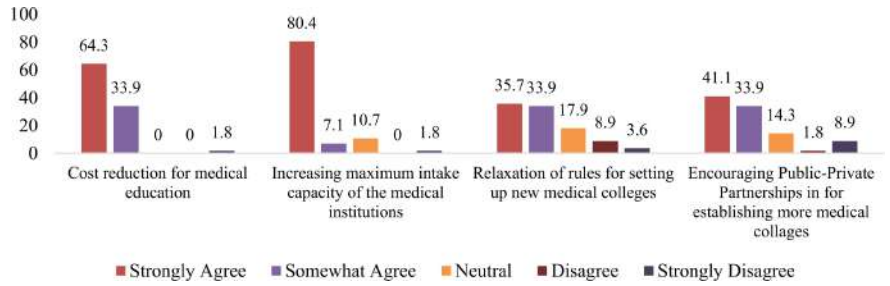
	Strongly Agree	Somewhat Agree	Neutral	Disagree	Strongly Disagree
An effective way to ensure adherence to standards	60.8	23.5	11.8	3.9	0
An effective way to ensure adherence to quality	60.8	21.6	5.9	7.8	3.9
An effective way to ensure adherence to affordability	56.9	19.6	17.6	3.9	2
An effective way to ensure adherence to availability	45.1	35.3	11.8	5.9	2
An effective way to ensure proper healthcare	56.9	23.5	13.7	5.9	0

Opinion on Human Resources Problem in the Healthcare Sector

All the medical institutions covered and the majority of the hospitals/doctor's clinics agreed that there exists a shortage of healthcare human resources. Those aware of the shortage of human resources in the healthcare sector were asked for their suggestions on strategies that can work to mitigate the challenge. The majority of the respondents were of the strong opinion that the shortage of healthcare professionals in the market can be mitigated by

reducing the cost of medical education (64.3 percent) and increasing intake capacity in medical institutions (80.4 percent), while a significant portion also expressed their opinion on relaxation of rules for setting up medical colleges (35.7 percent) and encouragement of public private partnership (41.1 percent).

Figure 2.40: Solving HR Shortage in the Health Sector



CHAPTER 3

Competition Issues in the Healthcare and Pharmaceutical Sectors

Introduction

Amid the COVID-19 pandemic, healthcare has become a paramount concern for policymakers worldwide. The WHO's position paper emphasised the need for resilient health systems, promoting universal health coverage (UHC) and health security.[1] It called for a renewed national and global commitment to prepare countries against public health threats for sustained progress.[2] The pandemic's widespread lockdowns prioritised public health over economic interests, leading to substantial adverse economic impacts.[3]

During the pandemic, competition policy adjusted to the unique situation. Measures were implemented to ensure the smooth supply of vital goods, including healthcare and food. Several articles and reports have analysed the response of competition policy to the pandemic situation.[4] Typically, competition policy responses during the pandemic are dual-focused: ensuring a smooth supply of essential goods like healthcare and food, and addressing post-lockdown economic recovery. For the former, the key approach was to ensure competition enforcement does not hinder necessary business cooperation.

This paper presents an illustrative analysis of how *ex ante* competition policy and *ex post* competition law enforcement can enhance access to healthcare. The scope of this paper primarily revolves around healthcare services and pharmaceuticals.

Competition Policy Approach

To ensure a competitive marketplace, merely enforcing competition laws may prove insufficient. A conducive policy environment promoting competition is crucial, achieved by eliminating entry barriers, addressing market imbalances, and facilitating business establishment and operations.

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Patents and Competition Policy

In the pharmaceutical market, intellectual property (IP) policies, particularly patent rights and regulatory data exclusivity, have a significant impact on competition. While patent strategies are legitimate, innovators may use such strategies to hinder generic competition, including extending their market exclusivity beyond the patent expiration.[5] Access to medicine improves significantly with the presence of generic competition, which is highly dependent on the type of domestic IP laws a country adheres to.

For example, in India a new patent law in 1970 led to the growth of the domestic pharmaceutical industry and a high level of generic competition.[6] It recognised only process patents in pharmaceuticals, not product patents, which allowed Indian companies to reverse-engineer patented drugs and use a different process to manufacture them at a lower cost[7]. This has significantly improved access to drugs, not only in India, where out-of-pocket healthcare expenses are high, but also for poor populations in other parts of the world[8].

In 2005, India had to amend its patents law when the provision on product patents under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organisation (WTO) came into force. India incorporated the same along with other pro-competition provisions (TRIPs flexibilities) in its patent law. This approach helped in maintaining its level of generic competition to a significant extent.

One of the most talked about issues having adverse effect on competition in the pharmaceutical market is "evergreening" of patents – a strategy used for extending the life of patents beyond its period of protection.[9] This involves making minor changes to an existing drug or its formulation, even if the new version provides no or minimal therapeutic advantages. By obtaining new patents for these slight modifications, the company can effectively prolong its market monopoly and delay the entry of generic competitors. This practice has been a subject of debate and criticism, as it can hinder access to more affordable generic medicines and potentially increase healthcare costs for patients and healthcare systems.[10]

To deal with evergreening, the Indian patent law provides for stricter patentability criteria that ensure the quality of patents.[11] This provision has also passed the constitutional test. The Supreme Court of India in the famous *Gleevec* case upheld the rejection of patents stating that the drug was a modification of an existing substance 'imatinib' and therefore represented a case of 'evergreening' in absence of any evidence to support any enhanced therapeutic efficacy.[12]

There are many flexibilities in the TRIPs agreement, for instance, compulsory licence for domestic production as well as for exports, Bolar exception, exhaustion of Intellectual Property Rights, data protection under Article 39.3 etc., which if incorporated in domestic IP laws, there will be pro-competition effects in the market. International instruments like the WTO Doha Declaration on the TRIPs Agreement and Public Health, 2001 and the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, 2008 (GSPA-PHI) encourage countries to use such flexibilities in order to enhance access to medicines.

However, there are bilateral, regional, or plurilateral trade agreements, particularly involving developing countries, which not only mitigate available TRIPs flexibilities but also go beyond minimum standards prescribed under the TRIPs Agreement. Developing countries and least developing countries need to guard against signing such TRIPs-Plus deals.

Other Regulations and Competition Policy

The pharmaceutical sector is a highly regulated sector in most countries. From a competition policy perspective these regulations – mainly market approval and price regulation – need to be least restrictive in achieving regulatory objectives. For instance, the market approval process of biosimilar drugs (generic versions of biological drugs) has been flagged as overregulation, which creates barriers to generic competition.[13]

Similarly, price regulation of generic drugs can stifle competition by limiting market contestability. Price regulation should be a last resort, such as in cases of market failures. Another obstacle to competition exists with respect to doctors' prescription practice of using brand names. While doctors' main argument for such practice is "trust" of quality, a connection or relationship between prescribing doctors and pharmaceutical companies cannot be ruled out.[14] Therefore, investing in quality control to increase trust in generic substitutes can be pro-competition. The implementation of standard treatment guides will also increase transparency by reducing information imbalances and will thus be beneficial for competition.

Furthermore, policymakers should address entry barriers for setting up of new hospitals and medical colleges, which currently face high establishment costs and long gestation periods. Facilitating factors like land acquisition, medical equipment imports[15], increased health insurance coverage and proper regulation of medical education can enhance competition and access to healthcare.

Competition Enforcement

Competition agencies worldwide have addressed various anti-competitive behaviours and practices in the healthcare and pharmaceutical industries. Following are some of such practices illustrated with real cases.

Pay-for-Delay

In the pharmaceutical industry, pay-for-delay or reverse payment settlements occur when the original drug companies pay their generic competitors to hold off on releasing their generic versions in the market. This type of arrangement can stifle competition and prevent the lowering of prices due to generic competition.

In 2013, in the *Lundbeck* case, the European Commission found the presence of a pay-for-delay arrangement and imposed fines on all the parties involved €93.8 million on Lundbeck and a total of €52.2 million on the generic companies.[16] In 2016, the General Court upheld this decision.[17]

The US Supreme Court, in *Federal Trade Commission (FTC) v. Actavis* (2013), has also held that a pay-for-delay agreement can face an antitrust challenge under the rule of reason.[18]

Frivolous Litigation

The pharmaceutical industry is subject to intense regulation, including to ensure quality, safety and efficacy as well as affordability. However, these regulations open several avenues for litigations, which sometimes could be frivolous with the intention to curtail market competition. For example, some pharmaceutical companies have been accused of using their IP rights to delay or prevent generic entry[19].

In the case *Biocon v. Roche* (2016) before the Competition Commission of India (CCI), it was alleged that the Roche Group started indulging in frivolous litigation with the intention of preventing the entry of the generic version (biosimilar) of the biologic drug *Trastuzumab*. The CCI, finding a prima facie case of abuse of dominance, ordered an in-depth inquiry.[20]

Cartels

Cartels are arrangements between competing firms designed to limit or eliminate competition between them, with the objective of maximising their profits and without resulting in any objective countervailing benefits. Different forms of cartels are price fixing, limiting output, allocating customers of territories, bid-rigging or a combination of these. The pharmaceutical and healthcare industries are plagued by anti-competitive practices that have come under scrutiny by competition authorities.

In 2008, the Fiscalía Nacional Económica (FNE), Chile, filed a complaint against three retail pharmacies accusing them of concerted action resulting in increases in the prices of 206 drugs between December 2007 and March 2008. In April 2009, a settlement agreement was reached between FNE and Farmacias Ahumada, which agreed to pay a fine of US$1mn. In January 2012, Tribunal for the Defense of Free Competition (TDFC) imposed a maximum applicable fine of approximately US$20mn on each of the two remaining retail pharmacy chains. In September 2012, the Supreme Court upheld TDFC's decision, flagging that economic interest was placed before human dignity, life and individual health.[21]

The case of *European Commission v. F. Hoffmann-La Roche Ltd. And Ors.* (2001)[22] involves a collusive tendering agreement among multiple pharmaceutical companies. The investigation revealed bid-rigging activities related to vitamin provision in several European nations. The companies collaborated on bids, divided clients and territories and influenced procurement results. This collusion led to higher pricing and hindered competition. As a result, the European Commission imposed substantial fines on the involved companies.

On a similar line, in the case of *United States v. Taro Pharmaceuticals Industries Ltd.* (2019)[23], the U.S. DoJ pursued legal action against Taro Pharmaceuticals for its involvement in a collusive tendering scheme. Taro Pharmaceuticals and other entities allegedly manipulated prices, divided customers and influenced bidding for generic medications. This conduct affected the pricing of pharmaceuticals used to treat various health conditions, including hypertension, arthritis and epilepsy. Taro Pharmaceuticals agreed to pay a criminal fine and entered into a deferred prosecution agreement to resolve the allegations.

In India, collusive conduct was examined in the case of *Sudeep P.M. v. All Kerala Chemists & Druggists Association (AKCDA)* (2017)[24]. The CCI found that AKCDA had engaged itself in activities to control the supply chain and hinder potential new entrants in the pharmaceutical retail.

A study by CUTS International in 2011 had found the presence of collusive behaviour and vertical relationships between doctors/hospitals and pharmacies/diagnostic centres. An extremely high frequency of referrals combined with the prevalence of "cuts" for referring doctors was noted.[25] In the healthcare industry, "cuts" (also known as cut practice or referral fee) refer to the practice of doctors receiving commissions or a percentage of the money spent by patients on tests and treatments when they refer them to other doctors or treatment facilities.[26]

Vertical Restraints

Vertical agreements (that is, between undertakings operating at different levels of the production chain) are a common feature in the market as a substitute for vertical integration. The impact of vertical agreements on competition has to be evaluated based on the reasonableness of restraint they impose. These agreements typically include exclusive distribution, exclusive supply and tying agreements, which could limit competition and eliminate intra-brand competition.

The CCI has handled several instances where chemist and druggist associations at the national or state level attempted to regulate the appointment of stockists, sales of pharmaceutical products, and wholesale and retail margins. Many of these cases involved the requirement of a "No Objection Certificate" (NOC) as a condition for appointment of stockists and the fixing of "trade margin" for retailers and wholesalers.[27]

In October 2018, the CCI released a policy note titled "Making Markets Work for Affordable Healthcare" in which it made the following observations about trade associations:

> *"The cases before the Commission have shown that the entire supply chain of drugs is self-regulated by the trade associations who regulate entry by mandating a NOC prior to the appointment of stockists, control distribution by restricting/controlling the number of stockists and influence price by deciding the wholesale and retail margins of drugs. The Commission's past interventions have led to some positive outcomes and businesses and business associations have revised their policies and practices to bring them in alignment with the principles of competition."*[28]

The National Development and Reform Commission (NDRC), China, in 2011, found that two pharmaceutical companies (Shuntong and Huaxin) had signed exclusive distribution agreements with two domestic producers of active pharmaceutical ingredients (APIs), allowing them to control the supply of key raw material for a commonly used compound in high blood pressure treatments. These agreements required the API producers to obtain approval from both companies before selling the product to any other party. As a result, the compound reserpine tablet manufacturers could not afford the excessively high ingredient cost and were forced to suspend production, causing a shortage of supply in the market. The NDRC fined these companies RMB 7 million (c. US$1.1mn).[29]

Excessive Pricing

There have been instances where the unilateral conduct of companies resulted in excessive prices of drugs. The *Aspen* case in Italy is a good example. In 2016, the Italian Competition Authority, Autorità Garante della Concorrenza

e del Mercato (AGCM), imposed a fine on the Aspen pharmaceutical group for abuse of dominance in form of excessive prices concerning some essential off-patent drugs. The price increase ranged between 300 percent to 1500 percent. Despite being off-patent, new generic producers lacked the incentive to enter the market given the low volume of the market.[30]

Mergers and Acquisitions (M&As)

Though M&As may have efficiency gains, they may also compromise competition in a market. Thus, they may be subject to scrutiny by competition authorities. The competition assessment of the M&As evaluates the likelihood of increased prices, diminished quality, or restricted options. In the event of competition concerns, authorities may impose conditions or, in severe circumstances, prohibit the transaction.

In 2020 the European Commission while reviewing the acquisition of Pfizer's Consumer Health Business by GlaxoSmithKline (GSK), found that the deal would reduce competition in topical pain management products in countries like Austria, Germany, Ireland, Italy, and Netherlands. The products of GSK and Pfizer were broadly substitutable in the market. The acquisition was allowed, subject to a condition for the global divestment of Pfizer's topical pain management business under the *ThermaCare* brand.[31]

Similarly, in 2019, the US Federal Trade Commission (FTC) reviewed the merger of Bristol-Myers Squibb (BMS) and Celgene Corporation and observed that the transaction could lessen competition in the relevant market and create a monopoly by eliminating any future competition in development of drugs for treatment of psoriasis. Any new entrant in the market would face delays for drug development and obtaining marketing approval. The merger was allowed when Celgene consented to divest Otezla, a popular skin ailment drug, to Amgen, a California-based pharmaceutical company.[32]

In 2015, the CCI approved the Sun Pharma and Ranbaxy merger only when the parties agreed to divest certain products to a third party.[33]

Conclusion and the Way Forward

From the above discussions, we see that competition policy and law play a significant role in enhancing access to healthcare. In order to keep markets competitive, both *ex-ante* competition policy and *ex-post* competition enforcement are important tools.

Looking at the patent policy through the lens of competition policy is crucial for generic competition, which significantly enhances access to drugs. Competition authorities can advocate to their respective governments to

incorporate TRIPs flexibilities into domestic laws and guard against TRIPs-Plus provisions in bilateral or regional agreements.

Similarly, it is crucial to advocate for the removal of regulatory barriers to new market entrants. The optimality of regulations can be determined by the competition assessment exercise. Regulations need not be more restrictive than to achieve the stated objectives.

Additionally, competition authorities must give priority to enforcement in the healthcare industry, as this sector affects the low-income population the most. The recent pandemic has highlighted the importance of having a robust, accessible and affordable healthcare system, for which competition policy is an important tool.

Endnotes

1 https://www.who.int/publications-detail-redirect/WHO-UHL-PHC-SP-2021.01

2 *Ibid*

3 https://www.weforum.org/agenda/2021/02/covid-employment-global-job-loss/

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5 European Commission (2009a, b, c), para. 467 ("the term 'patent strategies' should be understood to encompass all strategies of a company concerning the use of the patent system to the benefit of the company in relation to generic competition. The term includes strategies on the timing and scope of filing as well as the manners in which patents are applied for")

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7 https://www.lawctopus.com/academike/intellectual-property-rights-in-pharmaceuticals/

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9 Evergreening of patents is a strategy to extend the life of patents by applying for secondary patents over related or derivative technologies, often for trivial changes to the invention.

[10] https://uclawsf.edu/2020/09/24/patent-drug-database/

[11] According to section 3(d) of the Patents Act, 1970, "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant" are not inventions, and hence, are not patentable.

[12] Novartis AG v. Union of India (Civil Appeal Nos. 2706-2716, 2013); https://docs.google.com/file/d/0Bxi2TzVXul5ZQ1BMeFNJbnV1Mkk/edit.

[13] See, e.g., Amit Sengupta, Biological Drugs: Challenges to Access (2018).

[14] See, e.g., CUTS, Unholy Alliances in Healthcare–Collusive Behaviour in Healthcare and Impact on Consumers: Evidences from Assam & Chhattisgarh (2011), https://cuts-ccier.org/pdf/Research_Report-Unholy_Alliances_in_Healthcare_Services-COHED.pdf.

[15] https://www.trade.gov/country-commercial-guides/india-healthcare-and-medical-equipment

[16] Case AT.39226 Lundbeck (Commission decision C (2013) 3803),

https://ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_39226. See also Johan Van Acker & Dina Ansari, The EU Commission imposes fines totaling up to €145 million on a Danish pharmaceutical group over pay-for-delay agreements (Lundbeck), e-Competitions June 2013, Art. N° 53996 (June 19, 2013)

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[18] FTC v. Actavis, Inc., 570 U.S. 136 (2013). See also Tim Frazer et al., The US Supreme Court holds that "reverse payment" patent settlements between brand-name drug manufacturers and would-be generic competitors should be reviewed under the antitrust rule of reason (Actavis), e-Competitions June 2013, Art. N° 52994 (June 17, 2013)

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[23] United States v. Taro Pharmaceuticals Industries Ltd., Criminal No. – 20cr213

[24] Sudeep P.M. v. All Kerala Chemists & Druggists Association (2017) SCC OnLine CCI 54

[25] See, e.g., CUTS, supra note 19.

[26] https://www.dailyo.in/politics/the-ethical-doctor-medicine-corruption-cut-practice-referral-diagnosis-hospitals-13219

[27] See, e.g., Rupin Chopra & Chanakya Sharma, CCI–Chemists and Druggists Associations Warned to Refrain from Indulging into Anti-Competitive Practices (2016), www.lexology.com/library/detail.aspx?g=eef58c14-38da-446f-ae71-cb592d51fd8b.

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[29] https://www.mondaq.com/china/antitrust-eu-competition-/157444/ndrc-fined-two-pharmaceutical-companies-for-abusive-conducts

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CHAPTER 4

Public-Private Partnership Model in the Healthcare Services Sector

Introduction

Public-private partnerships (PPPs) are understood as a variety of cooperative arrangements between the government and the private sector in delivering goods or services to the citizens. PPPs prove to be an effective tool for the government to coordinate with non-governmental actors to undertake integrated, comprehensive efforts to meet community needs. PPPs aim to take advantage of the expertise of each partner so that resources, risks, and rewards can be allocated in a way that best meets clearly defined public needs.[1]

One of the most important public services is Health itself as it is both a result and a contribution to development. Healthcare is a crucial component in the right, people-centred, egalitarian, and inclusive approach to development.[2]

Healthcare is a complex subject for policymakers and a complex sector to regulate for the government. It is a multi-headed activity with different components and widest reach. Therefore, the challenges are also complex and need nuanced policy approaches and directed investments. A one-size-fits-all approach should be discouraged in the healthcare sector. For the effective and efficient implementation of PPP models in healthcare, the implementation should be tailored for specific segments, which are ready for such investment. PPP should be utilised to plug in the weaknesses of those identified segments.

The COVID-19 pandemic prompted collaborations in areas of healthcare services such as diagnostics, technology, and treatment. The synergies that were seen in the management of COVID-19 are unprecedented, the CoWin portal[3] being the best example. There has been strong evidence to show that collaboration of the public and the private sectors can ensure accessibility

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and affordability of quality healthcare. Therefore, the feasibility of PPPs in the management of healthcare services needs to be explored.

Status of India's Healthcare Sector

The key to establishing an effective and efficient healthcare delivery system in any country is to ensure the three 'A's: Availability, Accessibility and Affordability. Despite being a country of a billion people, India has one of the lowest public spendings on health at a mere 1.4 percent of its Gross Domestic Product (GDP).[4] This is much less than the recommended 5 percent by the World Health Organisation (WHO).

In view of global standards, overall spending on healthcare by the government is considerably low. Consequently, the out-of-pocket burden on the country's citizens increases multi-fold. We have seen some very fruitful but sporadic healthcare initiatives by the government in its attempts to ensure healthcare for all.[5]

Health also has a central place in Sustainable Development Goal (SDG) 3 *"Ensure healthy lives and promote well-being for all at all ages"*, underpinned by 13 targets.[6] Therefore, strong political commitment is fundamental to increased investment in health-related major policy reforms which would contribute to India achieving the health SDG. The Ministry of Health and Family Welfare (MoHFW) has developed a national monitoring framework for Health SDG disaggregated into four broad thematic areas (Reproductive, maternal, newborn, child, and adolescent health; Communicable diseases; non-communicable diseases and Health Systems).[7]

Healthcare for all is probably India's most ambitious and necessary dream. It is also one of the rapidly growing industries in India. But despite being a prominent exporter of the health workforce to developed nations, India itself faces a scarcity of doctors and nurses. Hence, the dream would be impossible to achieve without an adequate number of well-trained and professionally content health workers placed to serve the socio-demographically diverse people spread across the vast subcontinent. Our governance and policymakers recognise the importance of health workers in India's health system and broader society. India has voluntarily adopted achieving 45 allopathic doctors, nurses, and midwives per 10,000 people as one of its SDG targets.[8]

Since 2018, NITI Aayog, the apex governmental think tank has been tracking India's and its states' performance for achieving this target. As of 2020-21, the most recent year for data reporting, numbers from NITI Aayog tell us that India lags the target by about 8 doctors, nurses, and midwives per

10,000 people translating to a shortage of over 50 lakhs of these health workers.[9] While this by itself might be disappointing, there has been improvement in the long run. The census data from 1981 to 2011, shows over a 220 percent increase in the density of allopathic doctors, nurses, and midwives per 10,000. However, this is mostly driven by the increase in nurses and midwives and not doctors.

A more interesting and important picture emerges when we look at states. Some states/union territories (UTs), such as Andhra Pradesh and Delhi, have already achieved the SDG target and are well above it while others like Jharkhand and Nagaland are arguably not going to achieve it even by 2030 if the current trends follow.

The National Health Protection Scheme (Ayushman Bharat)[10] was launched to cover the health expenditures of secondary and tertiary care of people living below the poverty lines. Opening of *Jana Aushadhi Kendra* which is a chain of pharmacy stores to provide medicines at doorsteps. These measures testify to the Indian government's commitment towards the targets set up by SDGs.

The Indian health care system is faced with many challenges which this country is fighting with remarkable synergies between industry, civil society, and governments at different levels. India has met with some progress in the reduction of the infant mortality rate, from 125 per 1,000 live births in 1990-91 to 50 per 1,000 live births in 2015-16, and the maternal death rate reduced from 212 per 100,000 live births in 2007-09 to 167 in 2013.[11] India progressed in reducing the spread of HIV and AIDS in various vulnerable categories, with prevalence declining from 0.45 percent in 2002 to 0.27 percent of the adult population in 2011. However, a quarter of the world's tuberculosis cases are reported in India, where almost 2.1 million people get infected from this disease and approximately 423,000 die each year.[12]

Identifying Segments of Healthcare for PPP

PPP models which are curated to certain local settings and community needs, can help in providing quality healthcare, ensuring access and affordability in a resource-constrained setting.[13] The PPP model has indeed been reasonably successful in India over the past few decades.[14]

Needs and challenges of the healthcare sector in India, as discussed in the previous section can be filled as gaps using the PPP models. Considering the different diversities of the country, its size, and the differential phases of development among regions, specific targets and programmes should be identified to implement PPPs in healthcare.

The flexible nature of PPPs provides a framework for developing and adapting existing structures to meet the specific needs of each project.[15] For instance, among the objectives of PPPs could be the establishment of a sustainable financial system; capacity-building reforms and management reforms in the public and private sectors; preventing unintended outcomes in the growth of the private sector in health; cost control and improving the health of the community; facilitating socio-economic development; improving PHC services coverage, quality, and infrastructure; as well as increasing the demand for health services.[16]

Some researchers maintain that despite several risks, feasible and desirable PPPs do exist and can be deployed innovatively, provided there are government regulations which are strictly abided by.[17] The setting up of a PPP appraisal committee has streamlined appraisals and approvals of projects, in addition to bringing in greater transparency and competitive bidding processes.[18]

PPP in healthcare has the potential to resolve the issues and ensure healthcare inclusion for the Indian masses. Starting with smaller projects and driving success for the same can help build credibility and get buy-in from all stakeholders.[19]

Several segments of healthcare are suitable for PPPs, including:

Hospital Infrastructure

PPPs can be used to build and maintain hospital infrastructure. Private companies can invest in hospital construction and provide services such as equipment maintenance and facility management, while the government can provide regulatory oversight. PPPs in hospital infrastructure are often structured as Design-Build-Finance-Operate-Maintain (DBFOM) or Build-Operate-Transfer (BOT) contracts.

Case Study 1.1: In the UK, the government has partnered with private companies to build and operate several new hospitals, including the Royal Liverpool University Hospital and the Midland Metropolitan Hospital. The partnerships are structured as DBFOM contracts, where the private companies are responsible for financing, designing, building, operating, and maintaining the hospitals over 30 years.[20]

Case Study 1.2: In Brazil, the government partnered with private companies to build and operate several new hospitals, including the Hospital Regional de Sorocaba and the Hospital Metropolitano de Belo Horizonte. These partnerships have helped improve access to healthcare services and reduce wait times for patients.[21]

Diagnostic and Laboratory Services

Private companies can provide diagnostic and laboratory services in partnership with the public sector. This can help improve the accuracy and speed of diagnoses while also reducing costs. PPPs in diagnostic and laboratory services are often structured as Service Contracts or Management Contracts.

Case Study 2.1: In Tanzania, the government has partnered with private companies to provide diagnostic and laboratory services in public hospitals and clinics. The partnerships are structured as Service Contracts, where the private companies are responsible for providing and maintaining the equipment and staff to perform diagnostic and laboratory services.[22]

Case Study 2.2: In India, the government partnered with private companies to provide diagnostic services through mobile vans equipped with state-of-the-art equipment. This has helped improve access to healthcare services in remote and underserved areas.[23]

Medical Equipment and Technology

Private companies can provide medical equipment and technology to public hospitals and clinics. This can help improve patient care and outcomes while also reducing costs. PPPs in medical equipment and technology are often structured as Supply Contracts or Lease Contracts.

Case Study 3.1: In Kenya, the government has partnered with private companies to provide medical equipment and technology to public hospitals and clinics. The partnerships are structured as Lease Contracts, where the private companies lease the equipment to the government for some time, and provide maintenance and training services.[24]

Case Study 3.2: In South Africa, the government partnered with private companies to provide mobile clinics equipped with telemedicine technology. This has helped improve access to healthcare services in rural and underserved areas, where patients often must travel long distances to receive care.[25]

Health Insurance

PPPs can be used to develop and implement health insurance schemes that are accessible and affordable for all. Private insurers can provide coverage for basic healthcare services while the government can provide oversight and regulation. PPPs in health insurance are often structured as Concession Contracts or Joint Venture Contracts.

Case Study 4.1: In Ghana, the government has partnered with private insurers to provide health insurance coverage to all citizens. The partnerships are structured as Concession Contracts, where the private insurers are

responsible for managing and administering the health insurance scheme, while the government provides oversight and regulation.[26]

Case Study 4.2: In Rwanda, the government partnered with private insurance companies to provide health insurance coverage to all citizens. This has helped improve access to healthcare services and reduce out-of-pocket expenses for patients.[27]

Primary Care

PPPs can be used to deliver primary care services in underserved areas. Private companies can partner with the government to provide clinics and other primary care facilities, staffed by trained healthcare professionals. PPPs in primary care are often structured as Management Contracts or Joint Venture Contracts.

Case Study 5.1: In India, the government has partnered with private companies to provide primary care services through telemedicine-enabled Health and Wellness Centers (HWCs). The partnerships are structured as Management Contracts, where the private companies are responsible for managing and operating the HWCs, while the government provides oversight and regulation.[28]

Case Study 5.2: In the Philippines, the government partnered with private companies to provide primary care services through community health centres. This has helped improve access to healthcare services in underserved areas, where there is a shortage of healthcare professionals.[29]

Effective Implementation of PPPs in Health Services and Challenges

In India, both the central and state governments have established numerous partnerships with the private sector to deliver healthcare services for nearly two decades.[30] More recently, the NITI Aayog has also highlighted the importance of such collaborations. The National Health Policy of 2017 recognised the significant role played by the expansive private sector and proposed strategies for involving it in attaining universal health coverage. The policy also emphasised the government's role in overseeing and regulating the mixed network of public and private healthcare providers.[31]

This approach of government collaboration with non-state entities has been a vital aspect of healthcare system enhancements in lower- and middle-income countries worldwide.[32]

However, concerns have arisen both domestically and internationally regarding the potential consequences of PPPs in the healthcare sector.[33]

These concerns encompass matters of fairness and inclusivity in healthcare accessibility, along with challenges related to transparency and responsibility.[34]

Issues like elevated expenses and user charges, the diversion of public funds towards private entities, service fragmentation, and compromised rights of healthcare workers have also been brought to the forefront. Furthermore, there have been ethical reservations about the implications of PPPs. Empirical data collected from various Indian states indicates a mixed record of PPP performance. While certain cases saw an enhancement in services due to PPPs, the majority experienced difficulties. Reports underscore problems such as irregular operations, instances of corruption, service quality deficiencies, obstacles to affordability and access, the decline of existing in-house services, inadequate accountability, as well as deficiencies in monitoring and mechanisms for addressing grievances. Interestingly, private entities involved in PPPs encountered analogous challenges to those faced by government agencies.[35]

Hence, the successful execution of PPPs in healthcare demands meticulous preparation, efficient administration, and robust governance structures. These measures are essential to ensure the realisation of PPPs' objectives while minimising associated risks. Nonetheless, several obstacles need to be confronted to guarantee the triumph of PPPs in healthcare.

Challenges in the Implementation of PPPs in Health Services

Political Risk

Political risk is a significant challenge in implementing PPPs in health services. Changes in government or policy priorities can disrupt PPPs and create uncertainty for private sector partners. It is important to establish a legal framework that is robust enough to ensure the continuity of PPPs even with changes in government.

The PPP for the management of the Rajiv Gandhi Jeevandayee Arogya Yojana (RGJAY), a health insurance scheme for the poor in Maharashtra, was disrupted due to political changes. The scheme was initially implemented by a private sector partner, but after a change in government, the management was transferred to a public sector entity. The transfer of management led to delays in payments to hospitals and providers, and some private sector partners withdrew from the scheme.[36]

Regulatory and Legal Framework

Weak regulatory and legal frameworks can create challenges in managing and operating PPPs in health services. This includes challenges in contract management, dispute resolution, and risk allocation. It is important to establish a regulatory and legal framework that is transparent and ensures accountability of all parties involved.

The PPP for the construction and management of the All-India Institute of Medical Sciences (AIIMS) in Bhopal faced challenges in contract management and dispute resolution. The private sector partner faced delays in receiving payments from the government, and disputes arose over the scope of work and project cost overruns. The lack of clarity in the contract and dispute resolution mechanism led to delays in the completion of the project.[37]

Financial Risk

Financial risk is another challenge in implementing PPPs in health services. Inadequate funding or lack of financial sustainability can impact the delivery of health services under PPPs. It is important to establish a financial model that is sustainable and ensures adequate funding for the PPP over the long term.

The PPP for the construction and management of a new hospital in Kolkata faced financial challenges due to inadequate funding and lack of financial sustainability. The private sector partner faced delays in receiving payments from the government and was unable to secure additional funding from external sources due to the high risk of the project. The lack of financial sustainability led to the termination of the PPP.[38]

Operational Risk

Operational risk includes challenges in project management, procurement, and service delivery, and can impact the quality and efficiency of health services under PPPs. It is important to establish strong project management systems, clear procurement processes, and effective service delivery mechanisms to ensure that the PPPs operate smoothly.

The PPP for the management of primary health centres in Andhra Pradesh faced challenges in procurement and service delivery. The private sector partner faced delays in procuring equipment and supplies and had difficulty in attracting and retaining qualified staff. The lack of operational efficiency led to a decline in the quality of healthcare services and dissatisfaction among the community.[39]

Social Risk

Social risk includes concerns about access to health services, equity, and social responsibility, and can create challenges in implementing PPPs in health services and engaging stakeholders. It is important to establish a transparent and accountable system that ensures that all stakeholders are engaged in the planning, implementation, and evaluation of the PPPs. It is also important to ensure that health services are accessible to all and that social responsibility is a key consideration.

The PPP for the management of a new hospital in Delhi faced social challenges related to equity and access to health services. The private sector partner faced criticism from civil society organisations and the community for focusing on high-end services and neglecting the needs of the poor and marginalised populations. The lack of social responsibility led to protests and negative publicity for the PPP.[40]

Conclusion and the Way Forward

Any doubts about PPP's long-term implications and sustainability necessitate a serious assessment. PPPs have the potential to transform healthcare systems by addressing critical challenges such as limited resources, inadequate infrastructure, and lack of skilled workforce. PPPs can leverage the strengths and resources of both the public and private sectors to improve the quality and accessibility of healthcare services and contribute to achieving the SDGs related to healthcare.

One of the key benefits of PPPs is increased access to healthcare services. In many countries, the public healthcare system is overstretched and unable to meet the growing demand for healthcare services. By partnering with the private sector, governments can increase the availability of healthcare services by leveraging private sector resources, expertise, and technologies. This can help to reduce waiting times, improve patient outcomes, and increase patient satisfaction.

PPPs can also improve the quality of healthcare services. The private sector brings with it a culture of efficiency, innovation, and accountability that can help to improve the quality of healthcare services. By partnering with the private sector, governments can leverage private sector expertise in areas such as healthcare management, technology, and innovation. This can lead to the development of innovative healthcare solutions and the adoption of best practices in healthcare management.

PPPs can also contribute to achieving the SDGs related to healthcare, such as SDG 3, which aims to ensure healthy lives and promote well-being for all at all ages. By improving the quality and accessibility of healthcare services,

PPPs can help prevent and treat diseases, reduce mortality rates, and improve health outcomes. PPPs can also support the development of educational programs and training for healthcare professionals, which can help to increase the availability of skilled healthcare workers and improve the quality of healthcare services.

However, successful implementation of PPPs requires careful planning, strong governance, effective risk management, and a clear understanding of the roles and responsibilities of each partner. PPPs are complex and involve multiple stakeholders with different objectives and interests. Therefore, it is important to have a clear legal and regulatory framework that defines the roles and responsibilities of each partner and ensures accountability and transparency.

In conclusion, PPPs have the potential to build sustainable and resilient healthcare systems that benefit individuals, communities, and societies. By fostering collaboration between the public and private sectors, PPPs can increase access to healthcare services, improve the quality of care, and contribute to achieving the SDGs related to healthcare. However, successful implementation of PPPs requires careful planning, strong governance, effective risk management, and a clear understanding of the roles and responsibilities of each partner.

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5 Supra Note 1

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CHAPTER 5

Regulatory Framework and Investment in Hospitals and Pharmaceutical Sectors

Introduction

India's healthcare sector was estimated to undergo a three-fold rise during 2016-22, growing at a CAGR of 22 percent to reach US$372bn in 2022.[1] Such rapid growth was propelled by steadily increasing domestic and global demand, resulting in huge employment, and rendering India's healthcare sector, a significant position in the global map of healthcare delivery. The current estimates attribute rising income, better health awareness, lifestyle diseases and increasing insurance penetration as major drivers which will help the sector grow further.[2]

Despite such fast growth and immense growth potential, the COVID-19 pandemic has brought to the fore the underlying infrastructural challenges which may become impediments to the attainment of Universal Health Care (UHC) and the Sustainable Development Goals (SDGs) in India.[3]

These challenges are mostly due to the lack of adequate investments, resulting in India's health infrastructure being below the global average or the WHO-prescribed norms. For instance, India reports 0.5 public hospital beds per 1000 population and 1.4 beds including public and private hospital beds per 1000 persons. Both these statistics are less than the WHO standard of a minimum of 3 beds per 1000 persons.[44]

Given the infrastructural bottlenecks and the existing capacity for healthcare delivery, it is estimated that at least US$256bn would be needed by 2034 to improve healthcare access, affordability, and quality and to achieve health-

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related SDGs in India.[5] When there is such a huge capital requirement but the domestic capital is inadequate, capital from foreign sources, in the form of Foreign Direct Investment (FDI) can become an important source for bridging the investment gap. Against this backdrop, this chapter investigates FDI[6]-related issues in India in two key healthcare segments – hospitals and pharmaceuticals. It explores the relation between regulatory frameworks for foreign investments in these two segments in India, discussing the corresponding investment regimes and assessing the barriers hampering such investment.

FDI Regulatory Framework for Hospitals, Drugs & Pharmaceuticals in India

The Indian healthcare market has undergone significant transformation – from being considered a primary responsibility of the public sector from the 1950s to 1970s, to undergoing commercialisation in the 1980s with a rise in private nursing homes and smaller private hospitals, to becoming more market-oriented since the 1990s and more globalised since 2000. To globalise the healthcare market, the government has often modified the FDI caps for healthcare segments. The FDI norms for healthcare in India can be broadly classified based on whether it is for the construction of hospitals, or greenfield/ brownfield investments.

The government has allowed up to 100 percent investment through the automatic route in hospital construction, medical devices, and greenfield projects related to pharmaceuticals. For brownfield projects related to pharmaceuticals, though 100 percent FDI is allowed, it is through automatic route up to 74 and beyond 74 percent, and government approval is required. (NITI Aayog, 2022; Consolidated FDI Policy, 2020).[7]

It is worth noting that while 100 percent FDI is permitted for the construction of hospitals under the automatic route, each phase of the construction development project must be considered separately. Also, an investor is permitted to exit on completion of the project or after the development of trunk infrastructure has taken place. In case the investor exits before the completion of the project, a lock-in period of three years since each tranche of foreign investment should have been completed. Such a lock-in period will be exempted in case a transfer of stake is made between two persons who are residents outside India. There are also other norms governing the land use requirements, provision of community amenities and other state/ municipal/local government requirements.

Additionally, it is the responsibility of the Indian investee companies to obtain the necessary approvals for various actions including building/layout plans, infrastructure facilities, external development and so on.

Earlier, 100 percent FDI was allowed in pharma without a distinction between greenfield and brownfield investments. In 2011, restrictions were imposed on brownfield investment, allowing investment only through prior approval of the FIPB and the Competition Commission.

In 2012, this was revised, and the government started allowing up to 49 percent FDI for brownfield investments in the pharmaceutical sector under the automatic route while foreign investments in the existing domestic pharma firms were to be allowed only after clearance by the FIPB.

In 2016, the FDI limit was increased to 100 percent for new projects and 74 percent for existing projects. The potential spillover effects of FDI inflows in this sector are considerably dampened by the imposition of restrictive FDI policies and weak intellectual property rights (Feinberg & Majumdar, 2001).

Currently, up to 100 percent FDI is allowed through automatic route in greenfield investments in pharmaceuticals and up to 74 percent through automatic route and beyond 74 percent through government approval for brownfield pharmaceuticals projects.

The brownfield investments are governed by clauses, as deemed necessary by the government, and are modified from time to time, depending on specific requirements. FDI in brownfield pharmaceuticals, under both the automatic and the government approval routes, is further subject to compliance with certain conditions. These conditions include maintaining the production level of the National List of Essential Medicines (NLEM) drugs and/or consumables and their supply to the domestic market at the time of induction of FDI. The benchmark for this level would be decided with reference to the level of production of NLEM drugs and/or consumables in the three financial years, immediately preceding the year of induction of FDI. Of these, the highest level of production in any of these three years would be taken as the level.

FDI Inflows to Hospitals, Drugs & Pharmaceuticals in India

The healthcare sector has reported an increase in FDI inflows, with significant inflows in the last few years and more so in the last year. Over the last two decades, the majority of the FDI inflows into Indian healthcare have been in drugs and pharmaceuticals, followed by hospitals & diagnostic centres and medical & surgical appliances (see Figure 5.1). In this context, a significant rise in the FDI inflows to the Indian pharma sector during 2020-21 relative to the previous year has been due to the investments for COVID-19-related demands for therapeutics and vaccines.

Figure 5.1: FDI Inflows in India's Healthcare Sector (2000-2020)[8]

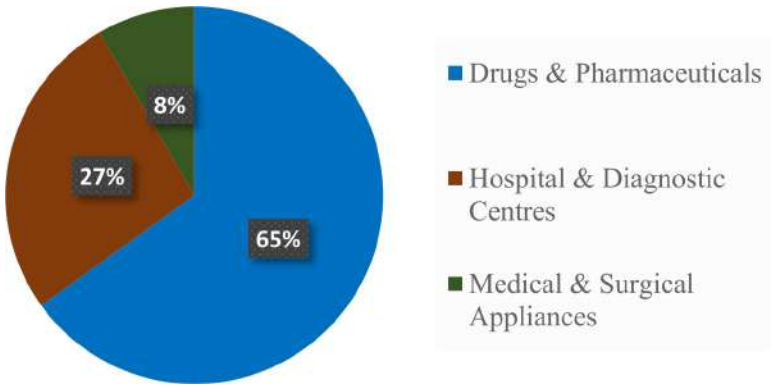


Figure 5.2 depicts the trend in FDI inflows to hospital and diagnostic centres in India over the last decade. While we observe an increase in FDI inflows over recent years, the overall share in total FDI inflows of India has been low, being less than 2 percent throughout this period.[9] More than 110 Private Equity and Venture Capital investors had invested in the healthcare delivery space till 2019, with a significant rise in the value of mergers and acquisition deals in hospitals in FY19 (NITI Aayog, 2021).

An analysis by Joseph & Ranganathan (2016) shows that the top 10 recipients of FDI inflows in hospitals and clinics in India constituted around two-thirds of the total inflow, the majority being made by private equity firms.

Figure 5.3 shows the trend in FDI inflows to the drugs and pharmaceuticals sector in India. It has remained one of the ten major sectors attracting foreign investments, averaging around four percent of total FDI inflows over the last decade. The 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacturing is likely to attract even higher investments both from domestic and foreign sources. FDI inflows in pharmaceuticals and medical devices combined was Rs 12,097 crore during FY21-22. The Department of Pharmaceuticals approved 21 FDI proposals worth Rs. 4,681 crores for brownfield projects during Jan-Nov 2022.

The recently introduced Production Linked Incentive (PLI) scheme is expected to attract higher levels of FDI inflows in this segment and position India on the map of the global supply chain.

Figure 5.2: FDI Equity Inflows into Hospital & Diagnostic Centres in India[10]

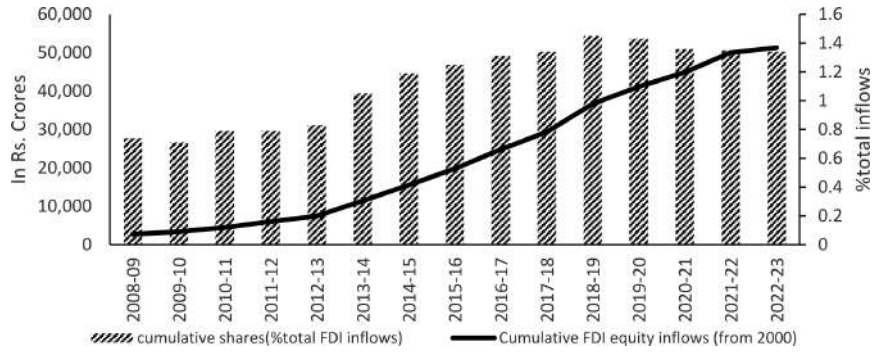
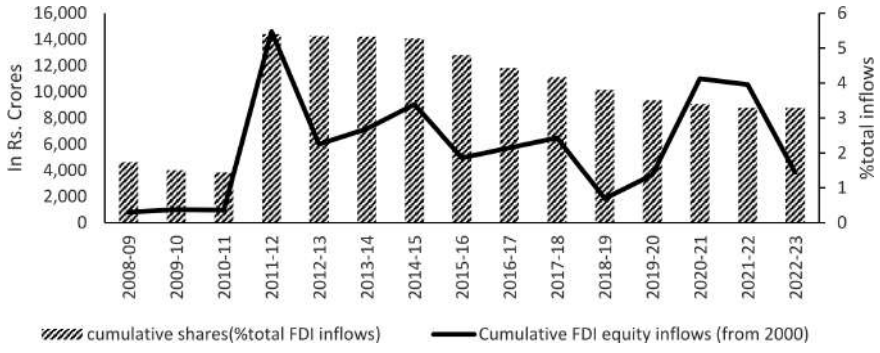


Figure 5.3: FDI Equity Inflows to Indian Drugs & Pharmaceuticals[11]



Regulatory Barriers Affecting FDI in Hospitals and Pharmaceuticals

Section 3 has shown that despite relaxing the FDI caps for hospitals, the inflows have been relatively low. This section outlines some of these barriers affecting the FDI inflows. Such low FDI inflows can be attributed to domestic constraints such as high initial establishment costs, manpower shortages, high cost of medical equipment, and regulatory deficiencies (Chanda, 2010).

These constraints increase the cost of establishing hospitals, which in turn results in higher costs for supplying hospital services. Though hospital services in India are characterised by increasing demand owing to rising income levels and insurance penetration, the constraints as outlined above adversely affect foreign investment in establishing hospitals by reducing

their profitability margins. Two observations are worth noting here. First, many of these regulatory and non-regulatory constraints are equally applicable to domestic investors, thereby also affecting domestic investment in this segment. Second, some of these constraints are not within the domain of the healthcare segment but in other areas, such as education, insurance, technology, etc. (Chanda and Gupta, 2014).

In India, many of the equipment and medical devices used in hospitals are imported, though the government actively promotes domestic manufacturing of these equipment and devices. Estimates suggest that almost eighty percent of medical devices are imported in India with customs duty and taxes levied on such devices as one of the highest in the world.[12]

According to the Ministry of Commerce and Industry data, imports of medical devices grew by 41 percent in 2021-22 as India imported medical devices worth Rs 63,200 crore in that year. Indian medical device industry considered custom duty and GST as major pain points.[13]

This may further be complicated by regulatory formalities such as end-use requirements and paperwork associated with the import of such equipment. Import duties, health cess and regulatory requirements raise the overall procurement and operating costs of hospitals, thereby decreasing their profitability (Chanda, 2007).

It is worth noting that the government released a draft National Medical Devices Policy in 2022, which aims to reduce import dependence on medical devices from 80 to 30 percent in 10 years and make India one of the top five global manufacturing hubs for medical devices by 2047.[14]

Another significant factor affecting investment in hospital services is the availability and cost of skilled healthcare professionals, such as doctors, nurses and para-medical professionals. Over the years, the government has taken various steps to increase the supply and enhance the quality of healthcare professionals. For instance, earlier hospitals were required to be 500-bed units to obtain permission for establishing training colleges but this limit has been reduced to 300-bed units in recently amended the Establishment of Medical College Regulations, (Amendment), 2020. However, the demand continues to outpace the supply of skilled resources in this sector. This leads to higher costs of procuring human resources for both foreign investors and domestically owned hospitals.

A low level of health insurance penetration also adversely affects FDI in hospitals in India, though insurance penetration has seen an increasing trend over the past few years. Higher insurance penetration is expected to increase the demand for hospital services by reducing out-of-pocket medical expenses for an individual. According to a survey by NITI Aayog, only 18

percent of the population in urban areas and 14 percent in rural regions have any form of health insurance coverage. This makes India one of the lowest health insurance penetration countries globally, with 0.4 percent penetration as compared to 4.1 percent in the U.S. and 2.7 percent in France.[15]

The government intends to increase the availability of insurance services by allowing greater foreign participation in the insurance segment. The permissible limit for FDI in the insurance sector was only 49 percent before June 2021, which has been modified to allow 74 percent through the automatic route (Government of India, 2021).

Land procurement costs and regulatory clearances also affect potential FDI in hospital services in India. The larger demand for hospital services comes from big cities. However, big cities are characterised by the rising and high cost of land. This may affect the decision to invest in establishing hospitals in these cities. Regulatory approvals for setting up supporting infrastructure (such as water supply and electricity) and cumbersome registration and compliance requirements could also be considered constraints to both foreign and domestic investor-owned hospitals (Chanda, 2007).[16]

In the pharmaceutical segment, government control on drug pricing affects the confidence levels of companies to invest respectable amounts in R&D (Festa et al., 2022). Though such controls are necessary for ensuring affordable medicines, they could potentially disincentivise investors if they feel such controls are excessive. Therefore, a delicate balance is required between the interests of consumers and producers pertaining to drug pricing.

India is significantly dependent on China for Active Pharmaceutical Ingredients (APIs). According to Bloomberg, 70 percent of India's imports of APIs come from China. This huge dependence made pharma companies operating in India vulnerable to supply shocks. Supply chain disruptions after the COVID-19 outbreak are testimony to this vulnerability. This excessive dependence increases business risk and adversely affects investments in this segment.

There is also an inadequate R&D infrastructure and a lower industry-academia connection for research. Drug Pricing Control Office establishes pricing parameters according to which the prices are to be decided, and this reduces the profitability of the companies that would invest in innovative drugs requiring huge capital. This sector has been characterised by a lack of product patents, due to which foreign companies do not introduce new drugs in the Indian market, discouraging innovation and drug discovery (Mahajan, 2019). All these factors combined resulted in low investments in this segment.

Thus, despite significant relaxation in FDI limits for hospitals and pharmaceutical segments in India, there exist regulatory requirements within these segments or related areas. Some of these requirements are for meeting specific public policy objectives. However, these regulatory requirements affect the investment attractiveness thereby impacting the actual inflow of FDI of these segments.

Conclusion and the Way Forward

India's healthcare is both over- and under-regulated. Areas of regulation that are pertinent to investment in hospitals and pharmaceuticals segments include standards for medical establishments, accreditation of medical professionals, and FDI. Regulations in some of these areas have changed in recent years to make them more investor-friendly. There has been considerable streamlining in recent years to establish and improve standards and ensure governance in various segments of the Indian healthcare sector.

It is to be noted that though the growing potential in India's healthcare sector is highlighted in various reports by industry associations and consulting firms, very little has been discussed regarding domestic regulations that affect investments in various sub-segments within this sector.

Therefore, the need of the hour is to look into the healthcare sector in its totality including infrastructure, manpower availability and costs, equipment costs, trade dependence and supply chain vulnerability, and insurance penetration, both from domestic and global perspectives. This synergistic approach and holistic policies will help in further increasing the much-needed domestic and foreign investment in hospitals and pharmaceutical segments of the Indian healthcare system.

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3 India is committed to achieving Universal Health care for all by 2030, which is fundamental to achieving the other Sustainable Development Goals (source: https://www.niti.gov.in/long-road-universal-health-coverage). UHC requires people to have access to quality health services (including prevention, promotion, treatment, rehabilitation, and palliation) by ensuring access, quality, and financial protection.

4 https://www.moneycontrol.com/news/business/real-estate/as-many-as-69-percent-of-hospital-beds-in-india-are-concentrated-in-urban-areas-pune-outranks-other-cities-on-health-parameters-6883371.html

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6 Here we focus only on the regulatory aspects of FDI inflows into hospital and pharmaceutical segments. We refrain from discussing the positives/negatives of FDI in these sub-sectors. The negative effects could arise if FDI in hospitals raise the hospitalisation costs and hence the medical expenditure of individuals and families. In such a case, the role of the government would increase and be required to guarantee cost-effective care to the population across remote areas and supplement foreign investments (Hooda, 2017). The negative side of FDI in pharmaceuticals may concern issues related to the availability and affordability of essential drugs, especially in rural areas or an emergence of foreign players resulting in a fall of the Indian generic industry.

7 *Ibid*

8 Source: Using data from Investment Opportunities in India's Healthcare Sector by NITI Aayog (2021): https://www.niti.gov.in/sites/default/files/202103/InvestmentOpportunities_HealthcareSector_0.pdf

9 Supra Note 6

10 Source: Author's calculations, based on data collated from quarterly FDI factsheets published by the Department for Promotion of Industry & International Trade (DPIIT), https://dpiit.gov.in/publications/fdi-statistics . Note: The cumulative inflows are for each financial year, as reported from the year 2000.

11 *Ibid*

12 https://news.abplive.com/business/budget/union-budget-2023-india-health-budget-industry-seeks-medical-devices-policy-reduction-in-customs-duty-1578782; accessed on July 31, 2023.

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[16] Project costs, land and construction of buildings constitute around 40 to 50 percent of total project costs, with medical equipment accounting for around 40 percent of costs and the remaining 10 to 20 percent for operational expenses and human resources. If a hospital spends a higher share of the investment cost on procuring land, this will affect the pricing of services, which along with other operational, maintenance and technology upgrading costs, puts pressure on margins and increases service costs and ultimately the level of healthcare affordability (see Chanda, 2007).

CHAPTER 6

Evolving Policy and Regulatory Landscape for Digital Health in India
A Narrative Review

Introduction

'Going digital' is a frequently used phrase in a variety of contexts across the world, but its precise meaning for a citizen seeking to access public services is frequently ambiguous. Will it facilitate their access, and if so, how will it affect their right to privacy, particularly in light of India's massive digital divide (Nedungadi et al., 2018)?

The Government of India introduced a 'Digital India' campaign in 2015 to transform access to services and information in the country. With nearly 1.14 billion mobile connections and 658 million active internet users, the Indian economy is becoming one of the quickest digital adopters in the world, according to the recent Digital 2022 report (Kemp, 2022).

During the COVID-19 pandemic, the adoption and growth of digital health solutions such as telemedicine, e-pharmacies and wearables surged in the healthcare sector (Gudi et al., 2021; Seethalakshmi, & Nandan, 2020). However, it is essential to recognize the practical challenges presented by the already fragile health systems, which have been exacerbated by the pandemic, and which prevent the effective utilisation of digital health.

Due to the rapid pace of digitalisation, it is necessary to assess the existing and emerging policy and regulatory framework, as well as how it adapts to the changing needs of the time. This chapter examines the evolving regulatory environment for digital health. We demonstrate disparities between the normative discourse developing around the expanding promise of digital health and the practical constraints of establishing a robust digital health

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ecosystem in the country, especially in light of the country's inadequate public health system.

As a phenomenon, digital health is defined as "the cultural transformation of how disruptive technologies that provide digital and objective data accessible to both caregivers and patients, leads to an equal level doctor patient relationship with shared decision making and the democratisation of care" (Meskó et al. 2017).

Through an equal and balanced doctor-patient relationship, the preceding normative definition of digital health promotes collaborative decision-making and democratisation of care. To accomplish this normative objective, it is necessary to pay attention to and address the practical and operational issues, so that the digital ecosystem along with the health system as a whole are strengthened to take advantage of the rapid technological advancements.

Through Aadhaar, the Pradhan Mantri Jan Aarogya Yojana (PMJAY), and most recently the Unique Health Identifier (UHID) under the Ayushman Bharat Digital Mission (ABDM), numerous programmes and missions with the aspirational objective of revolutionising healthcare service delivery have been introduced. With all due respect to the merits of these programmes, it is difficult to envision a flourishing digital health ecosystem, if the announcement of such programmes, missions, and initiatives is not accompanied by recognition and prioritisation of addressing the fundamental challenges of a deficient public health system.

Weak infrastructure, lack of trained human resources to adapt to the rapid digital shifts, low public health spending and existing digital divide with poor internet and electricity connections, are among the most pressing problems that must be addressed on an urgent basis, if not before, then simultaneously with bringing health systems up to speed with the digital innovations (Shenglin et al. 2020).

Indeed, accelerated technological advancements have integrated digital health into healthcare delivery. There is no denying that digitalising the functioning of the health system will potentially help the key stakeholders, namely the patients and the providers, engage in effective healthcare service delivery. For instance, some states have made progress in administering Electronic Health Records (EHRs) of the patients (Oommen & Antony, 2020a).

However, it is important to recognize the practical and operational aspects of this digitalisation process, as well as the potential utility of these data for providers and the health system in terms of facilitating healthcare services across primary, secondary and tertiary levels of care.
The key question is to identify the actual need at the citizen and provider

level that these programmes and missions can address. Further, what is required to truly leverage the digitalisation process push through these grand initiatives and missions? Would it require the healthcare providers and all institutions to upgrade their hardware to achieve the mission objectives? Who would shoulder the expenses?

In addition, how robust will this transition be in preventing any potential leakages of sensitive personal data, given the frequency with which we hear about healthcare data intrusions (Kurian, 2021)? With the failure of Aarogya Setu application to mandate contact tracing, and COWIN for COVID vaccination, fundamental questions are raised regarding the rapid and over-reliance on potential technologies as a magic wand to resolve the more fundamental health system deficiencies (Oommen & Antony, 2020b; Sirkar, 2021).

What lessons have we learned from our past engagement with the technology for healthcare delivery and have those lessons been incorporated into the newly proclaimed missions, frameworks and legislations?

Building on this backdrop, we provide a narrative analysis of the evolving policy and regulatory landscape for Digital Health in India in this chapter, along with critical reflections on the existing regulatory deficits, from the relatively disempowered citizens' perspective. We recommend that policymakers understand these disparities in the context of ground realities, and their possible implications for the protection of citizens' rights. This could aid in contextualising legislation and policies in the context of its citizens' needs, while successfully harnessing the emerging digital health solutions.

The two recurring themes that emerged from the review of various policies and frameworks are:

a) It is evident that **assurance-based approach has replaced citizen-centered and rights-based approach in policy design and practice**. On paper, some of the policies do refer to citizen-centered or rights-based approach but lack the attention to granular details in effectively implementing and upholding citizen's fundamental right to healthcare, information and privacy.

b) The need to re-emphasize addressing the glaring gaps in public health system, such as abysmal public spending, poor infrastructure, shortage of human resources for health in quantity and capacity, and weak governance of the health system; **these policies and initiatives aim for the aspirational goals of 'Digital India' and 'Digital Health', to be achieved in short period of time.** It is pertinent at this stage to

generate evidence from small scale or pilot studies and use the evidence and lessons for adapting the scale-up to the rapidly evolving needs of the situation.

Understandably, it is important to digitalise the health system to keep pace with the rapid technological developments, but it must be complemented by investments in strengthening the core components of the health system. With evidence-based policies that guide the transition to 'Digital India' and a robust legal framework that protects the citizens' fundamental right to privacy, both of the aforementioned goals must be prioritised concurrently. A detailed narrative analysis of the regulatory landscape for digital health is discussed below.

Current Policies and Regulations Governing Digital Health

Pre-National Health Policy 2017

The digitalisation processes in healthcare commenced with the Clinical Establishment (CE) Rules, 2012 under the CE Act 2010, which mandated the registration of CEs to maintain Electronic Health Records (EHRs) for each patient. These rules briefly mentioned the requirement by stating that "Clinical Establishments shall maintain Electronic Health Records (EHRs) for every patient". This requirement was not accompanied by any guidance or framework to govern the process of fulfilling this requirement of maintaining EHRs, their collection, storage, use and transmission, as well as the remedies for non-compliance or potential breaches involving citizens' data.

In response to the CE Rules of 2012, MoHFW established an expert committee to draft EHR Standards, which was opened to the public for comments, revised and published in 2013. EHR Standards 2013 were drafted to establish and maintain a uniform system for the hospitals and health care providers to maintain health records throughout the patients' life cycle, which may facilitate access to care across the continuum and geography of India.

The EHR Standards 2013 document clearly stated that it was a 'living document' that would undergo a periodic review and updates as necessary. The Standards were revised further in 2016 and referred to as EHR Standards 2016 v2.0. The explicitly stated objective of both documents were to support the evolution and timely maintenance of adopted standards for maintaining EHRs and promote interoperability among providers to facilitate easy access and quality care to the citizens.

Importantly, both 2013 and 2016 versions refer to citizens as the primary data owners and health providers as the custodians of citizens' data; as well

as the need for stringent compliance with appropriate privacy and security safeguards for protection of citizens' data. Referring to 'rights of the citizens' as 'privileges', both the standards state: "Patients will have sufficient privileges to inspect and view their medical records without any time limit. … Patients will have the privileges to restrict access to and disclosure of individually identified health information". For patients to be able to exercise these privileges, it has been emphasised that data privacy and security must be maintained at all times. Specific administrative, physical and technical standards have been identified as required safeguards for this purpose.

However, a careful review of the EHR 2013 privacy clauses reveals that they are merely prescriptive guidelines, allowing health care providers or organisations to select the privacy and security safeguards that best suit their capacity, purpose and interests; thus, contradicting its own mandate of always adhering to required safeguards.

The EHR 2013 states that "*How a healthcare provider satisfies the security requirements and which technology it decides to use are business decisions left to the individual organisation. In deciding what security measures to adopt, an organisation must consider its size, complexity, and capabilities; its technical infrastructure, hardware, and software security capabilities; the cost of particular security measures; and the probability and degree of the potential risks to the e-Personal Health Information (e-PHI) it stores and transmits.*"

EHR 2016 cites the Information Technology (IT) Act of 2000 and the IT Rules of 2011, as the applicable legislation for protecting the sensitive personal data and information of citizens. Both the 2013 and 2016 versions refer to the applicable ISO standards for protecting citizens' rights and ethical, legal and administrative responsibilities to be fulfilled by providers. However, hospitals and healthcare providers have the option to voluntarily select the ISO standards they will adhere to.

Given that these standards do not independently cover all aspects of privacy and security, the choice of healthcare providers in adopting the ones that align with their capacity and interests, may result in insufficient protection of citizens' rights insofar as the initiative to maintain or not maintain data and security rests on the healthcare provider rather than the individual whose data is being collected.

In the larger push for the digitisation of health records, it is essential to recognize the challenges inherent in implementing these standards, while the Indian public health system struggles with basic infrastructure issues, such as shortage of computers in many government hospitals, particularly in rural areas. This compounded by limited access to electricity, internet coverage and the capacity of the staff to rapidly adapt to the digitalisation

requirements would make it extremely difficult to implement the EHR Standards effectively (Sinha et al., 2021).

NHP 2017 to ABDM

After a haitus of nearly 15 years, the third edition of the National Health Policy (NHP) was published in 2017. NHP 2017 broadly referred to leveraging digital tools to ensure health care provision across the continuum of care, for medical education through National Knowledge Networks and access to digital libraries, and human resource training, management and governance. The policy also commits to establishing an institutional framework and capacity for Healthcare Technology Assessment and adoption.

Notably, recognizing the integral and expanding role of technology in delivery of healthcare services, NHP 2017 commits to establishing a National Digital Health Authority to regulate, develop and deploy digital health across the service delivery levels, that is, primary, secondary and tertiary.

The NHP 2017 adopts a 'assurance-based approach' rather than the 'rights-based approach' proposed in the draft National Health Policy 2015. The NHP 2017 presents ambitious goals, especially in the realm of digital health, such as establishing an electronic database of information on health system components at the district level by 2020 (see Box 6.1). The connection between the promising text of the policy with the huge amount of public investment in health needed to be able to achieve its intended goals is, unfortunately, absent.

Box 6.1: Relevant Goals of NHP 2017

The following were the specific goals set in the NHP 2017 with respect to Health Management Information:

a. Ensure district-level electronic database of information on health system components by 2020.

b. Strengthen the health surveillance system and establish registries for diseases of public health importance by 2020.

c. Establish federated integrated health information architecture, Health Information Exchanges, and National Health Information Network by 2025.

(Section 2.4.3.3., page 5, NHP 2017)

With the current spending that is, 1.15 percent of GDP, it is crucial to outline the pathways to address the core challenges of inadequate infrastructure, lack of trained human resources required to handle the rapidly increasing expectations of digital health, and concerns regarding access, affordability and quality of healthcare services (Mohan, 2017).

In the absence of a 'rights-based approach' in NHP 2017, implementation of the EHR Rules 2013 and 2016, which emphasize citizens as the owners of their data, is questionable, (Rathi, 2019). The positioning of citizens as owners of their data in EHR Rules 2013 and 2016, is contrary to the one presented in NHP 2017.

Several documents, including the National Health Stack (NHS) 2018 and the National Digital Health Blueprint (NDHB) 2019, laid the groundwork for The National Digital Health Mission (NDHM), which was developed in response to the NHP 2017 as a guiding document for leveraging digital technology in healthcare delivery. NHS 2018 intended to integrate the electronic administration of healthcare data, including the patients' and service providers' EHRs, and NDHB 2019 was drafted to provide the implementation framework for NHS.

NDHM was launched on August 15, 2020, with a pilot in six Union Territories (UTs) to create a digital health ecosystem that aimed to bring together all the stakeholders and facilitate healthcare delivery via digital technology across the continuum of care. A year later, the mission was implemented nationally under the name 'Ayushman Bharat Digital Mission (ABDM)'. Without public disclosure of the evidence or lessons from the pilot in six UTs, the national roll-out can be interpreted as a hasty decision that reinforces their assurance-based approach and heightens citizens' apprehensions.

Health Data Management Policy (HDMP) 2020 (revised in 2022), Health Data Retention Policy, Health Professionals Registry, and Unified Health Interface (UHI) were produced as part of the Mission to guide the development of Universal Health Identifier (UHID) (later renamed to Ayushman Bharat Health Account (ABHA)) with patient-centered care and privacy and security by design as their guiding principles (NHA, 2019).

The mission seeks "to develop the backbone necessary to support the integrated digital health infrastructure of the country". ABHA for all the citizens, streamlining the collection and maintenance of EHRs, creating registries for facilities and providers, and health information exchange to facilitate storage, sharing and use of health data are some of ABDM's key components. While these are essential components to build the national digital health ecosystem,

but their implementation is likely to be expensive to undertake. Numerous challenges can be anticipated at different stages and levels.

One of the potential criticisms is that the mission is intended to possibly benefit all the stakeholders (including IT industry, telecom industry, the insurance industry, private hospitals and healthcare providers) except its users (Neelakanthan, 2018). The aforementioned essential documents that contribute to the development of the mission, do not comprehensively list down the potential risks and challenges at the disempowered patient level, and the means by which the mission intends to address them.

In addition, the announcements of NDHM and subsequently ABDM, were criticised by scholars questioning the mission's ambitious goals without adequate attention for the legal, governance and policy frameworks required to guide its implementation, in the context of a public health system severely compromised by the COVID-19 pandemic (Indranil, 2022). The decision to implement ABDM prematurely, risks diverting attention, efforts and resources away from strengthening the health systems' core components towards digitalising an already weakened health system.

The government must understand the several characteristics, levels, structures, and processes of digitalisation by piloting it extensively in a few areas, documenting the experiences and lessons learned, and then progressively scaling it up. The absence of any reference to the evidence and lessons learned from the NDHM experiment in six Union Territories, which was announced in August 2020, demonstrates not only inconsistencies between policy statements and implementation on the ground, but also lack of accountability towards citizens for the use of public funds. It is critical to build evidence, make it accessible to the public, and use it to make informed policy decisions.

Only by strengthening the existing infrastructure, human resource capacities and governance framework, can the public health system effectively integrate digital health and the accompanying requirements into its functioning.

Figure 6.1: Evolution of the Policy and Regulatory Landscape on Digital Health in India

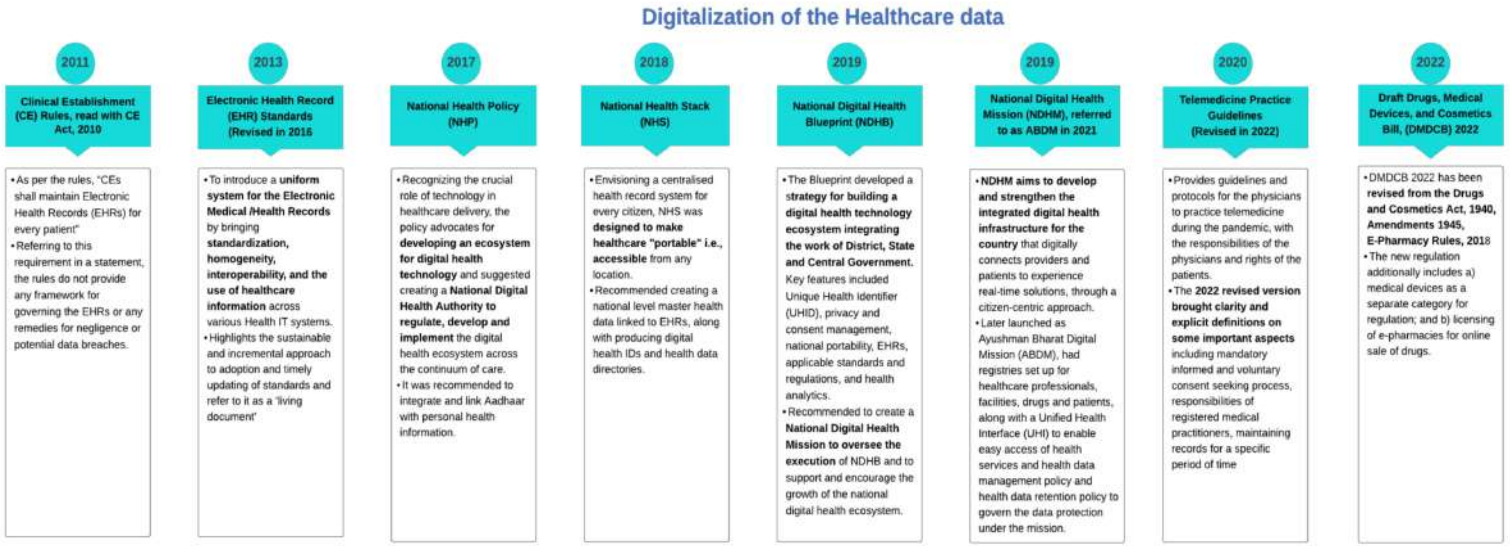
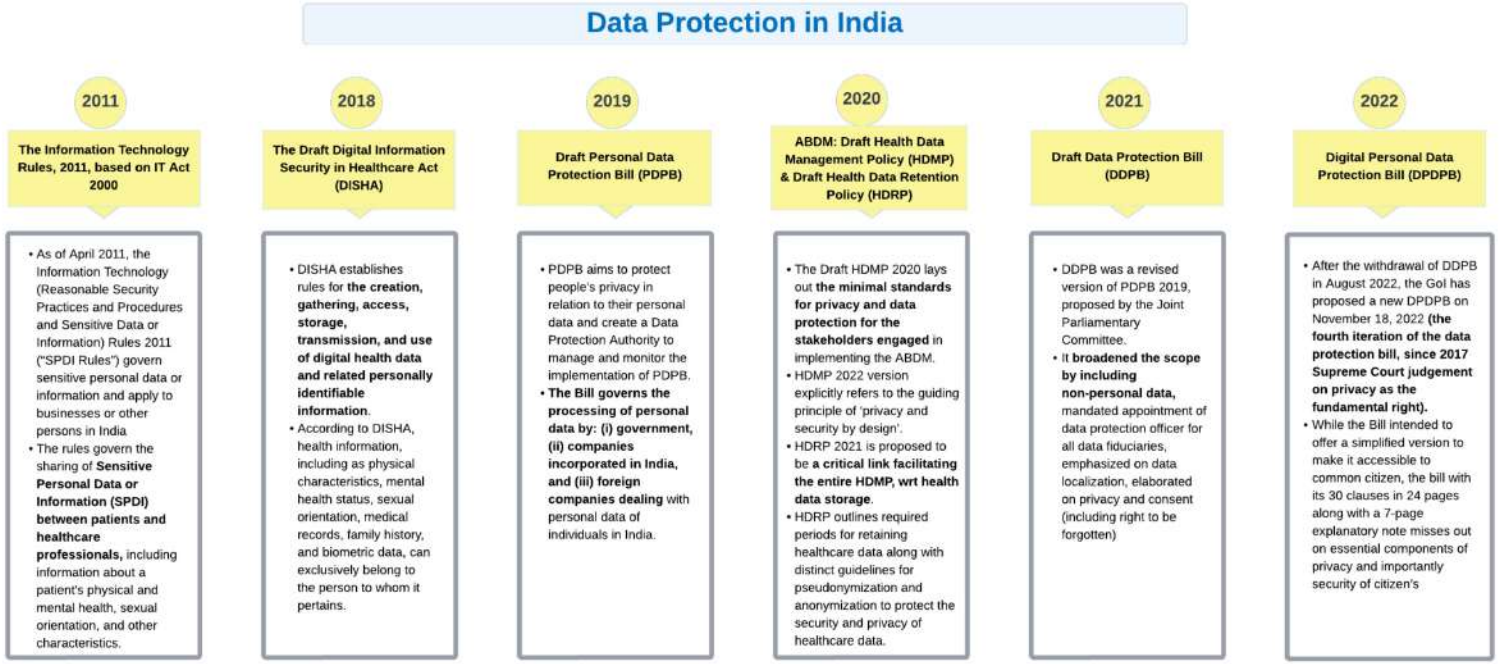


Figure 6.2: Evolution of Regulatory Landscape on Data Protection in India



Data Protection

Issues pertaining to the mission's emphasis on patient-centered care on the ground, and most importantly protecting citizens' right to privacy of their data including informed consent seeking process, lack of regulatory framework with the independence of data protection authority, and adequate security safeguards for protecting citizens' data, are critical for the implementation of a mission of this scale.

NHS mandates the establishment of health IDs, for beneficiaries, that are linked to their individual EHRs and EMRs and validated via primarily Aadhaar, or other identification documents. Concerns regarding the possession and control of sensitive personal healthcare data must be addressed by the NHS data repository (Narayanan, 2021).

While NHS 2018 refers to maintaining health records in a secure environment with citizens determining access rights, facilitated by consent-driven interactions between the data fiduciaries and citizens. Effective implementation of this component assumes that citizens understand their rights and are aware and informed enough to understand the potential implications of providing consent for data access.

Moreover, while the ABHA is promoted as voluntary for citizens to access care, it is anticipated, that similar to Aadhaar, it will eventually become a mandatory requirement for accessing care (Oommen & Antony, 2020b).

Aadhaar was intended to be a unique digital identifier for every citizen to access services, but in practice, it has been become a verification document, being demanded by all kinds of service providers in hard copy, which can be fraudulently misused or even duplicated in a variety of ways. Its implementation completely defied the purpose, for which the Aadhaar number was originally advocated by Government of India.

The authentication of the citizens for ABHA will be conducted through Aadhaar (as one of the verification documents), and hence the issues with Aadhaar are expected to be ported to ABDM also. In this push towards developing digital health ecosystem rapidly at the nationwide scale, while the digital infrastructure is in shambles with poor internet connectivity, abysmal digital literacy amongst the majority of country's citizens (Nedungadi et al. 2018), the mission relies on many unrealistic assumptions with its implementation.

The third important aspect under data protection is the absence of a regulatory framework (the recently enacted Personal Digital Data Protection Act, 2023 is yet to be implemented) that would govern the enormous amounts of

healthcare data that are being generated and are projected to grow exponentially.

Unfortunately, the work on drafting and revising the data protection legislation for more than five years left millions of citizens' personal and sensitive data vulnerable to being mishandled, sold, and manipulated without their consent (JPC, 2021; Marr, 2018; Cassidy, 2020).

The new Digital Personal Data Protection Act (DPDPA) 2023 focuses on personal data and attempts to present the legislation in a simple and plain language, with huge penalties imposed for data breaches. It still lacks attention to detail on specific privacy and security measures for protecting the rights and data of citizens. In addition, the criticisms of previous iterations of the Bill, including those regarding data localisation, continued exemptions to facilitate state surveillance, the independence of the Data Protection Board, and informed, unrestricted consent for citizens, remain unanswered.

In an attempt to simplify the language, the DPDP Act left clauses ambiguous and broad, thereby leaving room for misinterpretations and abuse of the legislation by the stakeholders in their private interests. In addition, the new law makes no mention of sensitive personal data, which according to the IT Rules 2011 includes 'physical, physiological and mental health conditions; sexual orientation and medical records and history', among others, which need to be handled more cautiously than the personal data.

In the context of ABDM, the privacy policy guided by the Health Data Management Policy (HDMP 2022) refers to ensuring 'privacy and security by design' and emphasising informed consent processes for collection, use or disclosure of personal data. However, in absence of adequate data protection framework, compliance to these policies become voluntary and has implications for citizens' right to privacy.

The Digital Information Security in Healthcare Act (DISHA) 2018, which included granular details on protecting privacy and security of citizens' data such as consent seeking throughout the data processing cycle, controlled access management, adequate privacy and security measures to protect citizens' rights, and was to be integrated into the general data protection framework with specific contextual elements for healthcare sector, were also not considered.

The ambiguities and loopholes in the current DPDP Act indicate, there is still a long way to go in comprehensively protecting citizen's right to privacy. Meanwhile, the healthcare data continues to be marginally governed under the 'sensitive personal data and information' of IT Rules, 2011, thereby

leaving gaps and opportunities for healthcare providers and data collection and management entities to misuse or exploit citizen's valuable healthcare data.

South Asia has been identified as one of the most susceptible regions for cyberattacks, (UNODC, 2020) and India has already witnessed the biggest breach of medical records so far (Kurian, 2021). Therefore, the urgency for having a robust and comprehensive data protection legislation needs to be translated into action now, more than ever.

Conclusion and the Way Forward

Digital health is a mixed bag of opportunities and threats. It can be a boon, improving access, affordability and quality of health care services through telehealth and telemedicine to millions of citizens. On the other hand, it can be disastrous, in the form of data breaches and cybercrimes, if not governed effectively and at the right time.

All the policies and frameworks within the digital health landscape endorse creation of robust digital health ecosystem. This, however, cannot occur in isolation; rather, it must be embedded in the larger health system standing firm on its strong core-pillars of infrastructure, increased public spending, improved capacities of its human resources and strong governance framework.

The benefits of this rapidly advancing digital health solutions can only be reaped with resilient, responsive health systems. There is a need to re-think our approach towards formulating and implementing the policies, missions and legislations that are grounded in the interests of the citizens and truly safeguard their fundamental right to privacy and information.

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CHAPTER 7

Telemedicine: Regulation and Promotion

Introduction

Telemedicine is defined by the World Health Organisation (WHO) as: *"The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for the diagnosis, treatment, and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities"*.[1]

This definition given by WHO underlines that telemedicine is an open science that is continually developing, including new advances in technology, and responding to changing health requirements and situations in communities, it has been recognised as an enabler for healthcare.

India is now the most populous country in the world, with people belonging to various socio-economic backgrounds. Because of this equal distribution of healthcare services and patient access has been the top goal in the list of public health management and delivery. The gap between rural and urban healthcare access can be estimated by the fact that nearly 75 percent of our healthcare professionals and doctors are present in urban areas, whereas nearly 65 percent of the Indian population is rural.

Another notable challenge is doctor-patient ratio. According to the WHO, the ideal doctor-to-patient (population) ratio should be 1:1000. However, in India currently the ratio is around 0.66 doctors for every 1000 people.[2]

Even within this ratio, the dispersion of practicing healthcare professionals is skewed between urban over rural areas. The public healthcare system in rural areas in India is not only underutilised due to poor quality of healthcare

This chapter has been contributed by Piyusha Majumdar, Assistant Professor, WHO /TDR Coordinator, IIHMR University, Jaipur

services but is also inadequate in terms of population coverage. Further, the gross shortage of specialists and chronic absenteeism of healthcare staff makes the situation even worse. This ratio is expected to remain low soon, as training new practitioners is an expensive and humungous task. Adoption of telemedicine, therefore, holds promise to expand people's access to high-quality healthcare across the country.

Though telemedicine had largely been treated as illegal in India till recently, the pandemic necessitated making it a legal process to enhance access and affordability of healthcare. During the time of the Nationwide lockdown in March 2020, patients' mobility was restricted, and all outpatient departments (OPDs) were closed, which prompted a historic move towards authorisation and adoption of telehealth services. As a Policy response, the Ministry of Health, and Family Welfare, in collaboration with NITI Aayog, released formal guidelines for telemedicine practice in the country.

The issuance of the Telemedicine Practice Guidelines, 2020 (TPG), brought upon standardisation and regulation of the telemedicine industry, a hitherto adverse proposition for the regulatory authorities. The guidelines have elaborated on the eligibility for practicing Telemedicine in India, the modes, and types of teleconsultations, delved into the doctor-patient relationship, consent, and management protocols, and touched upon the data security and privacy aspects of Teleconsultation.

This chapter will provide the details on the guidelines and argue if these are sufficient to provide regulatory certainty to realise the potential of telemedicine in India. It will also be focusing on the regulatory issues and challenges vis-à-vis telemedicine and recommendations on the regulatory/policy measures to overcome the challenges and realise the full potential of telemedicine.

History of Telemedicine in India

Telemedicine was introduced to India as a "Telemedicine Pilot Project" by The Indian Space Research Organisation (ISRO) in 2001. The Ministry of Health and Family Welfare (MoHFW) established a National Telemedicine Taskforce in 2005. Additional national programs in India include the Integrated Disease Surveillance Project (IDSP), the National Cancer Network (ONCONET), the National Rural Telemedicine Network, the Digital Medical Library Network, and the National Medical College Network that links medical colleges with the primary purpose of e-learning[3]

The Indian Government has introduced two major initiatives to address the healthcare needs of the community through telemedicine.

A) e-Sanjeevani OPD Portal: This portal is a dedicated to consultation services connecting patients and doctors. eSanjeevani OPD is an online service provided by the MoHFW that enables people to get medical appointments in the comfort of their homes. It is designed to be user-friendly and easy to use. To use the services, it is to be downloaded as the mobile application and registration is required. Once registered, it can be used for patients and family members. Health workers and officials, such as school teachers, can assist citizens in accessing the consultations, whenever necessary. The service is available during specific OPD timings.

This online OPD service is the first of its kind offered by a government to its citizens. It aims to bring healthcare services directly to patients' homes through secure video consultations between doctors in hospitals and patients at home. The portal was launched in May 2020 after the emergence of COVID 19.

B) eSanjeevani HWC Portal: The eSanjeevani HWC (Health & Wellness Centre) portal offers telemedicine services based on a Hub & Spoke Model. The "spokes" refer to Primary Health Centres (PHC) or Sub-Health Centres (SHC), while the "hubs" are District Hospitals or Medical Colleges. The portal enables the connection between these spokes and hubs to provide e-consultation services. It allows patients from anywhere in the state to have video-conferencing consultations with specialists and general practitioners. In this setup, the Medical Officers at each PHC-HWC can seek advice from specialist doctors located at the hub, which could be a Medical College or District Hospital. Community Health Officers (CHOs) working at SHC-HWC can also utilise this service to provide free telemedicine consultations to the beneficiaries at their facilities.[4]

India had not implemented telemedicine on a large scale till the emergence of COVID-19 pandemic, and not all attempts have been successful. Several judicial orders in India hampered the practice of telemedicine. There was an incident when a clinician was penalised under medical negligence charges for a case in which patient lost his life (Deepa Sanjeev Pawaskar and Anr vs. The State of Maharashtra on 25 July 2018). The Bombay High Court's judgement in this case sparked questions among doctors, especially RMPs, about whether they may provide medical advice over the phone or not.

The Bombay High Court refused the applicant's (Dr. Deepa's) anticipatory bail application, noting her arrest under Section 304 of the Indian Penal Code, 1860 (culpable homicide). While the Supreme Court overruled the Bombay High Court's ruling, many RMPs in India remained cautious about giving medical advice over the phone.[5]

Telemedicine Guidelines during COVID-19

When novel coronavirus brought the entire world to standstill, overwhelming hospitals, collapsed health systems, limited physical access to healthcare, unavailability of adequate human resource for health and its skewed distribution, India and other LMIC (Low- and Middle-Income Countries) responded by adopting telemedicine and other digital health technologies[6].

The Board of Governors of the Medical Council of India (MCI), the erstwhile medical education regulator in India, prepared Telemedicine practice guidelines in consultation with the premier planning body, the NITI Aayog (National Institution for Transforming India), to fill an important gap of legislation and a framework for ethical practice of telemedicine.[7]

On 25 March 2020, NITI Aayog released the new Telemedicine Practice Guidelines empowering Registered Medical Practitioners (RMPs) to provide healthcare services remotely according to the guidelines. The disciplines of medicine and clinical practice have undergone a complete facelift, to cater to the marginalised and underprivileged populace, with telemedicine and teleconsultation measures. The issuance of the Telemedicine Practice Guidelines, 2020 (TPG), brought upon standardisation and regulation of the telemedicine industry, a hitherto adverse proposition for the regulatory authorities. The ability of doctors to offer remote consultations has been legitimised after the notification of the Telemedicine Practice Guidelines, 2020 ("Telemedicine Guidelines").

These guidelines act as supplement to the existing laws and have helped to plug in the gaps which were present earlier. The purpose of these guidelines is to assist medical practitioners in developing a sound plan of action for providing effective and safe medical treatment based on available information, resources at hand, and needs of the patient, to protect both patients and providers. Telemedicine has been widely adopted by healthcare systems during the recent pandemic (Sherwin et al. 2020).[8]

Key Highlights of Telemedicine Practice Guidelines

- Healthcare Practitioners who practise allopathy and are registered with a state medical council come under the ambit of Telemedicine Practice Guidelines. Dentists and practitioner of other forms of medicine e.g., Ayurveda, Homeopathy and Siddhi medicine are not covered by these Guidelines. RMPs are not allowed to practice another system of medicine simultaneously.

- RMPs shall use their professional judgement to determine if telemedicine is an appropriate sort of consultation.

- RMPs commence a consultation with provisioning an introduction [details of name, qualifications, area of specialty] and the location of their affiliate medical establishment. The Regulations further require an RMP to obtain the patient's signature or thumb impression with the date of the signature, on the informed consent document shared with the patient. Explicit consent must be recorded in any form – physical, audio, video, graphics, electronic, text – this must be stored by the RMPs

- The specifics of a follow-up consultation have also been laid, wherein the patient may seek an appointment for a follow-up consultation after the expiration of 6 months, provided that the RMP has advised the patient to seek an appointment with him between the period of 6-12 months from the date of the initial consultation. There is an additional leeway provided to the platforms for affording "follow-up consultations" to the same patient, where the newly assigned RMP/available RMP is comfortable in comprehending the patient's medical condition after having been provided with adequate information (details of the condition and reports of all relevant investigations) by the patient. We see reliance being placed upon the professional judgment of the RMP who is available. The retention timelines for online consultation remain unchanged from what has been already prescribed for inpatient and outpatient records.

- Social Media: The Draft Regulations prescribe the key principles, behavioural obligations upon an RMP on social media. It is pertinent to note that the NMC Regulations do not prescribe any definition for "social media," and we may be constrained to the definitions provided under IT Act and allied rules, to rely upon the definition of social media.

- Training of RMPs: The Draft Regulations make considerable modifications to the TPG and prescribe Continuous Professional Development (CPD) training to RMPs desirous of conducting telemedicine practice in India; the earlier prescribed timeline of seeking a course certification within a period of 3 years from the date of notification of the TPG 2020 has been done away with. It now stresses on how the RMPs must familiarise themselves with the guidelines, as well as appreciate the shortcomings of the practice of telemedicine.

Challenges Related to Privacy and Data Usage

The guidelines lack clarity about privacy and data usage for patients and practitioners. The onus is entirely placed on doctors to maintain records of all exchanges of communication between themselves and patients. Privacy concerns arise as details, including a patient's address and other 'reasonable' identification, is required to be recorded by the practitioner[9]

Legal

Telemedicine Guidelines provided a framework for doctors on how to offer consultations. Doctors are at liberty to select whether to consult via consultation, can decide on the mode of consultation (online/in-person). On the same lines, the ability of a doctor to issue prescriptions is not unfettered: the Telemedicine Guidelines have categorised medicines in four broad categories – List O, List A, List B, and the Prohibited List. Depending on the type and mode of consultation, doctors may issue prescriptions subject to the restrictions for that category. Non-adherence to the restrictions that have been specified for the lists would be treated as professional misconduct under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.

Technological

Artificial intelligence/machine learning technology-based platforms are not authorised for telemedicine consultations or medication prescribing, although they may help the certified medical practitioner in arriving at a sound conclusion while determining the treatment for the patient concerned. If a digital platform is proven to be in breach of the Guidelines, it might be banned, and no licenced medical practitioner could use it to provide telemedicine. RMPs who continue to use a banned telemedicine platform and provide services through the same, however, face no special penalties.

Conclusion and the Way Forward

As a developing economy, India is an adequate telemedicine contender, together with its vast population. The Indian government is dedicated to delivering equal access to quality health care at affordable costs and digital medical care is crucial to transforming the health system.

Therefore, the integration of telemedicine into health systems reduces inequality and obstacles to access. India's Digital Health Policy promotes use of digital technologies and payment mechanisms to improve the efficiency and performance of healthcare institutions. The use of telemedicine services in basic health centres is emphasised to enhance the system and eliminate the rural-urban gap that exists in the Indian setting for timely and optimal treatment.

Learnings from practitioners' experiences suggest that telemedicine can be a good modality for assessment of chronic pain and to provide symptomatic supportive care for patients. Regulatory clarity, certainty and policy predictability are of paramount importance for an emerging technology like telemedicine. It has the potential to drive new businesses and service models and hence governments must rapidly create, modify, and enforce regulations. It is imperative that a balancing act of safeguarding citizens and ensuring fairness in markets needs to be done while letting innovation and businesses flourish.[10]

The Indian federation (both union and states) has a chequered past in terms of certainty in regulatory and policy aspects, despite its business and innovation-friendly nature. The Retrospective Taxation Law (now scrapped) bears testimony to the very fact. Akin to the regulations, the Guidelines released by the regulatory authorities have either dealt a death blow to certain segments like the RBI's new digital lending guidelines for the PPI's or have been a shot in the arm to certain segments like the recent OTT guidelines.

The guidelines of concern, Telemedicine Practice Guidelines 2020, have been a shot in the arm. It has allayed the concerns of many concerned parties, especially the physician community. The effectiveness of telemedicine depends on the practitioners' competence in specific skills, some of which are different from those required for a traditional face-to-face medical system.

Thus, we urge adding new forms of preparation for doctors-in-training as well as for those already in practice. Most Indian doctors lack competencies specific to telemedicine. Among competencies that will be needed for effective digital communication and good 'web-side' manners include those for effective remote examination, group interactions, handling of emergent situations, empathetic communication, interpersonal skills, and troubleshooting. Incorporating telemedicine in undergraduate and postgraduate medical education will be essential for India to be able to scale up telemedicine services.[11]

Endnotes

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CHAPTER 8

The E-Pharmacy Conundrum: Regulatory Challenges and the Ripple Effects on Market Competition

Introduction

The increasing popularity of online pharmacies during the pandemic can be attributed to the convenience they provide – remote access to medications when physical access is restricted.[1] This rapid ascent of e-pharmacy players in India has benefited consumers and piqued the interest of corporates, private equity, and venture capital players, drawn by the sector's high growth potential and returns. According to Research and Markets, the e-pharmacy market in India, valued at approximately ₹221.67bn in 2021, is projected to grow at an annualised rate of 63 percent between 2020 and 2025.[2]

E-pharmacy has emerged as a significant player in the healthcare industry, providing convenient access to medications and bridging logistical barriers for consumers. However, pharmaceutical retailers occasionally need more inventory which impedes their ability to meet patient demands. Such instances necessitate patients to seek medications from multiple pharmacies, which is an inconvenient and potentially risky venture. Instrumentalising digital technologies and platforms facilitating the delivery of medications to individuals' doorsteps has significant advantages, especially for populations with varying abilities.[3]

Despite the apparent benefits of e-pharmacy operations in India, there exist regulatory uncertainties. The legality of online pharmacies, particularly with regard to the sale of prescription drugs, has emerged as a significant point of contention.

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Uncertain Legal Position and Regulatory Framework

In August 2018, the central government issued draft rules on e-pharmacy under the Drug and Cosmetics (D&C) Rules, 1945, primarily setting out the requirements and conditions for the sale of drugs by an 'e-pharmacy'.[4] However, this was not taken forward. Similarly, a draft bill – the Drugs, Medical Devices and Cosmetics Bill, 2022[5] – was issued for public comments by the Government in July 2022, which is still pending.

There also have been some conflicting judgements by high courts as far as online sales of drugs are concerned. In December 2018, the Delhi High Court, in its interim/injunction order, stopped the sale of drugs without a licence by online pharmacies.[6] Subsequently, the Drug Controller of Inda wrote to all the states and union territories to take necessary action to comply with the Delhi High Court order.[7]

A contempt petition in the Delhi High Court was also filed since the online sale of medicines is continued. Recently the Court has directed the Centre and the Delhi government to act against people selling pharmaceutical drugs online without a valid licence.[8]

Similarly, in December 2018, a single bench of the Madras High Court directed online traders to not proceed with online business in drugs and cosmetics till the draft rules on e-pharmacy (of 2018) are notified.[9] Upon appeal the Division Bench of the Madras High Court stayed the order of the Single Judge. It opined that the authorities constituted under the D&C Act and Rules are competent to take appropriate action on violation of relevant statutory provisions and a sudden prohibition on online sales will cause grave hardship to the concerned patients who order medicines online.[10]

Therefore the two high courts took conflicting positions on online sale of drugs, with the Delhi High Court prohibiting the same while the Madras High Court allowing the same till the government brought into effect its rules on e-pharmacies.[11] This has added to the prevailing regulatory uncertainty that may adversely affect growth of and investment in e-pharmacy in India.

Currently, the Drugs and Cosmetics Act of 1940 and the Pharmacy Act of 1948 govern the sale of drugs by brick-and-mortar outlets and e-pharmacies.[12] Section 18 of the Drugs and Cosmetics Act, read in conjunction with the Drugs and Cosmetics Rules of 1945, prohibits manufacture for sale or for distribution, or sell, or stock or **exhibit or offer for sale**, or distribute any drug or cosmetic without a licence and mandates the supervision of retail sales of prescription drugs by a registered pharmacist.

Similarly, Section 42 of the Pharmacy Act stipulates that only a registered pharmacist can dispense medicines based on a valid prescription from a medical practitioner. It is important to note that the injunction issued by the Delhi High Court does not prohibit online pharmacies from conducting business altogether but rather subjects their sales to the requirement of obtaining a licence as per the existing legal provisions.[13]

The term "e-pharmacy" lacks a specific definition within existing legislation in India. The draft E-Pharmacy Rules of 2018 attempted to address this issue. Within the draft Rule 67-I defined "e-pharmacy" as the business involving the distribution, sale, stocking, exhibition, or offering of drugs through web portals or other electronic means.[14]

Additionally, the term "e-pharmacy portal" is defined as a web or electronic platform established and maintained by an e-pharmacy registration holder for conducting e-pharmacy business. These draft E-Pharmacy Rules establish the nature of the e-pharmacy business and shed light on the various operational modalities.

The Indian e-pharmacy market operates under three distinct business models: the inventory-led hybrid model, the franchise-led hybrid model, and the marketplace model. The inventory-led hybrid model involves the e-pharmacy company owning a stock of drugs while also incorporating multiple sellers on its platform, offering buyers a choice. The franchise-led hybrid model combines online sales with physical franchise stores, providing a blend of digital and in-person shopping experiences.

In the marketplace model, the e-pharmacy company serves as a platform connecting buyers and sellers, maintaining no inventory of its own. The Draft Rules have not provided any clarity on whether legal implications for E-pharmacies will differ based on their business model, along with whether E-pharmacies that operate as a marketplace require a licence under the D&C Act.

In addition, the Information Technology Act, 2000 in India also regulate e-pharmacies.[15] Under the IT Act, e-pharmacies qualify as intermediaries, as they facilitate the supply of medical services through electronic platforms. Consequently, they are granted safe harbour protection under Section 79 of the Act, which shields them from liability for unlawful acts committed by third-party retailers on their platforms, such as the sale of counterfeit or spurious drugs.[16] The classification of e-pharmacies as intermediaries under the IT Act presents a significant challenge in the regulatory framework.

Regardless of the operating model adopted by e-pharmacies, a common challenge arises in the need for a clean and authorised process to review

patients' prescriptions and sell prescription drugs. After the registration and approval from CDSCO, the draft rules mandate that each order for a prescribed medicine must be verified and checked by a team of registered pharmacists. Validated prescriptions are forwarded to the pharmacy store or warehouse from which the medicines are dispensed.[17]

It is the responsibility of the licensed store pharmacist to verify the validity of prescriptions, as medicines cannot be dispensed without valid prescriptions. Patients must receive their medicines in sealed, tamper-proof packaging from a licensed premise. Furthermore, a proper bill or invoice must be provided with details such as batch numbers, expiry dates, and storage instructions.

One notable aspect of the draft rules on e-pharmacy is the vague disclosure mandate imposed on e-pharmacies. While the rules prohibit e-pharmacies from disclosing patient information to anyone, they also require the disclosure of such information to central or state governments if deemed necessary for public health purposes. However, the rules do not provide clear guiding principles to interpret what circumstances would constitute a valid public health purpose.[18]

The lack of clarity in this regard raises concerns regarding the scope and circumstances under which e-pharmacies may be required to share sensitive patient information.

The draft Rule 67T (3) of the E-pharmacy Rules allows central and state governments to revoke registrations granted to existing e-pharmacies. However, this draft rule appears to overstep its parent legislation, the Drugs and Cosmetics Act of 1940, which does not foresee such licence cancellations by State Governments.[19]

While e-pharmacies have found currency among end-users and investors, regulators and brick-and-mortar stores are not so enamoured by these disruptive start-ups. All India Organisation of Chemists and Druggists (AIOCD) alleged online pharmacies in December 2022 over the "illegal and indiscriminate" discounts being offered by them. It stated that online pharmacies are violating regulations surrounding the sale of drugs and operating a pharmacy.[20]

The confusion due to regulatory uncertainty is eroding the trust of investors and consumers alike. Consumers who are uncertain about the authenticity and quality of medications offered by unregulated e-pharmacies may hesitate to engage and fear risks such as counterfeit drugs, substandard medications, or unauthorised access to their personal and medical information.[21]

This lack of trust could hinder the growth of the e-pharmacy sector and limit the accessibility and affordability of medications for patients. Counterfeit and spurious drugs are problems with both online and offline pharmacies, in former, however, it is easier to trace the source following the digital trail.

Addressing the complexities of e-pharmacy regulation necessitates a comprehensive, globally informed approach, drawing insights from regulatory measures implemented by countries such as the USA and the EU. For instance, the EU has instituted a system to protect consumers from illegal pharmacies, whereby every legally operating registered e-pharmacy displays a common logo.[22]

This logo serves as a hyperlink to the national authority's website, where a list of all legally operating pharmacies is maintained. This strategy not only ensures the safety of the drugs but also authenticates the e-pharmacy's legitimacy. A similar measure was recommended by the sub-committee for adoption in India.[23]

The USA also provides a useful model. E-pharmacies accredited by the Verified Internet Pharmacy Practice Sites display a seal on their websites, enabling customers to verify the e-pharmacy's legality. Implementing such practices in India could significantly enhance consumer trust and safety in the e-pharmacy sector. Another pressing issue is the prevalence of false-positive prescriptions.[24]

The US model, which allows e-pharmacies to dispense medicines exclusively through e-prescriptions, presents a potential solution. The model disallows the use of scanned prescriptions or images of prescriptions, a practice that could be adapted in India to include digitally signed prescriptions. These globally informed strategies could provide a robust framework for effectively regulating e-pharmacies in India, ensuring consumer safety, and fostering trust in this burgeoning sector.

Competition Concerns in the E-Pharmacy

India's online pharmacy segment, backed by top global investors such as Tiger Global, Sequoia Capital, Temasek, and Prosus, and large conglomerates such as Reliance Industries and Tata Group, is a testament to the sector's potential.[25] Without clear regulations, some e-pharmacies could adopt non-compliant practices for a competitive advantage.

Recently, there has been consolidation within the e-pharmacy sector via mergers and acquisitions. This phenomenon is likely to continue, and like in other e-commerce segments, there may remain only two to three e-pharmacy

platforms in the market. This concentration of market power could limit competition, reduce consumer choices, and potentially lead to higher prices.

Further extensive and sustained discounting practices in the e-pharmacy sector may create new competition barriers, as is evident in the e-commerce platforms.[26] This practice seems to represent a systematic competitive strategy in which capital has become a significant competitive tool.[27] This raises concerns that the market may eventually tip towards a player that can secure more capital and attract more users in the early stages through subsidies rather than offering the most innovative product or service.

There is evidence of significant entry as well as exit in the online market. Between December 2019 and November 2020, six new e-pharmacies entered the market while four stopped their operations. For most online markets worldwide, there seems to be a similar pattern.[28]

The resulting monopolistic or oligopolistic market structure, arising from the entry barriers created by network effects and the exit of efficient competitors, may not be easily self-corrected by market forces.

As the sector matures and regulatory frameworks begin to take shape, larger e-pharmacy players with substantial resources and established brand recognition may gain a competitive advantage. These dominant players can leverage their market position to negotiate better terms with suppliers, secure exclusive partnerships, and invest in technological advancements. Consequently, they may enjoy economies of scale, making it challenging for smaller players to compete effectively. This situation should be of concern to the competition authorities.

The Competition Commission of India (CCI) in its 2018 Policy Note titled "Making Markets Work for Affordable Healthcare" is aptly observed that: "*Electronic trading of medicines via online platforms, with appropriate regulatory safeguards, can bring in transparency and spur price competition among platforms and among retailers, as has been witnessed in other product segments. The Ministry of Health and Family Welfare, Government of India has taken a positive step in this direction by releasing draft rules on Drugs (Sale and Distribution) Rules, 2017 which aims at removing ambiguity on regulations to facilitate sales of drugs online. It is required that a level playing field is created between online and offline platforms for the sale of drugs.*"[29]

E-pharmacies enjoy certain technological advantages that traditional brick-and-mortar pharmacies do not, which serve as key differentiators. The ability to conduct online transactions and process orders allows e-pharmacies to gather valuable data. This data can be leveraged for analytics, enhancing

the marketing of online services. Regular updates to customers for ordering medicines, stocking in-demand medicines, and developing predictive algorithms for future use are all made possible through data analysis.[30] Additionally, the data can be instrumental in identifying patterns in the order of certain drugs and their potential overuse, leading to addiction.

The Parliamentary Standing Committee on Finance in its report 'Anti-competitive practices by Big Tech Companies' flagged how companies involved in digital trade and commerce can use data collection and processing to dominate the market or gain a competitive edge.[31]

The abundance of consumer and business data accessible by big tech firms, including e-commerce platforms, enables them in a position of advantage in the market, making it difficult for new players to enter the market, subsequently negatively impacting competition in the marketplace and consumer welfare. Some of the anti-competitive practices highlighted in the report include self-preferencing/platform neutrality, bundling and tying, deep discounting, exclusive tie-ups, search and ranking preferencing, etc.

As a solution to these competition concerns, the Standing Committees on Finance have suggested implementing an ex-ante regulatory framework in the form of a Digital Competition Act. The Government of India has set up a panel to explore the possibilities of a digital competition law and address the growing demand for ex-ante regulation.[32]

Moreover, the expansion plans of e-pharmacies indicate a potential presence in diverse offline service markets, such as diagnostics, in addition to online medicine sales.[33] This raises the possibility of leveraging dominance in one market to establish control in another. The interplay between online and offline operations also raises questions about the structuring of contracts between offline and online stores, particularly for e-pharmacies modelled as marketplaces without any inventory.[34]

Concerns about maintaining price parity through contractual clauses, as well as horizontal mergers leading to the reduction of competition in the e-pharmacy space, are legitimate antitrust issues. These complexities underscore the need for nuanced and comprehensive regulatory oversight to ensure fair competition and consumer protection in the rapidly evolving e-pharmacy sector.

Recommendations

- Government should quickly bring an optimal regulation for e-pharmacy, building upon the comments received with respect to the 2018 draft rules and the Drugs, Medical Devices and Cosmetics Bill, 2022 as well as after thoroughly consulting the stakeholders, including consumers.

- Government should ensure adequate resources to implement the Digital Personal Data Protection Act, 2023 to protect sensitive health data of citizens, including ensuring proper consent mechanism for sharing of data by e-pharmacy. However, in cases of medical emergencies and to save the lives of patients, their data can be shared without consent.

- The CCI may like to conduct a specific market study with respect to the digital health, including e-pharmacy ecosystem in order to understand present market dynamics and prevalent competition concerns, such as market concentration, entry barriers, vertical integrations, bundling and tying, deep discounting amounting to predatory pricing, exclusive tie-ups, self-preferencing and search & ranking preferencing etc. It may also like to look into regulatory and non-regulatory market distortive practices.

- The proposal of establishing a Digital Market Unit within CCI is a positive development but it requires adequate financial and human resources from the Government. To ensure effective coordination and avoid jurisdictional conflicts, mechanisms for better collaboration between CCI and other regulators and the upcoming Data Protection Board of India should be established.

- E-pharmacy platforms should embrace self-regulation, as suggested by the CCI in its e-commerce market study. These steps will foster fair competition and ensure a level playing field.

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CHAPTER 9

Regulation of Mental Healthcare in India

Introduction

Mental health is a major public health concern in India. The latest survey by India's National Institute of Mental Health and Neurosciences (NIMHANS) shows that nearly 150 million Indians are in need of mental health care services, but fewer than 30 million are seeking care. In 2017, 197.3 million were estimated to need care for their mental health conditions in the country.[1] The National Mental Health Survey (2015-16) indicates that 1 in 9 adults and 1 in 14 adolescents suffer from a mental health condition that requires care. In urban metropolitan cities, the prevalence is two-fold.[2]

The COVID-19 pandemic impacted the mental health of many adversely and highlighted the desperate need for improving mental health services. Increases in stress, anxiety, and depression along with new cases of psychosis and suicides were reported across the country.[3] Along with the fear of infection, stigma related to the infection, isolation and uncertainties related to the lockdowns, many experienced difficulties in accessing health services including mental health services.[4] The pandemic also impacted the mental health of healthcare workers adversely.[5]

Like many other countries, India is also set to face an additional set of challenges posed by climate change and its impact on the health and well-being of the people including direct and indirect impacts on mental health, for instance, due to rising temperature, food insecurity, and increasing disasters.[6]

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Mental Health Services in India

Mental health services are provided across the public and private health sectors with the private sector providing the larger share of services comprising 66 percent of all outpatient care and 59 percent of all inpatient care.[7] In addition, many non-profit organisations also provide services in the community extending the reach of mental health care services in the country. In addition to the mental health institutions (psychiatric hospitals), the General Hospital Psychiatric Units especially located within medical colleges, multi-specialty government hospitals, and hospitals attached to various public sector organisations such as railways also provide specialist mental health care services.[8] The National Institute of Mental Health and Neurosciences, Bengaluru is the designated institute of national importance for mental health.

Altogether, there are nearly 2 beds per 100,000 population in the country.[9] Multiple reports have highlighted the deplorable conditions of mental health in-patient services across the government-run hospitals in the country; information on the quality of care in private sector-run hospitals is not available.[10] Psychiatrists and clinical psychologists in addition provide outpatient services mostly concentrated in the urban areas of the country.

Within the public sector, mental health services are provided within the primary health care setting through the District Mental Health Programme (a flagship component of the National Mental Health Programme) currently active in 704 of 766 total districts[11] in India. Recent initiatives introduced by the government intending to improve the availability of and access to mental health services in the country include screening and provision of primary care for mental health conditions at all the Ayushman Bharat's Health and Wellness Centres, and the launch of a national tele-mental health programme,

Tele-Manasto provide online counselling through a toll-free number, 14416. Tele-psychiatry is recognised as formal means of providing mental health services in the country, the guidelines recognise the use of multiple modes of consultation while providing specifications for the consultation process, prescription guidelines, and documentation of care.

Beyond these, the mental health needs of specific sub-populations are also addressed at various institutions such as orphanages, juvenile homes, child protection centres, prisons, beggars' homes, religious places and faith healers. Mental health prevention and promotion are also included in other sector programmes, such as education, youth affairs, and women and child development. For instance, halfway homes are being set up through the Ministry of Social Justice and Empowerment, although there are very few operations across the country.

Regulating Mental Healthcare in India

Regulation of mental health services play an important role in the development and evolution of mental healthcare services. Mental health programming in the country is primarily guided by the National Mental Health Policy 2014, and Mental Healthcare Act 2017. Recently the National Suicide Prevention Strategy 2022 was also developed to guide suicide prevention activities in the country to reduce suicides in the country by 10 percent in 10 years.

The Mental Healthcare Act (MHCA) is the key legislation for mental health care in India, along with the Mental Healthcare (Rights of Persons with Mental Illness) Rules, 2018; The Mental Healthcare (Central Mental Health Authority and Mental Health Review Boards) Rules, 2018; and The Mental Healthcare (State Mental Health Authority) Rules, 2018. The MHCA replaced the Mental Health Act (1987).

The MHCA was needed as the Mental Health Act of 1987 was considered to be insufficient to protect the rights of persons with mental health conditions in accordance with the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) (United Nations, 2006). The MHCA was therefore enacted to give effect to the UNCRPD and bring more focus to the rights of persons with mental health conditions.

The MHCA is a comprehensive Act that encompasses almost all major dimensions of mental health. It ensures the right to access mental health services, treatment, and services for all persons, and empowers persons with mental illnesses in many critical ways concerning their treatment, privacy, dignity, and social integration. The civil, political, economic, and social rights of persons with mental illness are protected under the Rights of Persons with Disabilities Act (The Rights of Persons with Disabilities Act, 2016) which replaced the Persons with Disabilities (Equal Opportunity Protection of Rights and Full Participation) Act, 1995.

MHCA stipulates the establishment of a Central Mental Health Authority, a State Mental Health Authority (SHMA) at the state level and Mental Health Review Boards at district levels for implementation and overseeing the implementation of the MHCA. The MHRB is a well-conceptualised quasi-judicial body for grievance redressal for Persons with Mental Illness (PwMI) at the district level, which the SMHA establishes.

MHCA and Patient rights

The MHCA brings a paradigm shift in many ways in terms of protecting the rights of PwMI. It safeguards the patient's right to access various mental health care facilities (such as in-patient and out-patient services; rehabilitation services in the hospital, community, and home; halfway homes; sheltered

accommodation; and supported accommodation) and receive appropriate care. If the services are unavailable, PwMI is entitled to compensation from the state. The Act also outlines the procedure and process for admission, treatment, and subsequent discharge of PwMI and mandates that health insurers include provisions for medical insurance for treating mental illness on the same basis as for treating physical ailments. It also provides for confidentiality and prevents data sharing about a PwMI without their consent on any platform.

A major departure from the previous Mental Health Act 1987 is that it recognises the agency of the PwMI, allowing them to make decisions regarding their health, given that they have the appropriate knowledge to do so. It also provides for Advance Directives and Nominated Representatives to enable such decision-making in case of severe illnesses. Advance directives empower a mentally ill person to have the right to make an advance directive toward how she/he wants to be treated for the requisite illness and who her/his nominated representative shall be. This directive must be vetted by a medical practitioner.

MHCA and Mental Health Establishments

The MHCA includes provisions for registering mental health-related institutions and regulating the sector. These measures include setting up mental health establishments across the country to ensure that no person with mental illness will have to travel far for treatment and creating a mental health review board that will act as a regulatory body. MHCA 2017 tries to regulate almost all mental health establishments (MHEs). By including institutions belonging to other alternative health systems in the definition of MHEs, the Act has made uniform regulations in establishing and regulating mental health services. The Act governs both public and private mental health sectors.[12]

Finally, it promotes the use of modified electroconvulsive therapy (ECT) only under anaesthesia and with the use of muscle relaxants and mandates the use in children with permission from the Mental Health Review Board.

MHCA and De-criminalisation of Suicide

The MHCA aims at decriminalising the attempt to commit suicide by providing that the government must offer those individuals who have attempted suicide opportunities for rehabilitation as opposed to being tried or punished for the attempt. MHCA states that any person who attempts suicide shall be presumed to have severe stress and shall not be tried and punished under the Indian Penal Code. Decriminalisation of suicide will also help change the mindset of the people and reduce the procedural burden on the families in the times of distress. However, the act does not repeal the Indian Penal Code, thereby not entirely protecting persons who have attempted legal procedures.[13]

Implementation of MHCA 2017

Since its enforcement, there has been poor implementation on the ground. The Central and State Mental Health Authorities and then the Mental Health Review Boards (MHRB) at district levels form the backbone of the implementation framework of this legislation. Unfortunately, the actualisation of this structure has been hampered by various obstacles.

MHRBs are a quasi-judicial body comprising not just experts from the fields of law and mental health but - crucially - recognise the expertise that comes from the lived experience of PwMI or their caregivers (Chapter XI, MHCA). The Central and State Mental Health Authorities (CMHA and SMHA) are tasked to ensure the administration and implementation of the law. However, many states are struggling to establish the SMHA and MHRBs. Without these bodies, the enforcement of even the most important mandates of the MHCA remains ineffective.

For instance, the MHCA requires that the MHRB provide their decision on the capacity to consent within 72 hours. However, the overarching backlog of cases within the Indian judicial system poses a challenge to meeting this stipulated timeframe. this may be difficult considering the huge pendency of cases in the Indian judicial system in general. Recognizing these calls for alternative mechanisms, such as hospital-level boards, have gained traction to address the timeliness and efficiency of decision-making.

Table 9.1 summarises the status of implementation of the MHCA across the states and Union Territories (UTs) in India. The data presented in the table is largely derived from the compilation provided by the MHCA tracker, developed by the Keshav Desiraju India Mental Health Observatory,[14] offering a snapshot of the existing challenges and progress in mental health governance across the nation.

The implementation of the MHCA is severely lacking in many states. Particularly, with the MHRBs not even constituted in many states, the expected reforms that empower the PwMI will remain unrealised. The massive delay in setting up these essential bodies is partly attributable to the poor provision of financial and human resources for the implementation of the Act.[15]

Further, there lack of systematic and comprehensive capacity-building of members appointed to the SMHA/ MHRB and other stakeholders, including PwMI. Notably, civil society organisations, such as the Centre for Mental Health Law and Policy have developed training programs to address the gap.[16]

Table 9.1: Status of Implementation of the Mental Healthcare Act 2017 in the country

Indicators	Section	Implemented in States	Not Implemented
The state has constituted- the State Mental Health Authority	45	Madhya Pradesh, Andhra Pradesh, Chhattisgarh, Goa, Haryana, HP, Jharkhand, Karnataka, Kerala, Maharashtra, Meghalaya, Mizoram, Orrisa, Punjab, Sikkim, Telangana, Arunachal Pradesh, Assam, Delhi, Manipur, Tamil Nadu, Tripura, Uttar Pradesh, West Bengal, Uttarakhand	Bihar, Rajasthan, Jammu & Kashmir and Nagaland
Ex-officio and non-officio members appointed to the SMHA	46	Andhra Pradesh, Bihar, Chhattisgarh, Goa, Haryana, HP, Jharkhand, Karnataka, Kerala, Maharashtra, Meghalaya, Mizoram, Orrisa, Punjab, Sikkim, and Telangana	Arunachal Pradesh*, Assam*, Delhi, Gujarat*, Himachal Pradesh, Jammu & Kashmir*, Madhya Pradesh, Manipur*, Nagaland, Rajasthan*, Tamil Nadu, Tripura*, Uttar Pradesh*, Uttarakhand, West Bengal Jammu & Kashmir*
Appointment of CEO to the SMHA	52	Meghalaya, Mizoram, Maharashtra, MP, Karnataka, HP, Haryana, Gujarat, Goa, Delhi, Chhattisgarh, Bihar, Assam, Andhra Pradesh, and Arunachal Pradesh	Jammu & Kashmir*, Jharkhand*, Kerela, Manipur*, Nagaland, Orrisa,* Punjab*, Rajasthan*, Sikkim*, Tamil Nadu*, Telangana*, Tripura*, Uttar Pradesh*, Uttarakhand*, West Bengal*
Mechanism to receive complaints on the deficiencies in services in MHEs	55	Tamil Nadu, Karnataka, Himachal, and Delhi.	Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Goa, Gujarat, Haryana, Jammu & Kashmir, Jharkhand, Kerela, Madhya Pradesh, Maharashtra, Manipur, Meghalaya, Mizoram, Nagaland*, Orrisa*, Punjab*, Rajasthan*, Sikkim*, Telangana*, Tripura*, Uttar Pradesh*, Uttarakhand*, West Bengal*
Constitution of SMHA fund	62	Chhattisgarh, Jharkhand, Nagaland, Sikkim, and Tamil Nadu.	Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Delhi, Goa, Gujarat, Haryana, Himachal Pradesh, Jammu & Kashmir, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Manipur, Meghalaya, Mizoram, Orrisa*, Punjab*, Rajasthan*, Telangana*, Tripura*, Uttar Pradesh, Uttarakhand*, West Bengal*
Mental Health Review Boards constituted in the states	73	Delhi, Goa, Karnataka, Himachal Pradesh, Kerala, Maharashtra, Meghalaya, Nagaland, Orrisa, Punjab, Sikkim, Tamil Nadu, Tripura, Uttar Pradesh, Uttarakhand, and West Bengal.	Andhra Pradesh, Arunachal Pradesh, Assam, Bihar, Chhattisgarh, Gujarat, Haryana, Jammu & Kashmir, Jharkhand, Madhya Pradesh, Manipur, Mizoram, Rajasthan*, Telangana.

(*)No information was available in the public domain

A major threat to the effective implementation of the MHCA is the poor availability of mental health services and trained human resources. There are under 0.7 psychiatrists per 100,000 compared to six per 100,000 in high-income countries.[17]

The status concerning other mental health professionals, including clinical psychologists, psychiatric nurses, and psychiatric social workers, is much worse. The number of beds are also too few for the population of the country. The availability of community-based services, halfway homes, and rehabilitation centres is similarly poor. With such poor availability of services, fulfilling the mandates of the act in terms of ensuring the service provision remains a distant reality.

Perpetuating underlying reason includes chronic underfunding of mental health services in India. As a proportion of the Union Health Budget, the share of mental health remains around one percent of total health expenditure by the government and has not increased despite the MHCA and the urgent need to invest in mental health services identified by the COVID-19 pandemic.[18]

This is evident from the Union Government's overall allocation for mental health in 2021–2022 of INR 537.8 crore, including only INR 40 crore for the National Mental Health Programme (NMHP). In 2023, the Ministry of Health and Family Welfare received Rs 89,155 crore for health overall, however, the amount set aside for mental health remains approximately 1.03 percent. However, this does not include the state government funding of the state-run mental hospitals and mental health initiatives. In comparison, an estimation of the cost of implementation of the MHCA alone annually was INR 94,073 crore.[19]

The outcome is that India continues to struggle with a lack of effective mental health services that are available, affordable, accessible, and most importantly, acceptable. In addition, there is poor mental health literacy, the high social stigma associated with mental disorders, and continuing poor and delayed help-seeking for mental health conditions. Thus, there remains a high treatment gap – 85 percent on average across all mental health conditions.[20]

For those who do access care, the cost of treatment is often prohibitively high as people endure high out-of-pocket expenditure on account of mental health conditions both for outpatient care and in-patience care, especially as insurance coverage is quite low across both public and private sectors.[21] Numerous PILs filed by citizens and rulings of the courts – high courts and supreme courts – directing the state governments to implement MHCA. MHCA has supported many landmark judgments in the country related to

the decriminalisation of homosexuality, decriminalisation of suicide attempts, issuing guidelines for an advance directive for passive euthanasia and upholding the right to privacy and dignity for an accused with mental illness, and improving mental health services in the country as well as urging the states to establish rehabilitation services.[22,23,24,25,26]

Overall, enacting the MHCA is a welcome change as it places patient's rights in the centre, but meagre budgetary allocation for mental health continues to thwart any real changes for patients and service providers in the near future. There is also a general lack of interest in its enforcement, and enforcement is largely motivated by court cases and judicial activism.

Critical Notes on the MHCA

The MHCA lays the groundwork for progressive mental health legislation, the ongoing debates surrounding its implementation underscore the need for a more comprehensive and consultative approach. Critics argue that the Act makes it difficult for psychiatrists to undertake clinical practice, and requires much more paperwork and may increase litigations. Many of these concerns essentially reflect the huge gap between 'what is envisaged' and 'what is' with respect to the availability of services and resources, lack of rehabilitation services, and lack of systematic approach to fill this gap in addition to poor mental health awareness and literacy among patients and their families.

Specifications and nuances related to information sharing and the duration of maintaining records, add another layer of intricacy to the implementation of MHCA. To further advance the continuity of care for Persons with Mental Illness (PwMI) in communities, further provisions may be needed that mandate treatment provision for PwMI in communities beyond discharge through a community treatment order. As we navigate these complexities, a holistic and collaborative effort is required to ensure that the MCHA's progressive intent aligns with practical, patient-centric outcomes in mental health care across nation.

Definition of mental illness: Some concerns have been raised about the definition of mental illness, especially as it prioritises severe mental health conditions and is unclear. The MHCA 2017 defines mental illness as "*mental illness*" means a substantial disorder of thinking, mood, perception, orientation or memory that grossly impairs judgment, behaviour, capacity to recognise reality or ability to meet the ordinary demands of life, mental conditions associated with the abuse of alcohol and drugs, but does not include mental retardation which is a condition of arrested or incomplete development of mind of a person, especially characterised by sub normality of intelligence.

Although Section 2 includes mental illness as defined by international guidelines like ICD or the Diagnostic and Statistical Manual (DSM), the above definition implies a greater focus on people with severe mental health conditions, and inclusion of some conditions, like personality disorders, conversion disorders, phobia and panic disorders is unclear.

Advance Directives and Nominated Representatives: Mental health practitioners have raised significant concerns about awareness among patients and their families regarding mental health conditions, treatment, and rights. There is limited information available regarding the use of Advance Directives across different scenarios and circumstances in the country. Psychiatrists have raised concerns about this provision creating more litigations. Further, with non-functional MHRBs, reinforcement of this mandate remains difficult. Acknowledging immediate family members as the natural guardians have been advocated.[27]

Mental Health Establishments: Concerns have also been raised about the implications of mandatory registration of all health facilities treating people with mental health conditions. On one hand, while it is argued that this may interfere with the integration of mental health treatments with general health services, on the other hand, reluctance of the private health care providers to register themselves (reflecting on the experience of the implementation of the Clinical Establishments Act 2010[28]) may delay treatment. Further, this Act also implies to include the places beyond a health establishment, such as prisons, jails, juvenile homes, child protection centres, religious places where mental health treatments are often provided.

Capacity to consent: A need has also been identified for further clarification and guidance for the mental health providers on the Section 4 of MHCA 2017 regarding assessment of the capacity of the PwMI to make mental health care and treatment decisions, especially for patients with serious symptoms who may refuse treatment for lack of insight. It is felt that the current role of family members in decision making with respect to treatment of PwMI especially during the acute phases of severe mental illness is not acknowledged by the Act. A need is felt to enable the psychiatrists to provide involuntary treatment for supported (involuntary admissions) through the consent of parents and family members in addition to the nominated representatives.[29]

Direct compensation to patients: The Act provides compensation to PwMI by the State if they do not get mental health services. However, the Act does not emphasise the development of a clear road map to develop mental health services and improve the availability of HR and services in the country.[30]

Community-level programmes: While the Act speaks to almost all dimensions of treatment and care for PMI, including their right to community living, its relatively higher emphasis on severe mental illnesses and establishments excludes community-based initiatives and programmes.

Insurance for Mental Illness

Medical insurance is an effective way to reduce the financial burden of mental health treatment. The legislation related to the insurance sector – the Insurance Act falls under the Union list, and hence it is uniform throughout the territory of India.[31] The Act does not specifically provide for any bar on psychological or psychiatric illness or disorder while covering insurance. However, insurance service providers in India have excluded mental health conditions despite the mandate of the MHCA to include mental illnesses in all insurance coverage[Section 21 (4)].[32]

Securing adequate insurance coverage for mental illnesses is a real problem for many despite the legislative provision. As per the NSS-75th Round 2017-2018, right around the time the MHCA was enforced, only 16.2 percent of all hospitalisations due to mental disorders had government-funded health insurance coverage, while only 0.16% had private voluntary health insurance coverage.[33]

Among the government-funded insurance schemes is the Pradhan Mantri Jan Arogya Yojana (PM-JAY),[34] the world's largest health insurance scheme providing health coverage of INR 5 lakhs per health coverage family per year. It covers the bottom 40 percent of the Indian population and mental health disorders.

Presently, there is a directive for all insurance companies in 2018 to extend medical insurance to treat mental illness, recognising the right to equality in the treatment.[35,36,37]

Typically, the insurance policies now offer some improved coverage for in-patient hospitalisation in case of mental illness. However, individual insurance policies differ in how they cover mental illnesses, requiring the insurer to go through each policy in depth before finding a policy that best meets their needs.

In addition, technical challenges related to absence of a standard and uniform way to calculating insurance premiums and lack of a standard costing of mental healthcare services for OPD consultation, counselling, and hospitalisation further lead to the huge variations in the availability of insurance coverage.

Conclusion and the Way Forward

Mental health has recently gained considerable traction as a public health priority, particularly in the wake of the COVID-19 pandemic. The Mental Healthcare Act 2017 is the key legislation governing mental healthcare in India. MHCA is a progressive and empowering legislation.

It is a positive step towards long-standing problems by stakeholders in the sector by putting the patient in the centre and mandates the Government to provide services and protect the rights of PwMI. It has the potential to bring radical change to the way Mental Health is treated in India. However, meagre resource allocation, severe infrastructure, human resources shortage, and poor reinforcement of the action starting with the setting up of the SMHA and DMRBs which form the backbone of the act threaten any meaningful translation of the aspirations espoused by the MHCA.

The central point of most critiques for the MHCA is related to this formidable gap between the ideal envisaged or ensuring the right to treatment and the current reality amplified by poor mental health literacy and rampant social stigma in the country. The MHCA ushers a major shift in the way decisions regarding mental health treatments are being made in the country by providing PwMI more autonomy, even when they can't exercise this autonomy directly, through advance directives and nominated representatives.

Many mental health professionals worry the Act undermines the role of families, makes care for persons with serious illness especially requiring supported or involuntary admission in a mental health institute more difficult, introduces more paperwork, and invites more litigation.

Recognising and allaying such concerns is urgently needed along with a consensus building exercise with all stakeholders to develop a clear roadmap to implement these provisions. Mental health providers at all levels and especially psychiatrists need to be provided with the necessary support, guidance and they are empowered to uphold the rights of the patients as envisaged by the MHCA and implement the mandates of the legislation in their practice confidently.

Given the massive gaps in the implementation of the MHCA, active policy interventions and resource allocation and proactive enforcement of the MHCA by the government is an urgent need along with mobilisation and capacity building of relevant stakeholders (government, non-government bodies, professionals, society volunteers etc).

In the author's view, there is a serious need for the State and the Central Governments to priroitse the effective implementation of MHCA. This needs to be undertaken in tandem with the strengthening of the existing services and development of community-based care and rehabilitation services for Person with Mental Illness (PwMI) while supporting the families with members enduring a severe mental illness.

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CHAPTER 10

Bio-Medical Waste Management: Sad State of Affairs

Introduction

Bio-medical waste (BMW) with a high potential for disease transmission is generated from medical activities, many of which are hazardous, toxic and even lethal. The lax regulation and implementation of managing waste on the ground is a major cause of concern.

It is the improper disposal of biomedical waste that demands due attention. Hospital bins are found full of waste that is dumped at the garbage collection centre, where vehicles pick up all garbage and take it away for final disposal. Most sites are big attractions for rag pickers who may get infected while handling such infected items.

BMW's production rate in number is very low, but the consequences of this waste are hazardous to the health of hospital employees' patients and society. The average amount of hazardous waste generated daily per hospital bed in high-income nations is up to 0.5 kg, compared to 0.2 kg in low-income countries. It is estimated that 85 percent of waste generated by healthcare activities is general, non-risky waste, the remaining 10 percent is infectious and five percent is hazardous.[1]

Hospitals function day and night to save lives and employees working in the hospitals frequently meet the body fluids, infected materials, and infected tissues of patients. Similar risks of unintentional infection exist for medical professionals, nurses, support staff and technical personnel employed in laboratories as well as visitors.[2] Nosocomial infection possibilities increase in that situation for patients.[3]

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The management of BMW operations in the country is regulated by the Ministry of Environment, Forests, and Climate Change vide the Bio-Medical Waste Management Rules, 2016 (as amended), which repealed the BMW (Management and Handling) Rules, 1998.[4]

The pandemic of COVID-19 led to the generation of a huge amount of biomedical waste. During COVID-19, India suffered severe, substantial impacts due to a lack of resources and an unsound biomedical waste management system.[5]

Regulation Governing Biomedical Waste

The International Clinical Epidemiology Network investigated the current BMW practices, structure, and framework in basic, secondary, and tertiary healthcare facilities/institutions (HCFs) in India across 20 states between 2002 and 2004.[6] On average, they discovered that India's primary, secondary, and tertiary HCFs lacked a reliable BMW Management system in 82 percent, 60 percent, and 54 percent of facilities respectively. In Gujarat, India, some 240 people acquired Hepatitis B in 2009 because of reusing non-sterile syringes.[7] This is incisive of the core issue of biomedical waste management and lack of awareness.

In March 2016, the Ministry of Environment, Forest, and Climate Change published the BMWM Rules.[8] Further amendments to the Rules have been made in 2018 and 2019.[9] During the pandemic, the Central Pollution Control Board (CPCB) came up with guidelines for the handling, treatment, and disposal of waste generated during the diagnosis, treatment, and quarantine of COVID-19 patients.[10]

The Bio-Medical Waste Management Rules, 2016

The standard definition of "biomedical waste" provided in the Rules refers to any waste, which is generated during the diagnosis, treatment or immunisation of human beings or animals or research activities pertaining thereto or in the production or testing of biological or in health camps, including the categories mentioned in Schedule I appended to these rules.[11]

The Rules mandate that every healthcare facility take all necessary precautions to ensure that biomedical waste is handled without having an adverse impact on human health or the environment.[12] These Rules provide that, irrespective of the volume, any occupier or operator managing bio-medical waste must get authorisation from the relevant statutory authorities.[13] The Central Pollution Control Board, the State Pollution Control Boards and

Table 10.1: Sources of Bio-Medical Waste	
Major source of bio medical waste	**Minor source of biomedical waste**
• Hospitals • General hospitals • University hospitals • District hospitals • Healthcare dispensaries and centres • Emergency health care services • Maternity and obstetric clinics • Dialysis centres • Transfusion centres • Outpatient clinics • Long term hospitals and health care establishmentsÏ% Military medical services • Prison hospitals and clinics • Medical research centres and laboratories • Biotechnology institutions and laboratories • Biomedical and medical laboratories • Autopsy and mortuary centres • Animal testing and research activities • Blood centres and blood collection services • Nursing homes for the elder people	• Small clinics and health care establishments • Dental clinics • First-aid sick bays and posts • Specialised healthcare centres • Physician offices • Nursing homes for convalescent • Chiropractors • Psychiatric hospitals • Institutions for disabled persons • Activities involving intravenous or subcutaneous interventions • Illicit drug users and needle exchanges • Cosmetic tattoo parlours and ear-piercing • Funeral services • Ambulance services • Home treatment

Pollution Control Committees have the authority to cancel the consent to operate and the authorisation of healthcare institutions under the Rules for non-compliant hospitals.

The key feature is that if a CBMWTF (Common Bio-Medical Waste Treatment Facility) is located within 75 kilometres, no occupier could establish an on-site treatment and disposal facility.

Segregation of Waste by Colour Coding[14]

There are four colour codes – yellow, red, white, and blue – provided in the Rules. These four different coloured plastic bags, non-chlorinated, or containers must be used to collect biomedical waste as under[15]

Yellow:

- For human anatomical, animal anatomical and soiled waste
- For expired or discarded medicines and chemical waste
- In the case of chemical liquid waste use a separate collection system leading to an effluent treatment system
- Discarded linen, mattresses, and beddings contaminated with blood or body fluid waste
- To collect microbiology, biotechnology and other clinical laboratory waste use autoclave-safe plastic bags or containers

Red:

- For contaminated waste that is recyclable, such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, and syringes (without needles).

White:

- For waste sharps, such as metal needles, syringes with fixed needles, needles from needle tip cutters or burners, scalpels, blades, or any other contaminated sharp object that may cause punctures and cuts

Blue:

- Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes. The same will be used for the waste of metallic body implants.

Salient Features of 1st Amendment to The Bio-Medical Waste Management Rules, 2016 Published in 2018[16]

1. All healthcare facilities are required to post the annual report on their websites (regardless of bed count).
2. Routine mask and gown are segregated in "yellow" bin.
3. Disposal of glassware and metallic body implants in puncture-proof and leak-proof boxes or containers with blue-coloured markings.
4. Utilising sodium hypochlorite for chemical pre-treatment or treatment, 1 percent to 2 percent is the advised concentration.
5. For discharge into public sewers with terminal facilities, the general standards as notified under the Environment (Protection) Act, 1986 shall be applicable.
6. Non-bedded occupiers shall dispose of infectious liquid waste only after treatment by disinfectant.

Salient Features of 2nd Amendment to The Bio-Medical Waste Management Rules, 2016 Published in 2019[17]

1. The occupants of all bedded health care units are responsible for maintaining and updating the bio-medical waste management register daily.
2. All bedded healthcare units shall display the month's record of waste disposal management on their website.
3. Such healthcare facilities (regardless of bed count) must make the Annual Report available on their website by March 19, 2021.
4. Healthcare facilities with fewer than 10 beds must comply with the liquid waste output discharge standard by December 31, 2019.
5. Chlorinated plastic bags do not include urine bags, effluent bags, abdominal bags, and chest drainage bags.

Salient Features of Guidelines Published in March/July 2020[18]

The CPCB's responsibilities in combating the pandemic have been expanded. The focus was on COVID waste management, including lab waste disposal; PPE disposal; homecare waste disposal; solid waste disposal; liquid waste disposal; and the duties of stakeholders to troubleshoot the problems faced by health care workers and biomedical waste handlers. The guidelines' salient feature is the use of double-layered bags to ensure that the bags are strong enough and do not leak. The guideline specifies the separation of waste from isolation wards as "COVID-19 waste" (biomedical waste) and "generic waste" (without contamination) in accordance with the biomedical waste management criteria of 2016. The guidelines are used to stop the spread of infection in the community and general patients who are admitted to hospitals.

COVID-19: Big Contribution to Augment Bio-Medical Waste Management

The worst health disaster the world has ever experienced has occurred during the past two years. The COVID-19 pandemic and its subsequent versions have had an influence, economically and health-wise on people's lives.[19]

India's already strained waste management infrastructure came under more stress due to the COVID-19 pandemic.[20] A lot of gear and medical equipment is used by both healthcare professionals and patients that are utilised for treatment and protection, such as personal protective equipment (PPE), gloves, face masks, head covers, plastic coveralls, hazmat suits, and syringes.

The number of biomedical waste spiked day by day, from 559 tonnes per day to 619 tonnes per day between 2017 and 2019. However, the unfavourable circumstance was that less biomedical waste was treated, dropping from

92.8 percent to 88 percent.[21] There are 198 CBMWTFs in use and 28 more are being built. There are 1,318,378 HCFs using common biomedical waste treatment facilities (CBMWTFs), and about 21,870 HCFs have on-site treatment facilities.[22]

India generated 56,898 tonnes of COVID-19 bio-medical waste between June 2020 and June 2021. Maharashtra took first place in generating the maximum amount of 8,317 tonnes of biomedical waste. The state also has the highest number of 29 CBMWTFs.[23]

Box 10.1: Treament Mechanism of Biomedical Waste:[24] Available Options

Autoclaving: autoclaving involves steam sterilisation. This procedure is especially efficient because it is far less expensive than alternative approaches and poses no dangers to the individual's health. Even while autoclaving cannot be used to get rid of all biological waste, over 90 percent of it gets sanitised this way before being dumped in a landfill.

1) When operating a gravity flow autoclave, medical waste shall be subjected to:
   (i) a temperature of not less than 121° C and pressure of 15 pounds per square inch (psi) for an autoclave residence time of not less than 60 minutes; or
   (ii) a temperature of not less than 135° C and a pressure of 31 psi for an autoclave residence time of not less than 45 minutes; or
   (iii) a temperature of not less than 149° C and a pressure of 52 psi for an autoclave residence time of not less than 30 minutes.

2) When operating a vacuum autoclave, medical waste shall be subjected to a minimum of three pre-vacuum pulses to purge the autoclave of all air. The air removed during the pre-vacuum cycle should be decontaminated by means of HEPA and activated carbon filtration, steam treatment, or any other method to prevent the release of pathogens. The waste shall be subjected to the following:

   (i) a temperature of not less than 121°C and pressure of 15 psi for an autoclave residence time of not less than 45 minutes; or
   (ii) a temperature of not less than 135°C and a pressure of 31 psi for an autoclave residence time of not less than 30 minutes.

Contd...

Incineration: The main advantages of incineration are speed, simplicity, and ease of use. It eliminates trash and securely gets rid of any microorganisms. However, emissions can be especially problematic when burning hazardous chemicals. However, items must be reviewed and found safe to burn before incineration is considered a first option.[25]

Chemicals: Chemical disinfection is a typical biomedical waste management technique for liquid bio-medical waste. Chlorine is a common choice for this procedure, and it is added to liquid waste to destroy bacteria and microbes. Solid bio-medical waste can also be disposed of chemically, but it is recommended to grind the waste first to ensure maximum decontamination. After being decontaminated, liquid waste is dumped into the sewer system.[26]

Microwaving: Waste is chopped into little pieces, mixed with water, and then internally heated to destroy microorganisms and other potentially dangerous substances. The shredding component of this procedure reduces the amount of biomedical waste and is said to be more energy-efficient than incineration. Even while it cannot be used for all biomedical waste, it can be used for a good 90 percent of it, exactly as autoclaving.[27]

Irradiation: Irradiation disinfects bio-medical waste by exposing it to gamma rays, which are lethal to germs. This radiation source is the same one that is used to treat cancer with radiation. Since irradiation does not alter the waste's appearance, process designers frequently incorporate mechanical grinding or shredding upstream.[28]

Vitrification: Vitrification transforms biomedical waste into a chemical, that is stable and suitable for long-term disposal. High temperatures kill pathogens, and some combustible materials may burn or pyrolyze, producing an off-gas. The remaining substance is enclosed in glass, which has a very low diffusivity. There is little possibility of infectious substances significantly leaking out of glass.

Regulation Gaps in BMW Disposal

At places where COVID-19 waste finds its way to treatment facilities, lax regulation defeats the purpose. According to the BMW Management Rules, 2016 everyone must use a colour-coded system of waste segregation. The same should happen with COVID-19 waste. The Rules do advise putting all equipment, including PPE kits, goggles, and other accessories, in the red polybag and discarding it, but they do not specify it to home quarantine centres.

As a result, only yellow bags are offered to these quarantine facilities. Due to a lack of understanding and communication, these facilities place anything from food waste and disposable cutlery to masks, PPE kits, and gloves in yellow bags, which are then incinerated.[29] There is no COVID-19 waste disposal standard mechanism in place for home quarantine centres.[30]

Emerging Technologies for Treating BMW

Most biomedical waste substances do not degrade in the environment and may also not be thoroughly removed through treatment processes in vogue, like, incineration, autoclave, hydrolase, microwave, mechanical treatment, chemical disinfection, gamma irradiation, UV radiation, plasma pyrolysis among others.[31] The long-lasting persistence of biomedical waste can effectively have adverse impact on wildlife and human beings. Hence, biomedical waste management is given tremendous significance among treatment technologies. It is essential that every single applied innovation assures both the environment and public health protection. A few of the newer technologies being considered for BMW management are discussed in succeeding paras.

a. Photocatalysis – Photocatalysis is gaining increasing attention for eradication of pollutants and for improving the safety and cleanliness of the environment due to its great potential as a green and eco-friendly process. Nanostructured photocatalysts (nano photocatalysts) exhibit significant attributes such as non-toxicity, low cost, and higher absorption efficiency for photodegradation.
b. Solar heating – Solar heating is used in the form of a simple box type solar cooker or hybrid solar steam sterilizer to disinfect medical waste.
c. Electric arc plasma – Plasma arc technology has been developed by CSIR-CMERI with the support of DST for Hospital Solid Waste (HSW) disposal with minimum toxic emissions in the environment. This plant has about 95 percent waste volume reduction efficiency and is a viable technology for complete hospital solid waste treatment. Final emitted gas from this plant is less hazardous and below the permissible level of toxic emission according to Central Pollution Control Board (CPCB). This next generation technology not only reduces the waste volume but also contributes to environmental cleanliness.[32] It uses high temperature (above a minimum of 2000^{o} C) for the waste and produces synthetic natural gas. This gas is passed through a series of gas purification systems, which comprises a catalytic converter, redox reactor, scrubber, condenser, booster drive, and so on.
d. Use of biodegradable plastics, ozone for decontamination of BMW and digital technology[33] for efficient logistics are other modern management techniques for smart disposal of BMW in an eco-friendly manner.

Challenges

In the present scenario, all residential and public areas cannot properly separate biowaste according to the colour coding system. India has only 198 common BMW treatment facilities (CBMWTF), which is not considered enough as per working capacity.

Patients' loads are generally high in hospitals and emergency care centres. Thus, doctors, nursing staff and other health workers, though aware of the rules, are unable to satisfactorily segregate medical waste at the time of generation.

There is less information and training of doctors, nurses and BMW handlers in proper segregation, storage, transportation, and treatment to be conducted regularly and repeatedly. Further, lack of funding and commitment towards the safe disposal of BMW adds to the apathy.

Big hospitals have an onsite facility to dispose of their medical waste, but small clinics and nursing homes do not have such a facility. Proper disposal is not practical or economical for smaller institutes.

The negligence of waste handlers in performing poorly by not wearing the appropriate protective clothing can also lead to illnesses and infections. The biomedical waste trolley and container should not be used for other work, but negligence is also seen in this matter.

There is less chance to reduce a large amount of biological waste because there are not enough facilities for recycling or reusing waste. In addition, the existing technologies are expensive.

Biowaste processing equipment like boilers and incinerators can produce thermal heat, which is dangerous, and frequently the material is not adequately burned, increasing its toxicity. Every injection produces a waste syringe, and depending on the vaccine type, every 10 or 20 shots produces a waste glass vial. Restricted to the use of one syringe at a time, also generates massive quantities of biomedical waste.

Scope of Improvement

The situation is exacerbated by inefficient disposal methods, a lack of physical resources, and a deficit in medical waste management research. These problems can be remedied by fostering public-private partnership models.

For the disposal of biomedical waste, new eco-friendly technologies may indeed be adopted, which help to eliminate a significant quantity of hazardous biowaste.[34]

After enforcing strict rules, shortcomings in proper implementation and guidelines must be addressed by strict monitoring and regular updating. Hospitals should be penalised if any waste collector is discovered without the required safety gear.

Each garbage collector should be well informed about the rules for biowaste separation. All new employees and associated waste segregation staff should receive proper training and information on the harmful impact of improper BMW waste management.[35]

A portal should be launched by the State Pollution Control Board where patients may file complaints about the poor situation of bio waste management in healthcare centres. This portal should include a list of all hospitals and healthcare institutions organised by district. A qualified team may come and assess the situation and a fixed fine can be imposed. Additionally, BMW transport vehicles ought to have GPS and be monitored frequently.

Conclusion and the Way Forward

During the pandemic, an unpredictable pile of biomedical waste (BMW) accumulated. BMW's rapid growth has put a strain on current waste management facilities. A boost in BMW management needs rapid and proper segregation and disposal methods to avoid future consequences.

Literature review and statistical data available from the Central Pollution Control Board show that India lags in large-scale sorting, collection, careful storage, transfer, and disposal of biomedical waste. Although there are strict guidelines for bio-medical waste management, many hospitals often dispose of waste in inappropriate, chaotic, and indiscriminate ways due to negligence or laziness. Often, due to poor segregation practices, hospital waste is mixed with general waste, resulting in harmful overall waste flow. Waste disposal handlers are also not safe due to their exposure to various health risks and inadequate training in waste management.

Bio-medicalWaste generation and management issues are causing daily problems as they have a profound impact on the dramatically changing global environment, including air, water, and soil pollution.

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CHAPTER 11

Domestic Production of APIs in India

Introduction

The Indian pharmaceutical industry has undergone a roller-coaster ride since India became independent when it was completely reliant on imports of medicines into India. As the industry grew, the need for change in specific domestic policies was felt in the 1970s. These changes made India self-reliant and a thriving pharmaceutical hub and emerged as a major exporter to several countries, both developed as well as developing countries. India could produce low-priced generic medicines which was a critical factor enabling their penetration into global markets and the industry has thus earned the epithet, the 'Pharmacy of the World.' The pharmaceutical industry increased its share in exports of manufactured products from about 8.7 percent to nearly 11 percent between 2010-11 and 2019-20 (Kumar and Dhar, 2020).

However, globalisation focused on an 'economic efficiency' approach leading to the global supply chains being focussed on a single country, China. As supplies from China were affected due to the outbreak of this pandemic in that country, especially in critical sectors such as pharmaceuticals, countries became highly alert on the national security and public health implications of supply chain strategies focused on a single country. The Product Linked Incentive (PLI) Scheme (Phase-I) in the Indian pharmaceutical sector was notified in July 2020 to reduce import dependence on 41 products consisting of active pharmaceutical ingredients (APIs), drug intermediates (DIs) and key starting materials (KSMs) for which India is heavily dependent on China for imports.

With an allocation of ₹69400mn, this scheme had the highest allocation among all the schemes launched till then for the advancement of this sector. It was expected to attract a lot of interest from within India and outside as countries began to adopt measures to diversify API supply sources. However, the response of the industry to this scheme was not up to the expectations. This paper aims

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to develop a deeper understanding of the nature of import dependence of APIs, DIs and KSMs, and identify reasons for the lukewarm response of the industry to this scheme. It also proposes a few measures to be incorporated into any strategy that aims to reduce import dependence.

The Rise and Fall of the Indian API Sector

The Rise of an Indigenous API Industry in India

At the time of India's independence in 1947, the indigenous pharmaceutical industry was very weak and mostly confined to drugs produced from plant extracts. Foreign firms accounted for 99 percent of patents granted in pharmaceuticals and domestic firms were not allowed to produce them. Formulations were imported into India at very high prices and APIs were not produced in India.

As the Government of India encouraged the development of the indigenous pharmaceutical industry, domestic firms began to produce formulations based on imported APIs. The Hathi Committee (1975) which had investigated the reasons for the hesitation of Indian firms to enter the production of APIs found that the capital invested to turnover ratio for APIs was much lower as compared to formulations. This ratio was 1:1 for APIs at best and 1:2.6 for formulations on average and in some cases as high as 1:7.2.

Subsequently, various measures were adopted, such as assigning leadership roles to the public sector enterprises (PSEs) for the acquisition, development, and dissemination of suitable technologies and entrusting the Council of Scientific and Industrial Research (CSIR) laboratories with the task of developing appropriate process technologies required by the industry. Drugs for which the CSIR laboratories had developed process technologies included Ciprofloxacin, Omeprazole, Salbutamol, Vitamin B6, Lamivudine, Diclofenac Sodium, and Azithromycin.

The trade and industrial policies were also directed to meet the objective of promotion of indigenous production of APIs. The ratio parameter that was introduced in the pharma sector, linked the sale of formulation to the indigenous production of APIs from basic stages, which compelled firms to produce APIs from basic stages (Joseph 2016).

All these measures enabled the Indian pharma industry to become completely self-reliant in the case of formulations and 70 percent in the case of APIs. However, the emergence of a thriving API industry in China together with the liberalisation of import restrictions on pharmaceutical products and the removal of the ratio parameter by the Government of India in the early 1990s resulted

in the gradual flooding of the Indian market with APIs from China. This paved the way for the closure of many API manufacturing facilities in India.

Emergence of Import Dependence on China

Until the first half of the 1990s, the import of APIs was low and the European countries were the major source of supplies. Imports from China accounted for less than one percent during that period. However, towards the end of the 1990s, the share of China in India's import of APIs increased to more than 20 percent and reached 69 percent in 2021.

The study by Chaudhuri (2021) finds that there are 70 APIs in which India is dependent on China for 100 percent of its imports. As APIs from China are much cheaper, producers in India began to shut down API production facilities in India. Table 11.1 provides an illustrative list of closed API production facilities in India.

Table 11.1: Illustrative List of Closure of API Production Facilities in India

API	Name of Manufacturer	Commencement of Production	Status of operations
Penicillin	Alembic, Sarabhai, IDPL, HAL, Torrent, Ranbaxy, Standard	1960s	Stopped
Streptomycin	Alembic, Sarabhai, IDPL	1960s	Stopped
Vitamin B12	Themis, Alembic, MSD	1970s	Closed
Ascorbic acid	Sarabhai, Jayant Vitamins	1980s	Closed
Pravastatin	Themis, Biocon, Mylan	1990s	Closed
Erythromycin	Alembic, Themis, IDPL, Standard	1980s	Partially in operation for captive production for safety

Source: Compiled by Sarkar and Kaur (2016) and IDMA (2014)

The Chinese Government's support for the development of biotechnology in the 1990s led to the emergence of a fermentation-based API industry in China. Chinese firms were able to develop cost-effective technologies, which contributed to their acquiring a competitive edge globally. In addition, large-scale economies, government subsidies on inputs like electricity and common utilities and the natural advantage of having a sub-zero temperature that helps enable

refrigeration and preservation are some factors that contribute to reducing the cost of production. All these factors make Chinese APIs cheaper by 35-40 percent as compared to the cost of API production in India (Bart, Aggarwal, and Sandeep 2013; KPMG-CII 2020).

Import dependence has also been precipitated by some irrational policy measures of India. An industrial licensing policy that was not sensitive to domestic requirements and untimely liberalisation of import restrictions, among others, have contributed to this dependence. The case Pen-G and 6-APA brings out the factors that contributed to the import dependence more succinctly.

Evolution of Import Dependence: The Case of Pen-G and 6-APA[1]

Pen-G is the KSM for semi-synthetic penicillin and semi-synthetic cephalosporins. 6-APA, the drug intermediate (DI), which is derived from Pen-G, is the penultimate intermediate and is used for two large-volume semi-synthetic penicillin APIs – Amoxicillin and Ampicillin.

In 1990, India had four producers of Pen-G (HAL, IDPL, Alembic and SPL) with a total manufacturing capacity of 900 MMU (milli mass unit). This capacity was sufficient to meet only half of the domestic demand of Pen-G. The manufacturing capacity in China of Pen-G in 1990 was 5000-6000 MMU. Although Pen-G was put on the negative list for restricting imports, scarcity in domestic production prompted relaxation in import restrictions to promote exports of formulations. However, the imported KSM was diverted to the domestic market due to loopholes in the regulations, adversely affecting the domestic production of the KSM.

Simultaneously, measures were adopted to increase the domestic production capacity. During the period between 1998 and 2003 HAL and Alembic were allowed to increase their capacities and new players entered the market (JK Pharma, SPIC and Torrent).

At the same time, IDPL and SPIC had withdrawn from the production of Pen-G. All these had led to the production capacity of India increasing to 9000 MMU while China had increased its capacity in the range of 50000-60000 MMU. The huge capacity installed in China made it the largest producer of

Pen-G accounting for 35 percent of global production. Excess production in China led to the dumping of Pen-G into India at 40 percent cost margins.

There was also a major reduction in import tariffs, which further reduced the cost of imports. The import duty of organic chemicals including KSMs, DIs and APIs was reduced from 120 percent in 1990-91 to 7.5 percent in 2007–08 (Jha 2007). By 2012, the production capacity of Pen-G in India had declined to 2500-3500 MMU and that of China had increased to 160000 MMU. In 2003, Pen-G was removed from the negative list. After the removal of restrictions on the import of Pen-G, the domestic producers gradually withdrew from production – HAL (2003), JK and Torrent (2007) and Alembic (2011).

In a similar case of the DI 6-APA, relaxation in import restrictions led most producers to shut down their operations. Half of the 50 small-scale producers closed their operations by 1998. By the end of 2010s, the entire requirement of 6-APA was met by imports.

The Drug Pricing Policy and Growing Import Dependence

India was self-reliant on APIs until the mid-1990s when liberalisation in import restrictions led to a gradual influx of APIs from China. India had a more stringent price control policy before the 1990s. A cost-based price control system that existed until 2013 regulated the prices of both APIs and formulations.

The Drug Price Control Order (DPCO) of 1979 regulated the prices of 347 APIs and their formulations, covering 80-90 percent of the market. Subsequent DPCOs reduced the number of APIs covered. The 1995 DPCO covered only 74 APIs and formulations, covering only 25-30 percent of the pharmaceutical market. If the price control system were the culprit, India would not have been self-sufficient in APIs until the mid-1990s.

The approach to price control shifted from a cost-based to a market-based one in 2013, which leans towards the higher side driven by the price of top-selling brands. Most importantly, the new price control policy does not regulate the price of APIs; it regulates the prices of formulations of those APIs, which figure in the National List of Essential Medicines (NLEM). Hence, only around 18 percent of the market comes under purview.

It should be noted that 16 out of the 41 products that are subjected to the PLI scheme that is aimed at incentivising indigenous production of KSMs/DIs/APIs for which India is excessively dependent on China are not under the price control system as they do not figure in the NLEM that existed at the time of the announcement of the scheme. There are many APIs which do not fall under DPCO but are still imported in a significant way from China (Joseph 2020).

PLI 1.0 and Self-reliance in APIs

The disruptions in the supplies from China due to the COVID-19 outbreak in Hubei province when the pandemic began to spread in India in the early 2020s, sent shock waves to policymakers in India. There were major apprehensions about the production of medicines, even those required for treating COVID-19 conditions, in India due to a shortage of supplies from China.

In February 2020, the Government of India appointed a committee (Drug Security Committee) to investigate the issues of drug security in India in the context of the COVID-19 outbreak in China. The committee identified 58 APIs in which India was heavily dependent on China.

To reduce import dependence on KSMs, DIs and APIs, and incentivise their indigenous production, the Government of India notified a PLI Scheme, phase-I (PLI 1.0) in July 2020.[2] This scheme includes 41 products that cover all the APIs and their DIs and KSMs that the Drug Security Committee had identified as highly import-dependent.

Product Linked Incentive Scheme: Features and Response

The objective of PLI 1.0 is the promotion of domestic manufacturing of 41 important KSMs, DIs and APIs with a focus on attaining self-reliance. It consists of products from both fermentation and chemical synthesis technology areas. The eligible firms of the scheme would benefit from incentives worth ₹69400 million over a period from 2022-23 to 2028-29.

Although the scheme is available from 2020-21, a gestation period of two years is provided for fermentation-based products and one year for chemical synthesis-based products. Incentives to the producers will be distributed over six years. For chemical synthesis-based products, the incentives will be distributed at a 10 percent rate annually during the period between 2022-23 and 2027-28.

Whereas for the fermentation-based products, the rate of incentive will be diminishing over the years from 20 percent during the first four years starting from 2023-24 to 15 percent in the fifth year (2027-28) and to 5 percent in 2028-29.

To become eligible for the scheme, firms need to meet three key requirements, which are given below.

(a) The project should be a greenfield venture.
(b) The net worth of the applicant should not be less than 30 percent of the committed investment.
(c) The beneficiaries are required to meet the domestic value addition (DVA) requirements. Stipulated DVA for fermentation-based products is 90 percent and for chemical synthesis-based products is 70 percent.

A total of 248 applications were received in three rounds of applications, out of which 51 were selected as beneficiaries (Department of Pharmaceuticals 2022). This is against the maximum number of 136 beneficiaries provided in the guidelines. Despite repeated calls, no beneficiary is identified in 7 out of the 41 products. It also appears that the drop-out ratio is quite high for this scheme. A comparison of the number of beneficiaries that the DoP has released at different times and names of beneficiaries released at different rounds suggest that 19 firms, which were identified as beneficiaries, had withdrawn from this scheme.

From an industry consisting of more than 3,000 firms, making only 248 applications is not encouraging. It was also expected that foreign firms would be interested in availing of this scheme as many of them are endeavouring to diversify their supply sources. However, no beneficiary is a foreign firm.

Areas where Improvements are Required

Getting a Proper Understanding of the Nature of Import Dependence

The general narrative in India on the import dependence is based on the share of China in India's total import of APIs. The discussions have not considered import dependence to production, due to lack of data on production. There are also limitations in developing a firm understanding of whether the dependence is on DIs or APIs. In some cases, the same ITC-HS code that is used for capturing trade contains both DIs and APIs. For example, ITC-HS code 29419030 covers both Ciprofloxacin API and Ciprofloxacin Acid DI. These limitations of data make it difficult to have the correct picture and make the right interventions.

We did a product-wise study of import dependence and export performance of the 41 products covered in PLI 1.0 (Joseph and Kumar 2021). It was found that some of the products do not have high import dependence. For example, in the case of 1,1 Cyclohexane DA, the import dependence on China is only 9.4 percent. In this study, we collected data on the production of 14 out of the 41 products. In seven of the products, the quantity of production was much more than the imported quantities.

We also analysed the export performance of the 41 products to get more insights. In those products where the import dependence is high, we do not expect much exports from India. Contrary to our expectations, we found that exports have increased between 2010-11 and 2019-20.

For example, the export of 1.1 Cyclohexane Diacetic Acid (CDA) has increased seven times over this period. Irrespective of the technology orientation of the product, i.e., whether fermentation-based or chemical synthesis-based, we saw

an increase in exports over the years. A similar observation is made by the Global Business Reports (2019) in the case of APIs in general that India has increased its market share over time in API exports and is now a major exporter to all key markets including China.

In fact, in five of its products, China is among the top three leading export destinations. The fact that India is import dependent on China and at the same time China is also a major export destination for some of those products indicates the need for a better grasp of the trade dynamics. It may be possible that India is importing KSMs and DIs and exporting APIs. But this may not be captured by the trade statistics following ITC-HS codes where the same code may contain API and its DI/KSM. The inputs that we received during our interactions with API traders also suggest that India's dependence on China is for KSMs and DIs and not APIs.

Creating Confidence Among Investors

Firms would invest in production in India if they see a prospect of producing in India at prices cheaper than the cost of imports. As cheaper imports from China are critical for maintaining their global competence in the export of formulations, investors will face investment uncertainty if the proposed measures do not ensure the price competitiveness of domestic production. The growing export orientation of the Indian pharmaceutical industry is being driven by cheaper imports of inputs than by capabilities acquired through research and development (R&D) (Dutta and Gajbhiye, 2021). Imports of APIs/DIs/KSMs from China are 35-40 percent cheaper, in general, as compared to indigenously produced products.

Also, technology plays a very crucial role in reducing import dependence as Indian producers have constraints in overcoming some of the advantages of Chinese producers like scale of operation and climate.[3] India needs a strategic engagement with the public sector research laboratories in the development of technologies required by the industry, like that provided during the 1970s and '80s to achieve self-reliance.

The other area where the scheme fails in building investor confidence is the insistence on totally new manufacturing facilities (greenfield). With piled-up idle capacities already prevailing, it would make little business sense to invest in the creation of new facilities.

The third aspect of building investor confidence is in having an integrated and holistic approach. The history of the development of the indigenous pharmaceutical industry in India shows the significance of an active industrial policy that goes in tandem with trade and science & technology (S&T) policies (Joseph 2016). In the absence of a holistic framework, the investment uncertainties facing the investors do not get addressed.

The products under the PLI Phase-I scheme have been found to have substantial domestic production as well as exports. India can, therefore, take the leverage provided by the difference between applied and bound rates and raise tariffs to discourage imports and encourage domestic production. And, in those cases where dumping is taking place, anti-countervailing duties can be imposed.

Raising tariffs without ensuring that production in India is scaled up cost-effectively, the price of medicines in India will increase, which in turn will impact exports. Therefore, the strategy should have a technology dimension aimed at the development of green and cost-effective technologies that can provide Indian manufacturers with a competitive edge.

Accommodating MSMEs Adequately into the Strategy

Studies have found that micro, small and medium enterprises (MSMEs) account for nearly three-fourths of the production of KSMs/Dis/APIs in the Indian pharmaceuticals sectors (TIFAC 2020). The history of the Indian pharmaceutical industry shows that the focus of the large private sector firms has been on formulations and not APIs. Production of APIs is largely for captive consumption and the MSMEs, which are not able to establish brands, focus on APIs (Abrol, John, and Guha 2019).

The focus of the PLI Phase-I scheme, however, is on large firms. In the antibiotics area, where more than half of the budget for the scheme is allocated, each of the beneficiaries was required to incur a minimum investment of ₹4000mn. Even though this criterion was done away with in the revised guidelines that were issued on October 29, 2020, the number of beneficiaries and the minimum annual production requirements remained the same. This implies only those who can invest to achieve the originally set production goals could avail of the scheme (Joseph and Kumar 2021).

The data obtained for 13 of the beneficiary firms from the ProwessIQ database (Joseph and Kumar, 2021) shows that all of them are large firms if we use the definition of MSMEs that existed at the time of the announcement of the scheme. If the new definition is used, all except one (Sreepathi Pharmaceuticals Ltd) are large firms. Inclusion of smaller firms which are in the KSM/DI/API business in a major way is crucial to reducing import dependence and attaining self-reliance in KSMs/DIs/APIs.

Involving Public Sector Enterprises

Despite the two rounds of applications, no beneficiary is identified in five out of the 41 products, which are all antibiotics. It appears from our interaction with the industry that four of the five products – Neomycin, Gentamycin, Tetracycline and Clindamycin Base – are APIs that are used very little by the industry. However, we should note that such APIs may be of great significance

for public health although the private sector is not interested in the production. In such cases, Public Sector Enterprises (PSEs) should be tasked with the production of APIs and their KSMs and DIs.

Conclusion and the Way Forward

Globalisation focused on the 'economic efficiency' approach led to the global supply chains being focused on a single country, China. As supplies from China were affected due to the outbreak of this pandemic in that country, especially in critical sectors such as pharmaceuticals, countries became highly alert on the national security and public health implications of supply chain strategies focused on a single country.

The PLI Scheme (Phase-I) in the Indian pharmaceutical sector was notified in July 2020 to reduce import dependence on 41 products consisting of APIs, DIs and KSMs for which India is heavily dependent on China for imports.

The early lessons from the implementation of the Phase-I PLI scheme in the pharmaceuticals sector show the significance of having an industrial policy approach in reducing import dependence and attaining self-reliance. Our study, however, points to the need for a better grasp of the trade dynamics. For example, it is found that India is import dependent on China and at the same time China is also a major export destination for some of those products.

An industrial policy is not a stand-alone policy but it operates in a concerted and coordinated manner with several other policies such as trade policy, science & technology policy, and investment policy. Such an approach should be able to tap into the capabilities of both the private and public sectors. India's own experience with the development of an indigenous generic pharmaceutical industry in the 1970s and '80s underscores the significance of an industrial policy approach.

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Endnotes

1 This case study is based on the study of Bart, Aggarwal, and Sandeep (2013).

2 Another PLI Scheme in the pharmaceuticals sector was launched in March 2021 to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector with an outlay of ₹150000mn.

3 KPMG-CII (2020) points out that most Chinese plants have 10 times more overall capacity as compared to most plants in India.

CHAPTER 12

Pricing and Availability of Medical Devices

Introduction

The Indian Government has been steadily progressing towards instituting an accessible and affordable healthcare system across the country. The price control of drugs and medical devices has been recognised as a key tool to achieve this objective.

In pursuance of this approach, the recent policy documents including the National Medical Device Policy[1] which was approved by the Cabinet Ministry in April 2023[2] and the Parliamentary Standing Committee Report on the Medical Devices: Regulation & Control[3] identify price regulation of medical devices as an important area of focus and encourages the Government and the medical device industry to collaborate and progress towards a price-conducive ecosystem to cater to the needs of the public.

The price regulation of medical devices in India is dispersed across various laws including sectoral, consumer and general price regulation laws. Therefore, the legal understanding of price regulation of medical devices is derived through various pieces of parallel enactments.

Regulation of Medical Devices

The Drugs and Cosmetics Act, 1940 (D&C Act) is the primary statute that regulates medical devices in India. The Medical Device Rules, 2017 (MDR) issued under the D&C Act provides for the standards, clinical investigation, registration, and licencing of medical devices in India. The Central Drugs Control Standards Organisation (CDSCO) and state licensing authorities overlook the enforcement of the MDR. Under this framework, medical devices which are specifically notified by the Government are governed as 'drugs.'[4]

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Therefore, to regulate devices which are manufactured and imported in India, the Government notified individual devices as 'drugs' from time to time.

Subsequently, given the expanding market for medical devices, the Government recognised the need to regulate all medical devices in India. As a result, on February 11, 2020, the Government notified an expansive definition for 'medical devices' which covers all devices including software, accessories, and components where the intended function is diagnosis, prevention, monitoring, treatment or alleviation of any disease, disorder, injury, or disability.[5]

Effectively all medical devices have been brought under the ambit of the MDR since April 01, 2020. The CDSCO has also assigned risk classification for all devices by way of classification notices issued for various categories of medical devices including respiratory, pain management, ENT, oncology, urology, paediatrics, software as a medical device, nephrology, cardiology etc. Devices which fall within the definition but are not risk-classified by the CDSCO are non-notified devices at present. Typically, manufacturers and importers of such devices obtain a no-objection certificate from the CDSCO.

However, the primary medical device framework – the D&C Act and the MDR – itself does not contain any provisions for price regulation of medical devices. Nonetheless, this framework is integral to understanding the applicability of price regulation to medical devices as only notified and regulated medical devices are subject to the price regulation regime as detailed further below.

Evolution of Medical Device Price Regulation

The price control regime for medical devices runs parallel to the licensing regime. The legal basis for price control of medical devices is derived from the general price control regulation which flows from the Essential Commodities Act, 1955 (EC Act). The EC Act regulates the production, supply and distribution of certain commodities which are declared to be 'essential' to make them available to consumers at fair prices. In pursuance, a list of commodities has been included in the Schedule to the EC Act which are considered essential. One such item is 'drugs' as defined under the D&C Act.[6]

Hence, in the application, all notified medical devices by falling within the ambit of 'drugs' will be considered an 'essential commodity' in India.

The Drugs Price Control Order, 2013 (DPCO) has been issued under the EC Act, to enable the Government to regulate the price of all drugs and notify medical devices. The DPCO is administered by the National Pharmaceutical Pricing Authority (NPPA).

Traditionally, medical devices were excluded from the ambit of price control given that the DPCO was interpreted to apply only to pharmaceutical products by definition of 'drug' being restricted to medicines and pharmaceutical preparations. Subsequently from 1982 onwards when medical devices were first brought within the definition of 'drugs' under the D&C Act, devices which were periodically notified by the Government were subject to DPCO compliances.

Consequently, Disposable Hypodermic Syringes; Disposable Hypodermic Needles; Disposable Perfusion Sets; In Vitro Diagnostic Devices for HIV, HBsAg and HCV; Cardiac Stents; Drug Eluding Stents; Catheters; Intra Ocular Lenses; I.V. Cannulac; Bone Cements; Heart Valves; Scalp Vein Set; Orthopaedic Implants; Internal Prosthetic Replacements etc. came to be price regulated in India. However, on February 11, 2020, when the Government decided to regulate all medical devices and medical equipment by notifying them as 'drugs', it automatically subjected them to the provisions of DPCO.[7]

Hence, the NPPA regulates the price of medical devices through three mechanisms: price caps, price monitoring and trade margin rationalisation. These are discussed in detail below.

Price Regulation Under DPCO

The regulation of prices of devices under the DPCO is two-fold – price control and price monitoring:

Price Control Regime

A schedule to the DPCO contains a list of a few notified medical devices which the government believes are "essential" for the Indian population. The list contained in the Schedule is based upon the NLEMs which is issued by the Government periodically. Currently, the National List of Essential Medicines, 2022 forms Schedule-I to the DPCO. Coronary stents are one such example. Accordingly, the NPPA is empowered to fix the prices of devices listed in Schedule-I to the DPCO (Scheduled Devices).

Hence, ceiling prices are prescribed for Scheduled Devices which manufacturers, importers and distributors are required to comply with in setting the retail prices and determining the profit margins for the supply of the devices to consumers. At present, Intrauterine Devices, Bare Metal Stents, Drug Eluting Stents, and Condoms are regulated as Scheduled Devices.

Price Monitoring Regime

Whereas devices which are not included in Schedule-I to the DPCO are governed as Non-scheduled Devices. Unlike Scheduled Devices, the price is not fixed for Non-scheduled Devices. Nevertheless, such devices continue to be price-regulated and the manufacturers/importers/marketers of these devices are restricted from increasing the price of the device by more than 10 percent over any given preceding 12-month period.[8]

Exemptions for Patented Devices

A five-year exemption (calculated from the date of commencement of commercial marketing in India) from the applicability of DPCO is provided for medical devices which are proposed to be introduced in the Indian market are (i) are either patented under the Indian Patent Act, 1970 (**Patents Act**) or (ii) producing by a new process developed through indigenous research and development (process patent) patented under the Patents Act.[9]

Trade Margin Rationalisation Approach

Distinct from the price control and monitoring regime, the NPPA is also vested with certain discretionary powers to fix the price of drugs in the public interest under DPCO.[10] In such instances, the prescribed methods for price fixation for Scheduled and Non-Scheduled Formulations under the DPCO do not apply. Instead, the NPPA issued special orders about the pricing of the specific medical device which are applicable to its manufacturers and importers.

Typically, the orders issued by the NPPA under this provision prescribe certain ceiling price caps and profit margins i.e., caps on the profit margins of manufacturers/importers and distributors. The application of this provision is also known as the Trade Margin Rationalisation Approach (TMR) since it strikes a balance between the affordability for the patient with profitability for the manufacturers.

In India, as early as 2018, the NITI Aayog had contemplated adopting the TMR approach for devices considering the practice of excessive profiteering in the healthcare industry.[11] In putting forward this proposition, the NITI Aayog proposed a stringent approach whereby the trade margin was to be calculated as the difference between the price to patients (i.e., the maximum retail price) and the price at which the manufacturers sell the drugs/devices to distributors.

At a global level, the World Health Organisation (WHO) introduced the Guidelines on Country Pharmaceutical Pricing Policies, in 2020[12] to provide for a set of recommendations on how countries can approach price control. Broadly, inclining towards the TMR approach, the WHO has made pricing recommendations including regulation of mark-ups in the pharmaceutical

supply and distribution chain; use of internal reference pricing between similar drugs available within the territory of the country; application of cost-plus pricing formulae for pharmaceutical price-setting; use of external reference pricing; and promotion of use of generic medicines.

In addition to the DPCO price control and price monitoring regulations, the TMR approach has subsisted parallelly over the years with the NPPA imposing margin caps on several medical devices including knee implants[13]; pulse oximeters; blood pressure monitoring machines; nebulisers; digital thermometers; and glucometer.[14]

Impact of Price Regulation on Medical Devices

Price regulation of medical devices has a direct impact on the supply and availability of the devices in the market and the compliances required to be undertaken by the importers, manufacturers, marketers, and distributors of devices. Some of these have been discussed below in brief.

Price Fixation and Variations

In fixing prices of devices, the importers, manufacturers and marketers should adequately recognise if the medical device is scheduled, non-scheduled, or regulated by way of TMR. Accordingly, prices of medical devices for which ceiling prices have been prescribed by the NPPA (specifically Scheduled Devices and devices which are notified by TMR notifications) should be made available in the market in compliance with the prices fixed.

Scheduled Devices: The manufacturers, importers and marketers of Scheduled Devices should comply with the ceiling price caps notified by the NPPA from time to time.

Non-Scheduled Devices: There are no specific price caps, however, there is a restriction on increasing the price of Non-Scheduled Medical Devices by more than 10% over any given preceding 12-month period.

Devices Subject To TMR: If the NPPA deems a medical device to be necessary for public health or essential, the NPPA may notify ceiling pricing or profit margins for such devices therefore, requiring the manufacturers, importers, and marketers to ensure that the device is available at the notified price in the market. To implement the TMR approach and set price caps, the NPPA may seek pricing information from the manufacturers, importers, and marketers of all medical devices from time to time.

Further, in terms of undertaking price variations, all importers, manufacturers and marketers of medical devices will have to be cognisant of variations of the MRP declared on the label of their medical devices. The MRP of the product

should not be varied by more than 10 percent in any 12-months period, the variation of more than 10 percent will be recovered as 'overcharging' from the business concerned.

Ongoing Compliances

The DPCO requires that regulated medical devices and medical equipment must be labelled with their maximum retail price that is to be set by the importer/manufacturer/marketer. The said price must be prefixed by the words "Maximum Retail Price" and suffixed by the words "inclusive of all taxes." Further, all importers, manufacturers and marketers of medical devices and medical equipment will have to submit prices to distributors/stock lists, prices to retailers/hospitals and retail sale prices in the format prescribed in DPCO and undertake periodic filings with the NPPA.

Penalties

Any violation of DPCO is serious because its parent legislation, the EC Act stipulates that any breach of DPCO may result in imprisonment and fine for the company and person(s) in charge of the company for the conduct of its business. However, undoubtedly, the most draconian provision of DPCO is the liability to deposit any amount 'overcharged' by the importer or manufacturer in breach of DPCO in addition to the interest and penalty.

Conclusion and the Way Forward

While parallel developments under the D&C Act and MDR are coherent in terms of how medical device regulations are shaping in India, price regulation of devices continues to be a regulatory conundrum. While the efforts taken by the NPPA with respect to the adoption of TMR and inclusion of certain medical devices in the DPCO Schedule signify the clear intent to price monitor, there are pitfalls from an implementation and compliance perspective. Nevertheless, price regulation of medical devices in India is at a budding phase and it remains to be seen how the Government and the industry arrive at a robust mechanism.

Based on the recently approved Medical Device Policy, 2023, the focus of the Government is to promote innovation in the medical device industry through the establishment of academic and research institutions, innovation hubs and the creation of skilled domestic human resources. The Policy also envisages the creation of a coherent pricing regulation for medical devices to make available quality and effective medical devices to all citizens at affordable prices and at the same time balance the needs of the industry.

As can be seen from the previous sections, price regulation of medical devices in India is at a nascent stage and the jurisprudence currently evolving. While there is no specific guidance on law regarding the pricing of medical devices,

the DPCO continues to apply to all regulated medical devices in the same manner as it does to pharmaceutical products. While it is appreciated that all devices are price-regulated and that the NPPA has also made special efforts to adopt the TMR approach under extraordinary circumstances, there are certain nuances for the medical device industry which need to be considered. Some of the key considerations here are as follows:

Regulation of Non-Notified Devices

As discussed above, although a broad definition has been notified to cover all medical devices, devices which are yet to be assigned a risk classification by the CDSCO are non-notified at present. Consequently, while the MDR-related compliances (licensing requirements) should not be applicable, there is no clarity on whether the DPCO would be applicable given that such devices will still fall within the ambit of 'drugs' for the D&C Act read with the EC Act. Given that the consequence of non-compliance with the DPCO is high, further clarity is anticipated on these aspects.

Risk in Price-Capping for Scheduled Devices

Medical device life cycles are fundamentally different from that of pharmaceutical products. Typically, medical devices involve several components each of which could be regulated as a distinct medical device. For instance, standalone software embedded in a medical device could be an independent device as well form a component of another medical device.

Therefore, in such instances if the final product is regulated as a Scheduled Device and the component device continues to be non-scheduled, issues with respect to pricing and profitability may arise since the cost of the component medical device itself may be significantly higher than the ceiling price of the Scheduled Medical Device. In such instances, manufacturers, importers, and distributors of Scheduled Medical Devices would be awry of entering the Indian market due to low profitability.

Specific Considerations for the Trade Margin Rationalisation Approach

While TMR is generally favoured, there are divergent views on its adoption. Some medical device companies believe that the point of first sale for importers should be the point where the medical device is sold to the first hand i.e., the distributor. Whereas, a contrary approach is to cap the profits basis the difference in price to the consumer and the price of manufacturing/import of the device.

Further, there are several procedural and conceptual ambiguities in the application of the TMR approach currently given that there is no transparency and intelligibility on what datasets the NPPA used to compute margins, how

this information is verified and other considerations have been considered for determining 'public interest' to reach the trade margins.

Separately, it may be noted that the Competition Commission India in its Market Study on the Pharmaceutical Sector in India[15] noted the challenges of applying the TMR approach to all products. Notably, one such challenge which was recorded was that since TMR is applied on a case-to-case basis, healthcare professionals may be inclined towards prescribing products which are not price-regulated through the TMR approach. Therefore, in the adoption of TMR availability of alternate therapies will need to be examined as well.

Endnotes

1 Approach Paper on Draft National Medical Device Policy, 2022, accessible at: https://pharmaceuticals.gov.in/sites/default/files/Public%20Notice%20and%20Approch%20paper%20on%20draft%20NMDP%202022.pdf (last accessed on December 22, 2022).

2 Ministry of Chemicals and Fertilizers Press Release dated April 26, 2023, accessible at: https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1919984

3 Hundred Thirty Eighth Report On "Medical Devices: Regulation & Control" Pertaining to Department of Health & Family Welfare presented by the Department-Related Parliamentary Standing Committee on Health And Family Welfare One, accessible at: https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/14/160/138_2022_9_17.pdf (last accessed on December 22, 2022).

4 Section 3(b) of the Drugs and Cosmetics Act, 1940 defines 'drug' to include "devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette."

5 Ministry of Health and Family Welfare Notification S.O. 648(E) dated February 11, 2022, accessible at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTU0OA== (last accessed on December 2, 2022) defines 'medical device' as "all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of –
   (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
   (ii) diagnosis, monitoring, treatment, alleviation, or assistance for, any injury or disability;
   (iii) investigation, replacement or modification or support of the anatomy or of a physiological process;
   (iv) supporting or sustaining life;

(v) disinfection of medical devices; and
(vi) control of conception."

[6] Drugs have been classified as 'essential commodities' under Entry 1, Schedule, EC Act.

[7] National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Order dated March 31, 2020, accessible at: https://www.nppaindia.nic.in/wp-content/uploads/2020/04/Order-dt.01.04.2020-for-govt-Mediacl-Devices-under-DPCO-2013.pdf

[8] Paragraph 20, DPCO.

[9] Paragraph 32, DPCO.

[10] Paragraph 19, DPCO.

[11] NITI Aayog, Rationalization of Trade Margins in Medical Devices - A Consultation Paper, (June 08, 2018).

[12] World Health Organisation Guidelines on Country Pharmaceutical Pricing Policies, 2020, https://www.who.int/publications/i/item/9789240011878 (last accessed on December 22, 2022).

[13] Notification dated August 17, 2017, National Pharmaceuticals Pricing Authority, http://www.nppaindia.nic.in/wp-content/uploads/2018/08/NPPA-has-fixed-Ceiling-prices-of-orthopedic-implants-knee-replacements-under-para-19-of-Drugs-prices-control-order-DPCO-2013-1.pdf (last accessed on December 22, 2022).

[14] Notification dated July 13, 2021, National Pharmaceuticals Pricing Authority, https://www.nppaindia.nic.in/wp-content/uploads/2021/07/Notification-TMR-5-Medical-Devices.pdf (last accessed on December 22, 2022).

[15] Competition Commission India Market Study on the Pharmaceutical Sector in India, available at: https://www.cci.gov.in/images/marketstudie/en/market-study-on-the-pharmaceutical-sector-in-india1652267460.pdf (last accessed on December 22, 2022).

CHAPTER 13

Regulation of Pathological Laboratories in India

Introduction

The legal backing for the regulation of pathological laboratories (PL) in India is provided by Section 2(c)(ii) of the Clinical Establishments (Registration and Regulation) Act (CE Act), which covers all investigative and diagnostic facilities, including pathological, bacteriological, genetic, radiological, chemical, biological investigations etc. However, implementation is yet to get off the ground across the country and systematic regulation of pathological laboratories is at a very nascent stage.

The CE Act came into being in 2010 as a result of fairly detailed deliberations in a working group set up by the erstwhile Planning Commission to "examine issues related to clinical establishments, professional services regulation and accreditation of health care infrastructure for the 11th Five-Year Plan". It was felt that the existing state-level enactments were inadequate to regulate the rapid growth of Clinical Establishments (CEs) across the country and that the regulatory structure needed strengthening. A fairly elaborate regulatory structure for CEs has been provided under this Act.

Pathological laboratories are legally a subset of the larger CE universe. The Act provides for apex level policy body – the National Council for Clinical Establishments – which is responsible primarily for setting up standards for ensuring proper healthcare by the clinical establishments and ensuring periodic review, among others.

Based on the resolutions passed by Arunachal Pradesh, Mizoram, Himachal Pradesh and Sikkim, the Act was enacted for these states by the Union legislature under the provisions of Article 252(1) of the Constitution of India.

This chapter has been contributed by Sanjay Mitra, Former Defence Secretary of India

It was expected that other states would follow suit and legislate. Unfortunately, that has not happened. There have been reports on misgivings within the medical fraternity about the regulatory burden, particularly for smaller establishments run by registered medical practitioners themselves.[1]

As of now, only 16 States & Union Territories (UTs) have adopted the central enactment (the CE Act, 2010). Several others have either amended pre-existing state laws or have issued fairly comprehensive rules to ensure proper regulatory coverage. Despite the misgivings mentioned earlier, there has been steady movement forward. States like Tamil Nadu and West Bengal which had their state laws have gone ahead and substantially harmonised the provisions with the all-India enactment, while others like Odisha, have harmonised through detailed rules and regulations. States have also framed rules and issued standard operating procedures (SOPs) to ensure proper implementation of the Act.

Table 13.1: States/UTs which have adopted the Clinical Establishments (Registration and Regulation) Act, 2010

States		Union Territories	
1	Arunachal Pradesh	1	Andaman and Nicobar Islands
2	Himachal Pradesh	2	Chandigarh
3	Mizoram	3	Dadra and Nagar Haveli and Daman and Diu
4	Sikkim		
5	Haryana	4	Lakshadweep
6	Jharkhand	5	Puducherry
7	Rajasthan		
8	Bihar		
9	Uttarakhand		
10	Uttar Pradesh		
11	Assam		

Table 13.2: States/ UTs which have not adopted the Clinical Establishments (Registration and Regulation) Act, 2010 but have their Acts
States: 16 (including erstwhile Andhra Pradesh)
Union Territories: 01 (Delhi)

States	Union Territories
1 Andhra Pradesh	1 Delhi
2 Maharashtra	
3 Madhya Pradesh	
4 Punjab	
5 Orissa	
6 West Bengal	
7 Jammu & Kashmir	
8 Chhattisgarh	
9 Tamil Nadu	
10 Meghalaya	
11 Kerala	
12 Karnataka	
13 Manipur	
14 Nagaland	
15 Tripura	
16 Goa	

Table 13.3: Those states/ UTs which have neither adopted the Clinical Establishments (Registration and Regulation) Act, 2010 nor have their state Acts

S.No	State	Union Territories
1	Gujarat	1 Jammu and Kashmir
		2 Ladakh

Source: MOHFW

In all, 11 Union Territories and 5 States have adopted the Central CE Act. These are Arunachal Pradesh, Andaman and Nicobar Islands, Himachal Pradesh, Chandigarh, Mizoram, Dadra and Nagar Haveli, Daman and Diu, Sikkim, Lakshadweep, Haryana, Puducherry, Jharkhand, Rajasthan, Bihar, Uttarakhand, Uttar Pradesh and Assam.

Sixteen states (Andhra Pradesh, Telangana, Maharashtra, Madhya Pradesh, Punjab, Odisha, West Bengal, Chhattisgarh, Tamil Nadu, Meghalaya, Kerala, Karnataka, Manipur, Nagaland, Tripura, and Goa) and Delhi are yet to adopt the central law and are using their enactments. In quite a few, the pre-existing law has either been substantially amended or rules issued afresh to broadly harmonise with the former, such as West Bengal, Kerala and Tamil Nadu, Gujarat, Jammu & Kashmir and Ladakh are in a regulatory vacuum.

By July 2020, as many as 23475 CEs were shown as registered on the national portal. Another 2228 registered through the offline mode. This is likely to be a much smaller subset of the actual number.

State-level Developments – A Review

In most states, data about Pathological Laboratories (PL) tends to get subsumed within the larger database for CEs in general and it is difficult to get a clear idea.

However, states like Telengana, do maintain a detailed database for PLs with information regarding the services provided and registration status. It even provides information about the action taken, if any, against the PLs. In Telengana for example, information as of August 2022, indicates regulatory action against 69 out of 3346 registered PLs. Grounds for action include overcharging, non-display of tariff chart, irregularities regarding RT-PCR tests, sample collection by unqualified personnel, wrong test reports, functioning without registration, disposal of biomedical waste and the non-renewal of license by local bodies. In some cases, the PLs were also made to pay fines.

An interesting variation shows up in the law in West Bengal. The West Bengal Clinical Establishments (Registration, Regulation and Transparency) Act, 2017, which seeks "to provide for registration, regulation and transparency in the functioning and activities of clinical establishments licensed under this Act, to preserve minimum standards of facilities and

service to be provided by them to the service recipients", sets up the West Bengal Clinical Establishment Regulatory Commission (CERC). The Commission is expected to:

(i) monitor the functioning of clinical establishments;
(ii) regulate and supervise functions of clinical establishments as prescribed;
(iii) examine and adjudicate the complaints filed by aggrieved patient parties against clinical establishments, and pass orders:
(iv) make regulations about fixing rates or charges and also ensure compliance by clinical establishments;
(v) enforce transparency in dealing with patients by the clinical establishments;
(vi) tender advice and make suggestions for improving patient care services and redressal of grievances;
(vii) undertake planned or surprise inspections to examine and ascertain strict compliance by clinical establishments with provisions of this Act;
(viii) hear appeals arising from orders and decisions passed by the Adjudicating Authority in the Districts;
(ix) have the power to award compensations;
(x) ensure that only properly trained medical and para-medical personnel like doctors, nurses, technicians, and pharmacists are employed by the clinical establishment.

The West Bengal CERC has been operational since 2019 chaired by a retired apex court judge. It has several eminent doctors and other expert members and functions quite independently of the State Ministry of Health and Family Welfare.

The state database does not separately indicate PLs. However, the WB-CERC does maintain meticulous records of its deliberations and orders. In several cases, the body has taken action against PLs on grounds of overcharging, wrong tests and delayed serological reports. In a *suo motu* case, it forced the closure of a PL using the name of a deceased doctor. It has imposed fines or directed refunds, up to ₹25000 in some cases. Interestingly, it also directs PLs (and CEs) to deposit the sums assessed as penalties with reputed philanthropic organisations like the Ramakrishna Mission and Bharat Sevashram.[2]

Looking at other states, TN has a legal requirement regarding the annual publication of lists of clinical establishments, but the list does not appear to be available in the public domain. In HP, more than 7000 CEs have been registered. Nearly 1500 have had their registrations cancelled, mainly on account of complaints to the CM sewa helpline, but there is no formal mechanism for supervision. It is reactive.

In Assam, implementation of the CE Act has commenced. Preliminary registration of CEs is underway. In Bihar, the implementation is through the District Registrars, and a state-level database is absent. Delhi operates under the Delhi Nursing Homes Act 1953. Data is available for 1235 registered nursing homes, but the website does not furnish details regarding cancellations. Discussions reveal that action is taken based on complaints, for example, against allegations of overcharging during Covid 19. However, action was taken under the Delhi Epidemic Diseases Act and Section 188 of the Indian Penal Code and not the CE Act or the Delhi Nursing Homes Act. The central portal does not reflect data for UP, but state officials indicated that information is being collected.

Maharashtra has its state law – the Bombay Nursing Homes Registration Act, 1949. It has been mulling over the CE Act for quite some time now. In 2014, there were reports of a possible Ordinance.[3] Around that time, the state government also contemplated the setting up of a multi-stakeholder committee to go into the issues. The matter continued to pend despite serious pressure from the civil society. In 2017, acting on a high court order, the government carried out a sample check and found that nearly 15 percent of the medical establishments were operating without due authorisation.[4]

Karnataka has a specific enactment, the Karnataka Private Medical Establishment (KPME) Act, 2018. It sets up a fairly elaborate structure for the regulation of CEs, with the involvement of various stakeholders. The Karnataka PME site provides fairly detailed information, accessible to the general public about each registered CE – names and qualifications of the personnel, physical infrastructure, fee schedules, treatment charges, and other relevant clearances like fire, pollution control etc. The Act also provides for recovery of amounts on account of matters like overcharging and violation of the patient charter.

Kerala has also begun to move ahead. Like most states, it has established the State Council for Clinical Establishments. The state register of CEs is up on the website. The district registrars have been registered and 2651 laboratories have been registered (August 2022). Unlike Karnataka, the details of the individual CEs and PLs are not readily accessible.

The state-wise status review shows that most states are yet to commence systematic regulation of pathological laboratories. Though the state councils and registrars have been notified, they are yet to become fully effective. In most states, the basic enumeration and registration exercise is yet to be completed. Further, the database is not clear, with pathological labs subsumed within the broader category of CEs. Even the MOHFW portal does not distinguish between the two. Inspections are mostly held by the district registrars at the time of registration & licensing. Once the PL is operational,

public complaints or in some cases, *suo motu* action following press publicity, tend to drive remedial action.

National Accreditation Board for Testing and Calibration Laboratories (NABL)

Through its accreditation process, the NABL also provides an alternate voluntary mechanism for the self-regulation of pathological laboratories. The NABL is a constituent of the Quality Council of India. It was established in 1988 to provide "government, industry associations and industry in general with a scheme of Conformity Assessment Body's accreditation which involves third-party assessment of the technical competence of testing including medical and calibration laboratories".[5]

It operates through a system of third-party assessors who carry out detailed appraisals of the facilities, systems and procedures of various entities including pathological laboratories after which it is accredited and certified as competent to carry out a specific task. However, it is not a regulator and has no power to impose penalties. The compliance burden of regulatory requirements such as central and state laws, rules, regulations, directions and court orders continues to lie with the respective laboratory.

That said, the NABL is an important part of the proper functioning of pathological laboratories. Since it provides an independent assessment of competencies, it is widely used as a gatekeeper mechanism by several important organisations like the Central Government Health Scheme (CGHS) (for central government employees and pensioners), Employees' State Insurance Corporation (ESIC) (for those covered by the relevant statute) and the Ex-servicemen Contributory Health Scheme (ECHS) (for ex-servicemen), that offer medical and diagnostic services to their members through empanelled Health Care Organisations (HCOs). Therefore, it is in the interest of a pathological laboratory to voluntarily submit to the accreditation process if it wishes to be included in the panels of HCOs and access the business opportunities provided by these organisations. Accreditation is also a must for inclusion in major health insurance schemes like Ayushman Bharat.

Accreditation status, however, can change. The NABL does suspend and in some cases withdraw, accreditation status after an elaborate process. Grounds include "refusal to allow examination of documents & records, denial of access to testing and calibration areas, wrong representation of the scope of accreditation, willful and/ or repeated misuse of NABL symbol, misleading reporting of facts, brings NABL into disrepute in any manner etc., repeated valid complaints against the laboratory, and actions taken by statutory/ regulatory bodies against laboratory's operation". These powers appear to be sparingly used. The website, accessed on September 16, 2022, shows that 55 laboratories had had their accreditation status suspended for 03 months.

The NABL substantially stepped up its accreditation process during Covid enabling nearly 2700 laboratories to carry out standardised tests.

NABL accreditation has improved the quality of testing in some cases, for example, in the TB culture-Shanmugam et al case.[6] On the other hand, an analysis of HbA1C and glucose test results from 147 NABL-accredited laboratories highlights the lack of standardisation in nomenclature, analytical performance and methodology of tests.[7]

Some experts recommend categorisation of NABL accreditation status depending upon the scope of the facility. That is, a basic facility with limited tests and equipment could acquire a rating different from one with a wider range of tests and equipment. This could allow laboratories to systematically upgrade their capabilities and address user concerns regarding the full capabilities of the relevant facility.

Point of Care Testing (POCT)

The CE Act does not cover point-of-care testing. This refers to tests carried out outside the laboratory and close to the site of patient care, including at home. Urine, blood and blood gas tests are some examples. The oximeter introduced most people to the concept of POCT during the COVID-19 pandemic. POCT raises a whole new set of regulatory issues covering matters like the kind of tests to be allowed at home or outside the laboratory, qualifications of persons performing the tests, quality and integrity of sample collection and most importantly, proper interpretation of the test results. POCT is growing rapidly and as the use of handheld devices and smartwatches grows, we will have to think of an appropriate regulatory framework.[8]

Conclusion and the Way Forward

The administrative capacity of the state health departments is the main constraint in the effective regulation of PLs. It is simply too big a task. NABL accreditation appears adequate to start operations but is certainly insufficient for continued vigilance. Several state governments host PL-wise data on their respective websites. But requirements of login & passwords do not allow access to the general public. Only Karnataka appears to have sought, obtained and hosted DP-wise data with public access, including the names and qualifications of the medical/paramedical personnel, fee schedules and other facilities, on its website. However, there is no obvious system to update the information.

Going forward, the most viable way appears to be a combination of an independent statutory body like in WB-CERC, facility categorisation and the hosting of the latest PL-wise data on a specific website that is accessible to the public. The sheer scale of the problem would necessarily imply that regulation would be reactive and driven by complaints.

Endnotes

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CHAPTER 14

Unlocking the Potential of Medical Tourism in India

Introduction[1]

Medical tourism is a type of tourism, which involves the use of evidence-based medical healing resources and services (both invasive and non-invasive) (United Nations World Tourism Organisation, 2018). This may involve diagnosis, treatment, cure, prevention, and rehabilitation. The global medical tourism sector has seen significant growth in recent years (World Travel and Tourism Council, 2019). The market size of the global medical tourism industry is projected to quadruple to US$207.9bn by 2027, from US$54.4bn in 2022 (Statista, 2022).[2]

In 2021, around 14 million people travelled across borders for medical tourism.[3] Rising healthcare costs, demographic changes, epidemiological transition and a long waiting list for surgeries in the home country are some of the reasons for the growth of medical tourism (Hafizan et al., 2018; Lunt et al., 2011, Martínez Álvarez et al., 2011).

India is among the world's leading medical tourism destinations. In 2020, India received a total of 1,82,945 medical tourists (Ministry of Tourism, 2021). India is known for both modern and traditional medical practices. The country can offer cost-effective quality medical treatment, with foreign patients saving 65-90 percent of the costs compared to developed countries like the US.[4] India's traditional medicine practices, like Ayurveda and Yoga, are now globally well-known.

According to the International Trade in Health Services Survey, 2015-16, around 19 percent of medical tourists in India travel again to avail treatments for diseases like obesity, stress management, lifestyle diseases, degenerative diseases, neuro-muscular and muscular-skeletal problems through traditional

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medicines (Directorate General of Commercial Intelligence & Statistics, 2017).[5] India's modern medicine services involving both elective procedures and complex surgeries also bring overseas patients, particularly from West Asia, Africa, and others.

The Union Cabinet, in 2018, identified medical value travel among the 12 Champion Services Sectors for export promotion. The Government of India is taking a holistic approach to promoting medical tourism by highlighting its curative and wellness elements (Wong et al., 2014). It announced initiatives such as medical visas[6] and Ayush visa[7] under programmes like 'Heal in India'[8] to facilitate medical tourism. The Ministry of Tourism is in the process of preparing a detailed 'National Action Plan' for implementing the Draft National Strategy and Roadmap for Medical and Wellness Tourism.

In this context, the objective of this chapter is to present an overview of the medical tourism sector in India, focusing on the country's potential. It identifies the regulatory gaps, in both domestic and international regulations, which may adversely impact India's ability to achieve the full potential of the medical tourism sector. It suggests ways and measures to address the barriers through domestic reform and international engagements such as mutual recognition agreements.

Overview of the Medical Tourism Sector in India

The Indian medical value travel industry is valued at US$5-6bn in 2022 and is projected to grow to US$13bn by 2026.[9] Before the coronavirus pandemic-related lockdown and travel restrictions, the industry registered a double-digit growth of around 15 percent (Federation of Indian Chambers of Commerce and Industry, 2016).

India's Comparative Advantage: Quality Services and Low Cost

The Medical Tourism Associations 'Medical Tourism Index (MTI)[10] ranks India at the 10th position (refer to Table 14.1) among 46 countries, based on supply-side factors such as tourist popularity, medical facility quality, hospital accreditation, healthcare costs, economic stability, and the overall environment of the destination.[11]

Demand for India's medical treatment ranges between 4 percent and 8 percent (according to different estimates) of the world's medical tourism market.[12] India has been among the top destinations for super-specialties, including organ transplantation.[13] Factors such as the low cost of procedures and surgeries, highly qualified doctors and medical professionals, and availability of quality equipment and diagnostics have contributed to India's emergence as a medical tourism destination.[14]

Table 14.1: Ranking of Top 10 Medical Tourism Destinations, 2020-21		
Country	**Rank**	**Score**
Canada	1	76.47
Singapore	2	76.43
Japan	3	74.23
Spain	4	72.93
United Kingdom	5	71.92
Dubai	6	71.85
Costa Rica	7	71.73
Israel	8	70.78
Abu Dhabi	9	70.26
India	10	69.8

Source: Medical Tourism Index, 2020-21 https://www.medicaltourism.com/mti/home (last accessed August 24, 2022)

The costs of treatment in India are among the lowest globally for a range of medical and surgical procedures (see Table 14.2), which makes it an attractive destination for medical tourists. Medical costs in India range between a tenth and a sixteenth of the cost of comparable treatment in Europe and the US (see, United Nations Economic and Social Commission for the Asia and the Pacific, 2009).

Medical treatments such as angioplasty, hip resurfacing, and knee replacement are among the least costly procedures in India compared to those in other medical tourist destinations (refer to Table 14.2). The affordability of medical treatment gives India's medical tourism sector a comparative advantage over other medical tourist destinations.

Emerging Competitors

Joint Commission International (JCI) recognition is considered the premium standard in global patient care and is the benchmark of global standards on quality, patient confidence, and security (PK, 2019). It also plays an important role in hospital marketing campaigns (Turner, 2010). While India has more than 1400 National Accreditation Board for Hospitals & Healthcare Providers (NABH) accredited hospitals, there were only 40 JCI-accredited hospitals in 2022 (refer to Table 14.3), which is much lower compared to the number in Thailand, UAE and Saudi Arabia.

Table 14.2: Medical Treatment Prices Across Countries, 2021

In US$

Treatment	US	India	Turkey	Mexico	Thailand	S. Korea
Angioplasty	28,200	5,500-6,200	2,840-3,400	5,000-12,000	10,938	17,700
Heart Byepass	1,23,000	7,000	14,000-17,000	15,000-35,000	17,188	26,000
Heart Valve Replacement	1,70,000	8,500-11,500	28,400-34,100	10,000-35,000	21,188	39,900
Hip Replacement	40,364	7,000-14,000	6,100-12,000	13,500	7,813	25,000
Hip Resurfacing	28,000	8,800	1,500-2,000	12,000	7,000	19,500
Knee Replacement	35,000	6,000-12,000	5,500-9,000	12,500	6,563-12,500	20,000
Spinal Fusion	110,000	12,000	4,000-7,000	16,000	9,500	23,000
Dental Implant	1,500	90-500	100-860	975	1719-2813	1,500
Lap Band	14,000	6,500	-	5,000	13,000	10,200
Gastric Sleeve	16,500	7,500	3,250-5,500	6,500	9,000-15,000	9,950
Hysterectomy	5,200	3,800	-	6,000	3585-7,700	10,400
Breast Implants	6,400	7,500	2300-3000	4,200	1,750	5,000
Rhinoplasty	6,500	6,200	2,604	3,600	313-625	4,100
Face Lift	11,000	7,200	2800-5400	6,200	2,813	6,000
Cataract Surgery (per eye)	3,500	1,400	1000-2200	2,500	1,800	2,700
IVF Treatment	15,400	6,500	2,800	6,500	3,750-15,625	8,000

Source: Medical Tourism Index, available at https://www.medicaltourism.com/compare-prices (last accessed September 22, 2022), https://medsurgeindia.com/cost/dental-implants-cost-in-india/#skeletabsPanel1 (last accessed September 22, 2022) and https://www.health-tourism.com (September 22, 2022)

Table 14.3: Number of JCI Accredited Hospitals in 2022, by Country

Country	No. of JCI-accredited hospitals
Brazil	63
China	48
India	40
Indonesia	23
Japan	30
Saudi Arabia	105
Thailand	59
UAE	207

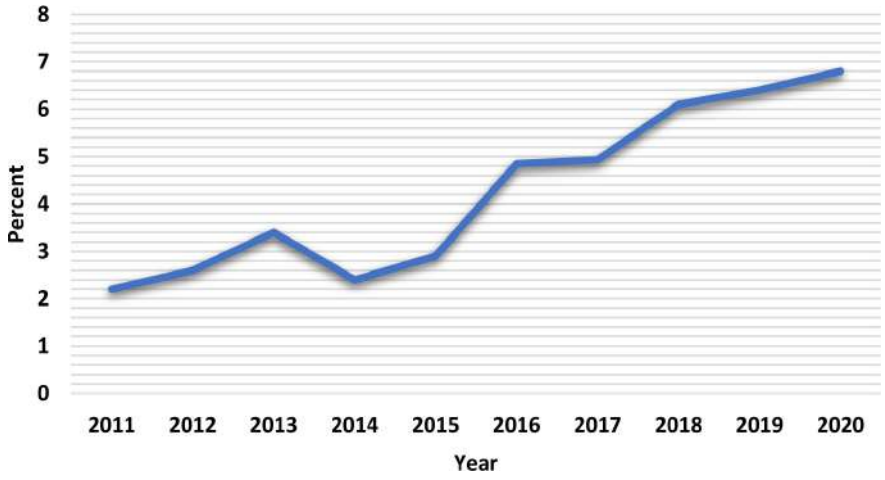
Source: Joint Commission International (JCI), 2022, available at https://www.jointcommissioninternational.org/about-jci/

In terms of affordability as well as the presence of JCI-accredited hospitals, Thailand has emerged as a major competitor to India in the medical tourism sector.

Foreign Tourists Arrivals (FTAs) for Medical Purposes

During the period 2011-2020, the number of foreign tourists arriving for medical purposes has shown an increasing trend, with a dip in 2014. In 2020, the number of medical tourists accounted for 6.8 percent of total tourist arrivals, increasing from around 2 percent in 2011 (see Figure 14.1). The majority of the medical tourists to India are from countries such as Iraq, Maldives, Nigeria and other African countries, Afghanistan, Oman and Bangladesh (see Table 14.4).

Figure 14.1: Foreign Tourist Arrivals in India for Medical Purposes (2011-2020)



Source: India Tourism Statistics, various years, Ministry of Tourism, available at https://tourism.gov.in/market-research-and-statistics

In addition to the low-cost quality services, the availability of highly skilled medical professionals and a growing number of JCI-accredited hospitals (although still low) emerge as key enablers of medical tourism. While the Indian government is promoting the medical tourism sector through its international engagements, there remain some regulatory issues, which are discussed in the next section.

Table 14.4: Top 10 Originating Countries for Medical Tourists in India, 2019 and 2020

In Percent

Originating Country	2019	2020
Iraq	82.77	93.4
Maldives	9.15	76.1
Nigeria	48.88	53.1
Afghanistan	26.19	34
Oman	29.71	28
Sudan	25.85	30.3
Tanzania	20.68	25.2
Bangladesh	15.40	18.1
Kenya	14.20	16
US	0.08	0.1
Germany	0.07	0.1
UK	0.1	0.1

Source: India Tourism Statistics, various years, Ministry of Tourism, available at https://tourism.gov.in/market-research-and-statistics

Regulatory Issues in Medical Tourism

In the international trade context, medical value tourism is considered a Mode 2 services delivery where the patients seeking medical services travel from one country to another country. While services such as online diagnostics, online consultations and telemedicine are classified as Mode 1 services; the establishment of cross-border hospitals and medical facilities is referred to as Mode 3 services trade and cross-border temporary movement of healthcare practitioners is classified as Mode 4 services trade. Regulatory barriers in any of the other three modes of trade in health services can impact Mode 2 trade or medical value tourism.

These regulatory issues, range from a lack of recognition and accreditation of hospitals, lack of recognition of healthcare professionals and workers to a dearth of acceptance and approval of drugs, visa issues to an absence of regulatory framework for insurance such as non-portability of health insurance, lack of a framework to share data and information and for online consultation, and legal recourse to remedy medical malpractice (for details see Ministry of Tourism, 2022; Bhat, 2015; Martínez Álvarez et al., 2011).

India has tried to ease the visa-related issues for medical tourists by introducing a new category of visa - a medical visa (M-Visas) - that can be issued to foreigners travelling to India for healthcare reasons and hence it no longer remains a major issue in the promotion of medical tourism (Malhotra and Dave, 2022). India has also allowed foreign hospitals to establish a presence, which has facilitated inter-hospital referrals and medical value tourism. Some of the other regulatory issues are discussed below:

Lack of International Recognition and Accreditation of Hospitals

To practice medical tourism, hospitals in India must comply with international quality standards. Medical tourists from the US, UK and other developed countries attach importance to JCI-accredited hospitals, when choosing the destination for medical treatment (Prakash et al., 2011) and are less aware of the national accreditation of hospitals under the NABH. It is often easier to get overseas insurance coverage if the hospitals are globally recognised. The majority of the hospitals in India are still not recognised by accreditation bodies such as NABH, JCI and ISO (Shandilya et al., 2021). Moreover, none of the government hospitals are accredited by the JCI. Competing countries such as Saudi Arabia, China, UAE, and Thailand have a greater number of JCI-accredited hospitals,[15] which may in the future shift medical tourists to those countries.

Lack of Recognition and Acceptance of Modern Medicine, Ayurveda Drugs and Traditional Practices

The restriction on cross-border mobility of healthcare workers due to the non-recognition of qualifications and degrees is a major barrier to the movement of healthcare workers in both modern and traditional medicine. For example, only a handful of countries such as the US, UK and Australia recognise the Indian medical degree. However, it does not give the right to practice, without a state license as in the US where one needs to complete their residency in the US and then apply for a state board licence.[16]

At present, India has a mutual recognition agreement (MRA) for nursing with Singapore but there are hardly any MRAs to ensure easier mobility of other healthcare workers and professionals. The non-recognition of degrees hampers the ability of Indian doctors, Ayurvedic practitioners, nurses and other healthcare workers to practice in foreign markets, especially in developed countries. For example, Ayurvedic practitioners are not licensed in the US, and there is no national standard for Ayurvedic training or certification.[17]

Furthermore, the licensing and credential requirements for complementary health practitioners in the US vary from state to state and across services, requiring the practitioners to pass a state exam, undergo certain training,

etc.[18] Similarly, due to the lack of recognition of traditional medicine degrees and qualifications in the UK, there is difficulty in the movement of professionals and skilled healthcare service providers in traditional medicine despite the growing recognition of yoga and Ayurveda in the country. Thus, if a patient from these countries takes a treatment in India, they may face issues in the continuity of the treatment. Further, doctors from countries, which do not recognise Indian qualifications and degrees may be hesitant to refer patients to India.

Despite the increasing popularity of the Ayurveda system of medicine, the industry is still battling to get recognition for its products and services in export markets like the US and the EU. For example, the US Food and Drug Administration (FDA), in 2017, warned against the use of some Ayurvedic medicines on the grounds of safety and clinical efficacy.[19] Several herbs used in the manufacture of ayurvedic medicines are not approved by the USFDA, due to which, ayurvedic medicines cannot be sold in the US.

Moreover, there is no registration of herbal medicines and these are not included in the National Essential Medicine List of the United States of America (World Health Organisation, 2019). This creates a problem for medical tourists from countries such as the US in getting the medicines in their home country after they have been treated in India, resulting in issues of treatment continuity (Ministry of Tourism, 2022; Bhat, 2015; Martínez Álvarez et al., 2011).

Coverage and Portability of Health Insurance-related Issues

Most medical tourists have to pay out of their pocket for treatment abroad due to the non-portability of their health insurance. Insurance providers avoid covering medical treatment abroad because of their concerns about malpractices, regulation abroad and follow-up care (Kamassi et al., 2020). While UK nationals can only use their health insurance plans for medical treatments in the European Union and Switzerland, the US health insurance plans only cover treatments in the country or cover specific medical treatments abroad like hip replacement. Treatments such as dental treatment, dialysis and cosmetic procedures are often out of the purview of insurance plans.

In India, while Ayurveda is covered under health insurance plans, guidelines for naturopathy, unani, siddha, yoga and homoeopathy are yet to be announced.[20] In many cases, where private insurers cover traditional medicine treatments, some only include Ayurvedic treatments while only a few cover all the other treatments. The insurers only cover 7.5 percent to 25 percent of the sum assured.[21] There are limited insurance options in India as well

due to restricted coverage of all traditional medicine treatments in local insurance plans (Ministry of Tourism, 2022).

Issues with respect to Follow-up Care and Legal Recourses

The US, the UK and other European countries' guidelines on medical tourism warn patients against the absence of required follow-up care after the medical procedure. If something uneventful occurs on the patient's return, the home countries are left with little or no information to guide proper follow-up care (American Medical Association, 2018).

Subsequently, in these circumstances, the patient wants to know his/her legal rights and get proper retribution. However, as of now, there is no international guideline on legal recourse and the issue remains uncovered in international law. This has become a major barrier in inducing medical tourism as foreign countries remain clueless about the rights of the travelling patient and non-coverage of medical errors in the national legal jurisdiction. The legal systems of different countries are varied, preventing the patients from receiving any legal recourse.[22]

Lack of Nodal Body and Gaps in Regulations

Although various ministries and private hospitals are involved in the promotion of '*medical value travel',* in India*,* without a nodal ministry to lead the medical tourism sector, there are gaps in coordination among the various stakeholders (like airline operators, hotels and hospitals) and therefore the patient may not have a smooth experience. Additionally, there is a lack of an overarching government regulation to facilitate such coordination, and monitor this sector, and there is a lack of accountability, gaps in monitoring of quality of services, and transparency within the medical tourism sector and their service providers (Ministry of Tourism, 2022; Kaur and Kaur Hira, 2019).

Towards Focussed Growth of Medical Tourism

Barriers to recognition of hospitals, medical practitioners' degrees and qualifications and/or medical practices can adversely impact the medical tourism industry. Medical Value Travel is one of the 12 Champion Services Sectors identified by the Government of India, and given the huge potential of the sector, a focused action plan is required. To tap into the potential of the sector, it is important to better utilise trade agreements, MRAs and memorandum of understanding (MoUs) to facilitate the removal of barriers, attract more foreign investment, and make India a globally recognised medical tourism destination. In this context, some recommendations are given:

Seek International Accreditation for More Indian Hospitals and Enhance their Global Visibility

Currently, India has around 40 JCI accredited hospitals, across many prominent metros as well as tourist cities in Maharashtra, Karnataka, Tamil Nadu, and Kerala. There is a strong need for Indian hospitals to seek JCI accreditation and, since many of them are in the private sector, government can encourage the private sector through incentives/subsidies to take JCI accreditation. Also, India may try to get NABH accreditation approved with trading partners as it negotiates trade agreements with key suppliers of medical tourists like the EU and the UK.

The establishment of hospital chains abroad will also help with brand visibility and facilitate medical tourism. For example, the Indian hospital chain, Apollo Hospitals has a subsidiary – Apollo Radiology International (ARI)[23] in the UK while another hospital chain, Max Healthcare Limited was registered as a Private Limited Company in the UK in 2005 to provide wholesale pharmaceutical products.[24] Such presence of Indian hospitals abroad has made the brands known to foreign consumers, thereby facilitating medical tourism. At the same time, India needs to attract FDI into the healthcare sector. With well-known foreign hospital chains being located in India, it will be easier to attract patients.

Need for Recognition of Standards and Practices through Trade Agreements, Mutual Recognition Agreements and Collaborations

Non-recognition of degrees is a major barrier to medical tourism. India can use trade agreements with countries such as Australia, the UK, and Canada and regions such as the EU to facilitate easier mobility of its healthcare workers and recognition of its products and practices. For example, countries like the UK and Canada have an ageing population and a shortage of healthcare workers including doctors, nurses, physiotherapists, midwives, dentists, and other medical professionals. The MRAs between India and countries such as Canada, the US and the UK, enable doctors and professionals from India to practice in these countries to help mitigate the shortages.

There can also be provision for MRAs for bilateral recognition of Indian degrees, traditional practices as well as AYUSH products, which are not yet registered and/or recognised abroad. In this context, it is important to collaborate and build trust and partnerships with service providers in partner countries both for traditional and modern medicines and have government-to-government engagement and collaboration.

Facilitate Portability of Health Insurance

One of the key stimulants of medical tourism would be a high degree of portability of health insurance plans. The private insurance companies may be encouraged to design plans that can offer partial to complete portability from one country to another. At present, plans can be ported from one insurer to another but this is not possible beyond borders. The insurance providers may be given incentives to explore the possibility of extended insurance coverage when the beneficiaries avail medical treatments abroad.

There is a need for collaboration, consultation and partnership between governments and private insurance providers to discuss this issue and to resolve the barriers related to the portability of health insurance. The Indian health insurance providers must make a move to the global insurance market. They could build a liaison with foreign insurers and jointly design insurance plans to cover medical tourism. The issue of portability of health insurance can also be discussed in forums like the G20 with the support of organisations like the World Health Organisation.

In addition to portability, the coverage of insurance needs to be broader. Currently, health insurance plans in many developed countries do not cover dental, cosmetic and dialysis treatments in another country. This can be another issue for discussion and consultation between insurance companies, the government and other stakeholders like healthcare providers.

An Appropriate Post-Operative Care Strategy Including Cross-Border Data and Information Sharing

Most of the medical tourists from developed countries have apprehensions about post-operative care in foreign countries like India. They also have questions about the level of support extended to the patients after they return to their home country. Thus, the hospitals must provide clarity on these issues and disseminate correct information in this respect, extending to the foreign patients all kinds of post-operative assistance required. All medical records and prescriptions must be made available to foreign patients and the home country to gain the trust of medical tourists. This step will significantly induce medical tourism.

The use of digital platforms can help facilitate the availability of all prescriptions at any time for the future use of foreign patients. The ability to interact with doctors online and ability to share data and information online cross-border is crucial for post-operative care. Cross-border sharing of health data is highly sensitive and there is a need for a system of data sharing with trust through international engagements.

Need for a Redressal Mechanism

The development of the medical tourism sector in India has been constrained by the lack of legal redress for medical malpractice/negligence. In the absence of an international redressal mechanism, there can be redressal mechanisms at the local level to compensate the affected foreign patients. The hospital providing medical tourism services can set up a local committee to check and prevent any kind of medical malpractice/negligence.

Conclusion and the Way Forward

The Government of India is actively promoting the medical tourism and wellness sector, given its huge potential. Visits of foreign tourists for medical purposes are rising and this trend has been accredited to India's comparatively affordable prices and high-quality services. However, apart from infrastructure-related and other issues, there are regulatory gaps, in both domestic and international regulations, such as a limited number of hospitals with JCI accreditation, lack of coverage or portability of health insurance or non-availability of legal recourse and remedy and/or non-recognition of alternative medicine such as Ayurveda, which may adversely impact India's ability to achieve the full potential of the medical tourism sector.

It is suggested that India may address these issues by enhancing collaboration with partner countries, signing MRAs for complementary medicine and recognition of Indian practitioners abroad, facilitating discussion between the government and insurance companies and at various multilateral forums such as the G20.

In addition, there is a need for provisions for cross-border data and information sharing with a trust. To facilitate the post-operative care of foreign patients, hospitals may be encouraged to digitise the critical prescriptions and patients' details, ensuring that these are available in times of post-operative care needed in the patients' home country. Data has to be collected and stored digitally and there should be provision for online consultation and information sharing.

While discussing medical tourism in international forums and trade agreements, different regulatory aspects related to the recognition of traditional and modern medical practices and drugs, financial coverage and data and information sharing need to be covered.

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CHAPTER 15

The TRIPs Waiver and Equitable Access to COVID-19 Vaccines and Drugs

Introduction

In response to the devastating social and economic disruption caused by the COVID-19 pandemic, the World Trade Organisation (WTO) responded through various interventions including the Ministerial Decision on the TRIPs Agreement (Decision).[1]

In one sense, the Decision marks another milestone in an enduring debate - how far does the present level of intellectual property protection exacerbate global health inequities? More specifically, the Decision is a compromise borne out of a long-drawn battle between two proposals at the WTO. The original proposal by India and South Africa sought a three-year waiver of obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) that covered patents, trade secrets, copyrights, and industrial designs of COVID-19 drugs, vaccines, diagnostics, and other technologies (TRIPs Waiver Proposal).

In response, and opposition to the TRIPs Waiver Proposal, the European Union (EU) advocated for the suspension of only those specific procedural requirements that increased complexity and time while issuing compulsory licenses on patents (EU proposal).

At its core, the lack of consensus rested on whether intellectual property protection necessitated by TRIPs constituted *the* significant hurdle in scaling up manufacturing capacity and ensuring equitable access to COVID-19 vaccines, drugs, and other technologies. This begs for an in-depth and dispassionate analysis of facts.

This chapter has been contributed by Pradeep S Mehta, Secretary General and Sneha Singh, Research Associate, CUTS International

Since the first emergency use authorisation[2] by the WHO in December 2020, more than 12.7 billion doses[3] of COVID-19 vaccines have been administered (last updated on November 21, 2022) and more than 18 billion doses[4] have been secured globally within the price range of US$2-US$40 per dose. Such capacity has been attained without a waiver of IP obligations, rather, the underlying IPRs have facilitated extensive licensing and manufacturing contracts[5] even among direct competitors.[6]

Notably, it is also true that the gross inequity in access to these vaccines is alarming. Even though the WHO Strategy to Achieve Global COVID-19 Vaccination[7] target of vaccinating 70 percent of the global population by mid-2022 has been achieved, its success is dampened by gross disparities in vaccination rates. Only 31 percent of the population in Africa has received at least one dose and it continues to have the slowest vaccination rate of any continent. Moreover, the threat of emerging variants reducing the efficacy of existing vaccines necessitates that vaccine manufacturing capacity be adequately decentralised and upgraded.

Thus, between the TRIPs Waiver Proposal and the EU Proposal, the international community was tasked with finding the right policy solution to diversify vaccine supply chains to rapidly and radically ramp up manufacturing capacity. It is safe to say that a significant portion of the goal was achieved before the WTO could arrive at a consensus. Yet, if we are to boost potential manufacturing capacity[8] in Low and Middle-Income Countries (LMICs) to mitigate vaccine inequity at even faster rates, we must break the Decision down into sustainable and actionable policy options for LMICs to tackle the current public health crisis and prepare for future ones.

Accordingly, the following will be the structure of the chapter. Section 1 will briefly detail the negotiating history of the Decision. Section 2 will undertake a granular analysis of the Decision and compare it against the TRIPs Waiver and EU Proposals. Section 3 will consider lessons learned and suggest some policy prescriptions that may be considered at the domestic and international levels for resolving global health inequity in the short and long term.

A Brief Negotiating History of the TRIPs Waiver Decision

Perhaps in anticipation of being left behind in the race to procure sufficient vaccines and treatment, India and South Africa proposed the TRIPs Waiver Proposal[9] in October 2020 - before a single COVID-19 vaccine had gained regulatory authorisation. They called for a three-year waiver of obligations under the TRIPs agreement that related to patents, trade secrets, copyrights, and industrial designs of COVID-19 drugs, vaccines, diagnostics, and other

technologies. The assumption underlying the proposal was that the flexibilities offered by the TRIPs agreement were not sufficient or unambiguous enough to mitigate the restrictive effects of IP protection.

Thus, the answer to criticisms directed at the lack of transparency and restrictive clauses in voluntary licenses could not be compulsory licensing alone, given the various time-consuming procedural requirements qualifying this TRIPs flexibility. A radical waiver exempting the breach of the aforementioned IPR was the best bet for scaling potential manufacturing capacity.[10] Amid a raging pandemic, the logic, though not flawless, brought forth a surge of support from the Global South, barring a few exceptions.

As mentioned, the EU Proposal tried to address some of these limitations by making it easier for WTO members to issue compulsory licenses. However, most were squarely based on policy space offered by existing rights and flexibilities in TRIPs.[11] Such clarifications include the right to do away with prior consultations with the patent holder, and the right to determine adequate remuneration based on humanitarian considerations and good practices during national emergencies and pandemics.[12]

The two proposals would have remained gridlocked if not for the reversal in the US stance towards the TRIPs Waiver Proposal. Accordingly, in the run-up to the 12th Ministerial Conference of the WTO (MC12), India, South Africa, the EU and the US shook hands on a WTO response to the pandemic. This was the controversial "Quad Outcome" that was catalysed by US support and facilitated by the WTO DG.[13]

Leaked just weeks before MC12, the draft Quad Outcome was decried as an abandonment of the TRIPs Waiver Proposal by its originators. Not only did most provisions align with the EU Proposal in text or spirit, but the ones that went beyond, such as the flexibility to use test data for market authorisation were merely a restatement of existing TRIPs flexibilities. Further, due to the US insistence, the Quad Outcome was limited to COVID-19 vaccines only.

The final Decision modifies the Quad outcome in several ways but carries with it all of the aforementioned limitations, as will be elaborated below.

Deciphering the Ministerial Decision

Implications of the Decision

At the outset, the Decision is almost entirely in keeping with the EU Proposal. It primarily contains clarifications on existing TRIPs flexibilities related to compulsory licensing in Articles 31 and 31*bis* of the TRIPs. Except for one occasion, i.e., with regard to Art 31(f), it does not provide for a

waiver of TRIPs obligations. Consequently, contrary to how it is generally referenced, it's rather unfitting to call the Decision a waiver.

Further, in terms of its scope, the application of the Decision is limited in two crucial ways. First, the subject matter covers only vaccines. At this stage, WTO Members are negotiating on whether and on what terms the Decision could be extended to COVID-19-related diagnostics and therapeutics.[14] Second, developing countries possessing sufficient manufacturing capacity have been encouraged to voluntarily exclude themselves from availing the decision. Thus far, only China has made a binding declaration to that effect.

Despite its limitations, the Decision is noteworthy in several ways. First, it is a big political and multilateral win – symbolising consensus between the global north and south on an issue as polarising and contentious as intellectual property rights. Second, it is a guarantee against coercion and intimidation faced by developing countries when utilising TRIPs flexibilities. Third, by allowing developing countries to voluntarily exclude themselves from benefitting from the Decision, it deploys an unprecedented method of rationalising the Special and Differential Treatment (SDT) at the WTO.[15]

Scope of IPR Covered

The Decision allows eligible Members to limit patent rights granted under TRIPs by clarifying and waiving provisions related to compulsory licencing of patents as covered by Art 31 and Art *bis* of the Agreement.

Additionally, it clarifies that WTO members will not be constrained by Art 39.3 of the TRIPs in enabling rapid approval for the use of COVID-19 vaccines. The original obligation under Art 39.3 requires that Members protect undisclosed test or other data submitted for marketing approval from unfair commercial use. Given the importance of regulatory authorisation especially in relation to biologics such as vaccines, test data must not become a bottleneck in expediting cooperation. The Decision recognises so, and is a reaffirmation of the caveat provided within Art 39.3 itself – Members are required to protect such data against disclosure, *except* where necessary to protect the public.

Unlike the TRIPs Waiver proposal, the Decision does not cover trade secrets, copyrights and industrial designs.

Necessity of Limitation on Patent Rights

The Decision specifies that limitations on patent rights through compulsory licensing are permitted to the extent necessary to address the COVID-19 pandemic.[16] This has temporal and subject matter implications.

First, even though Members are allowed to apply the provisions of this Decision until 5 years from the date of the Decision[17], if the WHO were to declare the pandemic to be over before this period, or reassess it to be an epidemic, then the applicability of the Decision may be brought into question.

Second, other public health concerns cannot be addressed through the COVID-19 vaccine technologies made accessible by the Decision. For instance, the use of frontier medical technologies like mRNA goes far beyond mitigating the current pandemic and encompasses the future of vaccines and genetic medicine against non-infectious diseases like cancer and Alzheimer's.[18] However, technologies and vaccines manufactured under a license through the Decision cannot be repurposed for other health concerns.

Scope of Subject Matter

On the one hand, the 'COVID-19 pandemic's necessity stipulation restricts the scope of when and how the compulsory license may be utilised. On the other hand, the clarification provided in the Decision regarding the 'subject matter of a patent'[19] assures that the compulsory license can include any ingredients and processes necessary for the manufacture of the COVID-19 vaccine. Usage of the term 'include' means that inputs and ancillary products or processes that are not strictly required for the manufacture of vaccines may also be covered by the Decision.

Further, the Decision reaffirms the right of eligible Members to compulsorily license multiple patents simultaneously. This could theoretically expedite vaccine manufacturing by eliminating the time and effort spent by manufacturers (including companies currently manufacturing COVID-19 vaccines[20]) in negotiating multiple licenses, given the network of patents[21] applicable to a particular vaccine/technology.

Notably, the Decision has done away with the contentious clause in the leaked Quad Outcome text that required Members to identify and stipulate all the patents that would have been covered by the compulsory licence. This is certainly a lower administrative burden to discharge for countries interested in utilising the Decision. This also means that the Decision permits a relatively broad compulsory license with automatic product/process-based applicability on ingredients and processes in the vaccine value chain.

Eligible Members

For the purpose of this Decision, all developing country Members are eligible Members. However, developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision. Such a commitment can be made through a statement to the WTO General Council.[22]

Thus, under the Decision, developing countries are automatically eligible unless they make a statement otherwise. Further, usage of the word 'includes' indicates that binding commitments can be made through statements by eligible Members at fora other than the General Council. In comparison, under Art 31*bis,* eligible importing members must notify their intention regarding the utilisation of the system.

The implications derived from the two approaches are significant. Under Art 31*bis,* importing Members need to establish that they have insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to the Annex of the amended TRIPs Agreement.[23]

While the removal of this administrative burden in the Decision related to COVID-19 is understandable (since the capacity in question has been determined), perhaps a similar extension of the provision could be accorded under Art 31*bis* based on good faith to increase the moribund utilisation of compulsory licencing.[24]

The exclusion of developed country members and the call to developing country members with sufficient capacity to voluntarily exclude themselves has some adverse effects on the potential outcomes of the Decision.

First, IP holders and vaccine manufacturers in developed/developing countries with sufficient capacity and knowledge will be excluded from being a part of the solution i.e., mitigating the gross inequity in availability and access to vaccines.

Second, even if we were to consider that the Decision is aimed more towards building new capacity rather than mitigating vaccine inequity in the short term, the terms of the Decision skew the field to the detriment of emerging players. Vaccine manufacturers in the global South will not be able to export to developed countries. This prevents emerging vaccine manufacturers in the LMICs from accessing an extended, high-income market that could incentivise economies of scale.

Apart from insulating the pharmaceutical players in the North from competition, this also takes away options from consumers in developed countries which also have little to no manufacturing capacity of their own. On the contrary, it has been argued that creating a limited but assured market for the new producers in the South is a desirable amount of protectionism to encourage local manufacturing.

Exportation, Anti-diversion Requirements and Notifications

As mentioned, among the many clarifications in the Decision, the lone waiver covers Art 31(f) of TRIPs. This provision has been contentious long before the pandemic, having now been circumvented twice, once through an amendment resulting in Art 31*bis* and now through a temporary waiver (albeit with some qualifications).

While 31(f) bars Members from exporting the predominant part of the supply produced under compulsory license, Art 31*bis* allows such exportation, subject to certain procedural conditions.[25] Now, the Decision provides a second option for an eligible Member wanting to export the predominant supply by combining the two kinds of licenses allowed by TRIPs – one for domestic markets (Art 31) and one for export purposes (31*bis*) and adding a different set of conditions.[26]

The Decision requires eligible Members to undertake *all reasonable efforts* to prevent the re-exportation of the products manufactured under compulsory licenses that have been imported into their territories under the Decision. Members must ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products manufactured under the authorisation in accordance with this Decision, and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPs Agreement.[27]

This obligation is reminiscent of that under Art 31*bis:*[28] *"Importing Members shall take* reasonable measures within their means, proportionate to their administrative capacities *and to the risk of trade diversion to prevent re-exportation of the products that have been imported into their territories under the system."*

Notably, unlike Art 31*bis,* the Decision

- is stricter in its demand for reasonable measures instead of those that are within means and proportionate to administrative capacities. does not address what would happen in the event an eligible importing Member experiences difficulty in implementing this provision. While Art 31*bis* stipulates that developed country Members provide technical and financial cooperation to facilitate its implementation,[29] the Decision is silent on this aspect.
- presumes a risk of trade diversion.

Further, unlike Art 31*bis,* the Decision does not require that exported vaccines bear distinguishing labels or marks. However, while notifying the Council for TRIPs regarding measures undertaken per the Decision, Members need to specify

- the name and address of the authorised entity,
- the product(s) for which the authorisation has been granted and
- the duration of the authorisation.

The quantities imported have to be notified by the importing Member as soon as possible after the information is available. In conjunction with the strict anti-diversion requirement to take "all reasonable measures" it seems that providing identifying labels/markers could arguably form such a possible measure, given that most jurisdictions modified their compulsory licensing frameworks in light of Art 31*bis*.

Remuneration

Article 31(h) requires that remuneration be based on the economic value of the authorisation. With slight modifications, Art 31bis (2) specifies that adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the *importing* Member of the use that has been authorised in the exporting Member. Additionally, it ensures that remuneration is not afforded twice, by both importing and exporting Members.

The Decision allows Members to take into the account *"…humanitarian and not-for-profit purpose of the specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines in order to support manufacturers in eligible Members to produce and supply these vaccines at affordable prices for eligible Members."*[30]

Much like the restriction on eligible Members, this provision tries to support local production in exporting developing countries.

Table 15.1: Comparing the Decision Against Original Proposals at the WTO

Criteria	Decision	TRIPs Waiver Proposal	EU Proposal
Scope of IPR Covered	Patents and pharmaceutical test and other data for marketing approval	Patents, trade secrets, test and other data for marketing approval, copyrights and industrial designs	Patents only
Effect of Proposal on TRIPs Obligations	Part clarification and part waiver (Art 31(f)) of patent rights	Complete waiver of aforementioned IPRs	Part clarification and part waiver (procedural requirements) of patent rights
Scope of Products	COVID-19 vaccines only. A decision on diagnostics and therapeutics will be made within six months.	COVID-19 drugs, vaccines, diagnostics, medical devices, personal protective equipment, their materials and components and other technologies.	COVID-19 vaccines and therapeutics.
Scope of Beneficiaries	All developing country Members are eligible. However, developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision.	All WTO Members	All WTO Members
Necessity	Patent rights may be curtailed to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in the Decision.	N/A – However, the proposal does specify that it would be applicable during the span of the pandemic. Indirectly setting a sunset clause to the decision.	
Re-exportation	In exceptional circumstances, an eligible Member may re-export COVID-19 vaccines to another eligible Member for humanitarian and not-for-profit purposes, as long as the eligible Member notifies the same.	No stipulation	Art 31*bis* (para 3) allows for eligible countries within a regional trade agreement to re-export to each other when they share the same health problem.
Duration	Five years	At least three years	No explicit stipulation/open-ended

Why the original TRIPs Waiver Proposal would not have worked?

The Decision itself was the fruit of heated negotiations that lasted almost two years. They galvanised reactions across the world to rapidly scale expectations from the outcome. To many, the original TRIPs Waiver Proposal was legally, economically and morally indispensable. Even if not a panacea, its existence was the starting point for effectuating any solution. However, for several others, the very idea of a waiver was inappropriate, given the foundational role that intellectual property had played in operationalising an unprecedented pandemic response.

Even if the original proposal had found consensus, its eventual impact would have been subject to many caveats. First, a waiver at the WTO only means that countries are free to suspend WTO obligations, but they are by no means obligated to give direct effect to the waiver through domestic laws.[31]

TRIPs only sets the minimum standards of IP protection and Members are free to go beyond them. Countries that IP holders are based in were least likely to suspend the domestic protection of IPRs, especially considering that a waiver of TRIPs obligations would not mean that other obligations under Regional Trade Agreements (RTAs) or Bilateral Investment Treaties[32] or for that matter, domestic laws[33] will cease to operate.

If a set of WTO Members continue to protect and enforce IPR in their territories, even as they are restricted from initiating WTO disputes against developing nations and LDCs that suspend their TRIPs obligations, there will be a clear disincentive for IP holders to expand their presence beyond friendlier ecosystems and diversify their manufacturing base.

While the TRIPs Waiver Proposal could have theoretically expedited vaccine manufacturing by eliminating the time and effort spent by manufacturers in surveying the network of patents applicable to a particular vaccine/ technology and negotiating for multiple licenses – all the while remaining open to the risk of litigation for patent infringement. The waiver could have granted immunity from legal action to manufacturers in developing countries and LDCs when producing patent-protected COVID-19 vaccines, therapeutics, and diagnostics.

Further, when dealing with vaccines specifically, removing patents from the equation only amounts to a partial solution because building manufacturing capacity would require the extensive transfer of technologies, do-how and know-how. Case in point, the bench-to-bedside process for an mRNA vaccine can involve over fifty thousand steps, highlighting the extreme difficulty in reverse-engineering biologics.[34]

The TRIPs Waiver Proposal attempts to resolve this by covering trade secrets within its ambit, but this creates more problems than it solves. Thus, the TRIPs waiver, even if successful in untangling complex patent networks, would have remained ineffective in providing access to technologies, know-how, test data, and critical ingredients that are equally important constraints in scaling up manufacturing capacity.

Unfortunately, this limitation also applies to the final Decision which focuses primarily on patent rights and does not address how compulsory licensing alone, without commensurate focus on the transfer of technologies will suffice.

Table 15.2: Main Constraints in Legal Options at International and National Level

IP related Resource Constraint	IPR Waiver	Voluntary Arrangement
Technologies & know-how protected by trade secrets	Enabling domestic measure (s): Forced Technological Transfers Roadblocks(s): the availability of highly skilled human resources; technology absorption capabilities; extent of cooperation provided by the original creators; IP holders	Enabling domestic measure(s): Incentives and de-risking of diversification of supply chains through public investment and pre-market commitments Roadblock(s): Non-transparent and exclusive contracts; unaffordable products

Lessons and Prescriptions – The Way Forward

At the WTO

The Decision tries to address an emergency but stopping here instead of taking the conversation forward would mean that we lose an opportunity to arrive at a long-term solution. Moreover, while the Decision facilitates the use of compulsory licenses in several ways, it also throws up certain hurdles, and some of these could have been prevented by incorporating existing provisions in Art 31*bis*. Members will be better off negotiating a simpler Art 31*bis* incorporating the best of both mechanisms.

Especially for LDCs, time and political capital at the WTO will be better spent by redirecting the existing mechanism under Art 66.2 of TRIPS to build their capacity to better deal with future public health emergencies. Under Art 66.2, developed country Members are legally obligated to provide incentives to enterprises and institutions in their territories to promote and encourage technology transfer to LDC Members. Appropriate incentives could range from production and capacity subsidies, concessional loans, and volume guarantees (by developed countries on behalf of LDCs) to more aggressive measures like a direct governmental intervention to finalise partnerships.[35]

Going forward, the WTO TRIPs Council should utilise the existing experience of the WTO Working Group on Transfer of Technology[36] and the WHO, WTO, and WIPO Joint Initiative[37] on Intensified Cooperation in Support of Access to Medical Technologies to extract the best practices in the domain while avoiding pitfalls that may delay or restrict the benefits of such licensing/transfer.[38]

The Council should take the initiative to serve as a platform that brings governments, IP holders, prospective manufacturers along with institutions such as the WHO, the WIPO, Coalition for Epidemic Preparedness Innovations (CEPI), Médecins Sans Frontières (MSF) and Gavi, the Vaccine Alliance as well as professional institutions such as the International Society of Pharmaceutical Engineering (ISPE) together to iron out details like the desirable scope of transfer of medical technologies; standards for measuring the progress of such transfers, among other issues. The pandemic can catalyse an opportunity for the WTO to try its hand at collateralise and adopt a multistakeholder, result-oriented approach for resolving deadlocks.[39]

Further, the WTO could continue to monitor and warn against supply chain disruptions due to trade restrictive policies like export bans of critical ingredients or final products. The WTO has worked extensively to highlight these bottlenecks[40] and such information[41] must guide the trade measures taken by its Members.

In the future, codification of relevant norms can take place by continuing discussions on the new Trade and Health Initiative (THI) (WT/GC/223) proposed by a few WTO Members. THI covers export restrictions, customs services and technical regulations, tariffs, transparency, and review mechanisms. Apart from multilateral rules to deal with trade during crises, countries should also revise provisions in RTAs that would enable them to meet the same regulatory objectives.[42]

At National Level

Governments dropped the baton when they didn't make their funding to pharmaceutical companies conditional upon a commitment to voluntarily license and transfer technologies related to vaccines. As a general policy prescription, any significant public investment in private companies for essential drugs, technologies and vaccines should, as a rule, be made contingent upon the sharing of relevant IP, technologies and know-how. For instance, the US Defence Production Act could have been used to condition future procurement deals upon pharmaceutical companies seeking more opportunities to license and transfer technology.[43]

Alternatively, an open option for developed nations during public health exigencies such as the pandemic is to directly buy technologies and know-how for their transfer to developing countries and LDCs on easy terms.[44] This is where multi-track diplomacy can play a role. In fact, instead of arguing for a waiver or settling for (largely) a reiteration of existing TRIPs flexibilities, countries could have used bilateral, regional, and multilateral channels to ensure that developed countries take immediate and concrete steps to incentivise/persuade vaccine producers to voluntarily license technologies to suitable partners in developing countries and LDCs.

An option with developing countries is to implement the Decision (overcoming patent restrictions) and fill the gaps through government-driven initiatives to share technology and know-how. For instance, to begin with, India could take the lead by making IP and technologies associated with its indigenously developed vaccines, drugs and therapeutics available to C-TAP.[45] South-South cooperation to expedite the sharing of skills, test data, know-how, do how and technologies can usher in an inclusive vaccine development model.[46]

Ideally, a synergy between governments, regulators, businesses, and civil society should be cultivated by preserving consent and mutual trust between all partners. An argument against utilising voluntary deals is that these represent the status quo and harken to a business-as-usual approach which the world can no longer afford. The fact that mechanisms such as the WHO's COVID-19 Access Pool[47] (C-TAP) that facilitate diversified manufacturing through voluntary, non-exclusive, and transparent licenses, remained unutilised till recently, has been considered as a failure of such routes.

The shortcomings of an incentive-based system must be addressed without throwing the baby out with the bathwater. If the initial reliance on voluntary licensing has been low due to limitations in available avenues for cooperation, technical resources at the disposal of IP holders and the very resource material and components required for manufacture, then attention must be

paid to resolving these constraints. The pandemic's learning curve has given way to massive gains in efficiency and output. To ensure that this momentum catches on, various measures can be pursued to ensure equitable access to COVID-19 vaccines and drugs.

Multiple models for such collaboration exist. The goal is to emulate or surpass them. The arrangement between the UK's AstraZeneca and the Serum Institute of India is an excellent example of what can be achieved through coherence between market mechanisms and regulatory imperatives. Upcoming voluntary licensing arrangements in Rwanda, Senegal, and South Africa are also encouraging.[48,49]

Notably, the sharing of information and know-how through the C-TAP system would be more efficient as compared to individual licensing arrangements between various developers and manufacturers. Such mechanisms are already showing results. Voluntary and non-exclusive arrangements have materialised for the dissemination of serological testing technology[50] and the production of Paxlovid,[51] an oral drug treatment for COVID-19, via the Medicines Patent Pool (MPP), a United Nations-backed public health organisation.

In turn, developing countries should maintain a predictable and transparent regulatory ecosystem. After all, voluntary technological transfers are contingent upon the effective protection of trade secrets. In pursuing such partnerships, the Decision should be used as a big stick to ensure that softer words of persuasion are not ignored. In other words, for the next five years, LMICs have gained some tools to threaten partners into cooperation.

Plugging Policy Gaps

The exercise of negotiating a TRIPs Waiver and arriving at the Decision has highlighted various legal and policy vacuums. These must be addressed to ensure that future endeavours to arrive at a global response to public health emergencies are faster and more effective.

First, to deal with criticisms directed at the lack of transparency and the use of restrictive clauses in voluntary licenses and production contracts, a cooperative mechanism based on competition law principles needs to be evolved. Adequate and timely cross-border cooperation among regulators can facilitate the dissemination of information and best practices to arrive at non-exclusive and transparent voluntary licenses.

In the long haul, a global competition framework can prevent regulatory arbitrage by IP owners. The trilateral initiatives of the WHO, the WTO and the WIPO can be boosted by a pillar dedicated to competition. The institutional

experience of the UNCTAD Branch on Competition Law and Consumer Policy can be the starting point.

More ambitiously, a new framework could try to adapt the present practice of Standard Essential Patents (SEPs) in the electronics and telecom industries to the needs of the health industry. This could ensure that patents related to frontier mRNA technology in particular, and other medical technologies that are indispensable during public health emergencies are licensed at fair, reasonable and non-discriminatory terms (FRAND).

Second, the fact that we cannot have a compulsory license for trade secrets (due to their nature) means that we need to design appropriate policy tools to facilitate the transfer of technologies where patents alone don't suffice. A multilateral framework (or perhaps a plurilateral arrangement led by a coalition of the willing) at the intersection of IP, trade and competition policies that build on the experience of relevant rules and mechanisms can be the starting point.

For instance, building on the experience of Art 66.2,[52] TRIPs and the UNFCCC Technology Mechanism[53] can be the starting point for a pragmatic and enforceable framework that incentivises the development and sharing of technologies. In this effort, focus must be paid towards attracting and coordinating massive investments that will reduce risks associated with expanding production capacity and facilitate the training of staff for absorption of technology in LMICs with nil or low capabilities.

Chad P. Bown (Peterson Institute for International Economics, USA) and Thomas J. Bollyky (Council on Foreign Relations, USA) proposed a COVID-19 Vaccine Investment and Trade Agreement[54] (CVITA) which would draw lessons from the public-private initiative of Operation Warp Speed[55] and allow for coordination in investments and subsidisation across the supply chains and institute a real-time market information system for the availability of vaccine inputs, technologies and final products. A broader, permanent and stakeholder-based framework should be envisaged to provide more impetus to market-based transfer of technologies.

In sum, a renewed and institutionalised attempt at cooperation at the level of firms and nations would be our best shot to address the long-term inequity in the development and production of vaccines, drugs and therapeutics for COVID-19 and beyond. Countries need to evaluate trade-offs of voluntary and coercive approaches against their regulatory imperatives and consider which option suits their short and long-term objectives.

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15 There is some momentum on the issue of 'reforming' the manner in which SDT is currently availed by developing countries through self-designation. Developed countries like the US, EU, and Canada have advanced proposals to reform the practice of self-designation by developing countries to avail SDT and replace it with objective criteria.

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23 The exception to this is LDCs since it is assumed that they lack manufacturing capacity and do not need to state anything about it.

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CHAPTER 16

Regulatory Issues in Medical Education in India

Introduction

Today we live in the era of knowledge explosion and easy access to information. During this time reliable information sources have become fewer and more necessary. Education plays a pivotal role in realising the full potential of an individual, constructing a peaceful and just society and thereby forming a well-developed self-sufficient nation. India will have the highest population of young people in the world over the next decade and our ability to provide high-quality educational opportunities to them will determine the future of our country.[1] Health and education have come out on top of the list of priorities for countries across the globe and in India as well.

The present status of health in India if assessed critically reveals that the burden of disease in India remains large and the availability of doctors to handle the said challenge is quite inadequate in terms of quality and quantity.[2] The World Health Organisation's (WHO) standard for doctor- population ratio is 1:1000, while the same ratio in India is allegedly at 1:834 but that is inclusive of AYUSH doctors and allopathic doctors as well.[3]

There is a wide gap between the availability and the requirement of physicians of first contact and specialists in rural and outreach areas. Needless to say, there is a need for further expansion of medical education facilities at graduation and post-graduation levels.

The medical profession in India consists of four different types of streams namely, Allopathy, Ayurvedic, Homoeopathic, and Unani. While Allopathy, which is also known as the Western medical system, is the most popular, other streams are also widely used. Admission to the undergraduate and graduate levels of government-approved colleges is through competitive exams. In 2021, 16.4 lakh candidates had registered for the National Eligibility cum

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Entrance Test- Undergraduate (NEET-UG) which is an entrance test for medical undergraduate education.[4]

There are approximately 89,875 undergraduate seats available through the NEET-UG for the allopathic stream.[5] The Graduates can also go for higher degrees such as Doctor of Medicine, Master of Science, Fellowship of the Royal College of Surgeons (FRCS), and Membership of the Royal College of Physicians (MRCP). The paper, the regulatory gaps in allopathic undergraduate and postgraduate education as these remain heavily over-applied in the country.

The availability of seats in the ratio of the registering candidates shows the stark difference in the medical education system we want to achieve. Due to the recent, Russia-Ukraine imbroglio, the migration of students to low-cost medical education countries due to lack of adequate seats coupled with expensive private medical education was brought to renewed notice of the government.[6]

To curb this brain drain, the Prime Minister called for greater private participation in the sector to plug the gap in the supply of medical seats.[7]

Since 2014, to increase the number of medical doctors in the country, the government has tried to increase the number of medical colleges. To ensure this, A Centrally Sponsored Scheme was introduced in 2014 to provide central funding support for opening new medical colleges. Three phases of the Scheme have been approved to date under which 157 colleges have been sanctioned. Against 381 medical colleges in 2014, currently, there are 596 medical colleges (313 GMC and 283 private medical colleges).[8]

The increase of medical colleges however has yet not catered to the numerous applicants who apply for the undergraduate competitive exam. through this paper, the author will aim to identify regulatory issues that affect the position of medical education in the country.

Recent Changes in Regulations Governing Medical Education

The regulation of medical education and health professionals is an important aspect of the governance of health systems. This has been an area of concern and institutional weakness in many low and middle-income countries (LMICs) including India.[9]

There have been varied developments in the field of medical education regulations the entirety of which will not be covered however the most recent ones will be the ones in focus. Given below is Table 16.1 for major initiatives for regulatory reforms of medical education in India to date:

Table 16.1: Chronology of Regulatory Developments in Medical Education

Year	Major Developments
1933	Indian Medical Council Act, 1933 (pre-independence)
1934	Establishment of the Medical Council of India (MCI)
1956	The Indian Medical Council Act, 1956 (post-independence)
1982	Medical Education and Review Committee (Mehta Committee) • Recommended reform in medical education, such as entrance examination for admission to undergraduate (UG) and postgraduate (PG) medical courses, revising the curriculum of UG and PG, and setting up institutional norms for standardising medical education
1986	Expert Committee for Health Manpower Planning, Production and Management (Bajaj Committee) • Recommended formulation of national medical and health education policy, cadre-wise coordinated planning and setting of the university of health sciences within states in India. • Estimated availability of human resources for health.
2008	National Knowledge Commission—subcommittee on medical education • Recommended converting the MCI into a full-edged professional body conducting examination and licensing of medical professionals only
2011	The National Commission for Human Resources for Health Bill, 2011 (withdrawn) • Recommended reform in the regulation of health professional education by dissolving the MCI, the Nursing Council, the Pharmacy Council and the Dental Council and replacing them with one comprehensive regulatory institution High-Level Expert Group on Universal Health Coverage • Recommended establishing more medical institutions in the public sector in underserved areas, reserving 50 percent seats for local communities in private institutions. • Sector medical institutes, fixed fees and revision of medical curriculum
2015	An Expert Committee led by Dr Ranjit Roy Chaudhury recommended an overhaul of MCI and replace it with a new institution
2017	The National Medical Commission Bill, 2017 • Proposed to replace the existing MCI with a new body, the National Medical Commission (NMC). It encountered severe resistance from professional associations and medical students. Upon introduction, the Parliament referred it to the Parliamentary Standing Committee. The National Health Policy, of 2017 recommended recreating the regulatory mechanism for health professional education
2018	The Indian Medical Council (Amendment) Ordinance, 2018 notified, which repealed the Indian Medical Council Act, 1956 and consequently the MCI was replaced by an interim Board of Governors
2019	The National Medical Commission Act, 2019 was passed by the Parliament thus paving the way for the constitution of a new regulatory body for medical education, the NMC

The Centre has set up regulatory bodies for monitoring the standard of medical and dental education, promoting training and research activities. Until 2019 these regulatory bodies were governed under the Indian Medical Council Act of 1956, the main functions of the Council included the maintenance of uniform standards of medical education in the country.[10] This Act and all regulations under it erstwhile were replaced by the National Medical Commission Act, 2019 (NMC Act).

Medical education has also been included briefly in the National Education Policy (NEP), 2020. The NEP has suggested changes in the duration and structure of the course, integrative healthcare and stress on preventive medicine.[11]

National Education Policy 2020

NEP 2020 is the first education policy of the 21st century. It is built on the foundational pillars of Access, Equity, Quality, Affordability and Accountability. This Policy is aligned to the 2030 Agenda for Sustainable Development for the country. It aims to make both school and college education more holistic, flexible, multidisciplinary, and suited to 21st-century needs.[12]

The NEP aims, among other things, to internationalise the higher education sector so that larger numbers of international students can study in India while providing greater mobility to students in India who may wish to visit, study at, transfer credits to, or carry out research at institutions abroad, and vice versa. The brief changes in the NEP are visioned around ground-breaking reforms to cater to the local and nationwide needs with the curriculum and skill training rooted in addressing the problems of the country in all its length and breadth.[13]

Medical education would come under higher education outlined under NEP 2020 for which the Department of Higher Education was the nodal department. This means that the Department of Higher Education will set up a new framework for the regulation and maintenance of standards in higher education as per its constitutional mandate. However, the NEP 2020 deviated from the 2019 NEP and excluded medical and legal education from the proposed new regulatory architecture. This might need to be revisited in the future since it prevents the full benefit of the new regulatory architecture from accruing to multidisciplinary Higher Educational Institutions.[14] Be that as it may, NEP 2020 has multiple provisions which would be advantageous towards medical education if and when implemented.

Financial Support for Students: Under NEP efforts will be made to incentivize the merit of students belonging to Scheduled Castes (SC), Schedule Tribes (ST), Other Backward Classes (OBC), and other Socio-Economically Disadvantaged Groups (SEDGs). The National Scholarship Portal will be

expanded to support, foster, and track the progress of students receiving scholarships. Private higher educational institutes will be encouraged to offer larger numbers of free seats and scholarships to their students.[15]

As is well known, medical education is one of the most unaffordable education streams in the country. The cost for a medical education degree can vary from ₹7.5 Lacs for government colleges to ₹1 crore for private institutes. This gap is felt more forcefully when coupled with the low number of seats in government colleges.[16]

Keeping this cost-heavy medical education in mind the Prime Minister had invited the private sector to take up a bigger role in delivering medical education.[17] However, the involvement of private players in the medical education system would do less to make medical education affordable unless supported by fee rationalisation of medical education costs.

Online Education and Digital Education: Under NEP a comprehensive set of recommendations for promoting online education consequent to the recent rise in epidemics and pandemics will be undertaken. This would allow for ensuring preparedness with alternative modes of quality education whenever and wherever traditional and in-person modes of education are not possible.

A dedicated unit to orchestrate the building of digital infrastructure, digital content and capacity building will be created in the Ministry of Education to look after the e-education needs of both school and higher education.[18] The government's vision of a digital university to reach all students across the country, with its promise of personalised teaching at the doorstep, should be considered a landmark step in Indian education.[19]

A 'Phygital' model combines online course instruction with weekly or fortnightly in-person educational sessions. This model is currently proposed for school education, however, the issue of limited seats until new colleges are functional can be addressed using this model. This model can also be used for fee regulation exponentially for students who are likely to move abroad for their degrees. The need for the Phygital mode of education is felt more and more with the pandemic making students' lives digital.

Medical education occupies a distinctive space, necessitating a balanced amalgamation of both theoretical knowledge and hands-on, practical skills. The acquisition of these practical skills is paramount in the holistic development of future healthcare professionals. Unfortunately, the advent of online medical classes has created a gap, depriving students of crucial practical learning experiences that are integral to their medical education.[20]

The National Education Policy introduces the establishment of the National Educational Technology Forum (NETF) as an independent entity. NETF is designed to serve as a platform for the free exchange of ideas on the use of

technology to enhance learning, assessment, planning, and administration. The NEP aims to seamlessly incorporate technology across all education levels to improve classroom processes, support teacher professional development, enhance educational access for disadvantaged groups and streamline educational planning, administration and management. However, excluding medical and legal education from the purview of NEP 2020 will result in these higher education institutes missing out on the advantages provided by the policy.[21]

National Medical Commission Act, 2019 and Rules thereunder

For many decades, the former MCI was accused of corruption and mismanagement but also proved to be resistant to reform.[22] The formal process of formulating the NMC began in 2016 but faced severe resistance from many quarters, including medical students, medical colleges and professional associations.[23] In the meantime, when the NMC Bill was pending in Parliament, the existing MCI was superseded by a government-appointed Board of Governors (BoG) in 2018.[24] The NMC Act[25] was ultimately approved by the Parliament in 2019.[26]

The NMC Act was introduced to provide for a medical education system that improves:

a. Access to quality and affordable medical education
b. ensures the availability of adequate and high-quality medical professionals all over the country.

Table 16.2: Differences between MCI and NMC Responsibilities

Medical Council of India Responsibilities	National Medical Commission Responsibilities
• Recognition of medical qualification • Curriculum design and regulation • Standard of examination for awarding medical degrees • Recognition of medical colleges and medical courses by ensuring minimum standard • Licensing of qualified medical professionals and maintaining a registry • Disqualification of medical professionals in case of professional misconduct • Protecting the rights of registered medical professionals	• Examination—common national entrance and exit examination test for UG and PG medical courses • Setting and maintaining the standard of medical education • Rating of medical institutions based on deemed minimum standards • Maintain a national registry of medical professionals • Regulate professional conduct and promote medical ethics • Recognition of medical colleges and medical courses by ensuring minimum standard • Recognition of postgraduate medical degree awarded by the Diplomate of National Board

'Selection' of Commission

The onset of the NMC Act has been touted as a historic reform which will potentially steer medical education towards a transparent, qualitative and accountable system. Notably, a key change is the transition from an 'elected regulator' to a 'selected' one, ensuring individuals of unblemished integrity, professionalism, experience, and stature are entrusted with the responsibility of overseeing medical education.[27]

Section 4 of the NMC Act states the composition of the commission will be of a chairperson,[28] 10 ex-officio members[29] and 22 part-time members. Previously during the regime of the MCI, the members were selected through election.

As the commission members are appointed exclusively through nominations by the central government, there is a chance of prejudice. This could lead to the emergence of nepotism and the promotion of a lackey culture that had infested the MCI. Even the Medical Advisory Council, under Section 11 of the NMC Act, has nominated members from the states, thereby diminishing the states' role to a consultative capacity.[30]

Establishment of a New Medical Institution

In the aftermath of the Ukraine imbroglio, it becomes evident that a rigid system with limited flexibility can adversely affect the aspirations of aspiring medical professionals.

A re-evaluation of the approval mechanisms, perhaps involving more state-level autonomy, could not only alleviate the challenges faced by returning students but also pave the way for a more dynamic and resilient medical education landscape in the country. In India, the establishment of any medical institution, to start a postgraduate course or to increase the number of seats, there is a need to get approval from a Medical Assessment and Rating Board under Sections 26 and 28 of the NMC Act.[31]

However, opening even one medical college is not lucrative enough for private players.[32] In this continuum, a shift towards a collaborative and inclusive decision-making process emerges as a vital step in ensuring the holistic development of the medical education sector.

These students faced the lack of seats in the government colleges which still have relatively affordable fees whereas the private colleges prefer remaining small in the number of intakes. In 2020 there was an announcement related to the relaxation of rules for establishing a medical college. The newly formed NMC had deleted the quantum of land required for setting up a

medical college and its affiliated teaching hospitals. In 2020, the NMC eased rules for establishing medical colleges, removing land quantity requirements for both the college and affiliated teaching hospitals.

Establishment Of Medical College Regulation, (Amendment), 2020 rules which came into force only from the year 2021-2022, was lauded by the Centre.[33] the regulations prescribed for a new regulation which mandated the availability of a fully functional 300-bed multi-speciality hospital for at least two years at the time of application for establishing a new medical college. This hospital should have all necessary infrastructure[34] with a minimum of 60 percent indoor bed occupancy. It should also have, it said, been providing services[35] in all medical departments.[36] This means that before establishing a college, or even being eligible for one, the person or agency will have to first establish a fully functional hospital.[37]

The medical college groups that have such funds prefer setting up another smaller college as the fees for 50 percent of seats are capped as per the NMC guidelines 2022.[38] There are only so many people in the other 50 percent that can cross-subsidise the rest. Even 10 percent vacant seats lead to a significant dent in profits which leads to colleges preferring to stay small.[39]

Minimum Requirements for a Teaching Hospital's Creation and Expansion

The power to make regulations has been given to the NMC under Section 57 of the NMC Act. This includes regulations for the form of the scheme, the particulars thereof, the fee to be accompanied and the manner of submitting the scheme for establishing a new medical college starting any postgraduate course or increasing the number of seats under Section 57 (2) (ze) of the act.

Under this rule-making provision, the Minimum Requirements for Annual M.B.B.S. Admissions Regulations, 2020[40] were established which state any legally established hospital can be a teaching hospital if it has the required amount of patient load, and provides teaching spaces. Furthermore, the increasing scale of 50, 100,150, 200 and 250 needs an increase in other facilities like hospital beds, examination halls, equipment etc.

The private colleges and small medical do not have funds to do said expansions. The regulations for each category or slab of medical students are over-prescriptive as they highlight not only the number of books in the library but also the number of exam halls, and equipment's amongst others. The 2021 Economic survey states that India tends to favour prescriptive regulation over supervision to reduce accountability on the regulators; however, this is an approach that leads to overregulation.[41]

As per the rules, the regulator has chosen not to prescribe the amount of land required as it should depend upon the municipal norms. There has been a simplification of the regulations to focus more on quality. This move

would encourage student-faculty interaction, small group teaching and bedside classes while bringing down the cost of establishing a medical college substantially.[42]

Conclusion and the Way Forward

In the long term, there should be a focus on establishing more colleges, by aiming to establish one college per district to meet the demand for seats.[43] However, setting up more colleges is a long-term solution for an immediate problem. India's health sector needs more doctors at the earliest[44] and the gestation period for establishing a medical college can take a long time and is a cost-intensive measure. Keeping in mind the issues in establishing medical institutes and along with the independence of NMC, we recommend the following:

Infrastructure Status to Healthcare

There is a demand and supply gap in the health care sector and yet the health care projects are not seen as attractive investments. Recently, the proposed data centres were given infrastructure status which will provide access to foreign investment and private capital, help borrow funds at lower cost, and thus enable rapid deployment of data centres across the country.[45]

The Health Sector, specifically medical institutions deserves similar benefits especially when they tend to not expand due to the high gestation period and economic investment. In essence, the entire Healthcare industry deserves this status and more investment should be directed towards this industry to create systems and structures that can bring healthcare and health education to the community in an accessible and affordable manner.

To rebuild and energise the healthcare sector after the pandemic, we must develop our country's capacity now by bettering medical education in affordability and accessibility, and thus buttress our healthcare system.

Fee Rationalisation while Encouraging Public-Private Partnership Model

One of the leading causes for students to choose education abroad is the high fees in Indian Medical Colleges. In a recent step by the Rajasthan Government in this direction, a committee under the chairmanship of a High Court Judge will decide upon the fees of medical courses in the state after going through the fee structure of other states. A draft of Rajasthan Private Education Fixation of Fee Bill, 2021[46] was released by the Government of Rajasthan and will be brought to the assembly soon.

Recently, the National Medical Council (NMC) decided that the fees of 50 percent seats in private medical colleges and deemed universities should be on par with that of government medical colleges of that particular state and

Union Territory.[47] The fee rationalisation at par with global fee structures will help students envision medical degrees in the country instead of moving out to countries abroad.

Independence of the Regulating National Medical Commission

The NMC is responsible for entrance examinations, setting and maintaining standards of medical education, and recognition of medical colleges and medical courses by ensuring minimum standards amongst others.

Most members of NMC are nominated solely by the Central Government which can be a potential reason for bias and corruption to breed. The responsibilities of the NMC are more powers that are extremely concentrated. The extreme centralisation of power is potentially fatal[48] for the NMC as it will make it susceptible to the mistakes of MCI which was considered to be highly corrupt and ineffective. The central government must thus reline few powers to the state and focus on having an NMC which is unlike its predecessor MCI.

To rejuvenate medical education in India and address concerns such as insufficient seats, a scarcity of colleges, elevated fees, and the NMCs' centralised dependence, the Central Government should adopt a systemic change strategy. This approach involves implementing comprehensive reforms aimed at reducing exorbitant fee structures, augmenting the capacity of seats and colleges, and conferring healthcare infrastructure status. Undertaking these measures will be instrumental in fostering positive transformations within the medical education system.

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[29] President of the Under-Graduate Medical Education Board, Post-Graduate Medical Education Board, Medical Assessment and Rating Board, Ethics and Medical Registration Board respectively. The Director General of Health Services, Directorate General of Health Services, New Delhi, the Director General, Indian Council of Medical Research along with Director of any of the All India Institutes of Medical Sciences, to be nominated by the Central Government, two persons from amongst the Directors of Postgraduate Institute of Medical Education and Research, Chandigarh; Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry; Tata Memorial Hospital, Mumbai; North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences, Shillong; and All India Institute of Hygiene and Public Health, Kolkata; to be nominated by the Central Government; and one person to represent the Ministry of the Central Government dealing with Health and Family Welfare, not below the rank of Additional Secretary to the Government of India, to be nominated by that Ministry.

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CHAPTER 17

The Design and Regulation of Health Insurance in India

Introduction

In the early 2000s, Ellis, Alam and Gupta wrote about the issues that plagued healthcare and health financing in India. They noted the fragmented nature of health financing, low population coverage of health insurance, over-reliance on out-of-pocket payments to fund healthcare and the resultant excessive financial burdens these pose to households in India.[1] More than two decades later, little has changed.

Health insurance in India continues to be fairly fragmented. Government schemes such as the former Rashtriya Swasthya Bima Yojana (RSBY) and the current Pradhan Mantri Jan Arogya Yojana (PMJAY) attempt to provide some form of insurance cover for the very poor. Government employees and ex-servicemen are covered by the Central Government Health Scheme (CGHS) and Ex-servicemen Contributory Health Scheme (ECHS) respectively.

Employees' State Insurance Corporation (ESIC) offers health coverage to employees drawing wages up to ₹21,000. Commercial health insurance offers an avenue to anyone who wishes to cover themselves (either individually or as a group) in exchange for the payment of a premium.

Despite multiple insurance schemes offered by government, public and private entities, less than half (34[2]-41 percent[3]) of all Indian households currently have at least one member with health insurance ownership. Again, this simple ownership of health insurance does not imply effective access, which is likely to be much smaller. More than half of India's healthcare spending continues to be funded out-of-pocket.[4] The rising cost of healthcare exacerbates the problem further.[5]

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Without access to prepayment and pooling mechanisms, healthcare can end up being unaffordable for many, leading them to forgo care.[6] Even when they do access care, it can end up being catastrophic for households without insurance.[7]

Given the low levels of coverage, there is plenty of scope for more formalised pooling and prepayment mechanisms. However, this scope has not been properly explored. For instance, as per the latest National Health Account (NHA) estimates, India's growing commercial health insurance segment accounts for only about 7.25 percent of all health spending in India (a marginal increase of 7 percent from the previous year). Collectively, group and retail insurance cover a maximum of 12 percent of India's population.[8]

This low uptake despite high out-of-pocket payments could indicate limited awareness or access, and a mismatch between what is offered and what is needed.

Even when people do have access to some form of insurance, they may not necessarily be able to effectively utilize them. For instance, in 2019-20 nearly 71 percent of all complaints on health insurance were about customers' inability to get their claims settled.[9] While many of these claims-related issues appear to arise more immediately from claims-based underwriting practices, non-standardised and difficult-to-understand policies, etc.[10] they are indicative of a more fundamental problem with India's health insurance, namely, the disconnect of health insurance from healthcare.

This chapter looks at how to think about reimagining health insurance regulation in India. The first section sets the background by discussing the need for redesigning health insurance contracts in India. In the second section, we propose a pathway of reform that envisions the adoption of managed care models of health insurance regulated through the regulatory system of managed competition. Finally, we lay out our long-term recommendations for regulatory reform to move towards a system that delivers both financial protection and good quality healthcare.

Need for Redesigning Health Insurance Contracts in India

Most health insurance policies currently offered in India, both commercial and government-provided (PMJAY for instance), are designed as hospitalisation-based indemnity contracts. This means that consumers are compensated for the actual financial costs they incur on in-patient care up to a predetermined limit. In this case, insurers play no role in the actual provision of healthcare and patients are free to direct and control their healthcare (along with doctors).

As insurance is typically designed to cover low-frequency, high-impact events to protect consumers from the significant financial burden associated with health expenditures, such an indemnity structure would seem theoretically sensible at first glance.

When designing a health insurance policy, insurers only modify this theoretical construct to account for information asymmetries, be it provider-led (where patients and payors lack the knowledge to resist or challenge medical opinions given by healthcare providers) or consumer-led (where payors have no knowledge of the actual state of consumer health or if they are likely to actively take measures to maintain health or minimise costs when accessing care). This modification takes the form of features such as copays and restrictions on care for pre-existing diseases, among others.

However, we argue that in practice there is more than just information asymmetries to correct for. The very assumption that consumers are rational decision-makers, which is fundamental to this theoretical approach, may be difficult to validate in the healthcare domain.

Firstly, one's health status is a matter about which one may have little information without any prior medical intervention. However, a range of behavioural factors may impede the very seeking of such knowledge.

Secondly, even when such knowledge becomes available, there is a tendency to doubt the doctor's diagnosis and shop around for a second or third opinion (where such a choice is available), exacerbated by a highly fragmented provider landscape.

Thirdly, even if the doctor's diagnosis is trusted, the capacity to recognise that the health condition is best addressed via a combination of preventive care and insurance, cannot be taken for granted on the part of the consumer.[11]

Fourthly, consumers severely undervalue and under-consume primary care and instead wait to see if they fall sick and pay a far larger amount for higher levels of care at that point.[12]

Acknowledging these actual consumer characteristics would then compel us to recognise that a good health insurance product seeks to achieve both good health outcomes and adequate financial protection as tending to one's health cannot be separated from the capacity to pay for such tending.[13]

India's current indemnity insurance design, through its separation of healthcare from financing and a deliberate focus on just the latter, is ill-suited to achieve these twin objectives of good health outcomes and adequate financial protection.

Models of Managed Care and Competition as Alternatives

Recognising the limited role that indemnity insurance can play in actually providing necessary and quality care for enrollees without escalating costs, most health systems around the world have been moving away from pure indemnity structures in favour of health financing models that would simultaneously target financial protection and better healthcare of consumers while checking cost escalation.[14] One such movement has been towards managed care models.

Managed Care Models

Managed care does not refer to a single specific model, but rather "*a variety of methods of financing and organising the delivery of comprehensive healthcare in which an attempt is made to control costs by controlling the provision of services*".[15] Essentially these are models in which payors (insurers) contract with or own selected healthcare providers to offer comprehensive care for members. A healthcare system informed by the basic principles of managed care:[16]

1. monitors and coordinates care through the entire range of services (primary care through tertiary services);
2. emphasises prevention and health education;
3. encourages the provision of care in the most appropriate setting and by the most appropriate provider (e.g., outpatient clinics versus hospitals, primary care providers versus specialists);
4. promotes the cost-effective use of services through aligning incentives (e.g., by capitation of providers, cost-sharing by consumers).

For health insurance to provide better health outcomes and financial protection, we argue that India should adopt these managed care functions when designing health insurance. It should however be noted that despite their more comprehensive approach to financing healthcare, managed care models have their limitations. Take the case of ESIS which by taking on both financing and healthcare provision already has a managed-care structure. However, the scheme performs poorly on access, quality and outcome parameters.[17]

The scheme is rife with concerns of inefficiency and under-provision of care in the absence of strong accountability measures and choices for consumers. Thus, for these integrated structures to produce better financial and health outcomes, it is equally important that consumers be *able to choose* from among products that provide complete offerings. In such a system the role of the regulator is to then ensure that consumers can make an informed and meaningful choice to optimise benefits.

Principles and Functions of Managed Competition

A movement to managed care models would need a complementing regulatory design to produce favourable outcomes. Managed competition offers one such regulatory design to embed managed care entities. Adopting rules of equity, the design of managed competition seeks to ensure universal acceptance without the traditional preconditions of health insurance like risk rating of consumers, differential premiums for consumers with pre-existing diseases and explicit rejection of health insurance coverage to some consumers. Moreover, managed competition aims to create incentives for insurers to prioritise the quality and affordability of services for consumers.

Managed competition was first proposed in the 1980s by health economist, Alain Enthoven in several of his early writings about the American health insurance system.[18] The lack of regulation in the American health insurance system has led to rising costs to the system along with inadequate and inappropriate care for consumers. In his theory of managed competition, he proposed that a sponsor or regulator acting on behalf of the insurance subscribers can create a market of health insurance and regulate the same. In the absence of regulation, insurers can engage in behaviours that might impact consumers adversely.[19] Firstly, insurers could engage in risk selection whereby they enrol healthy (low-risk) applicants and send away sicker (high-risk) applicants to reduce their claims payouts. Secondly, insurers could reject policy renewal for existing customers who have developed a disease during the policy tenure.

Thirdly, insurers could offer health insurance policies that cover select services and hence distinguish themselves from other players in the market. Consequently, they can avoid competition with other insurers that provide the entire suite of healthcare services. The concerned insurer is then free to set prices as well as determine the quality of services to offer.

Lastly, the existing insurers in the market can create entry barriers for other players to restrict competition in the market. In managed competition, using principles of microeconomics, regulators seek to create a competitive market that incentivises equity (which Enthoven terms as equality of opportunity or access) and improvement in price and quality of services (value-for-money competition).[17]

These objectives can be ensured by applying the principles of managed competition. To achieve the first objective of equitable coverage, the regulator institutes certain rules of participation for insurers. All insurers are required to enrol every applicant, charge a uniform premium amount, and provide a basic expansive package of benefits. Compliance with these rules is verified through the regulator's close monitoring of plans' behaviour, for example, patterns of enrolment.

Finally, the theory also recommends employing a compensation mechanism called risk adjustment which aims to equalise risks for the insurer. The fixed premium contributions by consumers are pooled in a common fund. The funds are then transferred to the insurers based on the number of enrollees they cover and the health risks of their enrollees. The latter component is the risk adjustment component. The regulator strives to match the risk adjustment as closely as possible to the additional cost the insurer incurs for a sicker patient.

Consequently, it is expected that the insurers will accept the sicker applicant just as eagerly as they do a healthy applicant. Hence, by setting rules, selecting insurers, monitoring insurer behaviour, and using risk adjustment, the first objective of managed competition – equitable coverage is ensured.

The second objective of managed competition is to create a market where organisations compete by reducing their prices and improving their quality of services. Since the quantum of funds received by each insurer participating in the system is determined by the number of enrolees and the level of their health risks, it is expected that insurers would want to enrol a higher number of members and those categories of members for whom a risk adjustment component is added.

Hence, by informing consumer choices through the dissemination of performance-related information the regulator can encourage competition among insurers to provide consumers value-for-money so that they enrol with them. When it is time to switch insurance plans, consumers should utilise such information and prefer enrolling with those organisations that perform better, prompting insurance-provider entities to compete with each other to provide better quality services.

These principles as described above can be distilled into the following functions: 1. Setting rules of equity to ensure universal coverage; 2. Selecting participating plans to ensure compliance; 3. Monitoring enrolment behaviour to ensure compliance; 4. Creating price elastic demand to encourage value-for-money competition; and 5. Managing risk selection through risk adjustment.

The concept has found application in the national health insurance systems of the Netherlands, Germany, Israel and Colombia. Their experience leaves practical guidelines to consider when adopting managed competition reforms. They also offer insights into the kind of challenges countries may need to look out for in managed competition implementation.

Firstly, the success of a risk adjustment scheme in matching insurer costs for high-risk members is dependent on the number of factors or risk adjusters

it considers. For example, the adjustment may account for the age, sex, and diseases of consumers for arriving at the compensation amount to insurers. This implies that risk adjustment requires constant revisions to match the additional cost to insurers.[20]

Secondly, while all systems provide the option of switching plans at varying regular intervals, such choices may not be effectively exercised as indicated by the low switching rates across countries - 6·5 percent in the Netherlands,[21] 5 percent in Germany,[22] 1-2 percent in Israel[23] and 1 percent in Colombia.[24]

Thirdly, the regulator must provide high-quality performance information to consumers to inform their choices. The nature and quality of such information differ across the health systems. While the Netherlands provides comparative information on health plans,[25] in Germany, Israel and Colombia, the dissemination is limited to provider performance, is relatively nascent,[26] and is provided in an untimely manner,[27] respectively.

Adoption of managed competition would also require robust grievance redress mechanisms to address citizen complaints. Hence, the regulator needs to consistently improve risk adjustment mechanisms, provide good quality information on provider and insurer performance, and develop robust grievance redressal procedures for a managed competition system to work well and produce desired outcomes.

Transforming the Health Insurance Architecture: The First Step

Health insurance in India is regulated by the Insurance Regulatory and Development Authority of India (IRDAI) which was incorporated as a statutory body under the Insurance Regulatory and Development Authority Act, 1999. Currently, only India's commercial health insurance sector is regulated by IRDAI- meaning, schemes including ESIS, CGHS, PMJAY and other state health insurance schemes do not fall within the regulatory purview of IRDAI and are instead managed by other public entities.

The commercial health insurance segment has about seven stand-alone health insurance companies in addition to the health insurance business of non-life insurance companies. Despite being considered a distinct line of business under the Insurance Laws (Amendment) Act, of 2015, health insurance comes under the non-life insurance sector headed by member non-life.[28]

It is also worth noting that only the insurance side of health financing falls within the purview of IRDAI and not healthcare. However, as we argue in this paper, an indemnity insurance structure disconnected from healthcare is unlikely to produce optimum results for consumers. In the near to medium term, we advocate changes to the current system to allow for the emergence

of integrated offerings and better regulatory coordination. In the long term, as managed care becomes the dominant form of insurance contracts, we advocate for a broader regulatory shift to create a system that is based on the principles of managed competition.

Near to Medium-Term Reforms: Integrated Offerings and Regulatory Coordination

For any movement in the direction of integrated offerings for people to choose from, there needs to be space for innovation and piloting. Encouragingly, some innovations are being led by insurers, providers and third parties (including insurance, health tech firms and managed care service providers) in this direction where either insurers contract with primary care centres to provide care (often through third parties) or providers add-in a financing instrument (such as subscriptions) to allow financing of care. However, current regulation is unclear regarding where such contracts fall and how they would be regulated.

When such innovations are being led by providers or third parties, they face other restrictions, all tied to their role in the insurance space. The only ways in which they can enter the space currently is as distributors or insurers. However, both these options come with practical issues. For instance, their functions do not necessarily fit neatly within the current distributor definitions. Alternatively, if they were to enter as insurers they would have to meet the prohibitively high capital entry requirement of Rs. 100 crore.

IRDAI regulation currently only makes space for wellness features to be offered under healthcare plans through network hospitals. While this can be considered a move in the right direction, both the industry and consumers can benefit from allowing for better and more direct merging of insurance and healthcare functions. Allowing commercial insurance and private healthcare providers to act in concert ensures that citizens can choose between more complete offerings such as Kaiser Permanente in the US.

With the emergence of new players in the market, who have been attempting to bridge the gap between insurance and healthcare provision, there is a need for regulation to shift to account for a transformed space.

Similarly, to expand access to voluntary insurance the regulator has to lower entry barriers from the current ₹100 crores at least to the levels required by the European Union (₹20 crores). This follows the recommendation made by the Mirai Chatterjee committee in 2020 to IRDAI.[29] In addition to allowing the entry of multiple smaller players who have been experimenting with innovations in healthcare delivery and finance to offer better products,

such a move would also allow regional and low-income population-focused players to enter this space, as has happened in micro-lending and micro-savings.

For health insurance to be effective, the regulator must have some oversight over the provider landscape, be able to prescribe protocols and processes for them and facilitate data sharing between insurers and providers that would potentially help improve risk assessment, claims management and healthcare quality control. This would require better coordination between IRDAI, the Ministry of Health and Family Welfare and other healthcare regulators. That private healthcare providers do not currently fall under any unified regulator is an added problem to solve here.

For better coordination between healthcare and insurance regulation, we argue that a dedicated separate vertical for health insurance be created within IRDAI. Given the fragmented nature of healthcare, we would go one step further to recommend the creation of a unified healthcare regulator that also regulates all forms of healthcare financing in the medium term.

Long-term Reforms: Setting up Managed Competition Systems

As a long-term strategy for effective regulation of the integrated offerings, principles of managed competition can be leveraged. One way to do this would be for the regulator to set up a health insurance exchange whose features embody a managed competition system with defined and comparable benefit packages, sophisticated risk adjustment mechanisms, high-quality performance information and regular switching options.

Meanwhile, managed competition can also enable the redesign of healthcare sub-systems such as ESIS and state-level universal health insurance schemes. By employing the strategic regulatory mechanisms under managed competition, managed care entities can be incentivised to perform better.

Moreover, the implementation of managed competition in systems will do away with the risk rating procedures, enrolment rejections due to pre-existing diseases and differential premium amounts based on consumer risks. The gradual adoption of these principles across health systems has the potential to improve outcomes for consumers.

The performance of a managed competition system relies heavily on state capacity, the presence of active regulation, the institution of data privacy safeguards, and the development of sophisticated systems of risk assessment. The piloting of such a system within a local context, perhaps in a state which has made significant strides in delivering universal health coverage and has political buy-in for the same can be the first step in testing how this

model may play out in the Indian context. This exercise can also shed light on the prerequisites for such a system and how to develop them.

As observed in other countries, such systems are gradually improved through the addition of more variables for risk adjustment and regulatory reform. These considerations along with those of the local context are important for yielding effective outcomes from such reform.

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CHAPTER 18

Road Safety in India: A Public Health Challenge

Introduction

Road transportation is a dominant mode of transport in India[1] in terms of traffic share and its contribution to the national economy. Therefore, India is increasing its road network very rapidly. Road transport is a subject in the concurrent list as per the Indian Constitution. Consequently, both Central and state governments can make laws related to transportation and road safety. Road-owning agencies under the Government of India usually construct expressways and highways that are four-lane or more, whereas state road-owning agencies construct intrastate two-lane roads. Several other road-owning agencies at the state level construct rural and city or town roads.

Making new roads or maintaining the existing roads is a socio-economic and political issue in India and several times elections are fought and won on that basis as well. Putting together all types of road lengths, India is in the second position in terms of having the largest road network, after the USA, which had 66.45 lakh km of road networks in 2017. India's road network has grown 59 percent to become the second-largest in the world in the last nine years. India has nearly 64 lakh km of total road network and the National Highways network alone stood at 145,240 km in 2022-23 compared to 91,287 km in 2013-14.

The number of vehicles[2] in India has also increased manifold. India is the third-largest automobile manufacturer in the world in 2023. Indian motor vehicle manufacturers produced 22.65 million motor vehicles in 2020-21 (Apr-Mar), though it was a substantial decrease from the record of 30.91 million units sold in 2018-19. The total number of registered motor vehicles was 326 million in 2020.

This chapter has been contributed by George Cheriyan, Director and Madhu Sudan Sharma, Senior Programme Officer at CUTS International

Though making new roads is a strong indicator of progress and every government wants to construct as many kilometres of new roads as possible, regrettably, ensuring the safety of common road users on these roads is not the utmost priority. But, as we know, there is a negative externality of expansion in road network and motorisation in the country, resulting in an increased number of road crashes, road traffic injuries and road crash deaths. Every crash, injury or death results in huge socio-economic loss to the nation, which indirectly neutralises the economic benefits of increased road networks and development arising due to this. There are myriad reasons for these road crashes.

One critical issue is the inadequacy of road design and engineering[3] as per local geographic and climatic conditions, including quality of material and construction, pathetic conditions of roads and vehicles, especially single-lane and having sharp curves, and weak accountability of road owning agencies regarding road safety, are the serious lacunas in the road construction process.

Other key challenges are poor enforcement of road safety laws, behavioural risk factors like overspeeding, driving under the influence of alcohol or drugs, riding without wearing a helmet or putting on a seatbelt and child restraint systems are some of the leading causes of road crashes and resulting deaths. Talking over mobile phones while driving, overloading to save on the cost of transportation and tiredness of drivers make Indian roads very risky. Other than the key risk factors mentioned above, weak vehicle safety standards in India also have become one of the major causes of road crashes in India.

Apart from these key risk factors, another critical concern is the weak vehicle safety standards in India., which have emerged as a major contributor to road crashes. These inadequate safety standards not only jeopardise the well-being of vehicle occupants but also pose a substantial threat to Vulnerable Road Users (VRUs).[4]

VRUs including pedestrians, cyclists and two-wheeler riders, disproportionately bear the burnt of road crashes and account for more than half of all road crash deaths and serious injuries in the country. It is often the poor, especially male road users of working age that constitute the category of VRUs. Hence, there is an urgent need to plan Indian roads and safety standards for vehicles.

In 2014, crash tests carried out by the Global New Car Assessment Programme (Global NCAP)[5] revealed that some of India's top-selling car models have failed the UN (United Nations) frontal impact crash test. Unfortunately, the awareness regarding the importance of safety features like airbags, anti-lock braking systems, etc., is seriously deficient for Indian

consumers. After developing testing facilities and airbag manufacturing in India itself, vehicle safety features such as six airbags, electronic stability control, effective Car Crash Standards and advanced braking should be made mandatory and enforced strictly so that vehicle safety is enhanced and people's lives on roads are saved.

It is heartening to note that taking all the above-mentioned scenarios and road safety challenges into consideration, the new Motor Vehicle Amendment Act, 2019,[6] and its corresponding rules came into force in September 2019. This MVA Act, 2019, and its rules have many new regulatory provisions for institutional framework, enforcement and behaviour-related road safety issues and their solutions.

To effectively address the risk factors contributing to road crashes the Motor Vehicles Amendment Act emphasises the importance of better enforcement and electronic monitoring of the traffic management system. Five key risk factors for common road users and Vulnerable Road Users (VRUs) need to be regulated effectively through better enforcement and more and more electronic monitoring of the traffic management system. Several new initiatives like automation of licencing, driving tests, fitness testing, crash investigations, E-training or education, e-challenging and e-enforcement need to be taken so that transparent, accountable and effective services can be ensured in the road safety domain. Proven speed detection devices such as radar and speed detection camera systems need to be installed.

More and more traffic calming measures and physical safety measures on roads need to be taken. Proper speed humps, raised platforms, roundabouts and optical road markings can reduce road accidents to a great extent. Public education, better emergency services and effective enforcement of all the road safety provisions of the MVA Act, 2019, need to be enforced at all levels to ensure road safety for all road users.

Road Safety in India: How it is a Public Health Issue?

Bringing up new roads is good for everybody and better roads in rural areas have helped in increasing accessibility of maternity & child healthcare and general health facilities. However, disregard for road safety on these roads has resulted in a high level of mortality and morbidity and has become a major public health challenge[7] worldwide, including in India.

Globally, every year, road traffic crashes[8] kill an estimated 1.2 million people. The figure for the injured is over 50 million which will significantly increase as per future estimates over the next decade. The situation is particularly critical in low- and middle-income countries (LMCs) where about 86 percent of deaths from road traffic injuries occur even though these

countries account for only 40 percent of all motor vehicles. The situation has been worsening year by year since 1987 till 2021.

As per the 'India Road Accident Report', 2020,[9] India recorded a total of 3,66,138 cases of road crash incidents across its 29 states and 7 union territories during the year 2020 which left around 1,31,714 persons dead and 3, 48,279 injured. The crash rate in India in 2020 may be slightly less due to the lockdown imposed because of the COVID-19 pandemic but the rate of road crashes seems much higher in the subsequent years. In the year 2019, the country registered 4,49,002 road crashes causing the death of 1,51,113 and injury to 4, 51,316 people.

The majority of the victims are men aged between 15 and 40 and economically active and deaths of breadwinners often push the families into deep poverty. Road accident injuries often overwhelm the emergency and casualty departments of most hospitals, which results in their coping poorly with the patient load. A significant proportion of non-fatal injuries result in traumatic brain damage and substantial disability.

Road Traffic Accidents (RTAs)[10] are the major preventable public health problems but, unfortunately, these are on the rise. Injuries due to RTA as one of the prime causes of the 'global burden of diseases' was in the 10th position in the year 2002, but according to 'Global Status Report on Road Safety 2013' it is in the eighth place and expected to be at the fifth place by 2030 if trends continue at the same pace. RTA is defined as, "An event that occurs on a way or street open to public traffic, resulting in one or more persons being injured or killed, where at least one moving vehicle is involved". "A collision between vehicles and pedestrians, animals, and geographical or architectural obstacles can be also termed as RTA".

According to "The National Crime Records Bureau, Ministry of Home Affairs,"[11] RTA accounted for about one-third of all unnatural causes of accidental deaths in the year 2020.

Every year, deaths reported due to RTA in India are the highest and account for 6 percent of the global burden, though it has only 1 percent of the vehicles globally. Total losses incurred due to road accidents amount to 3.14 percent of the GDP in India.[12]

Experts caution that the actual estimate of mortality as well as injuries due to RTA could be much higher than what is reported, which could be because of underreporting. As per the World Health Organisation (WHO), RTA is the second-most prime cause of mortality among 5-29-year-olds. The deaths due to RTA in India account for twice more than the deaths caused due to malaria, HIV, cholera, etc., all put together.

According to the Ministry of Road Transport and Highways' 2020 report, there were a total of 1,31,714 deaths due to road accidents in India.[13] Speeding accounted for 69.3 percent of deaths. Non-wearing of helmets resulted in 30 percent deaths and non-use of seatbelts caused 11.5 percent of deaths.

According to the World Bank's report, "Traffic Crash Injuries"[14] put a huge socio-medico-economic burden on society. About 50 percent of women were severely affected by the decline in their household income after a crash. About 40 percent of women reported a change in their working patterns post-accident, while around 11 percent reported taking up extra work to deal with the financial crisis. The income decline for low-income rural households (56 percent) was the most severe compared to low-income urban (29.5 percent) and high-income rural households (39.5 percent).

In India, the cost per seriously injured person comes at ₹3.64 lakh, while the cost per minor injured person stands at ₹77, 938 and the cost per death is estimated at ₹91.16 lakh, so death cost is 100 times more than injury cost. It shows that if one road accident death is prevented then the nation can save around ₹90 lakh per person[15], but the total cost of all the accidents, injuries and deaths is a tremendous burden on the society and the nation.

Regulatory Aspect of Motor Vehicles Amendment Act, 2019

There have been several Motor Vehicle[16] related legislations in India, passed over the years, to ensure better road safety.

The first central legislation, the Indian Motor Vehicles Act of 1914, was passed under British India. The Act enabled the local governments to regulate enforcement and to ensure the registration and licensing of vehicles and motorists to maintain road safety. The Act was adhered to until the Motor Vehicles Act in 1988.

The Motor Vehicles Act of 1988 made licencing of the motorists and registration of the vehicles mandatory. The Act introduced a Learner's license for all the drivers willing to obtain a licence and mandated the use of the "L" board and the company of an instructor when driving in a public place. The Act also laid down rules and regulations for permit control, traffic regulation, motor insurance and penalties. No person under the age of 20 is allowed to drive a vehicle in a public place. A learner's licence or driving licence should only be issued if he or she meets the eligibility requirement. With the Act, the limitations on third-party motor insurance were lifted and a cap for third-party liabilities up to ₹10 lakh for death and ₹5 lakh for serious injuries was proposed. Viewing drastic change in the traffic situations the Act was amended in 2019.

The Motor Vehicles (Amendment) Act of 2019 was implemented on September 01, 2019. Following are the sections which have a direct bearing on the effective regulation of the related issues and challenges to road safety. Section 118 is related to driving regulations, Section 112 regulates excessive speed, sections 128 and 129 regulate safety measures for drivers and pillion riders and wearing of protective headgear, Sections 183 and 184 regulate dangerous driving and at excessive speeds, section 185 regulates the behaviour of drunken driving, sections 189 and 190 regulate racing and trails of speed and using vehicles in unsafe conditions.

There are other sections like Section 194 regulates wearing seatbelts, using child restraint systems, driving over-crowded vehicles and Section 196 regulates violations of driving uninsured vehicles, etc.

The 2019 amendment introduced hiked penalties[17] for traffic violations which are risky for the common road users as well as for the drivers themselves. The penalties for driving/riding without a licence, driving/riding under the influence of an intoxicating substance, excessive speeding, driving without wearing a seat belt, helmet or headgear, driving/riding without insurance of the vehicle, dangerous driving/riding and jumping red light, driving/riding while talking on the handheld mobile phone, speeding & racing, not giving way to emergency vehicles like ambulance and fire vehicles, overloading two-wheelers, juvenile offences, driving/riding despite disqualification and overloading of passengers, really help in creating deterrent effect among road users.

The amendment also introduced provisions to regulate the offences committed by enforcing authorities or paying bribes, unauthorised use of a vehicle without a valid license, disobeying orders of enforcement officials, driving a vehicle without a permit, oversized or modified vehicles, overloading, using horns in silence zones, driving without registration of any vehicle and last, but not the least, are the main offences being committed by various road users and all these offences are directly related to behaviour or conduct of the road users or drivers or the riders.

To ensure road safety and to save the lives of crash victims, regulating the 'Golden Hour'[18] is highly critical. Here 'Golden Hour' means the period lasting one hour following a traumatic injury during which there is the highest likelihood of preventing death by providing prompt medical care after the accident. For this, the Government of India and some state governments have well-defined regulations and schemes of cashless and often free treatment for golden hour and also for rewarding good behaviour of those helping the crash victims.

There is a provision for safeguarding Good Samaritans[19] from any liabilities in civil or criminal proceedings. For instance, any injury or death resulted from the Good Samaritan's negligence in acting or failing to act while rendering emergency medical or non-medical care or providing any assistance.

As per Section 147[20] of the Motor Vehicles Act, there has to be an insurance policy against any liability in respect of the death of or bodily injury to any person arising out of the use of the motor vehicle in a public place. This provision helps the accident victims to get some benefits of insurance.

The 2019 Amendments also regulate the traffic in terms of lane driving, right of way, left, right and U-turns, and taking precautions at intersections, roundabouts, an indication of signals, traffic control signals, manual traffic control, overtaking, merging in traffic, speed management, keeping a safe distance, restriction on driving backwards or reverse direction, level crossing, entering a tunnel, a vehicle going uphill to be given precedence, proper stoppage on roads, use of horns at silence zones, passing along formation, vehicle lights, interacting with the other drivers, use of mobile phones or communication devices and action in case of minor or major accidents, etc.

The Act also has well-defined provisions for vehicle aggregators.[21] The amended provision provides that, to issue a license to an aggregator, the state government should follow guidelines as laid down by the Central Government. MoRTH has issued Motor Vehicle Aggregators Guidelines, 2022, which regulate aggregators' eligibility conditions, compliance with various provisions, fares, ease of doing business, customer safety, drivers' welfare, shared mobility, reducing traffic congestion, etc., which were completely missing earlier.

Though there are some good regulations[22] related to road safety, these need to be enforced effectively, then only we can ensure road safety on all kinds of roads either rural or urban or during day or night.

Regulatory Gaps in the Way of Ensuring Road Safety

Several regulatory gaps exist in the way of ensuring road safety at all levels in India, such as:

- The National Road Safety Board needs to be formed as provided under the law. Since the NRSB would be an apex advisory and regulatory body on road safety for Central and State Governments, therefore, not only its formation but also its effectiveness would be very crucial.

- The national-level standards or benchmarks[23] for effective enforcement of all the road safety provisions and effective emergency care of all the

trauma care victims of all the national and state highways need to be formulated by the Bureau of Indian Standards.

- The national road safety action plan, which is time-bound and has well-defined accountability provisions for the responsible officials, needs to be made by the Central and state governments.

- Municipalities or Panchayats need to effectively regulate non-motorised transport vehicles and vulnerable road users as per their mandates under the Motor Vehicle Act.

- As per the Supreme Court Committee on Road Safety Guidelines, a nodal agency for road safety has to be formed at the national and state levels for effective regulation. Though these nodal agencies have been formed they are weak bodies with inadequate resources.

- Though the Centre and some states have set up road safety funds, there are no clear guidelines for its effective regulation. So there is an urgent need to formulate road safety fund guidelines so that funds are better managed and irregularities are avoided.

- To ensure the safety of child pillion passengers aged between nine months and four years, their helmets need to be standardised on the lines of European standards.

- Though there are prescribed publishments and fines for driving under the influence of drugs, there is no mechanism to determine that the driver is under such an influence because of the nature and variety of some drugs. This is a huge regulatory challenge to ensure road safety.

Recommendations to Address Regulatory Challenges

Road safety is a public health and regulatory challenge in India that needs to be regulated effectively and efficiently in the future to prevent it from further worsening. Following could be some potential recommendations to address these regulatory and enforcement-related challenges:

- Strengthen the institutional framework of road safety and set up a well-functioning National Road Safety Board.

- It is necessary to make standard road designs, conduct routine road safety audits, and make long-term master plans for the city transport and traffic, besides doing audits of detailed project reports, engineering plans, and schemes and correcting the deficiencies that may cause

accidents. The designs of the expressways and highways need to take into account the local traffic needs of pedestrians, vulnerable road users, animals, and other traffic requirements with proper fencing and elevation to prevent animals from coming onto roads and set the stage for crashes.

- The design, construction, and operation of different classes of roads lie with different government agencies, resulting in a fragmentation of responsibility. There is a need to enhance coordination among such different authorities.

- Special enforcement plans and strategies for behavioural risk factors need to be devised. Seat belts in cars and crash helmets for cycles and motorcycles should be enforced strictly. Similarly, drinking and driving need to be drastically controlled.

- The safety of vulnerable road users like pedestrians, cyclists and two-wheelers needs to be ensured and appropriate road markings, signals and maintenance of roads need to be done.

- A strong road injury surveillance system needs to be developed in India. Therefore, there is a need for accurate data collection systems which can feed into planning interventions and designing better and more appropriate road systems.

- Right to emergency care and strengthening the prevailing pre-hospital services should be ensured.

- A robust integrated emergency care service system with adequate infrastructure for crash victims, especially within the golden hour, which can comprehensively address all medical and surgical emergencies inclusive of trauma-related care should be developed.

- Central and State Governments should come up with exhaustive trauma care policies, innovative plans, programs and schemes to save lives on roads.

- More and more education on traffic rules needs to be done. There is a basic lack of knowledge of road safety rules among users.

- Good discipline and behaviour on the road through abiding by traffic rules should be promoted and incentivised in various ways.

- The Government of India, in consultation with all state governments, should adopt the Vision Zero Approach for road safety.

- National and state road safety targets should be linked with the concerned Sustainable Development Goals (SDGs).

- Electronic monitoring data of all the highways from all the command centres should be shared with the state enforcement agencies for effective law compliance.

- National and state governments should work in convergence with the United Nations System to improve road safety as per global standards and norms. International commitments create political will at the highest level which is good for road safety.

- All the proposed Bharat New Vehicle Safety Assessment Programme (BNVSAP) provisions should be made mandatory as early as possible in the interest of common road users.

- Safe vehicles should be a pre-requisite for road safety and hence the role of vehicle manufacturers and Original Equipment Manufacturers (OEMs) is crucial. Standard Child Restraint Systems (CRSs), Standard Child helmets, Anti-lock braking systems (ABS) and airbags should be available in all variants of cars in India.

- The use of artificial intelligent systems, such as fatigue detection systems and intelligent brake systems, should be promoted, which can lead to a reduction in road crashes.

Endnotes

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CHAPTER 19

Ambulance Services in India – Are the Sirens Loud Enough!

Introduction

India has one of the highest road traffic fatality rates: approximately 18.9 per 1,00,000 population, compared to 8.7 in high-income countries.[1] Nearly 1, 51, 113 people died, and 4,51,361 were injured because of road accidents in 2019. National Institution for Transforming India (NITI) Aayog, a National level think tank of the government of India's report on emergency and injury care at district hospitals indicate that in India, with more than 1.5 lakh road traffic-related deaths, 98.5 percent of all ambulances are transporting dead bodies, 90 percent lack equipment and 95.0 percent have untrained personnel. It also states that most of the doctors in the emergency departments lack formal training in Emergency Medical Services (EMS), and nearly 30 percent of deaths occur due to delays in emergency care.[2]

Even in cases of childbirth, delays in reaching health facilities tend to range from two hours to three days, due to factors such as long distances and transportation difficulties-contributing to 33.8 percent of the total maternal deaths.[3] Ambulances played a crucial role during the COVID-19 pandemic. However, they are yet to receive the rightful attention in India. This paper attempts to examine road ambulance services in India about their availability, standards, quality and charging practices, and the regulations associated with them.

Ambulances in India

In India, ambulances are used primarily in three types of situations: during emergencies, to prompt the transfer of trauma patients to the nearest medical facilities; for transporting patients to and from their residences and hospitals;

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and, for inter-hospital transfers. The most common mode of patient transportation is a road ambulance, which could be two- to three-or four-wheeler vehicles, depending on geographical location, terrain, and type of emergency. National Ambulance Code (NAC), under the aegis of the Ministry of Road Transport and Highways (MoRTH), the Government of India (GOI) classified road ambulances (Table 19.1) for registration under the provisions of the Motor Vehicles Act, 1988 (MVA, 1988).

Table 19.1: Types of Ambulances Classified under the National Ambulance Code and their Minimum Requirements

Ambulance type	Functionality	Requirements as per NAC
Type A Ambulance, Medical First Responder	Provide emergency, out-of-hospital medical care to patients when stationary and cannot transport patients in a supine state or provide medical care inside the vehicle.	Only transport patients are not required to provide medical care inside the vehicle.
Type B Ambulance, Patient Transport Vehicle	For transporting patients from or between places of treatment, not expected to become emergency patients.	Required to have basic professional equipment for first aid and nursing care.
Type C Ambulance, Basic Life Support (BLS) Ambulance Vehicle	For transport and treatment of patients requiring non-invasive airway management or basic monitoring.	Required to have medical equipment for basic treatment and monitoring of patients to provide pre-hospital care.
Type D Ambulance, Advanced Life Support (ALS) Ambulance Vehicle	For transport and treatment of emergency patients requiring invasive airway management or intensive monitoring.	Required to have equipment for advanced treatment and monitoring of patients to provide pre-hospital intensive care.

Sources: *Automotive Industry Standard: Constructional and Functional Requirements for Road Ambulances (National Ambulance Code)*, 2013, available at: http://www.nisc.gov.in/PDF/AIS_125.pdf

Entities Providing Ambulance Services

The Government, Hospitals, Private Companies, Charitable Organisations, Religious Institutions, and Political parties are a few of the entities that provide ambulance services in India. The Government's National Health Mission (NHM) operates National Ambulance Services (NAS) across most states and union territories. They provide free emergency transportation with the Dial-108 model (Emergency Response System), which has one ambulance positioned for every 1,00,000 population. Dial-102 (Patient Transport Services) is a service for pregnant women and newborns. Some states also use empanelled vehicles for transporting pregnant women and children, such as Janani Express in Madhya Pradesh and Odisha, Mamta Vahan in Jharkhand, and Nishchay Yan Prakalpa in West Bengal.[4,5]

The National Highways Authority of India (NHAI), GOI has deployed approximately 550 ambulances on national highways.[6] Additionally, it operates the Incident Management Services, i.e., the provision of an ambulance, a patrol vehicle and a tow-away crane on national highway stretches of at least 60 km charitable institutions have been at the forefront of providing ambulance services in India. Private organisations work in partnership with state governments, hospitals and NGOs to offer ambulance services.

For instance, Gunapati Venkata Krishna, Emergency Management and Research Institute and Ziqitza Health Care Limited offer fleets of 14,197 (GVK - EMRI (Gunapati Venkata Krishna – Emergency Management and Research Institute) (and 3643 (Ziqitza Health Care Limited:http//zhl.org.in) ambulances hospitals and NGOs to offer ambulance services. For instance, Gunapati Venkata Krishna (GVK) Emergency Management and Research Institute and Ziqitza Health Care Limited offer fleets of 14,197 (Gunapati Venkata Krishna – Emergency Management and Research Institute) and 3643 (Ziqitza Health Care Limited: http//zhl.org.in) ambulances, respectively.

While political parties do provide ambulance services, they are often used for the party's publicity. They display their party's logo and leaders' photos, even though it goes against the regulatory protocols of displaying signs unrelated to ambulance services.[7.] The current digital-led healthcare has also promoted the uberfication of India's ambulance services, with ambulances now available via online bookings in metropolitan cities such as Delhi, Hyderabad and Bengaluru.[8]

Availability

The recommended ambulance-to-population ratio is one road ambulance per 1,00,000 population in the plains, and one per 70,000 population in hilly terrain or tribal areas.[9],[10],[11] Several sources provide information on ambulance availability in India. The data from these varied sources, however, seems

inconsistent. For instance, there is variation in the data sets provided by MoHFW and MoRTH.

According to MoRTH's Road Transport Yearbook (2017–2018 and 2018–2019), nearly 52,740 private commercial vehicles were being used as ambulances as per their primary permit, valid up to 31 March 2019.[12] However, further inspection of data from MoRTH shows that this figure of 52,740 ambulances may have also included public ambulances empanelled under NHM. According to MoHFW, NHM supports 10,993 and 9,955 ambulances under the Dial-108 and Dial-102 models, respectively, and 5,126 empanelled vehicles in some states.

We came across three separate sources, all maintained and published by the MoHFW, which provide differing information on the type and the total number of ambulances in India.

The state-wise data (Table 19.2) too seems erroneous on multiple accounts. It indicates that the number of existing ambulances exceeds the stipulated numbers, which seems unlikely. Moreover, the data from large states such as Bihar, Madhya Pradesh, Rajasthan, Punjab, Odisha, and Uttar Pradesh are undetermined. This conflicts with NHM's report that records Uttar Pradesh as having one of the highest numbers of ambulances in India, i.e., 4,720 ambulances.

1 Data on ambulances are reported under two categories, (i) Emergency Response System vehicles operational in States/ UTs under NHM (102/ 104/108 and others) and (ii) Ambulances functioning in the State/UTs other than NHM (at PHC/CHC/SDH/DH) and is sourced from Quarterly National Health Mission Report, September 2021. In MoHFW, GoI, available at https://nhm.gov.in/index4.php?lang=1&level=0&linkid=457&lid=686

   There is no information in the report on what *other than NHM* covers in the category "Ambulances functioning in the State/UTs other than NHM (At PHC/CHC/SDH/DH)". It may imply private ambulances stationed at public healthcare facilities and not financially supported by NHM.

2 The number of Commercial Vehicles (Private vehicles) in use as road ambulances (as per Primary Permit Valid as of March 31, 2019) is sourced from the Road Transport Year Book (2017-18 & 2018-19), MoRTH, GoI, available at https://morth.nic.in/sites/default/files/RTYB-2017-18-2018-19.pdf

As per the 254th Rajya Sabha session, there are nearly 1,691 advanced life support (ALS) ambulances in India.[13] However, a news article mentions approximately 1,601 ALS and 13,535 basic life support (BLS) ambulances in India.[14]

There are multiple reasons which have led to the discrepancies that occur in the data on ambulances in India. The most prominent ones among these are the lack of registration standards for issuing a license as an ambulance, and the absence of a single national database to store and showcase relevant data. India does not possess a platform that serves as the official repository of verified information on the number of ambulances distinguished by their type (A/B/C/D), by services BLS, ALS or patient-transport vehicles), by distribution (public or private), or by geography (urban, rural or tribal).

Additionally, while MoRTH's figure of 52,740 ambulances translates to the availability of one ambulance per 23,000 populations nationally, it does not factor in any inter-district variation, urban-rural geography, density of population or district-wise proportion of emergency cases.

The 1989 Supreme Court India judgment mandating (***The Supreme Court of India judgment (1989) mandated the provision of emergency medical care by hospitals regardless of a patient's medico-legal status under Article 21, Right to Life, the Constitution of India***) provision of emergency medical care by hospitals regardless of a patient's financial and medico-legal status to the current network of free transportation under Dial-102 and Dial-108 models, the emergency medical services as evolved both operationally and geographically. However, there is evidence to show that the available ambulance services are inadequate and insufficiently efficient to deliver prompt patient transport services.

The Comptroller and Auditor General (CAG), GOI reports from Jammu and Kashmir (2018), Arunachal Pradesh (2019), Karnataka (2019) and Bihar (2020) indicate insufficient numbers, shortages and uneven distribution of ambulances and essential equipment. According to the Jammu and Kashmir (2018) CAG report, 102 ambulances were not operational for more than three years.[15] The Karnataka CAG report (2019) observed a severe ambulance staff shortage in the state, which further impacted ambulance services.[16]

In the area of ambulance services transporting pregnant women, a study revealed that less than one-fifth of pregnant women used ambulances—based on the data from Himachal Pradesh, Andhra Pradesh, Telangana, Chhattisgarh, Gujarat, and Assam (2013–2014).[17]

Table 19.2: State-wise Availability of Ambulances in India

	Emergency Response System vehicles operational in States/ UTs under NHM (102/104/108 & others), 2021	Number of Ambulances functioning in the State/ UTs other than NHM (At PHC/ CHC/ SDH/ DH), 2021	Commercial Vehicles (Private vehicles) in Use (as per Primary Permit Valid as of 31 March 2019)
India	**27810**	**11660**	**52740**
Andaman & Nicobar Islands	1	52	0
Andhra Pradesh	628	120	243
Arunachal Pradesh	240	113	21
Assam	1035	0	2615
Bihar	1202	164	1
Chandigarh	6	8	0
Chhattisgarh	625	400	2
Dadra Nagar Haveli and Daman & Diu	11	27	67
Delhi	229	165	0
Goa	55	72	0
Gujarat	636	1510	0
Haryana	501	0	0
Himachal Pradesh	329	200	1104
Jammu & Kashmir	493	611	3476
Jharkhand	2140	271	11
Karnataka	909	777	10960
Kerala	315	447	7245
Ladakh	18	81	0
Lakshadweep	0	0	0
Madhya Pradesh	1460	0	1
Maharashtra	3611	3622	14533
Manipur	43	24	*30*
Meghalaya	50	16	312
Mizoram	65	9	43
Nagaland	80	12	0
Odisha	1131	280	0
Puducherry	11	43	0
Punjab	242	439	0
Rajasthan	1335	363	0
Sikkim	9	31	155
Tamil Nadu	1153	950	11347
Telangana	624	362	45
Tripura	50	50	0
Uttar Pradesh	4720	0	0
Uttarakhand	388	160	529
West Bengal	3465	281	0

These abysmal usage rates could be attributed to delays in transportation- ranging from two hours to three days- contributing to 33.8 percent of the total maternal deaths. This is despite the various NHM schemes to improve the transportation of pregnant women, especially in rural areas.

The chute time (***Chute Time is the time between the assignment of an ambulance and the moment it starts moving towards the scene***) for Dial-108 ambulances in Karnataka was more than the specified one minute in 85.0 percent of cases, and up to 100 minutes or beyond in some cases. The response time (Response time is the total time taken from assigning an ambulance to its arrival at the scene of emergency; it is a combination of triage time, chute time and travel time.

The standard norm is a response time of 20 minutes for urban areas 30 minutes for rural areas and less than 10 minutes in cases of for cardiac, respiratory and stroke cases) for emergency cardiac, respiratory, stroke and accident cases was more than 10 minutes in 60.0 percent of the cases, against the stipulated 10 minutes. Approximately 50 percent of the trauma patients were admitted to a hospital after the golden hour, the first hour after the injury, when the emergency treatment was most likely to be successful.[18]

In Madhya Pradesh, Dial-108 ambulance services took between 41 and 47 minutes, against the standard norm, to reach a case.[19] Moreover, a hospital-based analysis showed that the average time taken for road traffic accident victims to reach health facilities was three hours, and only 55.0 percent of the cases were reached within the golden hour.[20]

Registration and Licencing

Motor Vehicles Act, 1988 (MVA, 1988) applies to all regions across India. The state governments constitute their respective State Transport Authority (STA) and Regional Transport Authority (RTA) to exercise the powers and functions specified under the MVA, 1988 and Central Motor Vehicles Rules, 1989 (CMVR, 1989).

In 2011, a working group on emergency care, set up by the MoRTH, observed that the concept of an ambulance is missing from the Indian legislation. Limitations in the MVA, 1988 allowed goods and passenger vehicles to function as ambulances without essential safety features such as occupant restraints, certified electrical systems, etc. The working group hence recommended the need for the National Ambulance Code (NAC). This code formulated the constructional and functional requirements for road ambulances, which were notified in September 2016 via the Central Motor Vehicles (Ninth Amendment) Rules, 2016.

It also defined a road ambulance as a ***"specially equipped and ergonomically designed vehicle for transportation and/or emergent treatment of sick or injured people and capable of providing out-of-hospital medical care during transit or when stationary, commensurate with its designated level of care when appropriately staffed".***

However, their dedicated guidelines for the registration of road ambulances still do not exist in India. Anyone who has address proof along with certificates of vehicle's sale, insurance, and roadworthiness can apply for registration as an ambulance with the RTA's office, which is the nodal office for registration of all road vehicles. The RTA also holds the authority to suspend or cancel the certification. No specialised training or minimum educational qualifications is required to acquire a licence to drive an ambulance. The RTA's inspecting authority is solely required to inspect the vehicle physically at their office before granting the registration, which is valid for 15 years from the date of issuance.

States and union territories have the authority to set their own rules and standards for issuing licences to drivers (Section 28); for construction, maintenance (Section 111) and registration of road ambulances (Section 65); and, to decide about penalties — all within the scope of the Central Act.

Equipment and Facilities

Numerous studies have raised concerns over the lack of standards for a vehicle to be deemed an ambulance. A review conducted by Centralised Accident and Trauma Services (CATS) Delhi in 2018 showed that out of 265 state-run ambulances, only 31 had ALS facilities such as defibrillators and ventilators, approximately 60 were non-operational due to mechanical faults, and nearly 155 were older than six years. During the second wave of COVID-19, in 2021, the demand for private ambulances in Delhi increased fivefold compared to the previous months, amidst a severe lack of sufficiently equipped public ambulances.[21]

National Ambulance Code has specified minimum requirements in ambulances depending on their type: A, B, C and D road ambulances (Table 19.1*)*. Several types of equipment, most of which do not apply to Type A ambulances, are recommended. These include patient handling equipment such as stretchers, undercarriages, and vacuum mattresses; immobilisation equipment such as a set of fractures and traction sets; suction oxygen therapy equipment, i.e., portable oxygen, stationary oxygen, and mouth-to-mask ventilator with oxygen inlet; diagnostic equipment; various drugs; infusion material; equipment for the management of life-threatening problems; and personal-protection equipment. In addition to the necessitated equipment listed by the

NAC, supplementary devices may be introduced depending on the local needs of the state or district.[22]

It is the responsibility of the owner or the operator of the ambulance to ensure compliance with these regulatory requirements mandated by the NAC.

Ambulances supported by NHM under the National Ambulance Services have also specified details of more than 30 types of equipment, such as foot-operated and portable electric suction pumps, laryngoscopes, oxygen cylinders, etc., along with terms of their use, physical and technical characteristics, warranty, documentation, and more.[23] This requirement is advisory and not legally enforceable, except in the case where there is an agreement between ambulance operators and NHM.

NAC has also mandated guidelines for the physical appearance and clear visibility of ambulances on the road (Table 19.3). The Motor Vehicles (Driving) Regulations, 2017 prescribe that vehicles designated by the state government for emergency services, including road ambulances, should operate the sirens and flasher lights only when the vehicles are responding to emergency calls or alarms. When the siren and the flasher are on, the ambulance has the right of way over all the other vehicles. Furthermore, all road ambulances are exempted from the mandatory speed governors, i.e., speed-limiting devices or speed-limiting functions, as per Rule 118, CMVR (Amendment), 2015.

Communication Systems

People can call 102, 108, 112, 1033 and several other phone numbers for local and regional ambulances operated by the state governments and private operators. However, during emergencies, people often end up calling multiple helplines before they connect with the relevant ambulance services.[24] Also, India lacks standard protocols for seamless communication during ambulance transfer and pre-hospital care triage.

CMVR, 2016 introduced the Vehicle Location Tracking and Emergency Alerts System (VLTS), which includes fitting tracking devices in public-service vehicles and setting up a command and control centre monitored by the state transport department. National Informatics Center has been working on this with some states. For example, the command and control centres (***The Command and Control Centre is an IT-based monitoring system bringing various public services (all civic such as traffic and essential services such as police, fire, ambulance, disaster management, etc***.) across the city in one place for their management and coordination with each other) are operational in Uttarakhand, Goa and Rajasthan, for ambulances only.

Table 19.3: Recognition and Visibility of Road Ambulances as per the National Ambulance Code

Section	Characteristics
Colour	• The complete exterior colour of the road ambulance should be brilliant white (RAL Code - 9010) (***RAL code is a colour matching system which defines colours for paint, coatings, and plastics***) including front, rear and side bumpers.
Conspicuity Improving items	• This includes all markings, stripes and symbols on the road ambulances and should be in brilliant red (RAL code - 3024). • Mandatory to display the word "AMBULANCE", the Star of Life symbol and the emergency number on the vehicle. • "AMBULANCE" should be placed on a contrasting colour, red on white background (side of vehicle) and red on yellow background (front and rear end of vehicle) • "AMBULANCE" markings must follow a 7:1 length-to-height ratio and in mirror image to allow reverse reading for drivers ahead. • "FIRST RESPONDER" shall be used instead of "AMBULANCE" in Type A. • The ambulance calling number (YYY) must be displayed on the side and back. • Standards of colour and conspicuity-improving items do not apply to Type A road ambulance
Emblems	• Signs, symbols, or markings not included under conspicuity-improving items, such as government/ private/operator signs, and corporate identities, are only allowed in a non-reflecting manner. • Their size cannot be more than 60 percent of the "AMBULANCE" markings.
Warning lights	• Type A and B road ambulances are required to have flashers fitted as per the vehicle type. • Type C and D road ambulances should have blue and red warning lights with a minimum brightness of 100 cd in daylight and 200 cd at night.
Sirens	• All siren loudspeakers have to be mounted on the front of the vehicle in all types of road ambulances with the permitted frequency range between 500 Hz to 2,000 Hz. • A siren can only be used when the warning lights are on.
Recognition of personnel	• For the protection of ambulance personnel against heat and flame and their easy identification, their safety garments should conform to at least ISO (***International Organisation for Standardisation (ISO) 14116:2008 specify protective clothing requirement for protection against heat and flame. Clothing material should reduce the possibility of its burning and prevent the personnel from any hazards***).

Sources: Automotive Industry Standard: Constructional and Functional Requirements for Road Ambulances (National Ambulance Code), 2013, available at http://www.nisc.gov.in/PDF/AIS_125.pdf

Whereas, the ones in Bihar, Punjab, Chandigarh, Mizoram and Haryana are in progress.[25] However, the provision of VLTS is not mandatory for private road ambulances, even though state governments have the authority to mandate this for all road ambulances.

Staffing

Indian Public Health Standards (IPHS) recommends one driver along with two technicians for every ambulance positioned in a district hospital. However, no such staffing requirement or training has been mandated or even recommended by Indian legislation. The state governments, though, can prescribe their standards *vis-à-vis* staffing.

A tertiary hospital-based study revealed that the level of basic life support knowledge was poor in more than half the ambulance staff, nearly 76 percent of the ambulance personnel did not have any paramedical degree and only one percent had EMT qualifications.[26] A highly unskilled workforce directly impacts the quality of care, which urgently calls for guidelines on human resources.

During the pandemic, MoHFW released SOPs for ambulance drivers and technicians transporting suspected COVID-19 patients. They prescribed strict adherence to cleaning and decontamination protocols, standard precautions while managing patients, and training of all ambulance staff on common signs and symptoms of COVID-19.[27]

More recently, the National Commission for Allied and Healthcare Professions Act, 2021 has recognised emergency medical technologists and advance care paramedics as allied and healthcare professionals under the category of Trauma and Burn Care Professionals. However, their roles and responsibilities in a road ambulance will be better understood once the Act is implemented by the states.

Charging Practices

Local Circles, a community-based social media platform, conducted a national survey during the second wave of COVID-19. With a sample size of 38,000 across 389 districts, results showed that 70 percent of those in need of ambulances were overcharged. Almost 50 percent of the survey respondents were charged 500 percent or more over the regular price, while 10 percent were charged between 100 percent and 500 percent more. Only 30 percent of the respondents said they were charged per the regular pricing.[28]

A shortage of public ambulances and a lack of regulatory mechanisms to control the pricing allowed private ambulance operators to take advantage of the people's dire situations during COVID-19. For instance, in Gurugram,

Haryana, private ambulance operators charged between ₹15,000 and ₹40,000 for a distance of less than 5 km in the city.[29]

Observing the rise in complaints about such excessive charges, the Supreme Court of India recommended that a protocol for ambulances must be established to prevent the exploitation of citizens, along with the creation of a platform for reporting and redressal of such cases.[30]

The authorities did try to curb the pricing of ambulance services during the pandemic, using Section 67 of the MVA, 1988 to fix the prices of private ambulance operators. For instance, the Commerce and Transport Department of Odisha mandated standard charges for the ambulances of private hospitals and private operators in the state, at ₹10 per km for the first 10 km and additional charges ranging from ₹30 to ₹50 per km.[31]

While some state health departments, through NHM, fixed the transportation charges for private health facilities, NHM Haryana fixed the rate of BLS ambulances at ₹7 per km, and ALS and neonatal care ambulances at ₹15 per km.[32] However, similar regulations across multiple states proved ineffective due to confusion regarding powers and responsibilities among departments. Delhi government capped the maximum prices for private ambulances during the pandemic, but the order issued by CATS Delhi was not legally enforceable,[33] since only the appropriate disaster management authority could issue such orders, deriving powers from the Disaster Management Act, 2005.

The 108/102 ambulance services are available free to the users under NHM but may charge transportation to private facilities. Some private health insurance providers cover patient transportation charges, which maybe either be part of an insurance plan or an add-on emergency cover.[34] The Pradhan Mantri Jan Arogya Yojana offers a family health cover of ₹5 lakh a year, however, there is no mention of transportation costs or ambulance services in its benefit packages.[35]

Responsibilities of Citizens

A study found that one in 10 patients dies because motorists fail to give way to ambulances.[36] The Motor Vehicles (Amendment) Act, 2019 introduced punishments for those who obstruct the free passage of ambulances on the road, liable to imprisonment which may extend up to six months, or a fine of ₹10,000, or both.

Fear of intimidation by police and prolonged legal formalities are the main reasons why nearly 75 percent of Indian citizens hesitate in helping victims of road accidents.[37] In an effort to encourage the citizens, the MVA was

amended in 2019 to protect those who assist in transferring a victim of a motor vehicle accident to the hospital. According to the amendment, such persons cannot be forced to disclose any personal information for the medico-legal case or bear any medical expenses towards the treatment of the injured person. In October 2021, the Indian government launched the Good Samaritan Scheme under which anyone who saves the life of a road traffic accident victim within the golden hour is eligible to receive a certificate of appreciation and a cash reward of ₹5,000.[38]

Monitoring

Ambulance services are primarily provided via public-private partnerships. However, in the absence of reporting arrangements and accountability, state governments lack access to project databases, which hampers monitoring and data-gathering for research. Multiple CAG reports also emphasize the inefficient supervision and inadequate performance-monitoring of ambulances by state governments. This shows in the idling of ambulances due to procedural delays in tender procurement, delays in payments to the private providers, and non-fulfillment of maintenance per the prescribed timeline[19]. Inconsistency and incomplete reporting make information unusable for corrective actions.

Conclusion

The panic faced by the citizens during the second wave of the pandemic reinforced the need for a single portal that carries verified and up-to-date data on registered and operational ambulances. Equally importantly, there is a need to establish evaluation parameters for equipment availability, care processes, human resources, monetary charges as well as patient and staff safety. Moreover, India needs stringent educational requirements for ambulance staff, accompanied by well-formulated communication strategies and grievance redressal mechanisms that patients can access in emergencies.

COVID-19 has served as an urgent reminder that the legal framework which defines the roles of ambulance- services stakeholders needs clarity and standardisation, along with more stringent enforcement of several existing regulations.

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CHAPTER 20

Food Safety for Health and Wellbeing

Addressing the Challenges of the Regulatory System

Introduction

Environment and food safety have been two important topics in the world.[1] *Food safety is not just about what's on our plate, it is about food production, food distribution and more importantly it is about the way food is handled from farm to plate.* Having a sufficient amount of safe and nutritious food is a prerequisite to sustain life and promote public health and the *ongoing pandemic has brought this to the forefront once again. People have now become increasingly more cautious of what they eat when they eat, how much they eat and how safely it was handled, transported, stored, and cooked before reaching them.*

According to the World Health Organisation (WHO), an estimated 600 million, almost one in 10 people in the world, fall ill after eating contaminated food and 420,000 die every year, resulting in the loss of 33 million healthy life years. Such figures prove that access to sufficient amounts of safe and nutritious food remains a challenge globally and it demands some fundamental changes in the way governments work, responsibilities are assigned and implemented. It calls for the global need to further strengthen the food ecosystem to a greater extent to keep up with the increasing needs, expectations, perceptions, and preferences of consumers.

Local and international food marketing continues to have significant impacts on food safety and the health of the public. Food supply chains now cross multiple national borders which increases the internationalisation of health risks[2]. Innovation and advancement in technology would play a key role in meeting such growing new challenges but equally important is to scrutinise and reinforce the role of the food regulators of every country who are entrusted with the responsibility to ensure that the food the end consumer consumes is safe and nutritious. Their responsibility towards enhancing the performance

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of the food system through monitoring and surveillance activities and enforcing legal and regulatory requirements are crucial and cannot be undermined.

The concept of "Farm to Fork" is a budding new concept, which as defined envisages that food safety is one critical element that needs to be relevant through the supply chain of the food product. This continuum is necessary to prevent various food-borne illnesses.

Food Safety: Some Emerging Health Challenges

Changing consumer lifestyles, needs and preferences influence every facet of the economy but nothing as significant as the food sector. Given the fact that the majority of both urban and rural consumers tend to eat a lot outside and depend on ready-to-cook foods, the market develops at a rapid phase to meet their demand. Such drastic transformations within the sector bring along with it an array of new challenges.

Market Flooded with Ultra-Processed Foods

Deakin University published a study in 2020 on ultra-processed foods and beverage sales in 80 countries. The findings of this study showed that from 2009 to 2019 the rate of sales growth of ultra-processed food and beverages was highest in lower-middle-income regions of Asia when compared to the rest of the world. Among the Asian countries, India was leading the sales with a 7.8 percent growth rate, followed by Pakistan at 6.3 percent, however, the growth was close to stagnant in places like Germany (0 percent) and the United States (0.4 percent).

Now some studies[3] link the growing market of ultra-processed food and non-communicable diseases (NCDs). The Economic Survey 2020-21[4] of India highlights that NCDs are now responsible for more than 65 percent of all deaths in the country, or approximately six million-plus deaths. Between 1990 and 2016, the contribution of NCDs increased from 37 to 61 percent of all deaths in the country.

Earlier, the World Economic Forum and Harvard School of Public Health had highlighted the economic burden of NCDs in India in their study[5] wherein it states that India stands to incur a cost of US$4.58tn between 2012 and 2030 due to increasing NCDs and mental health conditions. Of this amount, cardiovascular disease (CVDs) alone would cost US$2.17tn, covering almost the majority of the economic loss. The study further states that while several nations have implemented stronger regulations on salt content in food products, and have subsequently seen lower rates of CVDs no such restrictions are in place in India.

Increased Patronage of Street Foods

The street food sector in India has almost 5.5 million vendors and they together contribute almost 14 percent to the informal economy. These enormous figures highlight the important role they play in India's economy. Consumers tend to prefer eating from them as their foods are comparatively much cheaper and easily available. However, often the evaluation of good handling practices and the microbial quality of street foods exposes that these foods present risks to the health of consumers and constitute a public health problem.

Besides, as the street food sector is not strictly regulated, despite freshly cooked food it threatens the safety of the consumer as often it is found that they use cheap ingredients and lack proper sanitary and hygienic conditions.

Putting Profits Before Health

Knowingly flooding the markets with unsafe food products at least by a few of the food manufacturers, with profit only as motive became evident with the recent exposure of internal documents of the world's largest packaged food and beverages company Nestle. The internal document acknowledges that 60 percent of its mainstream product portfolio is unhealthy.[6]

According to the document, about 70 percent of Nestle's food products and 96 percent of beverages, excluding pure coffee, fail to meet the minimum healthy threshold. In addition, 99 percent of Nestle's confectionery and ice cream portfolio also fails to meet the threshold rating.

Such companies spend billions of dollars every year to promote their unsafe foods and to lobby governments against several regulations including those related to food labels and reducing the marketing of unhealthy foods to kids.[7] They often object to any new positive changes in the existing regulations that are aimed at ensuring the welfare of larger consumers. Even if new amendments are brought into force, the industries tactically water down such provisions and attempt to exploit the loopholes in laws in their favour.

Excessive Food Marketing

Studies[8] show that there is a possible correlation between obesity and television junk food commercials. Even a short exposure to food advertising on television has a significant influence on children's buying preferences and habits. According to a study in 2018 by Cancer Research UK, children who are exposed to more than 3 hours of television were comparatively 250 percent more likely to be 'junk-food pestering' their parents, than children who watched significantly fewer television commercials.[9]

Given that in India, the advertisement of such unsafe food items is largely unregulated, it is high time we learn to adopt and follow the best practices of other countries. For instance, in the UK since 2007 junk food commercials have been banned from being telecasted on kid's channels and the country even recently placed a complete ban on such commercials on all channels before 9 pm.

Food Safety & Health in India

Food safety is described as "assurance that food is acceptable for human consumption by its intended use" in the Food Safety & Standards Act of 2006. Food safety entails handling, preparing, and storing food in ways that avoid foodborne illness. It guarantees that food is safe for human consumption. India is experiencing rapid population growth and socio-economic development including urbanisation and rising household incomes. Such exponential growth however is bringing its challenges. Rapid urbanisation is resulting in a growing number of slum dwellers, inadequate and overburdened infrastructure, food insecurity, and poor public services like improper waste collection and water and sanitation systems.

According to the WHO,[10] diarrhoeal diseases are responsible for more than half of the global burden of foodborne diseases, causing 550 million people to fall ill and 230,000 deaths every year. It further states that India along with other southeast Asian countries (one of the six WHO Region) ranks the third highest estimates of foodborne Disability-Adjusted Life Years (DALYs), with diarrhoea and infectious disease agents being most prominent.

It is also reported[11] *that foodborne diseases cost India about USD 28 billion or around 0.5 percent of the country's gross domestic product (GDP) every year, and every third person in the rich urban household may be affected by food-borne diseases by 2030, which is notably more than the average one out of nine.*

Food adulteration has always remained a big anxiety equally for both consumers and regulators. According to news reports[12], more than one-third of the food produced in India is adulterated and substandard. The government data given in Table 20.1 highlights the amount of food samples analysed past three years by various States and Union Territories and the corresponding amount of non-conforming food justifies such claims. Even those that are not adulterated are often either contaminated or spoiled due to a lack of proper storage and other infrastructure facilities along the food value chain. This significantly creates a negative impact on the daily lives of farmers, food producers, traders, consumers, and ultimately all citizens. The recurrent occurrence of food safety scandals in the country underscores the vulnerabilities of existing systems and shows how poorly they are regulated.

Table 20.1: Samples of Food Analysed, Found Non-Conforming During 2019-2020			
	2020-21	2019-20	2018-19
Food samples analysed	1,07,829	1,18,775	1,06,459
Total samples found non-conforming	28,347	29,192	30,415
i) Non-conforming samples-unsafe	5,220	4,526	3,900
ii) Non-conforming samples-sub standard	13,394	15,671	16,870
iii) Non-conforming samples-labelling defects/misleading/miscellaneous	9,733	8,995	9,645
Source: FSSAI Annual Reports			

While the stringent food law and setting up of the Food Safety and Standards Authority of India (FSSAI) and enactment of a more strengthened consumer protection law have paved the way for an efficient regulatory system in the country, much more needs to be done on the ground. The Food Authority has devoted all of its efforts to carrying out its duty by the slogan of "inspiring trust, ensuring safe and healthy food."

Food Safety and Standards Act, 2006: A Regulatory Perspective

In India, the Food Safety and Standards Authority of India (FSSAI) has been established under the Food Safety and Standards Act, 2006, (FSS Act), which is a consolidated statute related to *food safety and regulation* in India.

The food system is regulated in the country through activities that include – policy-making, standards setting, and enforcement and surveillance. The country strengthened its food safety policy through the enactment of the FSS Act and thereby created a single reference point for all matters relating to food safety, standards, and regulations. Since then, the country has from time to time, under pressure and otherwise, come up with various related regulations to address concerns in the food supply chain.

On food standard settings, currently, FSSAI lays down science-based standards to regulate the manufacture, storage, distribution, sale and import of food. As per the regulations, it has standardised 649 articles of food in 18 categories and all other foods require product approval.[13]

Apart from FSSAI, Agricultural Marketing and Grading (AGMARK) and the Bureau of Indian Standards (BIS), too, have framed standards on food items, but only a few of them are mandatory.

In the FSS Act, the following are the key provisions that contribute to the effective regulation of the food safety scenario across the country. Key provisions along with brief explanations of those provisions for better understanding are highlighted in Table 20.2.

Other than the above provisions, the Act also has provisions for offences and penalties that are prescribed in the Act from Section 50 to Section 67.

With a population of more than 1.3 billion, regulating food safety in such a sizable nation is a challenging undertaking. The Food Authority and the State Food Authorities are jointly responsible for this task. States and UTs carry out enforcement in the field to make sure that FBOs are conforming to food standards, while the Food Authority intervenes in policy at the national level, providing guidance and coordination and informing FBOs of various food safety requirements. The FSSAI helps by teaching and empowering the law enforcement officers of the States and UTs. The Commissioners of Food Safety are in charge of overseeing the Food Safety Authority's implementation of the FSS Act and the Rules and Regulations that were enacted under it.

New Initiatives and Scope for Improvement/enhancement for Better Food Safety[14]

Over the past couple of years, FSSAI has undertaken nationwide campaigns, food safety frameworks and new standards to create an environment of safe and wholesome food. A few initiatives are as follows:

- To replace the Food License and Registration System, the FSSAI created and launched the Food Safety and Compliance System (FoSCoS) in India on November 01, 2020. The licencing and registration process has been rationalised and made simpler in response to complaints about the former system's slowness. The "One-Stop Compliance Portal" for food safety is another goal of FoSCoS. The system has already been integrated with payment gateways, Food Safety Compliance via a Regular Inspection and Sampling System (FoSCoRIS), an audit module, an online return filing module, and a hygiene rating module. This has made it easier for food business operators to submit applications, payments, and annual returns.

  FoSCoRIS is a web-based mobile app that the FSSAI has created for inspections and sampling for monitoring, data gathering, and data analysis on a real-time basis. States have been encouraged to only use FoSCORIS for inspections. FoSCoRIS was used to conduct 60,222 inspections of food companies during the reporting year of 2021-22. Additionally, this system has been connected with FoSCoS to increase inspection transparency.

Table 20.2: Key Provisions of the FSS Act with a Brief Explanation	
Provision	Brief Explanation
Sections 11 & 12	The Constitution of the Central Advisory Committee (CAC) and its functions include ensuring close cooperation between the Food Authority (FA) and the enforcement agencies and organisations operating in the field of food. It states the committee shall meet not less than three times a year.
Sections 13 & 14	Establishing Scientific Panels, that consist of independent scientific experts and constitution of a Scientific Committee that consists of the Chairpersons of the Scientific Panels and six independent Scientific Experts not belonging to any Panels.
Section 16(3)(a)	Specifically mandates that FSSAI provide technical support to Central and State Governments on matters which have a direct or indirect bearing on food safety and nutrition.
Section 16(3)(n)	Mandates FSSAI to promote general awareness of food safety and food standards.
Section 29	FSSAI and State Food Authorities (SFAs) together are responsible for implementation and enforcement.
Section 31	To carry out food businesses in the country, FSSAI registration is required which is segregated into three different types, such as Basic Registration, State Registration and Central Registration. If the annual turnover is below 1.2 million then basic registration is sufficient, however, if it's between 1.2 – and 200 million then a state licence is required and if above 200 million then a central licence is mandatory
Section 32	Empowers Designated Officer (DO) to issue an *improvement notice* when a food business operator (FBO) fails to follow the food regulations stated in the *Act*.
Section 34	Empowers the Commissioner of Food Safety to impose emergency prohibition on FBO when the health risk condition exists even after a notice is served.
Section 36	Appointment of a DO at the district level who has the power to issue or cancel licence, and prohibit the sale of any article of food which is in contravention of the provisions of this Act.
Sections 37 & 41	Appointment of food safety officers (FSOs) at the sub-district level who have the power to carry out inspections and enforce activities in the area assigned to them.
Section 43	Recognises and notifies primary food testing laboratories, referral (appellate) labs and research institutes.
Section 44	FA may recognise any organisation or agency for food safety audit and checking compliance with food safety management systems
Sections 45, 46 & 47	Appointment of food analysts their *functions* and the *procedure to carry out sampling and analysis, including in the case of imported food articles.*
Section 68	Role of adjudication officer and their powers.
Section 70	Establishment of Food Safety Appellate Tribunal.

- To assess how well states are performing in terms of food safety and encourage them to improve, FSSAI has introduced a State Food Safety Index. This ranking is based on how well states and UTs execute on five key metrics: compliance, human resource and institutional data, infrastructure and surveillance for food testing, training, and capacity building, and consumer empowerment.

- According to the Food Safety and Standards (Food Safety Auditing) Regulations, 2018, FSSAI has recognised 29 food safety auditing organisations for conducting food safety audits about compliance with the hygiene and sanitary requirements listed in Schedule IV of the Food Safety and Standards (Licensing and Registration) Regulations, 2011. It has been agreed to audit all food establishments with Central Licenses that come under the six high-risk categories/kinds of enterprises.

- The "Strengthening of the Food Testing System in the Nation with Provision for Mobile Food Testing Laboratories" (SOFTeL) Central Sector Program was implemented during 2016–17. Food labs are being directed to undertake NABL accreditation. To ensure that the samples collected reach the laboratories without deterioration, sample collecting devices have been distributed to various States/UTs to construct an efficient network of Sample Management Systems (SMS) with cold chain facilities throughout all states/UTs.

- Amid the COVID-19 pandemic, FSSAI took extra precautions to guarantee continuous food supply and services. Food testing laboratories (National Food Labs at NCR and Kolkata, as well as privately authorised FSSAI labs) and import clearance of food goods were categorised as critical services during the lockdown.

- The FSSAI's flagship Food Safety Training and Certification (FSTaC) programme, which had previously been delivered in-person and trained food handlers in correct hygiene and production methods, was forced to move to an online platform as a result of COVID-19. Throughout these about 2,600 training sessions, more than 78,452 food workers got instruction. All 19 of the training courses that are necessary for Food Safety Supervisors under FoSTaC were made available online starting in October 2020. Through 7,477 regular online FoSTaC trainings conducted in 2020–21, 2,24,729 food handlers gained training.

- The Eat Right India movement, which aims to give people access to safe food, wholesome diets, and sustainable lifestyles, was continued by the FSSAI. To ensure that food is healthy for both people and the environment, Eat Right India uses a thoughtful combination of

regulatory, capacity-building, collaborative, and empowering techniques. Food fortification, the Hygiene Rating System, the Blissful Offering to God (BHOG) campaign, the Eat Right Home, School, Campus, and Station programme, the Clean Street Food Hub, the Clean Vegetable and Fruit Market, and Repurpose Used Cooking Oil (RUCO) campaign are all significant projects.

The scale at which FSSAI operates is humongous and with the onset of the pandemic, newer challenges for compliance, enforcement, and execution have arisen. A few challenges highlighted below embody the gaps, which may be enhanced or further reviewed to strengthen the apex regulatory body in the country. Few gaps pertain to maintaining synergies with the unorganised and informal sector. A lot of state funding is delayed or does not fulfil the requirements thereby delaying the civic work needed for labs. While FSSAI has provided funds and high-end machinery to state labs, challenges remain in terms of manpower and sometimes fund utilisation.

Key Recommendations

The above analysis of food safety regulations in the country proves that food safety in India is still at a developing stage. Some of the priority elements that should be considered by the ministry concerned or by the food regulator for strengthening the food safety regulations are:

- Ensure better and more stringent enforcement of the rules and drastically improve market surveillance regularly. Facilitate effective coordination between the FSSAI at the Centre and the states and make sure that these departments always have a sufficient number of suitably qualified and experienced staff and possess adequate facilities and equipment to carry out their duties properly.

- To complement the efforts of the regulator, there is a need to expedite the progress/updation of food laboratories in the country and ensure those that are already involved in the analysis of food samples are equipped with modern testing gadgets, trained manpower and work by internationally approved procedures and performance standards.

- The importance of food safety standards should not be underestimated. Frequent and regular updates of existing food standards is very much vital to keep up with the latest findings and advances in technology. In addition, it helps to meet food and nutrition goals under SDGs. With increasing food-borne illness risks both human-induced and natural, it is high time India adopts a standard-driven culture benchmarked to global practices.

- Efforts should be taken to the extent possible to harmonise the Indian food standards with the standards of ISO, by adopting them as Indian standards. Meeting international standards is a robust way to maintain consumers' health, prevent foodborne illnesses and promote exports.

- The need for enhancement of technologies within the food sector particularly for food testing is vital. There is a lot of advanced research happening worldwide on food technology, which our experts need to be involved with so that they can imbibe it to suit our country's needs. Advances in technology in the food sector have helped many countries, including India to improve food safety.

- Timely and adequate information flow to food industries is vital and needs to be further enhanced. FBOs particularly the tiny, small and medium-scale industries often find it difficult to identify relevant procedural and compliance changes, as they cannot track regulatory changes. FSSAI should increasingly reach out to such small business operators with simplified versions of the new regulations and standards. More emphasis should be placed on training food handlers.

- Intersectoral convergence along with using local experts on food safety may be done. The state-level committees should ensure that food safety is one of the key topic areas.

Conclusion and the Way Forward

In conclusion, the FSSAI can take several measures to become a better regulatory body. These measures include strengthening enforcement, improving awareness, enhancing collaboration, updating regulations, improving communication, and investing in capacity-building initiatives for its staff. By implementing these measures, FSSAI can ensure that food safety standards are adhered to by food businesses across India, and consumers are protected from the risks associated with consuming unsafe food.

To elaborate further, FSSAI can also leverage technology to improve its regulatory practices. It can adopt advanced technologies such as blockchain and artificial intelligence to track the entire food supply chain, from production to consumption, and ensure that food safety standards are maintained at every stage. This can help improve traceability and accountability, making it easier for FSSAI to detect and address any food safety issues that arise.

Additionally, the FSSAI can explore international collaborations and partnerships to enhance its regulatory practices. Collaborating with international food safety agencies and organisations can help FSSAI gain

access to global best practices and cutting-edge technologies, which can be adapted to the Indian context. This can also help improve India's standing in the global food industry and increase its competitiveness in international markets.

Looking to the future, FSSAI can continue to focus on promoting innovation in the food industry. It can encourage the development of new, safe and healthy food products through collaborations with the industry, research organisations and universities. Additionally, FSSAI can work on developing robust regulatory frameworks for emerging food technologies such as plant-based meat, cultured meat and insect-based food products.

Overall, by leveraging technology, collaborating with international partners and promoting innovation, FSSAI can continue to evolve and improve its regulatory practices, ensuring that the food consumed by people in India is safe and of high quality. This, in turn, can help FSSAI become a more effective and efficient regulatory body, ensuring that the food consumed by people in India is safe and of high quality.

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CHAPTER 21

Nutrition Status in India through the Regulatory Lens

Introduction

For a food and nutrition-secure world, we must have a safe and nutritious food supply. The problem of access and availability of nutritious food is marred by multiple impediments including the COVID-19 pandemic, conflict, climate change, inequality, rising prices, and political factors. People around the world are suffering the domino effects of events that surpass borders. As per the USGCRP report, *'climate change is very likely to affect global, regional, and local food security by disrupting food availability, decreasing access to food, and making utilisation more difficult.'*[1]

Food safety and nutrition are inextricably linked: to achieve optimal human health and well-being, people must be both well-nourished and free from foodborne disease.[2]

According to statistics, more than 80 percent of the extremely poor live in rural areas of the world, and most rely on agriculture and/or natural resources for their living. The issues arising due to gender, ethnic origin, or status only add to their struggles. The role of the government, lawmakers, and regulatory agencies is something, on which so many issues boil down to. The availability of adequate, safe, and nutritious food in that order is the way to achieve the goal of basic human rights and duty towards the coming generations.

Hunger and Food Insecurity

Food security is a basic human right. According to the most recent State of Food Security and Nutrition Report (2022), efforts to alleviate hunger and malnutrition are underperforming. In 2021, 828 million people worldwide endured hunger – 146 million additional people than a year ago and 150

This chapter has been contributed by Dr Dolly Jani, Senior Manager, Food Safety & Quality Control Laboratory, The Akshaya Patra Foundation

million more than in 2019. The latest findings of the Global Hunger Index (GHI) for the year 2022 have presented additional unfavourable information for India. This is a matter of concern, considering that the global standing of India serves as a crucial benchmark for human development. India placed 107th out of 121 countries.

For decades, FAO has used the Prevalence of Undernourishment indicator to estimate the extent of hunger in the world, thus 'hunger' may also be referred to as undernourishment. A person is said to be food insecure when they lack regular access to enough safe and nutritious food for normal growth and development and also for an active and healthy life. This may be due to unavailability of food and/or lack of resources to obtain food. Food insecurity can be experienced at different levels of severity.

Malnutrition – Undernutrition Vs Overnutrition

Currently, India grapples with the complex challenge of triple-burden malnutrition, encompassing undernutrition, overnutrition, and micronutrient deficiencies across diverse age groups. While the prevailing perception attributes malnutrition to nutrient deficiencies or inadequate food availability, it is crucial to recognise its multifaceted nature, even in a developing nation like ours.

Recent developments underscore the inadequacy of existing approaches in addressing issues such as hunger, food insecurity, challenges within the agrifood system, and varied forms of malnutrition. According to the World Health Organisation (WHO), encompasses deficiencies, excesses, or imbalances in both energy and nutrient intake. The term encompasses undernutrition, including stunting (low height for age), wasting (low weight for height), underweight (low weight for age), and micronutrient deficiencies or insufficiencies (a lack of important vitamins and minerals).

The other is overweight, obesity, and diet-related non-communicable diseases (such as heart disease, stroke, diabetes, and cancer). The responsiveness of governments during the COVID-19 crisis, including efforts in food assistance, nutrition-specific programmes like food fortification, and nutrition-integrated agriculture initiatives, provides valuable insights into the imperative of developing disaster-ready policies for the future.

Status of Health in India- Official Figures

The economic growth indicates new opportunities and a movement towards an increase in the prevalence of non-communicable diseases, which is a trend in several developed countries such as the US, Canada, and Australia. The combination of people living in poverty and the recent economic growth

of India has led to the co-emergence of two types of malnutrition: undernutrition and overnutrition.

The pervasive issue of malnutrition persists as a significant challenge for India's population. Despite serving as a robust foundation for attaining food and nutrition security in the country, the revised National Food Security Act (NFSA) is instrumental in addressing this complex concern.

According to the most recent NFHS 5 (19-21), more than 50 percent of women in India are still anaemic, though nutrition indicators for children under 5 years old have improved from NFHS 4. Stunting decreased by 2.9 percent, wasting by 1.7 percent, and the prevalence of underweight decreased by 3.7 percent.

A noteworthy decline in malnutrition among women aged 15-49 years is evident, reducing from 22.9 percent to 18.7 percent, as reported in Annexure-1. The inaugural Comprehensive National Nutrition Survey (CNNS) has also highlighted the nutritional status of children.

Despite marginal improvements over the last few decades, the prevailing percentage of hunger remains disheartening, emphasising the need for sustained efforts in addressing this critical issue. In India 44 percent of children under the age of 5 years are underweight. 72 percent of infants and 52 percent of married women have anaemia. Research has conclusively shown that malnutrition during pregnancy causes the child to have an increased risk of future diseases, physical retardation, and reduced cognitive abilities (Chakrabarti, 2019).

According to the latest update by the United Nations on Non-communicable diseases and injuries – Child nutrition in India (published in 2022):

- Prevalence of stunting in children under 5 years (%) in the year 2020 – 30.9
- Prevalence of wasting in children under 5 years (%) in the year 2021 – 19.3
- Prevalence of overweight children under 5 years (%) in the year 2020 – 1.9
- Prevalence of anaemia in women of reproductive age (15-49 years) (%) in the year 2019 – 53

Source: Monitoring the health SDG goal: Indicator of overall health and well-being in India

*(*Monitoring progress on universal health coverage and the health-related Sustainable Development Goals in the WHO South-East Asia Region)

Statistics from the Anganwadi Services Scheme (AWSS) working under the Ministry of Women & Child Development (MWCD) for children in need of care and protection and children in conflict are often significantly different than independent national surveys for the same indicators. The national surveys are conducted in long intervals, say 10 years or so, and hence do not provide regular data on the nutritional status of children for data-driven policy and actions. The availability of reliable data and robust data collection techniques is a major hindrance in developing strategies for combating malnutrition. The use of technology to track the initiative's execution is one of the important components of Mission Poshan 2.0.

National surveys, occurring approximately every decade, fail to offer consistent data on children's nutritional status, hindering data-driven policy formulation. The scarcity of reliable data impedes the development of effective strategies against malnutrition. Mission Poshan 2.0 emphasises the crucial role of technology in tracking and enhancing the initiative's execution for optimal impact.

To monitor the success of various nutrition-related interventions, including the distribution of micronutrient supplements, the promotion of breastfeeding, and the provision of hot-cooked meals to children in *Anganwadis*, the initiative uses a technology-based platform called the POSHAN tracker. It is envisaged that through real-time tracking, supply alignment, and immediate relief may be provided.

Nutrition is a Relevant Issue

In most of the medical institutes and hospitals nutrition & dietary sciences take a secondary role. Our system of medicine is designed and understood by many as a curative science. This means that a person who falls sick due to any illness is brought under medical care for 'treatment'. In other words, a preventative approach for deficiency diseases or hidden hunger as mentioned earlier is generally missing. Food & nutrition is a majorly neglected area in health departments and as a result, the burden of non-communicable diseases caused due to malnutrition is playing havoc with the nation's health.

If we take a look at the panel of experts in the Department of Public Health Services which comprises illustrious doctors, there are fewer technical experts on nutrition. Nutritionists play a crucial role in integrating scientific findings from nutrition, dietetics, and food science. Medical practitioners are often specifically trained in dietetics & nutrition. Hence, there is a lack of nutrition expertise for large nutrition programmes in the country. The National Education Policy 2020 recognises the vital link between wholesome nutrition, optimal health, and enhanced learning, proposing health-related activities to foster overall well-being.

National Nutrition Mission – POSHAN ABHIYAAN 2.0

There are many schemes launched over several decades by various state and national agencies that directly/indirectly affect the nutritional status of children (0-6 years of age) pregnant women and lactating mothers. Despite these, the level of malnutrition and related problems in the country is high. There is no dearth of schemes but there is a lack of synergy and linking schemes with each other to achieve a common goal.

POSHAN Abhiyaan is one such scheme aiming for convergence mechanisms and other components required to create the synergy. POSHAN Abhiyaan was a multi-ministerial convergence mission started in the year 2018 with an ambitious vision to ensure the attainment of a malnutrition-free India by 2022. The objective of POSHAN Abhiyaan was to reduce stunting in identified districts of India with the highest malnutrition burden by improving the utilisation of key *Anganwadi* Services and improving the quality of *Anganwadi* Services delivery.

One of the key components involves the gradual scaling-up of interventions supported by the World Bank-assisted Integrated Child Development Services (ICDS) Systems Strengthening and Nutrition Improvement Project (ISSNIP) to all districts in the country. National Nutrition Mission aims to ensure holistic development and adequate nutrition for pregnant women, mothers and children. The Ministry of Women and Child Development (MWCD) is implementing POSHAN Abhiyaan. However, much remains to be done as it is in the fifth year of implementation.

Mission Poshan 2.0 is an integrated nutrition support programme for all states/UTs. It seeks to strengthen nutritional content, delivery, outreach, and outcomes with a focus on developing practices that nurture health, wellness and immunity to disease and malnutrition. The refurbished scheme includes steps to be taken to improve nutritional quality and testing in accredited labs, strengthen delivery and leverage technology under Poshan Tracker to improve governance. States/UTs have been advised to promote the use of AYUSH systems for the prevention of malnutrition and related diseases.

Another aspect of leveraging traditional knowledge in nutritional practices has also been taken up to support the development of Poshan Vatikas at *Anganwadi* Centres to meet the dietary diversity gap. Given that it offers a comprehensive and well-coordinated strategy to combat malnutrition, Mission Poshan 2.0 is extremely pertinent to India's nutrition security.

One of the main aspects of Mission Poshan 2.0 is its emphasis on enhancing women's and children's nutritional status during the first 1,000 days of life, which is thought to be a crucial time for growth and development. More

funding for nutrition and health services will be necessary when the focus shifts to women's nutrition. Mission Poshan 2.0 also stresses the project's involvement in the local community. By enlisting the aid of neighbourhood self-help groups and community-based organisations, the programme hopes to enable communities to take control of their nutritional results. The interventions are made to be sustainable and culturally suitable with the aid of this community-based approach.

Several schemes like Anganwadi Services, Scheme for Adolescent Girls (SAG), and Pradhan Mantri Matru Vandana Yojana (PMMVY) under the Umbrella Integrated Child Development Services (ICDS) Scheme are supposedly targeted interventions to address the problem of malnutrition in the country. Anganwadi Services Scheme aims to improve the nutritional and health status of pregnant women & lactating mothers and reduce the incidence of mortality, morbidity, and malnutrition. Under the Scheme, pregnant women and lactating mothers are provided supplemental nutrition, education on nutrition and health, immunisation, health check-ups, and referral services.

According to the Union Budget for 2022-23, the government has allocated ₹20,263 crore for the programme, which is slightly more than one percent more than the prior year. Moreover, political commitment is necessary to ensure that the programme remains a priority and receives the necessary funds and support. Implementing the programme effectively at all levels is crucial for achieving the programme's goals and improving the nutritional status of mothers and children in India.

PM Poshan Pradhan Mantri Poshan Shakti Nirman (Erstwhile Mid-Day Meal Scheme)

Around 27 years ago, in 1996, the National Programme of Nutritional Support to Primary Education (NP-NSPE) was launched as a Centrally Sponsored Scheme and in the year 2001, the Supreme Court of India ordered all the union territories and state governments to implement Mid-Day Meal (MDM) Scheme and provide cooked meals to school children from the government and government-aided schools.

The objective of the programme was to increase enrolment, retention, and attendance of students in Classes I through VIII at government-run and government-aided schools, as well as at Special Training Centres (STC), Madarasas and Maktabs funded by the Sarva Shiksha Abhiyan.

While implementing the MDM programme, the Central and state governments work hand in hand. The Central Government issues guidelines to be followed by state governments while executing the scheme. The *Panchayats*/Urban Local Bodies are in charge of the scheme in states where primary education

is entrusted to them. NGOs like the Akshaya Patra Foundation are working in several states in collaboration with local authorities as the implementation partners. Such public-private partnership models have shown a significant impact on the beneficiaries under the scheme.

The programme, which has been renamed 'National Scheme for PM POSHAN in Schools,' would be expanded to include all 11.80 crore elementary school students as well as those enrolled in pre-primary or Bal Vatikas of government and government-aided primary schools starting in 2021-2022. There will be strong encouragement for the TithiBhojan concept.

TithiBhojan is a community-based organisation, in which participants donate special cuisine to kids during holidays and special occasions. To give kids first-hand exposure to nature and gardening, the government is encouraging the creation of School Nutrition Gardens in schools. The produce from these gardens is employed in the plan to add extra micronutrients. More than 3 lakh schools currently have School Nutrition Gardens established. Every district has included a requirement for the social audit of the programme.

In regions designated as aspirational districts and those characterised by a high prevalence of anaemia, special provisions have been instituted to ensure the provision of supplemental nutrition items to children. To promote ethnic food and creative menus based on readily accessible ingredients and locally available vegetables, cooking competitions will be encouraged at all levels, from village to national levels.

Vocal for Local for Atmanirbhar Bharat: It will be encouraged for Farmers Producer Organisations (FPOs) and Women Self Help Groups (SHGs) to participate in the implementation of the programme. It will be encouraged to use traditionally produced foods that are farmed locally to boost regional economic development.

Students from esteemed universities and institutions, as well as trainee teachers from regional institutes of education (RIE) and district institutes of education and training, will be allowed to participate in field trips for progress monitoring and inspections (DIET).

Challenges in the Implementation of Food-Based Social Safety Net Programmes

- Budgetary Concerns: Adequate budget provisions are needed in the financial outlay of the country for effective nutrition programme intervention. Inter-Departmental Coordination: While multi-sectoral convergence is promoted, various agencies from the government departments – Women and Child Development (WCD), health and

education – are key players in the nutrition programmes. Such inter-departmental coordination poses various practical challenges. Another key issue is the dearth of nutrition experts in the management of these welfare schemes.

- Role of Apex Technical Institutions: Nationally the apex technical institution is the National Institute of Public Cooperation and Child Development (NIPCCID) and not the National Institute of Nutrition (NIN), which is an Indian Council for Medical Research (ICMR) institute. However, their role in nutritional management programmes, primarily, is providing guidelines or recommendations for maintaining good health in general.

Specific Guidelines for Nutritional Requirements

The Indian Council for Medical Research (ICMR) is working as the torchbearer for the country's dietary recommendations and thereby nutrient requirements. They specify the Recommended Dietary Allowances (RDAs), which are revised from time to time. These recommendations are scientifically set based on the age, gender, and level of activity involved for the individual. Such guidelines are very crucial means to guide healthcare professionals as well as regulators and policymakers in taking the right course of action towards achieving health goals.

It is indeed a challenging task to contextualise RDA to the Indian scenario, which has a background of the double burden of malnutrition, and diverse dietary habits but predominantly home-based cereal-pulse vegetarian diet. The lower bioavailability of several nutrients also adds to the situation.

But We Do Have a 'Food Safety and Standards Authority of India' (FSSAI)

The Food Safety and Standards Authority of India (FSSAI) is a statutory body established under the Food Safety and Standards Act, of 2006. Its main responsibility is to regulate and oversee the safety and standards of food products in India. One of the key areas of focus for FSSAI is nutrition. The organisation works to ensure that food products sold in India meet certain nutritional standards and guidelines.

The FSSAI also guides healthy eating and promotes awareness of the importance of nutrition in maintaining good health. FSSAI has been tasked with laying down science-based standards for articles of food and regulating their manufacture, storage, distribution, sale and import to ensure the availability of safe and wholesome food for human consumption.

The government body is mandated to establish science-based food standards, and support research projects and related innovative R&D proposals about food safety and quality control. Providing financial assistance to various institutions/Universities and recognised R&D laboratories, FSSAI oversees standards throughout its Scientific Committee and Panels. The regional Food Safety departments act as implementation agencies in respective states. Top of Form

FSSAI has developed various initiatives to promote healthy eating habits among the Indian population. For example, it has launched a food fortification programme to increase the intake of essential vitamins and minerals among vulnerable populations such as children, pregnant women, and lactating mothers. The organisation also promotes the use of healthy cooking oils and encourages the consumption of fruits and vegetables through various campaigns and programmes.

Overall, FSSAI plays an important role in promoting nutrition and ensuring the safety and standards of food products in India. FSSAI's 'Eat Right India' initiative is a comprehensive public health campaign aimed at promoting healthy eating habits and ensuring the availability of safe and nutritious food for all. The initiative is based on five key pillars: Eat Safe, Eat Healthy, Eat Sustainable, Eat Fortified, and No Food Waste.

The FSSAI has launched several initiatives under the 'Eat Right India' campaign, such as the 'Eat Right Challenge' to encourage schools, colleges, and workplaces to adopt healthy eating practices. The campaign also includes the 'Food Safety Mitra' initiative, which trains food handlers and vendors to maintain food safety and hygiene.

Another important aspect of the 'Eat Right India' campaign is food fortification. The FSSAI has launched a programme to fortify staple foods such as wheat flour, rice, oil and milk with essential vitamins and minerals. This initiative is aimed at improving the nutritional status of the population, especially vulnerable groups such as children and pregnant women. The FSSAI's 'Eat Right India' campaign also includes a focus on reducing food waste.

The organisation has launched the 'Save Food, Share Joy' campaign to promote responsible food consumption and minimise food waste at various levels. Overall, FSSAI's 'Eat Right India' campaign is an important initiative aimed at promoting healthy eating habits, improving food safety and hygiene, and ensuring the availability of safe and nutritious food for all.

The FSSAI regulations form part of the Food Law prescribing the minimum mandatory standards for food safety in our country. However, as can be

inferred from the list below, the FSSAI regulations are not specifically targeted towards setting nutritional or dietary standards for the country. Though few of the product-specific regulations as listed below are mandated to be followed by the food manufacturing and law enforcement agencies:

- Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011
- Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purposes, Functional Food and Novel Food) Regulations, 2016
- Food Safety and Standards (Food Recall Procedure) Regulation, 2017
- Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017
- Food Safety and Standards (Organic Food) Regulation, 2017
- Food Safety and Standards (Fortification of Foods) Regulations, 2018;
- Food Safety and Standards (Advertising & Claims) Regulations, 2018.
- Food Safety and Standards (Packaging) Regulation, 2018
- Food Safety and. Standards (Foods for Infant Nutrition) Regulations, 2020
- Food Safety and Standards (Safe Food and Balanced Diets for Children in School) Regulations, 2020
- Food Safety and Standards (Labelling and Display) Regulations, 2020 Safety and Standards (Ayurveda Aahara) Regulations, 2022
- Food Safety and Standards (Vegan Foods) Regulations, 2022

The FSS Regulations are addressed to the products and processes followed in the production and handling of foods in India. These laws and standards are not designed to alleviate hunger or malnutrition maladies. They act as tools for consumers and regulators in ensuring the authenticity, safety & quality of foods available in the Indian market.

Needless to add the above standards/regulations would not be sufficient in helping the healthcare professionals in addressing the prevailing malnutrition situation in the country.

Every Problem Has a Solution

Food regulations can play a critical role in overcoming nutrition issues by ensuring that the food products available to consumers are safe, nutritious, and meet certain quality standards. Various schemes and programmes that have been running across the country to address the problem of malnutrition are to be made accountable and answerable to this authority.

- Regulations that require accurate and comprehensive labelling of food products can help consumers make informed choices about the nutritional content of the food they consume, which can help overcome

issues related to overconsumption of unhealthy nutrients such as sugar, salt and fat.

- Regulations that mandate the fortification of certain staple foods such as wheat flour, rice, oil, and milk with essential vitamins and minerals can help overcome micronutrient deficiencies and improve the nutritional status of the population, especially vulnerable groups such as children and pregnant women.

- Regulations that restrict the use of harmful ingredients such as trans fats, high-fructose corn syrup, and artificial sweeteners can help overcome nutrition issues related to chronic diseases such as obesity, diabetes, and heart disease.

- Regulations that mandate food safety and hygiene can help prevent foodborne illnesses and ensure that the nutritional quality of food products is not compromised by contaminants, harmful substances, or adulterants.

- Regulations that promote healthy eating habits and encourage the consumption of fruits, vegetables, whole grains, and lean protein sources can help overcome nutrition issues related to inadequate consumption of essential nutrients and micronutrients.

Overall, food regulations can play an important role in overcoming nutrition issues by ensuring that the food products available to consumers are safe, nutritious, and meet certain quality standards.

As we try to search for solutions one needs to understand that there is involvement of multiple agencies like the Ministry of Health & Family Welfare, the Ministry of Education, the Department of Food and Public Distribution, the Ministry of Social Justice and Empowerment and so many other stakeholders. The role of different interest groups has to be assimilated and brought together under the central level authority focused on nutrition.

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Annexure-1. State /UT wise prevalence of stunting, wasting and underweight among children under 5 years and malnutrition among Women (15-49 years of age) as per the National Family Health Survey (NFHS-4 & NFHS-5).

S.No.	State/UT	Stunting (%)		Wasting (%)		Underweight (%)		Women whose Body Mass Index (BMI) is below normal (BMI <18.5 kg/m2) (%)	
		NHFS 4 (2015-16)	NHFS 5 (2019-21)	NHFS 4 (2015-16)	NHFS 5 (2019-21)	NHFS 4 (2015-16)	NHFS 5 (2019-21)	NHFS 4 (2015-16)	NHFS 5 (2019-21)
1	Andaman & Nicobar Islands	23.3	22.5	18.9	16	21.6	23.7	13.1	9.4
2	Andhra Pradesh	31.4	31.2	17.2	16.1	31.9	29.6	17.6	14.8
3	Arunachal Pradesh	29.4	28	17.3	13.1	19.4	15.4	8.5	5.7
4	Assam	36.4	35.3	17	21.7	29.8	32.8	25.7	17.6
5	Bihar	48.3	42.9	20.8	22.9	43.9	41	30.4	25.6
6	Chandigarh	28.7	25.3	10.9	8.4	24.5	20.6	13.3	13
7	Chhattisgarh	37.6	34.6	23.1	18.9	37.7	31.3	26.7	23.1
8	Dadra &Nagar Haveli and Daman & Diu	37.2	39.4	26.7	21.6	35.8	38.7	23.4	25.1
9	Delhi	31.9	30.9	15.9	11.2	27	21.8	14.9	10
10	Goa	20.1	25.8	21.9	19.1	23.8	24	14.7	13.8
11	Gujarat	38.5	39	26.4	25.1	39.3	39.7	27.2	25.2
12	Haryana	34	27.5	21.2	11.5	29.4	21.5	15.8	15.1
13	Himachal Pradesh	26.3	30.8	13.7	17.4	21.2	25.5	16.2	13.9
14	Jammu & Kashmir	27.4	26.9	12.1	19	16.6	21	12.2	5.2
15	Jharkhand	45.3	39.6	29	22.4	47.8	39.4	31.5	26.2
16	Karnataka	36.2	35.4	26.1	19.5	35.2	32.9	20.7	17.2
17	Kerala	19.7	23.4	15.7	15.8	16.1	19.7	9.7	10.1
19	Ladakh	30.9	30.5	9.3	17.5	18.7	20.4	10.5	4.4
18	Lakshadweep	26.8	32	13.7	17.4	23.6	25.8	13.5	8
20	Madhya Pradesh	42	35.7	25.8	19	42.8	33	28.4	23
21	Maharashtra	34.4	35.2	25.6	25.6	36	36.1	23.5	20.8
22	Manipur	28.9	23.4	6.8	9.9	13.8	13.3	8.8	7.2
23	Meghalaya	43.8	46.5	15.3	12.1	28.9	26.6	12.1	10.8
24	Mizoram	28.1	28.9	6.1	9.8	12	12.7	8.4	5.3
25	Nagaland	28.6	32.7	11.3	19.1	16.7	26.9	12.3	11.1
26	Orissa	34.1	31	20.4	18.1	34.4	29.7	26.5	20.8
27	Puducherry	23.7	20	23.6	12.4	22	15.3	11.3	9
28	Punjab	25.7	24.5	15.6	10.6	21.6	16.9	11.7	12.7
29	Rajasthan	39.1	31.8	23	16.8	36.7	27.6	27	19.6
30	Sikkim	29.6	22.3	14.2	13.7	14.2	13.1	6.4	5.8
31	Tamil Nadu	27.1	25	19.7	14.6	23.8	22	14.6	12.6
32	Telangana	28	33.1	18.1	21.7	28.4	31.8	22.9	18.8
33	Tripura	24.3	32.3	16.8	18.2	24.1	25.6	18.9	16.2
34	Uttar Pradesh	46.3	39.7	17.9	17.3	39.5	32.1	25.3	19
35	Uttarakhand	33.5	27	19.5	13.2	26.6	21	18.4	13.9
36	West Bengal	32.5	33.8	20.3	20.3	31.6	32.2	21.3	14.8

CHAPTER 22

Epilogue

Ensuring quality healthcare for citizens has been high on the government's agenda, particularly during and after the pandemic. Both the Central and state governments are making efforts to move in the direction of achieving universal health coverage and delivering quality healthcare services to all at affordable cost. Today, though the Indian healthcare network is among the largest in the world, the high out-of-pocket expenditures are still bothering the middle and lower classes.

While it has been reiterated several times that more investments in modernising the health infrastructure and improvements in health systems are needed, the role of regulations and competition in enhancing access to affordable healthcare has not been much talked about. The present edition of the India Competition and Regulation Report on the theme "Regulatory Deficit in Access to Equitable Healthcare" endeavours to fill this gap.

Based on the deliberations and recommendations in the preceding chapters, the following paragraphs try to draw a way forward for regulation and competition policy to achieve access to quality healthcare for all. The first step however is to improve awareness of various regulations in healthcare among different stakeholders, particularly end consumers and small businesses.

Promoting Competition in the Pharmaceuticals Market

(1) Ensuring effective implementation of the public health safeguards in the Patents Act, of 1970 is very important to engender generic competition in the pharmaceuticals market. In particular, implementing the anti-evergreening provisions [like sections 3(d) and 3(e)], unique to the Indian law, must be given due emphasis. Promoting generic competition significantly brings the prices of medicines down and hence enhances their affordability and accessibility.

From a competition policy perspective, any dilution of these public health safeguards, therefore, needs to be frowned upon. The draft Patent

(Amendment) Rules, released recently by the government for public comments, is one such example of dilution of public health safeguards. The Competition Commission of India (CCI) can use its advocacy function to discuss with the government.

(2) The market approval process of biosimilars (generic versions of biological drugs) has been flagged as overregulation, which creates barriers to generic competition. A scientific discussion should be launched to review the present mechanism of obtaining market approvals for biosimilars so that it promotes competition without compromising on quality control.

(3) Similarly, rationalising the existing drug price control mechanism is also important. The present regime also covers those drugs for which there is ample generic competition, thus having competition-distorting effects. It would be better if the price control mechanism is invoked only in case of market failures.

(4) Another obstacle to competition exists for doctors' prescription practice of using brand names. While doctors' main argument for such practice is "trust" of quality, a connection or relationship between prescribing doctors and pharmaceutical companies cannot be ruled out. Therefore, investing in quality control to increase trust in generic substitutes can be pro-competition. This is a pre-condition for enforcing doctor's prescriptions in generic names. There has been a long pending demand for harmonising generic drug approval mechanisms and quality control at the state levels, which needs to be facilitated.

(5) The CCI need to be more proactive in dealing with prevailing anti-competitive practices in the pharmaceuticals market. A few such practices include anti-competitive agreements, abuse of dominance, vertical restraints particularly exercised by drug distribution associations, frivolous litigations to stop entry of generic drugs, and anti-competitive mergers & acquisitions.

(6) The present PLI scheme applicable to active pharmaceutical ingredients (APIs), to reduce import dependence, has not yielded encouraging results. There is a need to properly understand the nature of import dependency – whether the dependency is on key starting materials (KSMs), drug intermediates (DIs) or APIs needs to be investigated first. Further, there is a need to boost investors' confidence and trust. Furthermore, including MSMEs and public sector units in the overall strategy can also yield positive results.

(7) Promoting e-pharmacy will have a pro-competition effect in the retail market. There is a sense of uncertainty due to conflicting high court judgements and pending regulation, which is hampering growth and

investment in the e-pharmacy segment. The government should come out with a pro-competition regulation as soon as possible.

(8) Growing concentration due to consolidation in the e-pharmacy platform market is a concern. Competition enforcement may not be sufficient to deal with such a situation, hence needs a whole-of-government *ex-ante* approach to create an enabling policy framework so that more platforms enter into an e-pharmacy segment and subsequently sustain themselves.

(9) To attract domestic and foreign investments in the medical device industry and reduce import burdens, the relevant regulatory frameworks need to be reviewed and unnecessary regulatory requirements may be removed.

Healthcare and Allied Services Market

(10) Though 100 percent FDI is allowed in hospitals, still certain barriers exist that may disincentivise investors. Since hospitals have several phases of construction, each phase may need to be considered separately, and an investor may be permitted to exit on completion of the project or after the development of trunk infrastructure has taken place. Additionally, barriers in related sectors, such as health insurance and medical education, can also inhibit the flow of investments in hospitals.

(11) Granting healthcare and infrastructure status can help attract more domestic and foreign investment in the sector.

(12) There is a huge scope for exploring public-private partnerships (PPPs) in healthcare sectors, particularly in segments, such as primary healthcare, hospital infrastructure, medical equipment and technology, diagnostic and laboratory services, ambulance services, health insurance etc. Regulatory barriers to achieving this potential need to be further studied and acted upon.

(13) While the enactment of the Mental Healthcare Act of 2017 is a step in the right direction, its implementation remains a concern, particularly at the state level. State governments need to prioritise the implementation of this Act, and the Centre can help with relevant resources to the lagging states. An added emphasis needs to be given to protect and promote the rights of persons with mental illness.

(14) The National Medical Commission Act, 2019 (which repealed the Indian Medical Council Act, 1956), and rules and regulations made thereunder, though made significant pro-competition improvements over its predecessor regime still poses regulatory hurdles in the establishment of medical colleges. Continuous feedback from stakeholders needs to be in place to keep the regulatory regime aligned with the changing realities.

(15) Reforms are also needed in the regulation of health insurance. There is a need to redesign health insurance contracts. Similarly, shifting to managed care models of health insurance regulated through the regulatory system of managed competition is a need of the time. In addition, there is a need for regulatory integration of health insurance and healthcare services, which can initially begin with integrated offerings and better regulatory coordination. To expand access to voluntary insurance, there is a need to lower the entry barrier from the current ₹100 crores to at least ₹20 crores. Further, more awareness generation programmes are needed to remove the prevailing information asymmetry in the health insurance ecosystem.

(16) Implementation of the Bio-Medical Waste Management Rules, 2016 (including its amendments) remains quite laggard, similar to the previous regulatory regime. An aggressive enforcement approach coupled with stakeholders' awareness generation is the need of the hour.

(17) There are huge benefits due to the propagation of digital health in India. However, there are risks also attached to the same, such as the protection of patient's health data and Adhaar data (sensitive data). While implementing the Digital Personal Data Protection Act of 2023, special emphasis needs to be given to sensitive health data.

Preventive Measures: Road Safety, Food & Nutrition Safety

(18) Road accidents are one of the biggest causes of death in India. There is a need to improve and strengthen the institutional framework for road safety. Further standardisation of all road designs (not only national highways), conduction of routine road safety audits, and making a long-term master plan for city transport and traffic are some of the measures that can rectify the present situation. In addition, better coordination between different government agencies involved is mooted. Also, there is a need to come up with an exhaustive trauma care policy to save lives on roads.

(19) Markets are flooded with ultra-processed and junk foods, influencing the food habits of the young generation and putting profits before health. This demands better implementation of existing regulations and formulation of new labelling requirements that are effective. There is also a huge need for mass-level awareness generation on the health effects of junk foods and changing lifestyles.

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