India Competition and Regulation Report 2023 (ICRR'23): Equitable Healthcare

National Reference Group Meeting : 19.04.2022

Minutes of the Meeting

Brief Introduction

CUTS International in association with CIRC, has been publishing biennial reports on the state of competition and regulation in India. The reports are designed to undertake reviews of level of competition and regulation to assess functioning of markets in the country.

ICRR'23 is ninth in a series of flagship biennial publications by CUTS and CIRC. It will focus on contemporary regulatory and competition issues in the healthcare sector. In healthcare the edition will look into: healthcare services; pharmaceuticals; medical devices; pathology; medical education; medical insurance; global issues; preventative health care; and AYUSH.

The work of ICRR'23 will be conducted under the guidance of its National Reference Group (NRG). The NRG is a group of experts created for the benefit of ICRR 2023 which will guide its formulation from start to finish. The first meeting of this group was held on 19.04.2022.

Agenda of NRG Meeting

Sessions
1. Brief Introduction to ICRR and CUTS by Pradeep S Mehta.
2. Introduction to ICRR 2023 and agenda of the meeting by Mr Nitin Desai.
3. CUTS Presentation on introducing the organisation, ICRR 2023 and components of the chosen theme 'equitable healthcare'.
4. Discussion round on the proposed chapter plan led by Chair of NRG.
5. Action Plan and Next Steps to be outlined.
Outcomes a. Revised chapter plan b. Researchers and contributors for each chapter c. Outline of Next steps with timeline

Key Points of Discussion

a. The goal of the ICRR'23 is not to simulate the market situation but to focus on regulatory insights. It is essential that the scope, goal and conceptual framework is clearly defined in the chapter plan as well as in the overview/introductory chapter while including evaluation/state of healthcare in India in the introductory chapter.
b. The introductory chapter needs to have a clear scope of the report which narrows the areas which the report will touch while acknowledging issues that are outside the intended scope of the report. The report will also need to adhere to a research type for all chapters such as primary or secondary research.
c. The report will need to capture that even though health is a state subject as per the Constitution of India, the burden of regulation, investment, and financial responsibilities often falls upon the central government. There is a regulatory gap in those issues and thus it needs to be addressed by the report. Centre-State relations and the regulatory framework that addresses the major subsystems of the public-private mix in the health service system. The inter- and intra-state dynamics of regulation are important to consider.
d. The members discussed that in the context of delivery of healthcare, the current chapter plan brings out issues related to practitioner facilities, supportive services, and professional action. However, public private partnership (PPP) is a contractual agreement, the report will need to highlight service-related regulations that focus on the privatisation of healthcare services. The core nature of the fiscal chain in healthcare will result in health delivery systems with increasing entropy and no value generation for better health outcomes. There is a lack of alignment in the financial motivation of the patient and the doctor. Both referral networks have their benefits, but do introduce non-indicated intervention.
e. Another focus area for the report will be telemedicine and the component of digital healthcare as a cross-cutting subject matter in all chapters. Tele-medicine regulations are currently in a nascent stage and will be changing based upon regulations centred around data and its protection. It will be essential that the report maps those contours in the form of one or more chapters.
f. ICRR 23 should initiate a conversation on ethical practice of pharmaceutical companies as well as healthcare practitioners. There are limitations to how collusion between medical practitioners and pharmaceuticals should be prevented. If proposed/upcoming/future ethical practices regulations target the practitioner instead of pharmaceutical and healthcare companies it will create an imbalance between the responsibility placed upon both ends.
g. As the report's current chapter plan elaborates upon standardised healthcare, it is important to highlight that Ayushman Bharat is not exhaustive in covering all healthcare systems, rather only those who are on the board of the platform. As the general sentiment of the masses is not in favour of this scheme, its implementation should come with clinical establishment law or state law, which could at least try to standardise health practises. Looking at the cost of health care, clinical establishments in the central have not followed the rules, and it is very difficult in private; there is no transparency about the charges being imposed on the patients; there should be transparency, and for that they must display the charges; look at Kerala.In terms of regulation and monitoring, these are some issues that are really burning in a bad sense.
h. The members emphasised that there is definitely a need for the report to look at comparative regulation of healthcare and, finally, that it might be important to have discourse around the rights of individuals, patients, and healthcare workers in India given the ambiguity between

multiple legislation, court cases, and the federal structure of healthcare. Only 11 out of 29 states have a clinical establishment act which is supposed to regulate private sector hospitals in particular. The report will need to deep dive into the questions of where it is not available, and if available how poor is its operation? As the medical devices in the public health centre can really disrupt the lab market it requires a central regulatory framework around it because without that, these small pilots happening in Assam, West Bengal happen in sec;lusion of other states. These states have clinical establishment laws but don't have the resources or people there to work. In most laboratories, second-hand machines report that what they get is not reliable.

i. The report should look into the regulatory gap that exists between affordable medicine and innovative medicine in the country. For this regard, the investments that relate to licensing for large corporations have become immensely important. Too much price control is a disincentive for innovative products to come onto the market. Medical device price regulation quickly entered the atmosphere of price control in various extraordinary majors, leading to a situation where we have been losing access to high quality and innovative products. The report should have a look into the Indian industry, which is so good at manufacturing generic medicine, but not getting into innovation and how this can be addressed using regulations. It should also expound upon the reasons for companies not moving up the value chain in innovation and coming up with new molecules.

j. One the issue of Health infrastructure, the members discussed the requirement for accuracy in health infrastructure should be one of the goals for regulations to address. As in India, 36 percent of cases have some of the other forms of medical negligence, medical malpractice. Thus, a regulatory structure that keeps in mind the medical devices and data generated through them will be beneficial for the report. The primary healthcare system (PHC) barely plays any significant role in the development of tertiary care, which must be based on commercial and financial considerations. This will give us perhaps one dimension to balance public spending and private provision of healthcare, writes Dr Peter Gildernew at the Institute of Public Health (IPH).

k. On the issue of Medical Education and its regulations, the members gave examples of renowned colleges known for producing the majority of postgraduate students who have skill deficiency at their core. Some doctors don't even know how to put a cannula into a patient. There is a need to include skill level training as well as decision level training in our medical education. It is good for the National Commission for Allied and Healthcare Professionals (NCAHP) to examine how exactly the implantation of this law is taking place and whether it is even possible for current schemes to start regulating an entire sector of by-line healthcare practitioners by introducing this law. Another regulation focussing on fee rationalisation is necessary. Medical education costs are so high, so we need to look into both quality and cost in both contexts.

l. On the issue of medical insurance the members discussed that some countries like the Netherlands and Sweden have a value-based insurance system. The report should highlight the need for focusing on better health outcomes as a financial motivator rather than looking at increasing scope and performance. In India the population for any insurance sector is 21percent which increased by 4percent during COVID-19 pandemic. ICRR 23 will need to look into regulations that will not favour public over private insurance and vice versa as this might result in a massive fraud in Ayushman Bharat, India, and the Swasthya Sathi Scheme, Bengal. Such inferences can be drawn from the American insurance system, which is linked to reimbursement of specific elements of a procedure, and is set at a very high cost. Thus a regulatory approach to cater to comprehensive insurance, which takes care of all our medical

needs from the day to death covered by insurance to the end of life, needs to be explored by our recommendations. The competitive nature of the insurance industry will mean that both the insurance and healthcare providers have incentives to control costs and still provide very good outcomes.

m. The members of NRG quoted that in the European OECD region, health expenditure rarely exceeds 7-8 percent, with the public sector accounting for about 6 percent of public expenditure as a share of GDP varied from 11 percent to 45percent of health, education, and social transfers. In the United States, they don't spend 7-8 percent in Europe.

n. The panel of NRG members on chapter plan of global issues remarked that there is a regulatory gap in regional FDAs and there is a role to look at harmonisation of regulation in the context not just of multilateral settings but by lateral and other major regional agreements, so for extensional health products. Areas of trade and health production regulation require more discussion. Certain MOUs and understandings between regulators, for example, the US FDA, whereby one can rely on the data generated by other jurisdictions to help with accelerating the approval process in the country. The issue is that even though the regulatory structure is in place, nothing has happened to validate it. Each country has its own stringent standards for drug approval processes. If we were able to bank on that and find a way to accelerate our own processes, it would lead to having access to better medicines in the country as well. Therefore, regulations for drug pricing and availability, along with E- health should be considered under global issues.

o. On the issue of preventative healthcare, the members discussed the origin of the issue of regulations in the healthcare system and the missing links between traditional and modern health. Health is never preventive; it is always an early diagnosis. Preventive health can be mostly considered from a nutritional and environmental perspective. AYUSH practitioners are now slowly being permitted across the state to practise allopathic medicine. Still, this is a question that needs to be looked into in these short-term training modules which allow AYUSH practitioners to ultimately practise allopathic.

p. On the issue of Indian health infrastructure, the NRG members remarked that the lack of infrastructure when compared to Indian public health service norms is stark. The chapter oplan and the report by extension should show the regulatory issues consequent to the shortage of infrastructure, IPHS norms and HR, whether it be about doctor population, nurse ratio, and imbalance between rural and urban. The status of health in the country certainly depends on the quality of health infrastructure, availability, and accessibility. Equally important, health is shaped by the political environment, which is related to public health, and also by nutrition, particularly in children, and so on. The report should start some evaluation of the health status of the country in the broader context, which can shed light on communicable diseases, malnutrition, etc.

In conclusion, the report should focus upon answering questions on how to improve regulation or what are the possible new approaches to regulation? One of the key focus areas of the report will be to discern whether competition in healthcare will result in increased efficiency, equity, accessibility, and affordability. The report should outline the cross-cutting theme and answer whether it will include digital as a factor in all chapters or one specific dedicated chapter in the report.

Key Suggestions

- A review of the chapter framework defining the scope of the report in essence.
- Inclusion of operational definition of healthcare and related terms.
- There is no chapter in the framework of the Ayushman Bharat Digital Mission that brings all stakeholders together on a single platform.
- There should have been a strategy for outreach and dissemination (seminars or anything else) in states (groups of states) from the beginning.
- The report should include state-level health regulation separately. For example, West Bengal has a dedicated regulatory commission which was established in 2017.

Annexure: List of Participants

S.No	Name	Designation and Organisation
National Reference Group (NRG) members		
1	Nitin Desai, **Chair**	Indian economist and international civil servant
2	Dipika Jain	Professor & Vice Dean and Director, Centre for Justice, Law and Society (CJLS), O.P. Jindal Global University
3	Darren Punnen	Nishith Desai & Associates
4	Dr. Milind Antani	Nishith Desai & Associates
5	Dr. Santosh Mehrotra	Chairperson, Centre for Informal sector and Labour Jawaharlal Nehru University
6	Ajay Shankar	Chairperson, Centre for Policy Studies, JKLU
7	Sanjay Mitra	Former Chief Secretary, West Bengal, Chairperson Supreme Court Road Safety committee
8	Amir Ullah Khan	Research Director Centre for Development Policy and Practice
9	Rupa Chanda	Regional Director, UNESCAP, Bangkok
10	Archana Jatkar	Associate Secretary General, Indian Pharmaceutical Alliance
11	Alok V. Kulkarni	Senior Consultant Psychiatrist, Manas Institute of Mental Health, Hubli
12	Neeraj Jain	Country Director, Path India
13	Dr. Sabine Kapasi	Member, Healthcare - Working Group, EoDB.
14	Dr. Nitya Nanda	Director , Council for Social Development

15	Sunil Nandraj	Public Health Researcher
16	Rama Baru	Professor, Centre of Social Medicine and Community Health, Jawaharlal Nehru University
17	Dr. Chandrakant Lahariya	Public Policy and Health Systems Expert

CUTS International Members		
18	Pradeep S.Mehta	Secretary General, CUTS International Jaipur, Rajasthan
19	Ujjwal Kumar	Policy Analyst and Deputy Centre Head, CCIER, CUTS International, Jaipur, Rajasthan
20	Madhu Sudan Sharma	Senior Programme Officer, International Jaipur, Rajasthan
21	Simi TB	Policy Analyst, CUTS International Jaipur, Rajasthan
22	Neelanjana Sharma	Senior Research Associate, CUTS International Jaipur, Rajasthan
23	Pratibha Jain	Programme Associate, CUTS International Jaipur, Rajasthan
Absent NRG members		
1	Indu Bhushan	Senior Associate Johns Hopkins Bloomberg School of Public Health
2	Saleema Razvi	Senior Economist, Copenhagen Consensus Centre