THE INDIA COMPETITION AND REGULATION REPORT, 2023

PROPOSED CHAPTER PLAN

CHOSEN THEME: EQUITABLE ACCESS TO HEALTHCARE

Background

1. The India Competition and Regulation Report (ICRR) series is a flagship biennial publication of CUTS and CIRC, presenting a compendium of policy-relevant research on the status of competition and regulation in India spanning across the sector and cross-cutting contemporary issues. This report is the eighth in a series that began in 2007. Earlier editions of ICRR can be found here.

2. The latest edition of ICRR i.e., 2021 edition focused on competition and regulatory matters in the digital space. The report contained contributions on competition policy and regulations in the area of digital economy, including artificial intelligence, emerging challenges for e-commerce ecosystem, privacy and universal access to healthcare and education using digital means. The objective of the 2021 report was to provide regulatory insights to make the digital economy more inclusive.

3. In the last 2 years, the world went through the biggest health crisis anyone has ever seen. The Covid-19 pandemic and the continuing variants have not only impacted the people but also marketplaces. Health systems of the world played an integral part in taking stock of the pandemic and preventing more damage than it did. The pandemic was also an eye-opener for policy makers and regulators, with millions of lives lost, the impact on the working class was immeasurable.

4. The forthcoming edition of ICRR 2023 will thus focus on contemporary regulatory and competition issues in the healthcare sector. Within the health sector, the edition will look into: healthcare services; pharmaceuticals; medical devices; pathology; medical education; medical insurance; global issues (like equitable access to vaccines, reform of international health regulation etc.); preventative health care (such as food safety, road safety etc.); and AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy). It will be a useful exercise to

identify contemporary regulatory and competition concerns that hinder access to healthcare and make recommendations to deal with such concerns.

5. As far as issues are concerned, the chapters of ICRR'23 could include: regulatory and non-regulatory entry barriers; cartels, collusions and other anti-competitive agreements; abuse of dominance; mergers and acquisitions; regulatory overlaps and turf war; consumer protection and consumer welfare; data protection; promotion of innovation; optimal regulation etc.

6. By the way the year 2023 also marks forty years of Consumer Unity & Trust Society (CUTS) International, and this edition of ICRR can reflect the past works that CUTS has undertaken and pave the way for future endeavours.

Chapter Planning

Regular chapters

The following two chapters have been a regular feature in all ICRR editions:

Chapter 1. Overview

This chapter presents macro economy status of India, recent economic reforms in a nutshell, and throws some light on the previous and the present editions of the ICRR, including some general information related with the theme of the given ICRR.

Chapter 2. Perception and awareness reporting

This chapter carries survey results of consumers and small businesses about their perception on the current regulation and competition issues, including those related with the theme of the given ICRR.

Substantive chapters

The substantive chapters of ICRR'23 can centre around the following proposed topics in the healthcare sector.

A. Healthcare Services

1. Public Private Partnership (PPP) model in healthcare services sector

   As per the National Health Policy, 2017, while the government recognises that primary healthcare will be in the domain of the government, there can be 'strategic purchase' of secondary and tertiary care from the private sector. What has been the extent and scope of such strategic purchase, if happening? What is the

experience? Has it enhanced access to healthcare? How is it being regulated? What are the regulatory and/or competition concerns with this PPP model? What are the ways to deal with such concerns?

2. Collusion between Doctors/hospitals and pharmaceutical companies and pathology/ diagnostic firms (including tied selling)

   India has a very high component of out-of-pocket health expenditure, any anti-competitive practice in this sector could further add to the burden on consumers' pocket. Presence of anti-competitive practices, such as collusion between doctors/hospitals and pharma companies/pathology labs, and tied selling, harms consumers and other market players. What have been the responses to solve this? Is competition enforcement enough to deal with it, or do we need hard regulations?

3. Digital Healthcare with focus on Telemedicine

   India's digital adoption increased substantially during the pandemic in the health sector. Previously, telehealth was an exception and not the norm; it became a necessity during the pandemic. Before the COVID-19 pandemic, India had not implemented telemedicine on a large scale, and the early attempts had not been that successful. In a 2018 case of Deepa Sanjeev Pawaskar & Anr v. The State of Maharashtra, High Court of Bombay upheld criminal negligence charges for a case that involved consultation over the telephone after which the patient lost her life. The effectiveness of telemedicine came under scrutiny after such decisions and as telemedicine was not clearly legal before issuance of the 25 March 2020 guidelines the practice was discouraged. Thus, a lack of clear policy or legislation and a ruling of criminal negligence left the future of telemedicine uncertain until COVID-19 brought it into sharp focus. What are the regulatory challenges, including data protection, vis-à-vis digital healthcare, particularly telemedicine?? What kinds of regulatory/policy measures are required to keep this market competitive?

B. Pharmaceuticals

1. ePharmacy – the impact of regulatory vacuum and consolidation in the sector on competition

   India is still to bring in regulation for ePharmacy, posing uncertainty for investors. Two high courts – Madras and Delhi – have taken divergent views on the online sale of drugs. The judgement by Madras High Court (higher bench) has allowed such sale till the government brings in rules on e-pharmacies. In 2018, the government came out with a draft rule (under the Drugs & Cosmetics Act, 1940), but the same is yet to be finalised. Further, in the recent past there has been consolidation in the e-pharmacy platform market. What is the impact of regulatory

vacuum and consolidation on competition in this emerging market? Are the draft e-Pharmacy Rules, 2018 an optimal regulation?

2. Regulation of biosimilars and its impact on competition

   Pharmaceutical sector is highly regulated and includes market approval (quality, safety and efficacy) regulation. From competition perspective such regulations need to be optimal i.e., not more restrictive than needed. But it has been generally flagged that the regulation of biosimilar (generic version of biological drugs) as over-regulation, which creates barriers to generic competition. Is the market approval regulation of biosimilars optimal? Does it inhibit generic competition? If yes, what should be the regulatory changes needed.

3. Domestic production of Active Pharmaceutical Ingredients (APIs)

   Not so long ago, India was a leading producer of APIs. But in the recent past it began importing APIs, mainly from China at the cost of its domestic manufacture. But again, the need is being felt to revive domestic manufacture of APIs. What were the reasons for wiping out the domestic API industry? How much regulations, particularly the cost-based price control, contributed to this? What incentives are available today for the revival of the API industry? Are these measures working well? What else is required?

C. Medical Devices

1. Recent regulatory changes and its assessment vis-à-vis domestic manufacture of medical devices

   Unlike the success story of pharmaceuticals, the success of domestic manufacturing of medical devices has not been that satisfactory. Domestic manufacturing of medical devices, particularly the high-end ones, has been a policy goal since quite some time. One of the demands had been a separate regulatory regime for medical devices, which have been regulated as 'drugs' under the Drugs and Cosmetics Act, 1940. Under the Act, a new regulation in form of the Medical Devices Rules, 2017 is in force now. Has the new Rules been helpful in the domestic production of high-end medical devices? Do we require any changes in the present regulatory regime?

D. Pathology/Diagnostic LABS

1. Should pathology centres be regulated? If yes, what should be the contours of such regulation?

   Pathology is a booming sector, but there is no regulation. The Clinical Establishment Act, 2010, which prescribes minimum standards for facilities and services for clinical establishments (includes path labs), enacted by the Parliament but has to be adopted by states as health is a state subject. Only a few states have

adopted the Act so far. Under the Act, the effort of the government is to enforce standard treatment protocols, ensure adherence to minimum standards and range of rates of medical/diagnostic procedures, which is essential to make proper healthcare available to the citizens by ensuring affordability and accessibility. Further, there is a system of accreditation by the National Accreditation Board for Testing and Calibration Laboratories (NABL), but accreditation is a voluntary process. Should pathology centres be regulated? If yes, what should be the contours of such regulation?

E. Medical Education

1. Assessing the new regulation for medical education

Medical Education in India is highly coveted and important. It is important that it be regulated optimally and in a manner that ensures sufficient supply of medical professions to keep the country safe and prevent burdening the on-ground staff. Shortage of doctors and medical personnel has been an issue in India. This shortage has partly been attributed to scarcity of medical seats available in medical colleges. The old regulation posed certain entry barriers vis-à-vis establishment of new medical colleges. In 2019, a new regulatory regime came into force; a statutory body National Medical Commission replaced National Medical Council as the regulator for medical education. What are the key changes in the new regulation with respect to the old one? What has been the impact of new regulation, particularly on establishment of new medical colleges? Are there still gaps from a competition perspective?

F. Medical Insurance

1. Do we need a separate medical insurance regulation?

At present, medical or health insurance is being regulated under the Insurance Regulatory and Development Authority Act, 1999. There has been a long-drawn debate on having a separate regulator for health insurance. The main reason for this is that due to the high prevalence of asymmetry of information, both patients and insurers are at a disadvantage because of their inability to resist or challenge medical opinion given by the healthcare providers. There is also a high prevalence of 'moral hazards' in the medical insurance space. All this demands a very high degree of conjunction and synergy between regulation of insurance and regulation of healthcare providers. Even the present regulator IRDA has proposed a separate regulator for the healthcare segment or it should be given statutory mandate to also regulate hospitals. Do we need a separate medical insurance regulation? If yes, what should be its contours?

G. Global Issues

1. TRIPS Waiver and equitable access to COVID-19 drugs

   The TRIPS waiver proposal has sought a three-year long waiver of obligations related to patents, trade secrets, copyrights and industrial designs that apply to COVID-19 drugs, vaccines, diagnostics, and other technologies. While the waiver still requires negotiation at global level, it remains unclear as to how the transfer of know-how with respect to complex formulations like vaccines will take place? Even if countries agree on the proposed TRIPS waivers, what will be its effect on the invention of new COVID-19 drugs? What will be the regulatory changes necessary for bringing this into effect?

2. Reforming International Health Regulations (IHR)

   The IHR is a multilateral agreement binding on 196 countries to monitor and report international health threats. It seeks to coordinate a balanced public health response, while minimising disruptions to international travel, trade and upholding human rights. Though the IHR had seen minor revisions since its inception in 1969, some major changes were made in 2005 in the wake of the SARS outbreak. The COVID-19 pandemic has really tested this tool of global health governance. It is widely believed that the IHR needs significant reforms in order to deal with future pandemics. What has been learnt during the present COVID-19 pandemic vis-à-vis IHR? Is there a need for reforms or major revisions in the IHR? What are the present issues with respect to such reforms? What should be the position of developing countries like India in reforming IHR?

H. Preventive Healthcare

1. AYUSH: Standardisation of AYUSH systems of medicine

   Standardising the AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy) systems of medicine is a long-standing demand. This demand stems from the lack of access to health care, due to shortage of medical professionals, to certain demographics. There has been some progress in this regard, such as the Ministry of AYUSH coming out with Ayurvedic Standard Treatment Guidelines recently. What are the various ingredients of standardising the AYUSH systems of medicines and how to go forward in implementing them?

2. Food Safety for Health and Wellbeing

   The need to detect, prevent, and manage food-borne risks is one of the key areas of priority for India. The Food Safety and Standards Act, 2006 consolidates various acts and orders that have hitherto handled food related issues in various Ministries and Departments. Its objective is to protect overall public health and regulate food safety in India. Under this act, a Food Safety and Standards Authority of India

(FSSAI) was established for laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. There are over 26 Food Safety and Standard regulations in India which cover various key issues ranging from licensing, import to labelling and display amongst others. Are these regulations sufficient for addressing the issue of food safety? What are the regulatory changes that are required to achieve a wellbeing focused food safety framework in the country?

3. Road Safety in India: A Health Issue

   In today's world road and transport has become an integral part of every human being. India was using the Motor Vehicles Act, 1988 which was amended in 2019 and The Motor Vehicle's Act, 2019 (MVA) was brought in effect. The act focused on regulatory changes featuring increased fines, severe penalties amongst others to increase road safety and awareness in the country. In December 2020, the Ministry of Road Transport and Highways issued the Motor Vehicle Aggregator Guidelines, 2020 under the 2019 amended act. These guidelines were issued as the 2019 amendment included the term aggregator for which regulations were not in place. It is important to further implore the gaps for which no regulations exist? What are the future regulations that India can issue under the MVAs rulemaking provisions?

Concluding chapter (epilogue) (as has been part of ICRRs)