



Regulatory Deficit in Access to Equitable Healthcare 01 January–31 March, 2024

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. This edition of the ICRR on ‘Regulatory Deficit in Access to Equitable Healthcare’ endeavours to fill this gap. In its [22 chapters](#), the publication covers some contemporary regulatory issues from a wide range of segments in the healthcare sector, which includes healthcare services (including digital health), pharmaceuticals, medical devices, pathological labs, medical education, medical insurance and also issues related with road safety and food & nutrition safety. There are some policy recommendations based on the deliberations in various chapters of ICRR 2023.

On a different note, in a move to streamline the import, clinical investigations and testing of medical devices, the Centre has launched the National Single Window System. In a notice dated January 1, Drugs Controller General of India, NSWS has been established as a genuine single-window system, which acts as a one-stop shop for all the approvals required by the investor and facilitates ease of doing business.

On a related another move, with an aim to bring better compliance with quality standards, the Ministry of Health and Family Welfare (MoHFW) notified the revised rules under Schedule M of the Drugs and Cosmetics Rules, 1945 in the Gazette of India.

As part of an important action, FSSAI is working on making regulations for nutraceuticals and health supplements more stringent after it found many non-compliant products in the market. Nutraceuticals are products derived from food sources that are believed to provide extra health benefits, besides the basic nutritional value found in foods and can be available in the form of pills, syrups, capsules, powders, gummies and chewable.

In this fourteenth volume of Occasional News Wrap, various dimensions of health regulation issues have been captured, which appeared by way of op-eds, articles, news etc. during the month of January-March, 2024.

S.N.	Article/Op-ed	Key Takeaway
1.	<p>India Launches a Single-Window Portal for Medical Devices Management</p> <p><i>By Sohini Das Business Standard Jan. 2, 2024</i></p>	<p>In a move to streamline the import, clinical investigations, and testing of medical devices, the Centre has launched the National Single Window System (NSWS).</p> <p>In a notice dated January 1, Rajeev Raghuvanshi, Drugs Controller General of India, said the NSWS has been established as a “genuine single-window system, which acts as a one-stop shop for all the approvals required by the investor and facilitates ease of doing business”.</p>
2.	<p>Blood is Not for Sale, Says Health Regulator</p> <p><i>By Abhishek Law Jan. 4, 2024 The Hindu Business Line</i></p>	<p>Blood at hospitals or private banks and centres is “Not for Sale” but the institutions are allowed a “Processing Charge”. All other fees are to be waived off too as processing charge covers them, India’s health regulator has said. The move is seen as one that aims at clamping down on a very prevalent practice of over-charging across hospitals and private blood banks.</p>
3.	<p>Health Ministry Revises Pharma Manufacturing Rules Under Schedule M</p> <p><i>By Sanket Kaul Business Standard Mumbai Jan. 6, 2024</i></p>	<p>With an aim to bring better compliance with quality standards, the Ministry of Health and Family Welfare (MoHFW) notified the revised rules under Schedule M of the Drugs and Cosmetics Rules, 1945, in the Gazette of India. Schedule M prescribes the good manufacturing practices (GMP) for pharmaceutical products. Some of the major changes introduced in the revised Schedule M include the introduction of a pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, and a computerised storage system for all drug products.</p>
4.	<p>FSSAI directs airlines, flight caterers to comply with food safety norms</p> <p><i>Business line Jan 17, 2024 ANI</i></p>	<p>The FSSAI has directed all airlines and flight caterers to strictly comply with food safety regulations and take prompt corrective actions to minimise food safety-related incidents. In a recent meeting, FSSAI CEO directed airlines and flight caterers to comply with labelling and display regulations to ensure passengers get information about the nature, origin and manufacturing-related details regarding the food served during flights.</p>
5.	<p>Law Decriminalising Use of Biological Resources by Vaid, Hakims and Ayush Practitioners</p> <p><i>TNN Jan. 23, 2024</i></p>	<p>The Biological Diversity (Amendment) Act 2023, decriminalising use of biological resources by Vaid, Hakims and Ayush practitioners, who have been practicing indigenous medicines as profession for ‘sustenance and livelihood’, will come into force from April 1, 2024.</p>

6.	<p>Cashless Treatment Facility to be Available Across Hospitals, Says GIC</p> <p><i>By Aathira Varier Business Standard Jan 25, 2024</i></p>	<p>The General Insurance Council on Wednesday announced the launch of the 'Cashless Everywhere' facility, under which policyholders can get treated in any hospital and avail a cashless facility. This initiative will aid in easing the burden of policyholders who get treated in a hospital not in the network of the insurance company and it will be available across hospitals in India.</p>
7	<p>Health Insurance May be About to Get a New Regulator</p> <p><i>By Subhash Narayan Business Standard Jan 28, 2024</i></p>	<p>The interim budget may set the stage for a composite licence for life and general insurance, a separate regulator for health insurance and an increased digital push for the delivery and sale of insurance products, two people aware of the plans said.</p>
8.	<p>Top Food Regulator Plans to Make its Certification Must for All Food Products</p> <p><i>HT Correspondent Feb 5, 2024</i></p>	<p>The food regulator is also going to set standards for 'Haleem' as part of standards for meat products. The move will effectively do away with the requirement of other certifications such as Bureau of Indian Standards (BIS) or AGMARK certification for food products. BIS is the national standards body of India that allows the licensees to use the popular ISI mark and AGMARK is a certification mark for agricultural produce.</p>
9.	<p>Govt. Plans to Have 25,000 Janaushadhi Kendras</p> <p><i>PTI Feb. 6, 2024</i></p>	<p>The government aims to have 25,000 Janaushadhi Kendras nationwide by March 31, 2026, with over 10,000 already operational. These centers offer medicines at significantly lower prices, saving citizens over Rs 28,000 crore in nine years.</p>
10.	<p>Civil Society Groups Express Concern on Changes Proposed to Patent Rules on Access to Medicines</p> <p><i>By PT Jyoti Datta Business Line Feb. 6, 2024</i></p>	<p>Over 25 civil society organisations and patient groups, among others, have expressed their concern to the Union Commerce Minister Piyush Goyal, over the proposed 'Draft Patents (Amendment) Rules, 2023'. An analysis of the proposed amendments reveals "that many of these changes would pose a significant threat to the fundamental Right to Health guaranteed under the Indian Constitution.</p>
11.	<p>Safe Food at Workplace: FSSAI Certifies 500 Hospitals as 'Eat Right Campuses'</p> <p><i>Indian Express Feb. 15, 2024</i></p>	<p>More than 500 hospitals and medical colleges in the country, mostly private, have been certified as 'Eat Right Campus' by the FSSAI. The initiative focuses on creating safe, healthy and sustainable food environments within various institutions and workplaces, including hospitals as part of FSSAI's 'Eat Right India' movement.</p>

12.	<p>India's Food Safety Regulator Has Changed Approach, Set Global Standards</p> <p><i>By Sunil Dsouza, Business Standard Feb. 16, 2024</i></p>	<p>In less than a decade, India's food and agriculture sector has blossomed in a way that can be termed nothing less than a boom. From agricultural and dairy production to the food processing industry, the numbers reveal the growth story. The country's total food grain production is estimated at a record 329.687 million tonne for 2022-23—higher by 30.869 million tonne than the previous five years' (2017-18 to 2021-22) average production of food grains.</p>
13.	<p>Tested Organic Food Coming On Your Plate, Courtesy Govt.</p> <p><i>By Dhirendra Kumar, Livemint Feb. 19, 2024</i></p>	<p>To enhance the quality of organic food available in the domestic market and ensure better pricing for farmers, the Centre plans to invest about ₹105 crore to add organic food testing capabilities to two dozen central and state-owned testing labs, two people aware of the development said.</p>
14.	<p>False Labelling Claims Will Lead to Cancellation of License and Legal Prosecution: FSSAI</p> <p><i>By The Hindu Bureau February 23, 2024</i></p>	<p>Food Safety and Standards Authority of India's Chief Executive Officer directed food manufacturers to present actual product compositional facts and abstain from using false labelling claims, which are against the FSSAI regulations. CEO urged FBOs and re-labellers to take part in mandated third party auditing for the nutraceutical industry in order to counter food fraud and counterfeit to ensure consumers' access to safe food.</p>
15.	<p>FSSAI Cracks Down on Contaminated Food on Flights; Directs Airlines to Ensure Proper Labelling</p> <p><i>By Sanjeeb Mukherjee Business Standard March 8, 2024</i></p>	<p>The Food Safety and Standards Authority of India has found "discrepancies" in the licence endorsed by food business operators serving air passengers. The discrepancies were noticed following the FSSAI's surveillance of the food supply chain. This happened after live worms were found in the refreshments offered by a major airline. This caused a furore in social media and elsewhere with people questioning the sanitisation process.</p>
16.	<p>India's Food Safety Regulator Working on Stricter Rules for Health Supplements</p> <p><i>By Shambhavi Anand, ET Bureau March 13, 2024</i></p>	<p>The Food Safety and Standards Authority of India is working on making regulations for nutraceuticals and health supplements more stringent after it found many non-compliant products in the market, said officials. Nutraceuticals are products derived from food sources that are believed to provide extra health benefits, besides the basic nutritional value found in foods, and can be available in the form of pills, syrups, capsules, powders, gummies and chewable.</p>

17.	<p>Panel Formed to Administer Pricing Reforms for Drugs, Medical Devices</p> <p><i>By Sohini Das Mumbai Business Standard March 12 2024</i></p>	<p>Soon, pricing regulations for drugs and medical devices in India may undergo reforms as the Centre appoints a committee to propose changes to the pricing framework. Industry sources suggest that a new Drug (Prices Control) Order (DPCO) may be in the works, considering the current DPCO 2013 is already 11 years old. Pricing regulations are periodically reviewed to ensure relevance for both the industry and consumers, informed a source.</p>
18.	<p>Pharmaceutical Bodies Welcome Uniform Marketing Code</p> <p><i>ET Bureau March 14, 2024</i></p>	<p>"We welcome the UCPMP. It is a balanced order that ensures that there is a healthy and ethical engagement between the pharmaceutical industry and medical professionals," Indian Drug Manufacturers' Association (IDMA) national president said. "It also brings clarity in the domain and has been updated as per current industry practices. The IDMA has always been in favour of ethical marketing practices for its members."</p>
19.	<p>Warning Labels for Informed Choices Over Food: How to Navigate Challenges</p> <p><i>Pradeep S. Mehta and T.B. Simi Deccan Chronicle, March 14, 2024</i></p>	<p>As consumers, let's reflect on the challenges we face in making informed choices, particularly in India, where the need for transparency in our complex marketplace has never been more pressing. The abundance of options, complex product information, and aggressive marketing tactics often make it difficult for us to purchase products that best suit our needs and pockets.</p>
20.	<p>New Marketing Code for Drugs Stirs Debate</p> <p><i>By Manu Kaushik, FE March 27, 2024</i></p>	<p>The department of pharmaceuticals (DoP) has come out with a new set of stringent marketing code for the pharma companies. The new code – known as Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024 is "mandatory" and would replace the previous one that was "voluntary" in nature, official sources said.</p>