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HEALTHCARE AND PHARMACEUTICAL LAW

NEWSLETTER

INTRODUCTION

The Healthcare industry in India comprises of hospitals, medical devices, clinical trials, outsourcing, telemedicine, medical tourism, health insurance, and medical equipment. The industry is growing at a tremendous pace owing to its strengthening coverage, services and increasing expenditure by public as well as private players.

The Ministry of Health and Family Welfare (MoHFW) is committed to rapidly immunization coverage and consolidate the health systems strengthening efforts keeping in mind the socio-cultural practices and beliefs in child immunization among tribal communities in India. Universal Immunization Programme (UIP) is one of the largest cost-effective public health interventions targeting close of 26.7 Mn newborns and 29 Mn pregnant women annually for reduction of vaccine preventable under-5 mortality rate, by providing free of cost
against 12 vaccine preventable diseases.

Growing incidence of lifestyle diseases, rising demand for affordable healthcare delivery systems due to the increasing healthcare costs, technological advancements, the emergence of telemedicine, rapid health insurance penetration and government initiatives like e-health together with tax benefits and incentives are driving the healthcare market in India.

- The hospital sector in India was valued at ₹ 7940.87 Bn in FY21 in terms of revenue & is expected to reach ₹ 18,348.78 Bn by FY 2027, growing at a CAGR of 18.24%.
- The Telemedicine market is the maximum potential eHealth segment in India, which is expected to touch $5.4 Bn by 2025, growing at a compound annual growth rate (CAGR) of 31%
- Over the next 10 years, National Digital Health Blueprint can unlock the incremental economic value of over $200 Bn for the healthcare industry in India.
- India has the world's largest Health Insurance Scheme (Ayushman Bharat) supported by the government.

India's healthcare sector is divided as follows:

Hospitals: Comprising of Government Hospitals (includes healthcare centres, district hospitals and general hospitals) and Private Hospitals (includes nursing homes, mid-tier and top-tier private hospitals).

Pharmaceuticals: It includes manufacturing, extraction, processing, purification, and packaging of chemical materials for use as medications for humans or animals.

Diagnostics: It comprises businesses and laboratories that offer analytical or diagnostic services, including body fluid analysis.

Medical Equipment and Supplies: It includes establishments primarily manufacturing medical equipment and supplies, e.g. surgical, dental, orthopedic, ophthalmological, laboratory instruments, etc.

LEGAL UPDATES

1. REGULATIONS FOR MEDICAL RESEARCH AND GOVERNANCE IN HOMEOPATHY

The National Commission for Homeopathy (Medical Research in Homeopathy) Regulations, 2023 ("**MRH Regulations**") came into effect on 01 December 2023. The MRH Regulations aim to set standards for medical research in homeopathy in India, including setting up of a research regulation committee to monitor research progress. The MRH Regulations set the standards for research on pre-clinical and clinical trials and regulates advance research of homeopathy on scientific lines in an interdisciplinary and integrative manner.

Further, the National Commission for Homeopathy (General) Regulations, 2023 ("**NCH Regulations**"), have also come into effect on 04 December 2023. The NCH Regulations aim to regulate the governance and collaboration of various stakeholders within the field of homeopathy such as mandatory joint sitting (at least once a year) of the National Commission for Homeopathy, the National Commission for Indian System of Medicine, and the National Medical Commission. Further, autonomous boards like the Board of Ethics and Registration for Homeopathy, Homeopathy Education Board, and the Medical Assessment Rating Board for Homeopathy are required to meet at least once a month to fulfil their assigned functions under the National Commission for Homoeopathy Act, 2020 and the NCH Regulations. The NCH Regulations also empower the National Commission of Homeopathy to engage experts and professionals to strengthen the governance, collaboration, and overall standards within the field of homeopathy.

2. DRUG CONTROLLER GENERAL OF INDIA LAYS DOWN NEW RULES FOR COMPOUNDING OF OFFENCES

The Jan Vishwas (Amendment of Provisions) Act, 20235 which was passed earlier this year, and is yet to be notified, provided for certain offences under the Drugs and Cosmetics Act, 1940 ("**Drugs Act**") to be compoundable offences. Accordingly, offences relating to contravention of the provisions of the Drugs Act for manufacturing of drugs, excluding adulterated or spurious drugs, will be compounded by the central government or the state government. In view of the above, the DCGI has made recommendations to frame rules for compounding of offences under the Drugs Act and the central government is expected to soon come out with the draft rules for the same.

3. PARALLEL APPROVAL OF DRUGS IN SYNC WITH GLOBAL MARKETS TO EXPEDITE THE LAUNCH OF NEW MEDICINES IN INDIA.

The Organisation of Pharmaceuticals Producers of India ("**OPPI**") representing multinational pharma giants like Novartis, Roche, Sanofi, AstraZeneca and Merck, has requested the Drug Controller General of India ("**DCGI**") to enable drug approvals in India in parallel with approvals being granted in the global market. This request is made due to the inadvertent delay of getting drug approvals in India as compared to the United Kingdom, United States, and the European Union.

The main challenge which causes this delay are complex clinical trials. OPPI envisions a transformative approach to drug approval processes, advocating for regulations that enable parallel filing of marketing approval applications in sync with major global markets. OPPI further focused on the importance of a predictable regulatory pathway with minimal ambiguity and enabling early access of innovative therapies to patients in India. According to the OPPI, the timelines can be easily reduced to less than 2 years if India participates in global trials for early access to innovation and for bringing innovative therapies to Indian patients. This can be further shortened if the overall review timeline is reduced to 12 months, or the review is done parallel to the global market.

4. GOOD MANUFACTURING PRACTICES (GMP) REVISED UNDER THE PHARMA MANUFACTURING RULES

On 05 January 2024, the Ministry of Health and Family Welfare ("**Health Ministry**") notified an amendment ("**GMP Amendment**") to Schedule M of the Drugs and Cosmetics Rules, 1945 ("**Drug Rules**"). Schedule M of the Drug Rules prescribes good manufacturing practices for pharmaceutical products. The GMP Amendment has broadened the scope of 'Good Manufacturing Practices' to 'Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products', thereby extending the compliances and quality standard requirements to premises, plants, and equipment.

The GMP Amendment extends the scope of its application to contract manufacturers as well. Every contract manufacturer is required to adhere to the compliances stipulated under the GMP Amendment, and the contract givers are required to evaluate the same. Sub-contracting and changes in the process, equipment, test methods, specifications are required to be undertaken with the approval of the contract giver. Other changes include introduction of pharmaceutical quality systems (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, and a computerised storage system for all drug products.

The GMP Amendment prescribes the following timelines for complying with the requirements: (a) large manufacturers (having a turnover in excess of ₹ 250 Crores) have been given a period of 6 months from the date of publication of the GMP Amendment (i.e., January 5, 2024); and (b) small and medium manufacturers (having a turnover of up to ₹ 250 Crores) have been given a 12-month window.

5. ALLAHABAD HIGH COURT DECLARES MEDICAL REPRESENTATIVES AS DEEMED 'WORKMEN' WITHIN THE MEANING OF THE INDUSTRIAL DISPUTES ACT, 1947

The Allahabad High Court delved into the classification of medical representatives as 'workmen' under the Industrial Disputes Act, 1947 ("**ID Act**") and ascertained that after coming into force of Sales Promotion Employees (Conditions of Service) Act, 1976, medical representatives would be deemed to be workmen as per the provisions of ID Act. In the instant case, a workman, who was initially appointed as a clerk in Nicholas Piramal India Limited was subsequently appointed as a medical representative.

The workman was alleged to be involved reason and justification while prescribing antibiotics. The pharmacists have also been directed to implement Schedule H and H1 of the Drugs Rules and sell antibiotics only on valid prescriptions.

6. NEW GUIDELINES ISSUED FOR INTENSIVE CARE UNIT ADMISSION AND DISCHARGE CRITERIA

The Health Ministry has introduced guidelines for regulating the admission and discharge criteria for intensive care units ("**ICU Guidelines**") for hospitals to decide the need of admitting a patient for treatment under the intensive care unit ("**ICU**"). The ICU Guidelines have been compiled by a panel of 24 doctors with expertise in critical care medicine. Altered level of consciousness of recent onset, hemodynamic instability, need for respiratory support, patients with acute illnesses requiring intensive monitoring and/or organ support or any medical condition or disease with anticipation of deterioration have been listed as criteria for ICU admission. Patients who have experienced any major intraoperative complication like cardiovascular or respiratory instability or have undergone major surgery also feature among the criteria.

According to the ICU Guidelines, blood pressure, pulse rate, respiratory rate, breathing pattern, heart rate, oxygen saturation, urine output and neurological status among other parameters should be monitored in a patient awaiting an ICU bed. The ICU Guidelines also include discharge criteria such as return of physiological aberrations to near-normal or baseline status, reasonable resolution and stability of the acute illness that necessitated ICU admission, patient/family agreeing for ICU discharge for a treatment-limiting decision, or palliative care.

7. INDIA'S FOOD SAFETY REGULATOR WORKING ON STRICTER RULES FOR HEALTH SUPPLMENTS

The Food Safety and Standards Authority of India ("**FSSAI**") is working on framing regulations for nutraceuticals and health products (including supplements) more stringent, since the FSSAI has conducted surveys, wherein many unregulated, expired and non-compliant products has been discovered and ceased.

The authority received several complaints in relation to non-compliant health supplements being sold in the market, pursuant to which FSSAI conducted a drive across the nation to in order to investigation nutraceuticals and health supplements for quality and safety throughout their manufacturing and sale process.

In September 2023, nutraceutical accounted for 31% of all billing at chemists, according to a survey of nearly 13,000 bills across 15 cities by research firm Pronto Consult. It said this indicated massive growth of 24% year-on-year in the segment.

8. NEW MARKETING CODE FOR PHARMACEUTICAL COMPANIES NOTIFIED; PHARMACEUTICAL ASSOCIATIONS TO SET UP DEDICATED PORTAL FOR HANDLING COMPLAINTS OF VIOLATIONS

The Department of Pharmaceuticals on 12 March 2024 has notified Uniform Code for Pharmaceutical Marketing Practices (UCPMP) 2024. In order to ensure strict compliance with UCPMP, all pharmaceutical associations are required to establish an Ethics Committee for Pharmaceutical Marketing Practices (ECPMP) and set up a dedicated UCPMP portal on their websites. Unlike the previous iteration of the code, the 2024 iteration has explicitly permitted pharma and medical device companies to provide brand reminders up to ₹1000 per item, and has also allowed another informational and educational items to be included in the category of brand reminders.

9. NEW LAW FOR REGULATION OF PRICES OF DRUGS AND MEDICAL DEVICES WILL COME INTO PLAY SOON

Indian Department of Pharmaceuticals has constituted a committee which has been tasked with a role to draft a new Drugs and Medical Devices (Control) order. The committee will also examine pricing regulation for drugs and medical devices with focus on balancing price availability for essential medicines and price moderation for medical devices without hindering growth of the industry.

The committee will consist three core members, which are as follows:

- Secretary, Department of Pharmaceuticals.
- Chairman, national Pharmaceutical pricing Authority.
- Senior Economic Adviser, Department of Pharmaceuticals.

10. IMPORT OF MEDICINES TO GET BOOST FROM INDIA'S FREE-TRADE AGREEMENT WITH FOUR COUNTRIES OF EUROPEAN FREE TRADE ASSOCATION

Four European Free Trade Association states, namely, Iceland, Liechtenstein, Norway and Switzerland, have signed a Trade and Economic Partnership Agreement with India for facilitating trade and investment flows. While India has secured soft investment commitments under the Agreement, EFTA states have been given concession on import duty on pharmaceutical products exported to India and have promised simplified customs procedure.

The countries acknowledges the relevance of the WTO Agreement on Subsidies and Countervailing Duties and agree to implement additional notification and consultation procedures. They also discuss the application of anti-dumping measures, allowing a Party to exempt originating products from global safeguard measures if they do not pose a serious threat of injury, consistent with WTO regulations. Additionally, the Agreement allows for bilateral safeguard measures if a Party encounters potential economic harm due to increased imports resulting from trade liberalization under the Agreement.

BRIEF ABOUT KEY LAWS AND REGULATIONS

1. **The Clinical Establishments (Registration & Regulation) Act, 2010 ("Clinical Establishments Act")**

The Clinical Establishments Act, *inter alia*, regulates all clinical establishments in India, and prescribes certain minimum standards for facilities and services provided by such clinical establishments. In terms of the Clinical Establishments Act, a 'clinical establishment' means, among other things, a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not. The Clinical Establishments Act mandates the registration of a clinical establishment. Every clinical establishment shall obtain a certificate of provisional registration and thereafter, upon fulfilment of prescribed standards, a certificate of permanent registration from the district registering authority. Further, the council established at the national and state levels under the Clinical Establishments Act is, inter alia, required to maintain registers and periodically review the minimum standards to be followed by the clinical establishments.

2. **The Clinical Establishments (Central Government) Rules 2012 ("CECG Rules") and allied state legislations**

The CECG Rules, inter alia, provide conditions for registration and continuation of clinical establishments. In terms of the CECG Rules, clinical establishments are required to charge rates for each type of procedures and services within the range of rates determined by the Central Government in consultation with the state governments and display such rates for the benefit of the patients at a conspicuous place in a local language as well as in English. Clinical establishments are required to maintain electronic records of patients and statistics, in accordance with the CECG Rules.

The Ministry of Health and Family Welfare vide its notification dated 18 May 2018 amended the CECG Rules and introduced minimum standards for medical diagnostic laboratories (or pathological laboratories). It stipulates that each clinical establishment undertaking diagnosis or treatment of diseases, pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services are carried on with the aid of laboratory or other medical equipment, to comply with the minimum standards of facilities and services.

Certain States in India have framed rules under the CERC Act or under respective state legislation for clinical establishment, prescribing inter alia the powers of registration authority, procedure for registration of clinical establishments and applicable fee. In addition to the legislations summarized above, our facilities are also required to comply with the certain state specific rules prescribed under the Clinical Establishments Act, such as, the Haryana Clinical Establishments (Registration and Regulation) Rules, 2018, the Uttar Pradesh Clinical Establishments (Registration and Regulation) Rules, 2016.

3. **The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994 ("PCNDT Act") and Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994 ("PNDT Act") and the rules framed thereunder**

The PCNDT Act and PNDT Act prohibit sex selection, before or after conception, regulate the use of pre-natal diagnostic techniques by restricting their usage for the purposes of detecting genetic or metabolic disorders or chromosomal abnormalities or certain congenital malformations or sex-linked disorders and seek to prevent the misuse of such techniques for the purposes of pre-natal sex determination leading to female foeticide. The PCNDT Act and PNDT Act mandate all genetic counselling centres, genetic clinics and genetic laboratories carrying out pre-natal diagnostic techniques, to register with the appropriate authority, failing which penal actions may be taken against them. Hospitals providing pre-natal diagnostic facilities fall within the purview of the PNDT Act. Further, the PCNDT Act and the PNDT Act prohibit advertisements relating to pre-conception and pre-natal determination of sex and any violation is punishable with fine and imprisonment.

The PCPNDT Rules prescribe qualifications of employees, required equipment and places for a genetic counselling centre, laboratory and clinic. The PCPNDT Rules stipulate the format in which an application for registration should be made by such centre, laboratory or clinic before the appropriate authority appointed under the PCPNDT Act and lays down the manner in which records are to be maintained and preserved by such genetic counselling centre, genetic laboratory or genetic clinic. The PCPNDT Rules provide for code of conduct and conditions to be followed by owners, employees or any other persons associated with a genetic counselling centre, genetic laboratory and genetic clinic registered under the PCPNDT Act. The PCPNDT Rules further require every genetic counselling centre, laboratory and clinic to intimate every change of employee, address and equipment installed, to the appropriate authority within the time prescribed and preserve such information as permanent records.

4. **The Medical Termination of Pregnancy Act, 1971 ("MTP Act") and the Medical Termination of Pregnancy Rules, 2003**

The MTP Act regulates the termination of pregnancies by registered medical practitioners by using medical or surgical methods and permits such termination of pregnancies only on specific grounds. It stipulates that medical terminations of pregnancies can be carried out only in certain stipulated circumstances by a registered medical practitioner who has the necessary qualification, training and experience in performing such terminations and only at a place equipped with facilities that meet the prescribed standards issued under the MTP Act and if such place is approved for the purpose. Further, in March 2021, the Medical Termination of Pregnancy (Amendment) Act, 2021 was introduced, which, inter alia, expands the scope of circumstances under which a registered medical practitioner can terminate pregnancies and imposes an obligation on the medical practitioners to protect the privacy of women undergoing the stipulated treatment. Under the Medical Termination of Pregnancy Rules, 2003 framed pursuant to the MTP Act, private clinics and hospitals can receive approval for such procedure only if the government is satisfied that termination of pregnancies will be done under safe and

hygienic conditions, and such clinic or hospital has the requisite infrastructure and instruments in place.

5. **The Transplantation of Human Organs and Tissues Act, 1994 ("Transplantation Act") and the Transplantation of Human Organs and Tissues Rules, 2014 ("Transplantation Rules")**

The Transplantation Act, and the Transplantation Rules have been enacted to regulate the removal, storage, and transplantation of human organs and tissues for therapeutic purposes, and for the prevention of commercial dealings in human organs and tissues. The Transplantation Act, inter alia, deals with the process for transplantation of human organs and tissues from living donors and cadavers to some other living person for therapeutic purposes, and provides for the roles and responsibilities of regulatory and advisory bodies constituted for monitoring tissue and organ transplantation in India. The Transplantation Act prohibits the removal of any human organ except in situations provided therein. No hospital can provide services relating to the removal, storage or transplantation of any human organ or tissue or both for therapeutic purposes unless such hospital is duly registered under the Transplantation Act.

6. **The Atomic Energy Act, 1962 ("AE Act")**

The AE Act aims to ensure safe disposal of radioactive waste and secure public safety, including that of persons handling radioactive substances. The AE Act empowers the GoI to, prohibit the manufacture, possession, use, and transfer, export and import, transport and disposal, of any radioactive substances without its written consent and requires any person to make periodical returns or other such statements as regards any prescribed substance in a person's possession or control that can be a source of atomic energy. Violations of certain provisions of the AE Act are punishable with a fine or imprisonment, or both. Further, the GoI, in order to prevent radiation hazards, secure public safety and safety of persons handling radioactive substances or radiation generating plants, is empowered to ensure safe disposal of radioactive wastes at such premises.

7. **The Atomic Energy (Radiation Protection) Rules, 2004 ("Radiation Rules")**

The Radiation Rules require that no person shall, without a license issued by the AERB, establish a radiation installation for siting, design, construction, commissioning or operation. The Radiation Rules also require a license for a person to handle radioactive material or operate a radiation generating equipment. A registration will be required under the Radiation Rules for sources and practices associated with medical diagnostic x-ray equipment including therapy simulator and analytical x-ray equipment used for research.

8. **The Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987 ("Radioactive Waste Rules")**

Under the Radioactive Waste Rules, an authorization is necessary for any person to dispose of radioactive waste, and the waste may only be disposed of in the terms of such authorization. A Radiological Safety Officer is required to be appointed to assist in the safe handling and

disposal of radioactive waste. Further, records are required to be maintained of all disposals and handling of radioactive waste and the persons carrying it out.

9. **The Radiation Surveillance Procedure for Medical Application of Radiation, 1989 ("Surveillance Procedures")**

The Surveillance Procedures seek to ensure that procedures and operations involving radiation installations, radiation equipment and radioactive materials are performed in conjunction with a pre-planned surveillance programme approved by the competent authority to ensure adequate protection. Any person desirous of handling any radioactive material or radiation equipment is required to obtain prior permission in the form of either a license or an authorization from the competent authority. The Surveillance Procedures prescribe the working conditions that are to be ensured at every medical radiation installation and provide safety guidelines regarding, inter alia, design safety of equipment, planning of radiation instalments, commissioning of radiation equipment or installations and isolation and disposal of radioactive effluents or damaged radioactive material.

10. The Safety Code for Medical Diagnostic X-Ray Equipment and Installations, 2001 (the "X-Ray Safety Code")

The X-Ray Safety Code, issued by the AERB, governs radiation safety in design, installation and operation of X-ray generating equipment for medical diagnostic purposes. The X-Ray Safety Code stipulates that all medical X-ray machines are required to be operated in accordance with the requirements stipulated therein and that it is the responsibility of the owner or user of medical X-ray installation equipment to ensure compliance with the stipulated provisions. The X-Ray Safety Code mandates that only the medical X-ray machines approved by the AERB can be installed for use in compliance with the specific requirements of the X-Ray Safety Code, including in relation to location and layout.

11. **The Safety Code for Nuclear Medicine Facilities, 2011 ("Nuclear Medicine Facilities Code")**

The Nuclear Medicine Facilities Code, issued by the AERB, governs the operations of a nuclear medicine facility from the setting up of such facility to its decommissioning. Nuclear medicine utilizes radio-pharmaceuticals to investigate disorders of anatomy, physiology and patho-physiology, for diagnosis or treatment of diseases or both. The Nuclear Medicine Facilities Code stipulates that a nuclear medicine facility can be commissioned, decommissioned or re-commissioned only with the prior approval of the AERB. The Nuclear Medicine Facilities Code further stipulates that radioactive material can only be procured after obtaining a license from the AERB. In addition to this, the Nuclear Medicines Facilities Code stipulates the responsibilities of employers, licensees, nuclear medicine physicians and technologists.

12. **The Clinical Thermometers (Quality Control) Order, 2001**

As per the Clinical Thermometer (Quality Control) order, 2001, no clinical mercury thermometer can be sold in the country without the Indian Standards Institution (ISI) certification mark given by Bureau of Indian Standards. The accuracy and quality of all

mercury-in-glass thermometers sold in the country are guaranteed by the Bureau of Indian Standards (BIS). Further, the accuracy of these thermometers are also governed by the Legal Metrology (General) Rules.

13. **The National Medical Commission Act, 2019 ("NMC Act")**

The NMC Act, 2019 provides for, among others, a medical education system that improves access to quality and affordable medical education, ensures availability of adequate and high quality medical professionals, encourages medical professionals to adopt latest medical research and enforces high ethical standards in medical services. The National Medical Commission, constituted under the NMC Act, is entrusted with the exercise of powers and functions under the NMC Act, including prescribing policies for quality medical education and for regulating medical institutions and professionals, and assessing healthcare requirements and developing a road map to meet such requirements. No person other than a person who is enrolled in the state or national medical register shall be allowed to practice medicine as a qualified medical practitioner and doing so is punishable with a fine or imprisonment or both.

14. **The Indian Nursing Council Act, 1947 ("Nursing Act")**

Under the Nursing Act, nurses, midwives or health visitors are required to hold recognized qualifications (as prescribed in the Nursing Act) for enrolment in the state register. Further, each state is entitled to establish a state council to regulate the registration of nurses, midwives or health visitors in the relevant state. The Nursing Act also empowers the executive committee of the Indian Nursing Council, constituted under the Nursing Act, to appoint inspectors to inspect any institution which is recognized as a training institution granting any recognized qualification or recognized higher qualification under the Nursing Act.

15. **The Guidelines for Exchange of Human Biological Material for Biomedical Research Purposes, 1997 ("HBM Guidelines")**

The HBM Guidelines, issued by the Central Government, lay down the manner in which human material with potential for use in biomedical research/ diagnostic purposes (including organs, cells, tissues, blood, and embryos) can be transferred to and from India and the mechanism to enable such transfers. The HBM Guidelines authorize the Indian Council of Medical Research ("ICMR") to set up a committee for consideration of proposals relating to, inter alia, exchange of biological materials for commercial purposes. The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 ("ICMR Code") The ICMR, in 2017, issued the ICMR Code which envisages that any medical research proposing to use human beings as research participants must be carried out if, after due consideration of all alternatives, the use of human participants is considered to be essential for such proposed study. The ICMR Code lays down the requirement of ensuring privacy and confidentiality along with ensuring that such studies are conducted in a transparent and environmentally friendly manner. As required by the ICMR Code, it is mandatory that all proposals on biomedical research involving human participants should be cleared by an independent and impartial institutional ethics committee to safeguard the welfare and the rights of the participants.

MARKET TRENDS

Market Overview (Healthcare and Medical Devices)

The Indian Medtech Industry was estimated to be $10.63 Bn in 2020 and is expected to reach $50 bn by 2025. Healthcare industry in India comprises of hospitals, medical devices, clinical trials, outsourcing, telemedicine, medical tourism, health insurance, and medical equipment. The healthcare sector is growing at a tremendous pace owing to its strengthening coverage, services, and increasing expenditure by public as well private players.

- The hospital industry in India, accounting for 80% of the total healthcare market, is witnessing a huge investor demand from both global as well as domestic investors.
- India ranks 10th in Medical Tourism Index (MTI) for 2020-2021 out of 46 destinations of the world. Foreign Tourists Arrival on medical purpose increases from 1.83 lakh in 2020 to 3.04 Lakh in 2021.
- The diagnostics industry in India is currently valued at $4 Bn. The share of the organized sector is almost 25% in this segment (15% in labs and 10% in radiology).
- 1,56,000 Ayushman Bharat centers, which aim at providing primary health care services to communities closer to their homes, are operational in India.
- More than 450 Mn ABHA IDs have been created, 2,19,546 Health Facilities have been registered, and around 2,28,794 Healthcare Professionals have been on boarded under ABDM, which shows that health services are being saturated, including by use of digital tools.

The medical devices sector in India comprises large multinationals, small and midsized companies. The size of the Indian medical devices market is estimated at ₹90,000 crore (US$ 11 billion) in 2022 and is expected to grow to US$ 50 billion by 2030 with a CAGR of 16.4 %. The Indian medical device market share in the global market is estimated to be 1.65%.

India is the 4th largest Asian medical devices market after Japan, China, and South Korea, and among the top 20 medical devices markets globally. Between 2020-30, the diagnostic imaging market is likely to expand at a CAGR of 16.4%. Export of medical devices from India stood at ₹19, 803 crore (US$ 2.40 billion) in FY22. The exports of medical devices during April-December, 2022 stood at ₹20,511 crore (US$ 2.49 billion), and are expected to rise to US$ 10 billion by 2025.

To increase export of medical devices in the country, the Ministry of Health and Family Welfare (MOHFW) and Central Drugs Standard Control Organisation (CDSCO) implemented the following initiatives:

- Re-examination and implementation of Schedule MIII (a draft guidance on good manufacturing practices and facility requirements)
- System for export labelling
- Clinical evaluation and adverse reporting clarification
- State licensing authority to extend free sales certificate validity from 2 years to 5 years to allow exports
- Create a list of manufacturers with export licensing for easy access to regulatory authorities.

Government Initiatives (medical devices)

The Government of India has commenced various initiatives to strengthen the medical devices sector, with emphasis on research and development (R&D) and 100% FDI for medical devices to boost the market.

- The Union Cabinet approved the National Medical Devices Policy, 2023 on April 26, 2023. The National Medical Devices Policy, 2023 is expected to facilitate an orderly growth of the medical device sector to meet the public health objectives of access, affordability, quality, and innovation. The policy is expected to help the Medical Devices Sector grow from the present US$ 11 billion to US$ 50 billion by 2030.
- Under the PLI scheme for Medical Devices, till now, a total of 26 projects have been approved, with a committed investment of ₹1,206 crore (US$ 147 million) to enable growth and innovation in the MedTech industry and make India as the global hub for manufacturing and innovation in the coming years.
- In September 2022, the government of India approved the setting up of an export promotion council for medical devices, under the Department of pharmaceuticals, with its headquarters in Noida.
- In August 2022, the Department of Pharmaceuticals greenlit the "Promotion of Medical Device Parks" programme from FY21-25 with a total financial investment of ₹400 crore (US$ 48.97 million), with a maximum support under the programme of ₹100 crore (US$ 12.24 million) for each Medical Device Park.
- In August 2022, the Department of Pharmaceuticals reconstituted the National Medical Devices Promotion Council (NMDPC) under the Chairmanship of the Secretary of the Department of Pharmaceuticals.
- In July 2022, the government tabled a draft for the new Drugs, Medical Devices and Cosmetics Bill 2022, to assure and offer thorough legal protections to ensure that the medical items sold in India are reliable, efficient, and up to required standards.
- In the Union Budget 2022-23, ₹86,200 crore (US$ 11.3 billion) was allocated as a budget for the pharmaceutical and healthcare sector.
- In October 2021, the government announced plan to draft a new drugs, cosmetics and medical devices bill to increase the acceptability of Indian medical devices in the global market.
- In October 2021, the government announced that 13 companies have been approved under the PLI scheme for medical devices, which is expected to boost domestic manufacturing in the country.
- In September 2021, the government sanctioned a proposal worth ₹5,000 crore (US$ 674.36 million) to build a medical devices park in Himachal Pradesh's industrial township, Nalagarh, in the Solan district.
- In September 2021, the government approved a medical devices park in Oragadam (Tamil Nadu) that is expected to attract an estimated investment of ₹3,500 crore (US$ 472.05 million) and offer direct and indirect employment to ~10,000 people.
- In July 2021, the government announced that they would build a medical park in Uttar Pradesh, which is expected to generate an estimated ₹500 crore (US$ 67.13 million) business in the state.

- In June 2021, the Quality Council of India (QCI) and the Association of Indian Manufacturers of Medical Devices (AiMeD) launched the Indian Certification of Medical Devices (ICMED) 13485 Plus scheme to undertake verification of the quality, safety and efficacy of medical devices
- To boost domestic manufacturing of medical devices and attract huge investments in India, the department of pharmaceuticals launched a PLI scheme for domestic manufacturing of medical devices, with a total outlay of funds worth ₹3,420 crore (US$ 468.78 million) for the period FY21-28.
- The Medical Devices Virtual Expo 2021 showcased Indian products and enabled direct interaction between Indian suppliers and buyers/importers from participating countries; 300 foreign buyers from the healthcare sector participated in this event.
- In March 2021, the PLI Scheme for pharmaceuticals worth ₹15,000 crores (US$ 1.96 billion) was launched. This scheme aims to enhance India's manufacturing capabilities by increasing investment and production in the pharmaceutical and medical devices sectors and contribute to the availability of a wider range of affordable medicines for consumers.
- On March 25, 2021, the Department of Pharmaceuticals released a revised notice on the Public Procurement Order (PPO), incorporating 19 medical devices in the revised guidelines of the PPO, which is expected to improve domestic medical devices manufacturing (and strengthen 'Make in India') and reduce import bills by ~Rs. 4,000 crore (US$ 538.62 million).
- In April 2021, in order to expedite the clearance of medical devices such as nebulisers, oxygen concentrators and oxygen cannisters, the government made it easier to import critical medical devices by easing the requirements for clearance under the Legal Metrology Act (Packaging Rules 2011).

India is the 4TH largest Asian medical devices market after Japan, China, and South Korea, and among the top 20 medical devices markets globally. However, it has the potential to surpass its peers in terms of size and scale; this is based on the government's support the sector has received over the past several years. India's medical devices market is projected to reach US$ 50 billion by 2030. Between 2022-2030, diagnostic imaging is likely to expand at a CAGR of 16.4%.

The Government of India has commenced various initiatives (*mentioned above*) to strengthen the sector, with emphasis on R&D and 100% FDI for medical devices to boost the market.

Government Initiatives (Healthcare Sector)

Some of the major initiatives taken by the Government of India to promote the Indian healthcare industry are as follows:

- PoshanAbhiyan is a Centrally Sponsored Scheme with the implementation of the scheme being done by States/UTs. To ensure that all Anganwadi Centres are equipped with Smartphones and Growth Monitoring devices (GMDs) such as Infantometer, Stadiometers, and Weighing Scale for Mothers and Infant, the Ministry has released revised guidelines for technical specifications and replacement of GMDs by the States.

- In the Union Budget 2023-24:
    - Under the Union Budget 2023-24, the Ministry of Health and Family Welfare has been allocated Rs. 89,155 crore (US$ 10.76 billion), an increase of 3.43% compared to Rs. 86,200.65 crore (US$ 10.4 billion) in 2021-22.
    - Pradhan Mantri Swasthya Suraksha Yojana (PMSSY) was allocated Rs. 3,365 crore (US$ 0.41 billion)
    - Human Resources for Health and Medical Education was allotted Rs. 6,500 crore (US$ 780 million).
    - National Health Mission was allotted Rs. 29,085 crore (US$ 3.51 billion).
    - Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) was allotted Rs. 7,200 crore (US$ 870 million).
- In July 2022, the World Bank approved a US$ 1 billion loan towards India's Pradhan Mantri-Ayushman Bharat Health Infrastructure Mission.

- To promote medical tourism in the country, the government of India is extending the e-medical visa facility to the citizens of 156 countries.

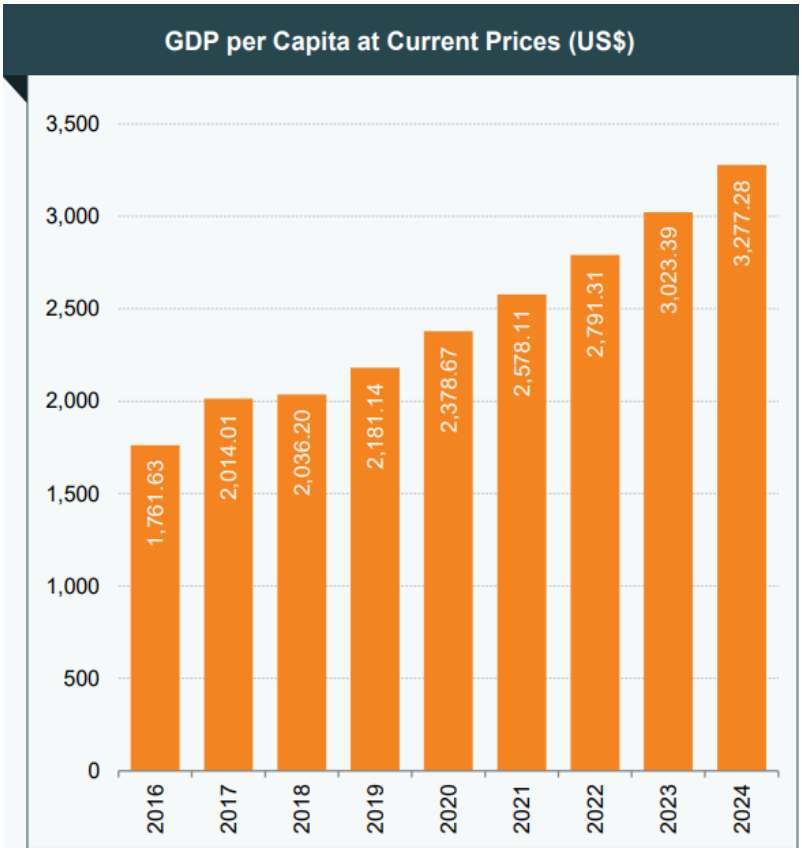
- In May 2022, the Union Government approved grants for five new medical colleges in Gujarat with a grant of Rs. 190 crore (US$ 23.78 million) each. These colleges will come up in Navsari, Porbandar, Rajpipla, Godhra and Morbi.

- In November 2021, the Government of India, the Government of Meghalaya, and the World Bank signed a US$ 40-million health project for the state of Meghalaya. The project will improve the quality of health services and strengthen the state's capacity to handle future health emergencies, including the COVID-19 pandemic.

- In September 2021, Prime Minister Mr. Narendra Modi launched the Ayushman Bharat Digital Mission. The mission will connect the digital health solutions of hospitals across the country. Under this, every citizen will now get a digital health ID and their health record will be digitally protected.

- In September 2021, the Telangana government, in a joint initiative with World Economic Forum, NITI Aayog and HealthNet Global (Apollo Hospitals), launched the 'Medicine from the Sky' project. The project will pave the way for drone delivery of life-saving medicines and jabs in far-flung regions of the country.

- According to a spokesperson, the Indian government is planning to introduce a credit incentive programme worth Rs. 500 billion (US$ 6.8 billion) to boost the country's healthcare infrastructure. The programme will allow firms to leverage the fund to expand hospital capacity or medical supplies with the government acting as a guarantor and strengthening COVID-19-related health infrastructure in smaller towns.



- In July 2021, the Ministry of Tourism established the 'National Medical & Wellness Tourism Board' to promote medical and wellness tourism in India.

- In July 2021, the Union Cabinet approved the continuation of the National Ayush Mission, responsible for the development of traditional medicines in India, as a centrally sponsored scheme until 2026.

- In July 2021, the Union Cabinet approved the MoU between India and Denmark on cooperation in health and medicine. The agreement will focus on joint initiatives and technology development in the health sector, to improve the public health status of the population of both countries.

- In June 2021, the Ministry of Health, and Family Welfare, in partnership with UNICEF, held a capacity-building workshop for media professionals and health correspondents in Northeastern states on the current COVID-19 situation in India, to bust myths regarding COVID-19 vaccines & vaccination and reinforce the importance of COVID-19 Appropriate Behaviour (CAB).