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INDIA

Law and Practice

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The key pieces of legislation and regulation governing pharmaceuticals and medical devices are as follows.

- The Drugs and Cosmetics Act 1940 (the "DC Act") and the Drugs and Cosmetic Rules 1945 (the "DC Rules") regulate the manufacturing, importation, sale and distribution of pharmaceuticals in India.
- The Medical Device Rules 2017 (the "MD Rules") (as amended from time to time under the DC Act) – along with the DC Rules – regulate the importation, manufacture, sale and distribution of all medical devices. Furthermore, the medical device is required to conform to the standards laid down by the Bureau of Indian Standards Act 1985 or as may be issued by the Ministry of Health and Family Welfare (MoHFW) from time to time. Where no relevant standard for a medical device has been laid down, it is required to conform to the standard laid down by the International Organization for Standardization (ISO) or the International Electrotechnical Commission (or any other pharmacopeial standards). If the standards have not been specified under any of the aforementioned two bodies, the device is required to conform to the validated manufacturer's standards.
- The New Drugs and Clinical Trials Rules 2019 (the "CT Rules") (as amended from time to time under the DC Act) regulate clinical trials, bio-equivalence studies, bio-availability studies and the Ethics Committee (EC) for new drugs and investigational new drugs for human use.
- The Narcotic Drugs and Psychotropic Substances Act 1985 (the "NDPS Act") regulates the production/manufacturing/cultivating, possessing, selling, purchasing, transporting, storing and/or consuming of any narcotic drug or psychotropic substance.
- The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 – along with the DMR Rules 1977 (as amended from time to time) – regulates the advertisement of medicinal products.
- The Uniform Code of Pharmaceuticals Marketing Practices issued by the Department of Pharmaceuticals (DoP) also provides directions on suitable promotional materials for medicinal products.
- The Code for Self-Regulation in Advertising issued by the Advertising Standards Council of India, a non-statutory body, regulates the publishing of advertisements in India – including those for medicinal products.
- The Consumer Protection Act 2019 prohibits false advertising by misrepresentations or false allurements.
- The Medicinal and Toilet Preparations (Excise Duties) Act 1956 provides for the levy and collection of duties of excise on medicinal products.
- The Essential Commodities Act 1955 and the Drugs (Prices Control) Order 2013 (DPCO) thereunder regulate the price of drugs and medical devices specified in the National List of Essential Medicines (NLEM).
- The Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro-Organisms/Genetically Engineered Organisms or Cells 1989 (the "1989 Rules"), issued under the Environment (Protection) Act 1986, regulate hazardous micro-organisms/genetically engineered organisms or cells.

- The Foreign Trade (Development and Regulation) Act 1992 (the "FTDR Act") and the rules thereunder provide for the development and regulation of foreign trade.
- The Biodiversity Act 2002 (the "BD Act") and the rules thereunder provide a mechanism for benefit-sharing arising from the use of traditional biological resources and knowledge.
- On 8 July 2022, the MoHFW notified draft of New Drugs, Medical Devices and Cosmetic Bill 2022 for public consultation. The objective of the bill is to amend and consolidate the law in relation to:
  (a) the import, manufacture, distribution and sale of drugs, medical devices and cosmetics to ensure their quality, safety, efficacy, performance;
  (b) clinical trials of new drugs; and
  (c) clinical investigation of medical devices.

In addition to the foregoing, there are specific guidelines for various issues – for example, the conduct of clinical trials, market authorisation of biosimilars, ribosomal DNA (rDNA) research, ethics, and the privacy of healthcare-related data.

Regulatory Bodies/Committees/Authorities
The key regulatory authorities in respect of drugs and medical devices are as follows.

- The Central Drugs Standard Control Organisation (CDSCO) headed by the Drugs Controller General of India (DCGI) is responsible for the implementation of the DC Act and the rules thereunder. It exercises regulatory control over the importation of drugs, the approval of new drugs and clinical trials, and meetings of the Drugs Consultative Committee and the Drugs Technical Advisory Board (DTAB). It also acts as a Central Licensing Authority (CLA) and co-ordinates the activities of state drug control organisations (SDCOs).
- The SDCO of a particular state regulates the manufacture, sale and distribution of drugs, medical devices and cosmetics at the state level. It monitors the quality of drugs, cosmetics and medical devices in the concerned state. It also acts as a state licensing authority (SLA).
- Various authorities and regulatory bodies are responsible for implementing the provisions of the NDPS Act as follows:
  (a) the Narcotics Control Bureau (NCB)'s functions include drug law enforcement and the receipt and monitoring of returns regarding controlled substances under the NDPS (Regulation of Controlled Substances) Order 1993;
  (b) the Central Bureau of Narcotics (CBN)'s functions include licensing and supervision of the cultivation of the opium poppy, licensing the manufacture of narcotic drugs, and controlling the importation and exportation of narcotic drugs and psychotropic substances (and precursors); and
  (c) state governments' functions include:
    (i) control on sale, use, consumption and movement of narcotic drugs, usually through the state excise department; and
    (ii) framing rules with regard to permission and regulation of the cultivation of any cannabis plant and the production, manufacture, possession, transport, import and export inter-state, sale, consumption or use of cannabis (excluding charas).
- The Indian Council of Medical Research (ICMR) is the apex body for the formulation, co-ordination and promotion of biomedical research.
- The DoP regulates various issues related to pricing and the availability of medicines at affordable prices, R&D, protection of IP rights,

and international commitments involving the pharmaceutical sector that require the integration of work with other ministries.

- The National Pharmaceutical Pricing Authority (NPPA) is responsible for monitoring, fixing and revising the prices of drugs and medical devices, as well as enforcement of the provisions of the Drugs (Prices Control) Order 2013.
- The Review Committee on Genetic Manipulation (RCGM) is responsible for authorising the conduct of R&D, the exchange of genetically engineered cell banks for R&D, and the review of data up to pre-clinical evaluation.
- The Genetic Engineering Appraisal Committee (GEAC) reviews applications and approval of activities where the final drug product contains genetically modified organisms/living modified organisms.
- The Department of Biotechnology (DBT) is responsible for administrating development and commercialisation in the field of modern biology and biotechnology.
- The State Biotechnology Co-ordination Committee (SBCC) is responsible for inspecting, investigating and taking punitive action in the case of violations of statutory provisions through the State Pollution Control Board (SPCB) or the Directorate of Health, etc.
- The District Level Biotechnology Committee (DLC) is responsible at the district level for monitoring the safety regulations in installations engaged in the use of GM organisms/hazardous micro-organisms and their applications within such environments.
- The Institutional Biosafety Committee (IBC) is the nodal point for the implementation of the biosafety guidelines and the interactions within an institution.
- Gazetted officers are authorised by the state governments to enforce drug advertising regulations.
- The Bureau of Indian Standards (BIS) is responsible for the harmonious development of the standardisation, marking, and quality certification of goods, as well as matters connected therewith or incidental thereto.
- The Pharmaceuticals Export Promotion Council of India (Pharmexcil) promotes pharmaceutical exports from India. All the exporters of pharmaceutical products must have a valid registration-cum-membership certificate issued by Pharmexcil.
- The Directorate General of Foreign Trade is involved in the regulation and promotion of foreign trade under the FTDR Act.
- The National Biodiversity Authority and state biodiversity boards are the main regulatory bodies under the BD Act.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

Any person who is aggrieved by any order passed by the CLA or the SLA may file an appeal to the central government or the state government respectively within the stipulated period. The respective government may make necessary orders following an inquiry and after hearing the appellant.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals and medical devices are regulated according to their categories. The DC Rules provide for the classification of drugs in various schedules. Each schedule has a guideline for labelling, storing, selling, displaying and prescribing a listed drug. The schedules are as follows:

- Schedule C – biological and immunological products, antibiotics, ophthalmic preparations, and all products for parenteral use;

- Schedule C(I) – drugs of biological origin (namely alkaloids, hormones, vitamins, and antibiotics for oral use);
- Schedule G – drugs that can be administered only under the supervision of a registered medical practitioner;
- Schedule H – drugs that are required to be dispensed on the prescription of a registered medical practitioner;
- Schedule H1 – drugs including antibiotics, habit-forming drugs, and a few anti-tuberculosis medicines;
- Schedule K – OTC drugs; and
- Schedule X – psychotropic drugs that must be dispensed on the prescription of a Registered Medical Practitioner (RMP). A special retail licence is required for selling these drugs.

Similarly, the MD Rules provide for a risk-based classification of all medical devices. Medical devices, except in vitro diagnostic medical devices, are classified according to Part I of the First Schedule, as follows:

- low risk – Class A;
- low-to-moderate risk – Class B;
- moderate-to-high risk – Class C; and
- high risk – Class D.

In vitro diagnostic medical devices are classified according to Part II of the First Schedule, as follows:

- low risk – Class A;
- low-to-moderate risk – Class B;
- moderate-to-high risk – Class C; and
- high risk – Class D.

2. Clinical Trials

2.1 Regulation of Clinical Trials

The CDSCO, via the CLA, regulates the clinical trials of drugs and medical devices. A clinical trial is required to be conducted in accordance with the Good Clinical Practice Guidelines issued by the CDSCO.

The CT Rules regulate clinical trials, bio-equivalence studies, bio-availability studies and investigations into new drugs for human use. The DC Rules regulate clinical trials for veterinary drugs.

The MD Rules regulate the clinical investigation of medical devices and the clinical performance evaluations of new in vitro diagnostic medical devices. The EC for clinical investigations of medical devices is established in accordance with the DC Rules.

The National Guidelines for Gene Therapy Product Development and Clinical trials 2019 (the "GTP Guidelines") provide guidance for conducting clinical trials in areas pertaining to gene therapy.

The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2019 and the National Ethical Guidelines for Biomedical Research Involving Children (collectively, the "Ethical Guidelines") provide general guidance for conducting clinical trials involving adults and children ethically.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Detailed clinical trials – or investigations or performance studies (as the case may be) – must be conducted in order to obtain market authorisation for any of the following.

- New drug – a "new drug" is considered "new" for a period of four years from the date of its first approval and can be:
  (a) a drug that has neither been used in India to any significant extent under the conditions prescribed, recommended or suggested in the labelling thereof nor recognised as effective and safe by the CLA for the proposed claims – and, as such, any use of which has been with the permission of the CLA;
  (b) a drug that has already been approved by the CLA for certain claims and is now proposed to be marketed with modified or new claims – namely, indications, dosage, dosage form (including sustained-release dosage form) and route of administration;
  (c) a fixed-dose combination of two or more drugs that have already been individually approved for certain claims and are now proposed to be combined for the first time in a fixed ratio (or if the ratio of ingredients in an already marketed combination is proposed to be changed) with certain claims – namely, indications dosage, dosage form (including sustained-release dosage form) and route of administration;
  (d) a vaccine, rDNA-derived product, living modified organism, monoclonal antibody, cell or stem cell-derived product, gene therapeutic product or xenografts intended to be used as a drug;
  (e) a modified or sustained-release form of a drug; or
  (f) a novel drug delivery system of any drug approved by the CLA.
- Investigational new drug – a new chemical or biological entity or substance that has not been approved for marketing as a drug in any country.
- Investigational medical device – a device that does not have a predicate device or a device that, after being authorised for marketing, claims for a new intended use or a new population or for a new material or a major design change.
- New in vitro diagnostic medical device – any in vitro diagnostic medical device covered under the MD Rules that does not have the CLA's approval for manufacture for sale or for importation and is being tested for the relevant analyte or other parameter related thereto in order to establish its performance.

An online application for conducting a clinical trial can be filed in a prescribed format, together with all the necessary documents and information. The CLA is required to evaluate the application within the prescribed time. An application for drugs discovered, researched and manufactured in India must be evaluated within 30 days. If the CLA does not respond within 30 days to the application for drugs developed in India, the applicant may conclude that permission to conduct the trial has been granted.

The clinical trial can be initiated only once the trial protocol and other related documents have been approved by the EC. If the EC rejects the protocol, the details of the same should be submitted to the CLA before seeking approval of another EC for conducting the clinical trial at the same site. The CLA is informed about the approval granted by the EC within the stipulated time of the grant of such approval. The CLA may grant permission to conduct the clinical trial or reject the application for reasons to be recorded in writing. The permission to initiate a clinical trial remains valid for two years from the date of its grant.

The MD Rules discuss two types of clinical investigations: a pilot study and a pivotal study. A pilot study is an exploratory study that is used

to acquire specific essential information about a medical device before beginning the pivotal clinical investigation. A pivotal study is a confirmatory study to support the evaluation of the safety and effectiveness of the medical device for its intended use. For an investigational medical device developed in India, the applicant is required to conduct pilot and pivotal studies in India.

On 14 October 2022, the MoHFW issued the New Drugs and Clinical Trials (Third Amendment) Rules 2022 to further amend the CT Rules. The new rules provide for the deemed approval or permission or registration (as the case may be) for various activities such as:

- the registration of EC;
- permission to conduct clinical trials; permission to conduct bioavailability or bioequivalence studies for the new drug or investigational new drug;
- permission to manufacture new drugs or investigational new drugs for clinical trial or bioavailability or bioequivalence studies or test and analysis;
- permission to manufacture unapproved active pharmaceutical ingredients – or to manufacture the pharmaceutical formulation for test or analysis or clinical trial or bioavailability and bioequivalence studies – if no communication has been received from the CLA after filing the necessary request or application.

Furthermore, said deemed approval or permission or registration shall be deemed to be legally valid for all purposes.

Waiver of the Requirement for a Local Clinical Trial in Certain Cases of New or Investigational Drugs

The CLA, with approval from the central government, may waive the requirement for a local clinical trial for the approval of a new drug already approved in other countries in the following cases.

- The new drug is approved and marketed in countries specified under the CT Rules and no unexpected serious adverse events have been reported, where:
  - (a) the applicant has given an undertaking in writing to conduct a Phase IV clinical trial to establish the safety and effectiveness of such new drug as per the design approved by the CLA; and
  - (b) there is no evidence or probability (based on existing knowledge) of difference in the Indian population with regard to:
    - (i) the enzymes or gene involved in the metabolism of the new drug; or
    - (ii) any factor affecting the pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug.
- The importation of a new drug for which the CLA had already granted permission to conduct a global clinical trial, which is ongoing in India, where:
  - (a) this new drug has been approved for marketing in a country specified under the CT Rules in the meantime;
  - (b) the applicant has given an undertaking in writing to conduct a Phase IV clinical trial to establish the safety and effectiveness of such new drug as per the design approved by the CLA; and
  - (c) there is no evidence or probability (based on existing knowledge) of difference in the Indian population with regard to:

(i) the enzymes or gene involved in the metabolism of the new drug; or
(ii) any factor affecting the pharmacokinetics and pharmacodynamics, safety and efficacy of the new drug.

- Furthermore, the requirements may be relaxed, abbreviated, omitted or deferred in the case of life-threatening or serious disease conditions, or rare diseases, and for drugs intended to be used for:
- diseases that are particularly relevant to the Indian health scenario;
- an unmet medical need in India;
- a disaster; or
- a special defence use.

The CLA may relax the requirement of local Phase IV clinical trials where:

- the new drug is an orphan drug; or
- the new drug is indicated for:
  (a) life-threatening or serious diseases;
  (b) diseases with special relevance to the Indian health scenario;
  (c) a condition that has an unmet need in India;
  (d) rare diseases for which drugs are not available (or are available at a high cost).

Waiver of the Requirement of Pivotal Studies in Certain Cases of New or Investigational Medical Devices

A pivotal clinical study is not required to be conducted for investigational medical devices classified under Class A of the MD Rules. However, in exceptional cases, the CLA may – for reasons to be recorded in writing – mandate conducting a pivotal clinical study of such devices (depending on the nature of the medical device).

For investigational medical devices developed and studied in a country other than India, the applicant is required to submit the details of the pilot clinical investigation or relevant clinical study data generated outside India along with the application. The CLA may grant permission to repeat a pilot study or to conduct a pivotal clinical investigation only.

Clinical investigation may not be required in the case of investigational medical devices approved for at least two years in the USA, the UK, Australia, Canada or Japan – provided certain conditions are met.

2.3 Public Availability of the Conduct of a Clinical Trial

It is mandatory to register clinical trials prospectively in the ICMR's Clinical Trials Registry – India (ICMR-CTRI), which is a free online platform.

2.4 Restriction on Using Online Tools to Support Clinical Trials

Trials registered on the ICMR-CTRI are publicly available and free to search.

2.5 Use of Data Resulting From the Clinical Trials

The CT Rules and the MD Rules require the investigator of a clinical trial to give an undertaking that they will maintain the confidentiality of the identities of all the participants and ensure the security of the clinical trial data. The Ethical Guidelines set out the principle of ensuring the privacy and confidentiality of the participants of the clinical trials.

2.6 Databases Containing Personal or Sensitive Data

The Information Technology Act 2000 as amended by the IT (Amendment) Act 2008 (the "IT Act") and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011 (the "IT

Rules") regulate the collection, storage and processing of personal data. The IT rules define the sensitive personal data or information (SPDI) of a person, which includes physical, physiological, mental health conditions and medical records and history. SPDI also includes medical records and health data recorded by fitness trackers.

On 7 December 2022, the Ministry of Electronics and Information Technology released a draft bill titled "the Digital Personal Data Protection Bill 2022" for public consultation. The bill is concerned with the processing of digital personal data within India. Under the bill, the digital personal data includes digital data collected online or offline. The provisions of the bill also apply to the digital data processed outside India. The bill sets out the rights and duties of citizens and the obligations of the Data Fiduciary. The obligations of the Data Fiduciary include maintaining the accuracy of data, keeping data secure, and deleting data after its purpose is fulfilled.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

Please see **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

All types of biologics, including biosimilars, are classed as "new drugs" under the DC Rules and the CT Rules. The applicant is required to conduct the following studies in respect of all types of biologics:

- pre-clinical studies;
- clinical studies; and
- post-market surveillance.

In addition, comparative data of the pre-clinical studies and clinical studies of biosimilars and reference biologics are required to be submitted for a biosimilar.

The following regulations and guidelines are also specifically relevant to the approval of biologics:

- the 1989 Rules;
- the Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India 2016, which lay down the regulatory pathway for a similar biologic;
- the Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment 2017, which provide guidance on handling hazardous biological material, recombinant nucleic acid molecules and cells, organisms, and viruses containing such molecules;
- the GTP Guidelines, which aim to guide and enable the stakeholders to comprehend and comply with the regulatory requirements for research and development of gene therapy products in India, as well as provide basic guidance for research involving human participants (including clinical trials) that pertains to the broad area of gene therapy;
- the Guidance Document for Industry: Submission of Stability Data and Related Documents for Review and Expert Opinion for Granting Post-Approval Changes in Shelf Life of Recombinant Biotherapeutic Products and Therapeutic Monoclonal Antibodies, which was published by the National Institute of Biologicals in 2016 and provides recommendations to holders of marketing authorisations for recombinant technology-based products who intend to make post-approval changes

in the shelf life of such products in accordance with CDSCO Guidance Document No PAC/1108 Version 1.1; and
- the Guidelines and Handbook for Institutional Biosafety Committee (IBSC).

In addition to the CDSCO, the approval of biologics is overseen by the RCGM, IBSC and GEAC.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

An original licence or a renewed licence for the manufacture for sale or distribution of drugs, unless suspended or cancelled, is valid for five years from the date on which it is granted or renewed. If the application for renewal of a licence in force is made before its expiry or if the application is made within six months of its expiry (after payment of an additional fee), the licence continues to be in force until orders are passed on the application.

An importation licence for a drug, unless suspended or cancelled, remains valid for three years from the date of its issue. If an application for a fresh licence is made three months before the expiry of the existing licence, the current licence is deemed to continue in force until orders are passed on the application.

The licence for manufacture, distribution, sale, importation and exportation of medical devices granted under the MD Rules remains valid unless suspended, cancelled or surrendered. The licensee is required to pay a prescribed fee every five years to prevent the cancellation of the licence.

If the licensee fails to comply with any of the stipulated conditions prescribed under the regulations, the CLA may suspend or cancel the licence by an order in writing – stating the reasons therein – after giving an opportunity to show cause why such an order should not be passed.

On 11 February 2020, the MoHFW introduced a new definition of a medical device, thereby bringing all devices under the purview of the MD Rules. On the same day, the MoHFW issued another notification requiring the registration of such newly notified medical devices on the online portal of the CDSCO according to the timeline specified therein.

On 16 March 2022, the DoP issued a draft Uniform Code for Medical Devices Marketing Practices. The draft is proposed to be a voluntary code for the marketing of medical devices specifically. The draft provides standards for the promotion, marketing and sale of medical devices, whereby the distribution of gifts or benefits to healthcare professionals is prohibited.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

An application for market authorisation of a drug or a medical device may be filed online. In the case of a new drug or an investigational new drug/medical device or a new in vitro diagnostic medical device, the application must be accompanied by detailed clinical trial data. Applications for other types of drugs must be accompanied by bio-equivalence and bio-availability studies.

On 31 December 2021, the MoHFW issued the Medical Devices (Amendment) Rules 2021, which require every medical device approved for manufacture for sale or distribution, or for importation, to bear a unique device identification in the manner as specified in said order. The rule will come into effect on a date notified by the central government.

On 24 August 2022, the MoHFW notified the Drugs (Seventh Amendment) Rules 2022 for enabling the parallel submission of applications for marketing approvals and manufacturing licences for new drugs in India.

On 30 September 2022, the MoHFW notified the Medical Devices (Fifth Amendment) Rules 2022, which amend the MD Rules. As per the amended rules, any person who intends to sell (or offer for sale), stock, exhibit or distribute any medical device (including in vitro diagnostic medical devices) is required to obtain a registration certificate from the SLA concerned. The rules also lay down the conditions for the registration certificate.

On 14 October 2022, the MoHFW notified the Medical Devices (Sixth Amendment) Rules 2022, which further amend the MD Rules in order to:

- provide for registration of all Class A medical device manufacturers through an identified online portal; and
- exempt Class A non-measuring and non-sterile medical devices from requiring an importation licence.

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

The DC Act and the DC Rules provide for limited access to drugs or medical devices, the importation of which is otherwise not allowed.

Small quantities of a new drug or investigational medical device may be imported for the treatment of patients suffering from life-threatening diseases (or diseases causing serious permanent disability or a disease requiring therapies for unmet medical needs) by a medical officer of a government hospital or an autonomous medical institution providing tertiary care – if duly certified by the medical superintendent of the government hospital or head of the autonomous medical institution (subject to specific conditions).

Small quantities of a drug or a medical device – the importation of which is otherwise prohibited – may be imported for personal use subject to specific conditions. Furthermore, the importation of small quantities of a drug or a medical device donated to a charitable hospital for the treatment of patients free of cost may be allowed by the CLA.

On 5 June 2020, the central government – in consultation with the DTAB – issued draft New Drugs and Clinical Trials (Amendment) Rules 2020 for compassionate use of any new unapproved drug for the treatment of patients by hospitals and medical institutions. However, there has not been any further development in this respect.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

The holder of the market authorisation for a new drug, an investigational new drug or an investigational medical device is under an obligation to conduct post-market surveillance or Phase IV clinical trials. The holder is required to submit a Periodic Safety Update Report as prescribed.

The DC Rules and the MD Rules mandate maintenance of records pertaining to sales, manufacture, batches, master formula, packing and processing, distribution, investigation, testing, and remedial action taken for drugs and medical devices.

The DC Rules and the MD Rules include provisions for product recall (drugs or medical devices) by the manufacturer, importer or authorised agent (as the case may be). The CDSCO has issued detailed Guidelines on the Recall and Rapid Alert System for Drugs for both voluntary and statutory recall.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

Third parties cannot access any information regarding pending applications for marketing authorisations for drugs and medical devices.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Adulterated, misbranded, spurious or illegally distributed drugs and medical devices are regulated under the DC Act, the DC Rules and the MD Rules (as the case may be). The manufacture for sale or distribution, selling, stocking, exhibiting or offering for sale or distribution of such drugs and medical devices is a penal offence punishable with imprisonment and/or fines of varying degrees based on the seriousness of the offence.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

The Customs Act 1960 (the "Customs Act"), along with the Intellectual Property Rights (Imported Goods) and the Enforcement Amendment Rules 2018 (the "IPREA Rules"), prohibits the importation of goods that infringe on intellectual property (except patents). The Customs Act empowers the customs authority to confiscate goods subject to the conditions and procedures specified under the IPREA Rules. The owner of the IP right is required to record their IP right at the Indian Customs IP Rights Recordation Portal. The owner also has to sign a bond with the customs authority undertaking to pay the costs of retention/destruction of the infringing goods and to indemnify the customs office.

Furthermore, Customs can – on its own initiative – suspend the clearance of the imported goods if there is prima facie evidence or reasonable grounds to believe that the goods are infringing IPRs. In such a scenario, the rights-holder or its agent must comply with the requirements of the recordal within five days – otherwise the goods may be released.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

The manufacturing plants of drugs and medical devices are subjected to authorisation. The CDSCO is the main regulatory body for granting the authorisation. The manufacture of any drug – or Class A and Class B medical device – is subject to the grant of a licence by the SLA. The manufacturing of Class C and Class D medical devices is subject to the grant of a licence by the CLA.

The DC Rules lay down the requirement of factory premises, plant and equipment for manufacturing, depending on the type of drug. These rules lay down the requirement for the location, building condition (as per the Factories Act 1948 (63 of 1948)), water treatment system, the disposal of sewage and effluents (as per the Environment Pollution Control Board), and biomedical waste (as per the Biomedical Waste (Management and Handling) Rules 1996).

The MD Rules lay down requirements for the manufacturing of medical devices for sale and distribution. These rules also stipulate a Quality Management System that a manufacturer is required to use. The MD Rules lay down requirements for the safety and performance of medical devices.

The licence remains valid if a licence retention fee is paid, before expiry, every five years from the date of its issue – unless it is suspended or cancelled by the licensing authority.

The manufacturer of the new medical devices is required to obtain a registration number under the MD Rules for the manufacturing of medical devices.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Establishments engaged in the wholesale of drugs and medical devices are subject to authorisation by the SLA. An application for obtaining a wholesale licence to sell, stock, exhibit, offer for sale, or distribute a drug or a medical device may be filed online. The licence is issued based on the category of the drug or medical device in question. A licence issued remains valid if the licensee deposits a licence retention fee, before expiry, every five years from the date of its issue – unless it is suspended or cancelled by the licensing authority.

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The DC Act and the DC Rules primarily regulate the importation and exportation of drugs in India along with other regulations. The importation and exportation of medical devices are regulated by the MD Rules along with the DC Act. The CLA grants the licence for importation or exportation subject to other relevant regulation(s).

6.2 Importer of Record of Pharmaceutical and Medical Devices

There are no specific requirements or qualifications required for a person to act as an importer of record.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The importation of drugs and medical devices in India is subject to prior authorisations from the CLA. Limited access to unauthorised drugs and medical devices is allowed in specific circumstances with specific conditions (see **3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations**). The importer of the new medical device is required to obtain a registration number under the MD Rules for importing medical devices (see **3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices**).

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The importation of drugs and medical devices into India is primarily regulated by the CDSCO

under the DC Act, the DC Rules and the MD Rules (as the case may be), along with other regulations. The DC Act and the MD Rules also stipulate labelling requirements for imported drugs and medical devices. By way of an example, the importation of the following is prohibited:

- any patented or proprietary medicine, unless there is displayed – in the prescribed manner on the label or container thereof – the true formula or list of active ingredients contained in it (together with the quantities thereof); and
- any drug that – by means of any statement, design or device accompanying it (or by any other means) – purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect (as may be prescribed).

Furthermore, the central government has powers to prohibit the importation of drugs and medical devices in the name of public interest.

6.5 Trade Blocs and Free Trade Agreements

India is a party to several regional and bilateral trade agreements, such as those with the UAE and various African and Asian countries. These trade agreements facilitate trade of various goods, including pharmaceuticals and medical devices.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

The DPCO controls the price of drugs and medical devices listed in the NLEM, which is updated from time to time based on the recommendation of the MoHFW. The NPPA is the regulatory body that regulates and monitors the price of drugs and medical devices in India.

The DPCO provides a formula for calculating the ceiling price and the maximum retail price (MRP) of the listed drugs and medical devices. In extraordinary circumstances, the government may fix the ceiling price or the retail price of any drug or medical device in the public interest. Also, if the ceiling price or the retail price of the drug is already fixed and notified, the government may allow an increase or decrease in the same.

The DPCO sets out conditions that the manufacturers, dealers and distributors are required to follow for listed drugs and medical devices. Furthermore, the DPCO stipulates that the government monitors the MRP of all drugs and medical device (including non-listed drugs and medical devices) and ensures that no manufacturer increases the MRP of a drug by more than 10% during the preceding 12 months.

7.2 Price Levels of Pharmaceutical or Medical Devices

According to the NPPA Policy 2012, the key principles for the regulation of a drug price are:

- the essentiality of drugs;
- the control of formulation prices only; and
- market-based pricing.

The DPCO provides that – at least initially – the source of market-based data will be the data available with IMS Health (a pharmaceuticals market data specialising company) and, if the government deems it necessary, it may validate such data by appropriate survey or evaluation.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

The government funds and operates several healthcare/insurance schemes for reimbursement of the costs of pharmaceuticals and medical devices for people from weaker economic backgrounds and government employees – for example, the Ayushman Bharat National Health Protection Mission and the Central Government Health Scheme.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

The government has created an institutional arrangement called the Health Technology Assessment in India (HTAIn) under the Department of Health Research. HTAIn is responsible for collating and, where needed, generating evidence related to the clinical effectiveness, cost-effectiveness and safety of medicines, devices and health programmes using the health technology assessment approach.

Under HTAIn, the Indian National Cost database aims to provide a one-stop shop for cost information for healthcare decision-making in India.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

The prescription of drugs by a physician or a medical practitioner is regulated by the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 (amended 2016) (the "IMC Regulations"), which stipulate that:

- a physician must write their name and designation in full – along with registration particulars – in their prescription letterhead;
- every physician should prescribe drugs with generic names legibly and preferably in capital letters, and they shall ensure a rational prescription and use of drugs;
- the attending physician may prescribe medicine at any time for the patient, whereas the consultant may prescribe only in the case of an emergency or as an expert when called for; and
- the prescription should also make clear if the physician dispensed any medicine.

Furthermore, the DC Rules stipulate that the prescription must be in writing, as well as signed and dated.

The Pharmacy Act 1948 prohibits a person other than a registered pharmacist from the compounding, preparing, mixing or dispensing of any medicine prescribed by a medical practitioner.

8. Digital Healthcare

8.1 Rules for Medical Apps

According to the new definition of a medical device under the MD Rules, any software or app used with an instrument or an article for diagnosis, prevention or monitoring of diseases/disorders may be classified as a medical device (see **3.1 Product Classification: Pharmaceutical or Medical Devices** and **8.2 Rules for Telemedicine**).

8.2 Rules for Telemedicine

The IMC Regulations regulate telemedicine and provide guidelines for technology platforms such as mobile apps and websites enabling telemedicine. Among other things, these guidelines:

- provide information on various aspects of telemedicine, including information on technology platforms and tools available to RMPs,

and how to integrate these technologies to provide healthcare;
- spell out how technology and transmission of voice, data, images and information should be used in conjunction with other clinical standards, protocols, policies and procedures for the provision of care; and
- cover norms and standards for the RMP to consult patients via telemedicine.

Furthermore, they require RMPs to obtain the patient's consent and maintain the records/documents for the period as prescribed from time to time. An RMP can provide medical attention through a mobile device.

8.3 Promoting and/or Advertising on an Online Platform

There are no special rules for the promotion and/or advertising of medicines and medical devices through online portals, company web pages and social networks. See **1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices**.

8.4 Electronic Prescriptions

Electronic prescriptions are regulated and allowed in India. According to the IMC Regulations 2020, RMPs providing teleconsultation can send an e-prescription or a digital copy of a signed prescription to the patient via email or any messaging platform. This entails the same professional accountability as a traditional in-person consultation.

There are certain limitations on prescribing medicines on consultation via telemedicine, depending upon the type of consultation and mode of consultation. The regulations also provide categories of medicines that can be prescribed via telemedicine that are notified from time to time. Pharmacies can only dispense prescription drugs upon the production of a valid prescription. Under the IT Act, whereby the law requires a document to be signed, it would be deemed legal only if digitally signed.

8.5 Online Sales of Medicines and Medical Devices

There are currently no specific rules that govern online sales of drugs and medical devices. Specific rules for the regulation of e-pharmacies are expected to be issued in the near future.

8.6 Electronic Health Records

The Electronic Health Record Standards for India 2016, issued by the MoHFW, provide for standardisation and homogeneity – and interoperability in the capture, storage, transmission and use – of healthcare information across various health IT systems.

The IT Act, the IT Rules, and the Information Technology (Intermediaries Guidelines) Rules 2011 govern the protection of data. On 24 August 2017, a nine-judge bench of the Supreme Court ruled that the right to privacy is a fundamental right for Indian citizens under Article 21 of the Indian Constitution.

The IT Rules provide guidelines that must be followed by a body corporate while collecting, storing and transferring information. Obtaining consent from the person providing the information is one of the most important requirements of the IT Rules. The person must be aware of the following:

- that the information is being collected;
- its purpose and intended recipients; and
- the names and addresses of the agencies collecting and retaining the information.

The body corporate (or any person on its behalf) holding SPDI must not retain that information for longer than is required. The disclosure of SPDI by the body corporate to any third party requires prior consent from the provider of such information.

In August 2020, the National Digital Health Mission (NDHM) was launched by the central government. The objective of the NDHM is to digitise India's healthcare ecosystem. It also aims to provide a health ID to all medical practitioners, clinical establishments and patients.

In December 2020, the central government approved the Health Data Management Policy (HDMP) of the NDHM. Among other things, the HDMP provides the framework for the creation of health IDs. Under the HDMP, the patient has complete ownership of the health data. It also provides a framework for the use of this data.

On 11 February 2022, the National Health Authority – under the Ayushman Bharat Digital Mission (ABDM) – announced integration with Aarogya Setu. Under the ABDM, a user can generate a 14-digit unique Ayushman Bharat Health Account (ABHA) number. The ABHA number can be used to:

- link their existing and new medical records (including doctor prescriptions, lab reports and hospital records);
- share these records with registered health professionals and health service providers; and
- access other digital health services while maintaining a common pool of medical history.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

Patents are regulated in India under the Patents Act 1990 and the Patents Rules 2003 (the "Patents Rules"). The most common issue encountered by patent applicants is patentability of the subject matter for which a patent is sought. Apart from being novel, inventive and useful, the subject matter must not fall within a list of inventions specifically excluded from patentability. Specific exclusions with regard to pharmaceuticals and medical devices are:

- an invention that could be contrary to public order or morality;
- any living thing or non-living substance occurring in nature;
- mere discovery of a new form of a known substance that does not result in the enhancement of the known efficacy of that substance;
- the mere discovery of any new property or new use for a known substance;
- 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;
- a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
- mere arrangement or re-arrangement or duplication of known devices, each functioning independently of one another in a known way;
- any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings – or any

process for a similar treatment of animals – in order to render them free of disease or to increase their economic value (or that of their products);
- mathematical methods, business methods, computer programmes per se and algorithms;
- plants and animals in whole or any part thereof; and
- traditional knowledge.

9.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known product are not patentable in India. Use, per se, is not patentable in India.

9.3 Patent Term Extension for Pharmaceuticals

There are no mechanisms for patent term extension in India.

9.4 Pharmaceutical or Medical Device Patent Infringement

When performed with the consent of the patentee, the following acts constitute an infringement of a patent:

- making, using, offering for sale, selling, or importing for those purposes a patented product in India; and
- using a patented process, and using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

The Patents Act provides for the following defences to patent infringement:

- use of a patented invention on foreign vessels or aircraft temporarily or accidentally within the territory of India;
- making, constructing, using, selling or importing a patented invention solely for use reasonably related to the development and submission of information required under any law that regulates the manufacture, construction, use, sale or importation of any product in India or any other country;
- importation of patented products by any person who is duly authorised under law to produce and sell or distribute the product;
- importation or manufacture of a patented product or a product made by a patented process by (or on behalf of) the government for its own use;
- use or manufacture of a patented product or a product made by a patent process – or use of a patent process – merely for experimentation or research (or for imparting instructions to pupils); and
- importation of the patented medicine or patented drug by the government for distribution in:
  (a) any dispensary, hospital or other medical institution maintained by (or on behalf of) the government; or
  (b) any other dispensary, hospital or other medical institution that the central government, having regard to public service, specifies by notification in the Official Gazette.

Furthermore, in any suit for infringement of a patent, every ground on which it may be revoked is available as a ground for defence.

Compulsory Licences

The Patents Act provides for a compulsory licence in the following circumstances.

- At any time after the expiry of three years from the date of grant of the patent, any interested person makes an application to the Indian Patent Office for a grant of a compulsory licence on any of the following grounds:
  (a) that the reasonable requirements of the public with regard to the patent invention had not been satisfied;
  (b) that the patented invention is not available to the public at a reasonably affordable price; or
  (c) that the patented invention is not used in the territory of India.
- If the central government is satisfied – in a national emergency or in circumstances of extreme urgency, or in the case of public non-commercial use – that it is necessary to grant a compulsory licence, then it may make a declaration to that effect by notification.
- The compulsory licence is required in order to manufacture and export the patented pharmaceutical products to any country that lacks the necessary manufacturing capacity in the pharmaceutical sector to address public health problems – provided the licence has been granted by such country or such country has, by notification or otherwise, allowed the importation of the patented drug from India.

9.6 Proceedings for Patent Infringement

A proceeding for patent infringement can be brought by a patentee or a holder of an exclusive licence. Furthermore, the holder of a compulsory licence is entitled to call upon the patentee to bring such proceedings. If the patentee refuses or neglects to do so within two months of being called upon, they may institute proceedings in their own name – thereby making the patentee a defendant.

The court may grant a relief that includes an injunction and, on the request of the plaintiff, damages or an account of profits. The court may also order the goods that are found to be infringing – and materials and implements used in the creation of the infringing goods – to be seized, forfeited or destroyed (as the court deems fit under the circumstances of the case), without payment of any compensation.

The invalidity of the suit patent is an available defence in infringement proceedings and can be invoked by filing a counterclaim by the defendant in a suit for infringement.

9.7 Procedures Available to a Generic Entrant

The generic entrant may institute a suit for a declaration that their use of a product or process would not infringe a patent if it is shown that:

- the person applied in writing to the patentee or exclusive licensee for a written acknowledgment and furnished them with full particulars in writing of the process or article in question; and
- the patentee or licensee has refused or neglected to give such an acknowledgment.

The generic entrant may also initiate opposition or revocation proceedings challenging the validity of a patent. Additionally, there is an option of obtaining a compulsory licence under specific circumstances.

There is no patent linkage in India and “clearing the way” is not a requirement for generic market entry. However, the Indian courts have introduced the concept of “clearing the way” in recent patent infringement cases. If a party intends to use a patented product or method, they must exercise due diligence. If they fail to

"clear the way", then the balance of convenience may shift in favour of the plaintiff in a court proceeding and may enable the grant of an interim injunction against the said party.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

India has no specific legislation or procedures for dealing with the counterfeiting of drug and medical devices (see **3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices**).

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The Trademarks Act 1999 (the "TM Act") prohibits the registration of names of chemical elements or international non-proprietary names as trade marks in India. There are no restrictions under the TM Act on the importation and distribution of non-counterfeit, genuine pharmaceutical or medical device products from other markets, regions or countries.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

Although trade dress is not specifically mentioned under the TM Act, the definition of a trade mark under the TM Act includes the "shape of goods, their packaging, and combination of colours". The aesthetics of any article or product of manufacture are protected and registered in India under the Designs Act 2000 and the Designs Rules 2001.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

There are no provisions for data exclusivity in India. Under the DC Rules, a "new drug" continues to be considered as a new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia – whichever is earlier. An applicant for a new drug is required to conduct extensive testing and clinical trials for obtaining market authorisation. Therefore, an application for manufacturing generic versions of a new drug during the four-year period is required to contain clinical trial data.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The central government, the CDSCO and other bodies issued various notices and guidelines to expedite the approval of COVID-19 drugs, diagnostic kits and vaccines. Some of them are listed below.

- A special notification regarding the conduct of clinical trials to make available suitable vaccines was issued by the central government.
- The CDSCO released an office memorandum dated 26 May 2020 providing for an expedited approval process for COVID-19 vaccines. As per the memorandum:
  - (a) pre-clinical trial data generated abroad may be considered as part of an application to conduct clinical trials; and
  - (b) clinical trial data generated outside India may be used to provide an abridged pathway for a COVID-19 vaccine.
- Provisions were made for high-priority processing of applications for R&D, repurposing,

importation, manufacturing, marketing and evaluation of drugs or vaccines and diagnostic kits for COVID-19.
- Draft Regulatory Guidelines for Development of Vaccines with Special Consideration for COVID-19 Vaccines were issued by the CDSCO. The guidelines are similar in nature to recommendations and do not replace any statutory requirements. The guidelines focus on safety, immunogenicity and efficacy parameters for developing COVID-19 vaccines.
- Guidelines for validation and batch-testing of diagnostic kits were issued by the ICMR-DCGI.
- Provisions were made for the relaxation of the data requirement and requirements for the importation licence.
- Emergency approvals for Covidshield, Covaxin, Sputnik-V, the Moderna vaccine, the Janssen vaccine, Corbevax, Covovax, and iNCOVACC were granted subject to terms and conditions.
- Restricted emergency use and manufacture approvals were granted to Remdesivir and Favipiravir tablets.
- A Liberalised Pricing and Accelerated National COVID-19 Vaccination Strategy was issued by the MoHFW on 21 May 2021, with the aim of liberalising vaccine pricing and scaling up vaccine coverage.
- Revised Guidelines for Implementation of the National COVID Vaccination Programme were issued by the MoHFW on 21 June 2021.
- Restricted emergency use and manufacturing approval was granted for Tocilizumab and an antibody cocktail (Casirivimab and Imdevimab).
- Restricted emergency use approval was granted for Molnupiravir in the treatment of adult patients with COVID-19 who have a high risk of progression of the disease.
- Emergency approval was granted to Covaxin for administration to children between the age of 12 and 18 years.
- EUA Emergency approval was granted for the administration of ZyCoV-D to adults and to children from the age of 12.
- A guidance notification was issued by the CDSCO in May 2021 for the importation of foreign COVID-19 vaccines by a private entity or government-sector entity.
- In April 2021, the CDSCO issued detailed guidelines and relaxed the conditions for the entry into India of foreign-made COVID-19 vaccines approved by the US Food and Drug Administration, the European Medicines Agency, the UK Medicines and Healthcare products Regulatory Agency, the Japanese Pharmaceuticals and Medical Devices Agency or the WHO Emergency Use Listing.
- In June 2021, the NPPA capped the trade margin of oxygen concentrators, pulse oximeters, blood pressure monitoring machines, nebulisers, digital thermometers and glucometers at 70%.
- Guidelines were issued by the MoHFW on 3 January 2022 for COVID-19 vaccination of children between 15 and 18 years and for precautionary doses to healthcare workers, frontline workers and members of the population who are 60 or older with co-morbidities.

11.2 Special Measures Relating to Clinical Trials

The following special measures were issued in relation to ongoing clinical trials:

- a notice regarding the conduct of clinical trials during the COVID-19 outbreak was issued by the CDSCO in March 2020;
- the registrations of BA/BE (bioavailability/bioequivalence) study centres were extended;

- a clinical trial protocol for convalescent plasma was issued; and
- a notice was issued by the CDSCO on 25 February 2021 with regard to the launch of software for online submission of all Serious Adverse Events reports through the SUGAM portal.

Please see **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The DC Act contains provisions that allow the central government to regulate, restrict, manufacture, etc, a drug in the public interest by way of notification in the Official Gazette. Please refer to **11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices**, **11.2 Special Measures Relating to Clinical Trials**, **11.4 Flexibility in Manufacturing Certification as a Result of COVID-19** and **11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19** for details.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The following simplifications and flexibility were introduced in relation to obtaining required certifications as a result of COVID-19:

- manufacturers of industrial oxygen were allowed to manufacture oxygen for medical use subject to conditions;
- the processing of applications to manufacture hand sanitisers was completed in three working days;
- hand sanitisers were exempted from the requirement of a sale licence;
- the validity of the WHO's Good Manufacturing Practices provisions and the Certificate of Pharmaceutical Products expiring was extended by six months from March to August 2020;
- prior permission from the CLA for manufacturing and stocking a vaccine for COVID-19 was deferred;
- the CDSCO issued various orders in 2021 relaxing the manufacturing and import licensing requirements for specified periods for all implantable medical devices, CT scan equipment, MRI equipment, defibrillators, positron emission tomography equipment, dialysis machines, x-ray machines and bone marrow cell separators;

On 18 January 2022, the MoHFW issued Drugs (Amendment) Rules 2022 stating that every active pharmaceutical ingredient (bulk drug) manufactured or imported in India must bear a quick response code on its label at each level of packaging, which stores data or information readable with a software application to facilitate tracking and tracing.

On 9 February 2022, the MoHFW issued a notification that relaxes the norms related to the manufacturing and stocking, sale or distribution of new drugs under Phase III clinical trials for the treatment of Covid-19 and related diseases in public interest, upon obtaining permission as per the CT Rules.

On 17 November 2022, the MoHFW issued the Drugs (Eighth Amendment) Rules 2022, thereby further amending the DC Rules. The Rules require that the manufacturers of drug formulation products (as specified in Schedule H2) shall print or affix on its primary packaging label – or, in case of inadequate space on the primary package label, on the secondary package label – a bar code or quick response code that stores

data or information legible with software application to facilitate authentication.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

The following import/export restrictions or flexibilities were introduced in relation to medicines or medical devices due to COVID-19:

- export restrictions were imposed on 26 Active Pharmaceutical Ingredients and formulations made therefrom;
- Draft New Drugs and Clinical Trials (Amendment) Rules 2020 were issued for compassionate use of any new unapproved drug;
- the exportation of items such as surgical or medical masks, medical coveralls, medical goggles, nitrile/nitrile butadiene rubber gloves, face shields and Personal Protective Equipment coveralls was completely restricted or limited to a certain quota;
- the validity of registration certificates or licences for the importation of drugs that were due to expire was extended subject to conditions;
- special conditions under which permission for the importation of drugs with a residual shelf life of less than 60% was to be allowed/extended where specified;
- a set of regulations were issued to allow for certain norms to be relaxed in order to facilitate ease in the importation and exportation of COVID-19 vaccines through a courier;
- the submission of applications for import registration for drugs, cosmetics and medical devices with self-attested documents was allowed, subject to conditions; and
- on 18 January 2022, the CDSCO issued amended the MD Rules – thereby relaxing those for manufacturers and importers that currently do not have U13485 certification and are in the process of obtaining ISO certification.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Please see **8.5 Online Sales of Medicines and Medical Devices** and **8.6 Electronic Health Records**.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The Indian government has so far not announced any intention to issue compulsory licences for treatments or vaccines related to COVID-19. As regards the rules, please refer to **9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices**.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

The government has no proposal to indemnify or exempt vaccine manufacturers from liability in the event of serious adverse reactions or side effects due to vaccines.

11.9 Requisition or Conversion of Manufacturing Sites

Please see **11.4 Flexibility in Manufacturing Certification as a Result of COVID-19**.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

In 2017, the central government issued Public Procurement (Preference to Make in India) [PPP-MII] Order 2017 (with subsequent revisions in 2018–20) to encourage the "Make in India" incentive and to promote the manufacturing and production of goods, services and works in India – with a view to enhancing income and employment where there is sufficient local capacity and competition. In order to implement the afore-

mentioned order, the DoP issued guidelines in relation to the procurement of medical devices in 2018. These guidelines were revised in 2021.

Similarly, in 2021, the DoP issued guidelines (in supersession of the earlier guidelines) for implementing the order in relation to the procurement of pharmaceutical formulations. There has been no change due to COVID-19.

Trends and Developments

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Obhan & Associates is a professionally managed law firm with a well-established practice in the areas of IP and corporate law. The firm was established in 2007 and has offices in Delhi and Pune. Obhan & Associates has been recognised for its expertise in patent, trade mark, copyright and design protection. The firm's corporate practice offers a broad range of transactional and advisory services to institutions and entrepreneurs, as well as to public and private companies. The firm has a well-balanced domestic and international clientele and represents a cross-section of industries, including fast-moving consumer goods, mechanical engineering, hardware and electronics, life sciences, pharmaceuticals, software, apparel, packaging and retail, process engineering, fashion brands, automobiles and parts, paints and chemicals, magazines and publications, and textiles. Obhan & Associates' life sciences and pharmaceuticals team has six experienced patent agents and lawyers who serve a varied client base that includes individual inventors, universities and national and international corporations.

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Patent Case Law Developments

After India's Intellectual Property Appellate Board (IPAB) was abolished in 2021, its jurisdiction (ie, appeals from decisions of various IP offices throughout the country) was transferred to the High Courts. Thereafter, the Delhi High Court set up an Intellectual Property Division (IPD) to deal exclusively with IP cases, while other major High Courts (Bombay, Madras and Calcutta) are reportedly in the process of creating similar divisions. By way of an example, the Madras High Court – in a writ petition filed by a litigant regarding its pending case before the IPAB – recently directed the state government of Tamil Nadu to notify its IPD.

Some of the key patent-related decisions of the Delhi High Court ("the Court") in the past 12 months are summarised under the following points.

Amending claims in Indian patent applications

Section 59 of the Patents Act 1970 ("the Act") requires that any amended claim must fall entirely within the scope of the claim as filed in the original specification. In Nippon A and L Inc vs Controller of Patents (MANU/DE/2303/2022), the original "product by process" claims were converted into a process claim, which had been rejected by the Controller under Section 59. The Court said that it was a common understanding that a product claim is broader in scope than a process claim and, therefore, the present amendment was narrower in scope and satisfied the conditions of Section 59.

What is not claimed is disclaimed

A divisional application is a further application divided out of the parent application. Under Section 16 of the Act, an applicant may file a divisional application suo moto or to remedy the objection raised by the Controller that the claims of the complete specification relate to more than one invention. A key requirement for dividing a patent application is that it must contain a plurality of invention.

In Boehringer Ingelheim International GMBH v Controller of Patents and Ors (MANU/DE/2531/2022), the Court closely examined the concept of plurality of invention and, specifically, considered whether divisional applications could be filed for claims that were not part of the claims

in the parent application. The Court concluded that "plurality of inventions" should clearly exist in the claims of the original parent application and within the scope of the parent specification. The Court observed that if the applicants were permitted to file divisional applications on the basis of disclosure in the complete specification without such inventions being claimed in parent applications, the fundamental rule of patent law that "what is not claimed is disclaimed" would be defeated.

Doctrine of equivalents

When assessing the scope of the patent claims and infringement, courts in India not only rely on the literal interpretation of the claim but also apply the principles of the "doctrine of equivalents" (DOE), purposive construction (or "pith and marrow"), and prosecution history estoppel.

Assessment of infringement

The Court in Sotefin SA v Indraprastha Cancer Society & Research Center & Ors (MANU/DE/0536/2022) held that – when it comes to assessing infringement – non-essential or trifling variations or additions to the product would not be germane, so long as the substance of the invention was found to have been copied. The doctrine of purposive construction must be applied when interpreting the claims. Further, the Court would also apply the DOE to examine whether the substituted element in the infringing product does the same work in substantially the same way to accomplish substantially the same result.

Application of the DOE in process claims

In FMC Corporation and Ors v NATCO Pharma Limited (MANU/DE/4962/2022), the Court held that DOE is applicable in the case of both product and process patents. The aforementioned triple test – ie, (i) substantially the same function, (ii) in substantially the same way and (iii) to yield the same result – is applied primarily to products or devices. However, in process claims, this test may have to be suitably adapted.

In order to claim infringement, the essential elements, the essential steps, and the manner in which the essential elements interact in each step to yield the given result in a claimed process must be substantially similar to the process in question. The variations in the two methods must be compared to ascertain whether they are minor, trifling and inessential and whether they have been introduced only to camouflage piracy.

Assessment of inventive step

Simplicity does not defeat an invention

The Court in Avery Dennison Corporation v Controller of Patents and Designs (MANU/DE/4319/2022) said the fundamental principles involved in analysing inventive step and deciding whether an invention is obvious or not are that:

- simplicity does not defeat an invention; and
- it is not permissible to analyse in hindsight.

Time gap is relevant

The Court in Avery Dennison Corporation (supra) also said that the time gap between the prior art document and the invention under consideration is one of the sure tests to determine the existence of inventive step. If a long time has passed since the prior art was published and a simple change resulted in unexpected benefits that no one had thought of in a long time, the Court would be inclined to hold that the invention is not obvious.

Elements to be considered

The Court noted in Agriboard International LLC v Deputy Controller of Patents and Designs

(MANU/DE/1055/2022) that, when rejecting an invention for lack of inventive step, the Controller must consider three elements:

- the invention disclosed in the prior art;
- the invention disclosed in the patent application under consideration; and
- the manner in which subject invention would be obvious to a person skilled in the art.

Without a discussion of these three elements, simply reaching the conclusion that the subject invention lacks inventive step would not be permissible – unless it is a case where the same is absolutely clear.

Maintainability and jurisdiction of High Courts

The Court in Reddys Laboratories Limited and Ors v Controller of Patents and Ors (MANU/DE/4389/2022) discussed the jurisdiction of the High Courts that emerged after the IPAB was abolished – specifically, with regard to the revocation of a patent and appeal against the orders of the Indian Patent Office (IPO).

Appeal against the order of the IPO

The IPO operates from four major cities (Kolkata, Delhi, Chennai and Mumbai). The Court held that appeals challenging the order or direction of the IPO would lie before the High Court with territorial jurisdiction over the IPO that covers the area from which the patent application originates and, as such, is the situs of said application.

Revocation of a patent

A petition for revocation of a patent can be filed by any interested person. The definition of "interested person" is inclusive and has been broadly interpreted by courts. It follows that a large number of persons may qualify as "interested persons". Further, the grant of a patent has an all-India effect. Persons interested in seeking the revocation of a patent could, therefore, be located anywhere in India.

The Court said that the question of jurisdiction would have to be decided on the basis of both the static effect and the dynamic effect of granting the patent. The place where the commercial interest of the applicant is affected would also be relevant in determining jurisdiction. Thus, the High Court with territorial jurisdiction in respect of revocation petitions will be decided not only on the basis of the local IPO where the patent application was filed and/or examined, but also where the cause of action for filing a revocation petition arose.

Known substance needs to be identified

Section 3(d) of the Act bars a new form of a known substance from patentability unless such new form exhibits enhanced efficacy compared with the known substance. In DS Biopharma Limited v Controller of Patents and Designs and Ors (MANU/DE/3418/2022), the Court clarified that an objection raised under Section 3(d) is not maintainable unless the alleged "known substance" is first identified by the IPO. The applicant cannot be expected to identify the known substance and then provide comparative data to show enhancement in the efficacy when contrasted with such known substance.

Applicant must not suffer for the fault or negligence of the patent agent

Responses to examination reports issued by the IPO must be filed within six months of the date of issue of the reports. An extension of three months is permissible, provided a request for the same is made before the six-month period expires.

In Bry-Air Prokon Sagl and Ors v Union of India and Ors (MANU/DE/4119/2022), responses to

examination reports were not filed in time in respect of six applications. Annuity was also not paid in respect of one patent, resulting in its lapse. Accordingly, the patent applications were deemed abandoned by the IPO. The Court found that petitioners were able to demonstrate that the patent agent was negligent. The Court also noted that there was no contributory negligence by the applicant and the applicant had a positive intent to prosecute the patent application. The applicant had also issued standing instructions to the patent agent to pay the annuity.

The Court held that the case fit the criteria for the exception of "extraordinary circumstances" where the applicant could not be allowed to suffer for the fault or negligence of the patent agent. The Court allowed similar relief in European Union v Union of India and Ors (MANU/DE/2142/2022), a case in which the facts were similar.

"Evergreening" a monopoly by serial patenting is not permissible

The case in FMC Corporation and Ors v GSP Crop Science Private Limited (MANU/DE/4480/2022) related to a patent for an intermediate used in the production of Chlorantraniliprole (CTPR). Both the product patent and the process patent expired on 13 August 2022. The Court noted that CTPR was the subject matter of at least 30 separate patent applications in India, suggesting an attempt at evergreening CTPR.

The Court said that multiple patents can be filed for different aspects of a particular product, if the tests for novelty, inventive step, and industrial applicability are satisfied and inventions are patentable. However, serial patenting in order to "evergreen" a particular monopoly is not permissible.

The Court also noted that the invention had not been worked on for more than 19 years since filing in India, which thereby raises doubt as to the industrial applicability of the patent itself. This appears to be a classic case in which the plaintiffs sought to find defendant(s) who could be sued in order to prevent the commercial launch of the CTPR product in some way after the product and process patents had expired by relying on an intermediate patent that had not been worked on, was prima facie invalid, and whose term was set to expire in a few months.

Interpretation of Section 3(i)

Section 3(i) of the Act bars from patentability "any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products". In Sequenom, Inc and Anr v Controller of Patents and EMD Millipore Corporation v Assistant Controller of Patents (MANU/DEOR/158713/2022), the patent applications were refused under Section 3(i). Noting that the interpretation of the provision could have a bearing on many patent applications, the Court has appointed an amicus curiae to assist the Court in this matter.

No further objections can be raised by the Controller or Examiner in the hearing

In Perkinelmer Health Sciences Inc and Ors v Controller of Patents (MANU/DEOR/0040/2023), the Court – without discussing the merits of the case – clarified that no new objections could be raised by the IPO at the time of the hearing. The Court said that the applicant should be made aware of all grounds of objection prior to the hearing and be afforded sufficient opportunity to contest the same at the time of the hearing. The Court also ruled that raising new grounds during

a hearing is improper and violates principles of natural justice.

Other Developments

Report of Economic Advisory Council to Prime Minister

In August 2022, the Economic Advisory Council issued a working paper entitled *Why India Needs to Urgently Invest in Its Patent Ecosystem* (EAC-PM/WP/1/2022) to the Prime Minister. The paper notes that, in India, it takes about 58 months on average to dispose of a patent application – compared with about 20 months in China and 23 months in the USA. The paper suggests that the major cause of this delay is the shortage of manpower in the IPO. Other causes include:

- procedural issues such as the lack of fixed timelines for various steps (eg, no fixed timeline for filing an opposition against a patent application); and
- compliance requirements such as submitting information pertaining to processing of foreign patent applications.

The paper recommends increasing manpower in the IPO from the existing 860 to about 2,800 during the next two years. The paper also recommends fixing timelines for various steps of the process (eg, filing of pre-grant oppositions) and also suggests revised timelines for certain tasks and reducing compliance requirements.

Increase in patent filings

There has been a significant increase in patent filings in India. The filings increased by more than 50% in the last seven years. A nearly five-fold increase in the grant of patents was observed in 2021-22 as compared to 2014-15. In January to March 2022, the number of domestic patent filings surpassed the number of international patent filings in India.

Launch of Grievance Portal by IPO

In October 2022, the IPO launched a Grievance Portal whereby stakeholders can lodge their grievances/complaints, if aggrieved by officials, for unnecessary demands and for quick resolution of the issues they face during the processing of their applications. The IPO is also holding regular open conferences to address grievances or suggestions on issues related to its functioning.

Procedural developments at the IPO

With a view to expediting the disposal of patent applications, the IPO issued three public notices in January 2023 that sought to bring changes in patent application processing.

The first notice clarified that only authorised patent agents are entitled to represent their clients in respective matters before the Controller of Patents. The notice also clarified that an advocate can take part in any hearing/proceeding before the Controller – provided that the advocate is duly authorised by the applicant or the party concerned and is not a patent agent – by filing Form 26 in the advocate's favour.

The second notice notified that requests for adjournment filed without mentioning "reasonable cause" will not be entertained. The notice requires stakeholders (ie, patent agents) to specify the reasonable cause in the request for adjournment, without fail.

The third notice asserted that a combined reading of Rule 129 with the proviso to Rule 129A of the Patent Rules 2003 (as amended) ("the Rules") provides at least ten working days as the inner limit and 30 days as the outer limit for hearings and adjournments. Therefore, in matters where minor procedural issues are involved, the IPO will endeavour to offer a shorter time period. However, in substantive matters related

to analysis of prior arts, claim construction, etc, a longer period would be offered in accordance with the Act and the Rules. In accordance with the principles of natural justice, the notice also clarified that:

- a fair opportunity to defend would be given to the parties; and
- adverse action would not be taken solely based on the issued public notice.

Protection of AI-based inventions

In response to the recommendations and suggestions made by the Parliamentary Committee, the Department for Promotion of Industry and Internal Trade (DPIIT) has issued its "Action Taken Report". The Committee is of the opinion that the increase in application of AI-based tools such as Aarogya Setu and CoWin in recent times for the purpose of using and extending essential services implies a likely surge in AI-based patent filings. Hence, granting proprietary rights to AI innovators and protecting AI-driven innovations by enforcing regulations and standards in India should be the way forward. The Committee has therefore recommended that the DPIIT channelise efforts to encourage and empower AI innovators by enacting suitable legislation or modifying existing laws on IP rights to accommodate AI-based inventions.

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