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India: Law & Practice

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Nishith Desai Associates

INDIA

Law and Practice

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Contents

Nishith Desai Associates (NDA) is a renowned Indian law firm known for its strong focus on research-based, futuristic legal services. Headquartered in Mumbai, with offices in major global cities including Singapore, Palo Alto and New York, NDA specialises in cross-border transactions, strategic legal advice and regulatory counsel. The firm is particularly noted for its expertise in emerging sectors such as technology, life sciences, fintech, international tax and dispute resolution. NDA adopts an interdisciplinary approach, combining law, business and policy insights to support clients ranging from start-ups to multinational corporations. Its unique *"blue sky thinking"* philosophy drives continuous legal innovation, supported by a robust internal research team. Nishith Desai Associates is widely recognised for its contributions to policy development and thought leadership, with frequent publications on cutting-edge legal issues. The firm has received accolades for its commitment to excellence, its ethical practice and its collaborative, knowledge-driven culture.

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LEGAL AND TAX COUNSELING WORLDWIDE

1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

Key Regulations in India

In India, there are multiple pieces of legislation and regulations that govern the pharmaceuticals and medical devices sectors. The industry is heavily regulated, with every aspect being regulated in some form.

The Drugs and Cosmetics Act, 1940 (DCA) is the primary legislation regulating the manufacture, import, distribution, sale and quality of drugs and devices in India, and clinical trials. The DCA is an umbrella legislation, with the Drugs Rules, 1945 (*"Drugs Rules"*), Medical Devices Rules, 2017 (MDR) and the New Drugs and Clinical Trial Rules, 2019 (NDCTR) being contained thereunder. Interestingly, the DCA regulates medical devices as *"drugs"*, meaning that medical devices are also subject to other laws that govern the pharmaceutical industry, as well as the DCA.

Separately, the government released a draft version of the proposed bill – the Draft Drugs, Medical Devices and Cosmetics Bill, 2022 (*"Draft Bill"*) – for public consultation in July 2022. The Draft Bill introduced several key changes, including recognising medical devices as a separate category of drugs. Once enacted, the Draft Bill will replace the existing DCA framework. However, there has been no action in relation to the Draft Bill since its initial release.

In addition to the DCA, Drugs Rules, NDCTR and MDR, the pharmaceutical and medical device industry is also governed by other laws, including the following key regulations.

Drugs (Price Control) Order, 2013

The Drugs (Price Control) Order, 2013 (DPCO) was issued under the Essential Commodities Act, 1955. It is enforced by the National Pharmaceutical Pricing Authority (NPPA), and its objective is to provide essential medicines and medical devices at affordable prices to the public in India.

Narcotic Drugs and Psychotropic Substances Act, 1985

The Narcotic Drugs and Psychotropic Substances Act, 1985 encompasses stringent provisions for the control and regulation of operations governing the production, possession, sale, transport and consumption of narcotic drugs and psychotropic substances.

Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and the rules framed thereunder

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 (DMRA) and the Drugs and Magic Remedies (Objectionable Advertisements) Rules, 1955 (DMR Rules) regulate direct-to-consumer advertisements in India and prohibit advertisements of certain drugs and medical devices related to the reproductive health of women or menstrual disorders in women, sexual wellness in human beings, or certain disease-related claims specified in the Schedule of the DMRA.

Uniform Code for Pharmaceutical Marketing Practices

The Uniform Code for Pharmaceutical Marketing Practices (UCPMP) regulates pharmaceutical companies undertaking marketing activities directed towards healthcare professionals, subject to certain conditions.

Uniform Code for Marketing Practices of Medical Devices

The Uniform Code for Marketing Practices of Medical Devices (UCMPMD) regulates marketing activities between medical device companies and healthcare professionals (HCPs) in India. The UCMPMD is applicable to medical device companies undertaking marketing activities directed towards HCPs in compliance with certain conditions.

Legal Metrology (Packaged Commodity) Rules, 2011

The Legal Metrology (Packaged Commodity) Rules, 2011 (PC Rules), notified under the Legal Metrology Act, 2009, regulate the packaging and labelling of pre-packed commodities in India. The labelling of medical devices is governed and regulated under the MDR and the PC Rules.

Environmental (Protection) Act, 1986 and the rules thereunder

The requirements to obtain environmental clearances to set up manufacturing units are laid out in:

- the Environmental (Protection) Act, 1986;
- the Air (Prevention and Control of Pollution) Act, 1981;
- the Water (Prevention and Control of Pollution) Act, 1974; and
- the Environment Impact Assessment Notification, 2006.

The Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016 govern the safe handling, storage, transportation and disposal of hazardous waste generated during manufacturing, research and development processes. For the pharmaceutical industry, these rules ensure the proper management of chemical residues, solvents and expired drugs, thereby minimising the environmental impact and ensuring worker safety. In the medical devices sector, the rules help manage hazardous components such as heavy metals, used reagents and discarded electronic devices.

The Biomedical Waste Management Rules, 2016 lay down the requirements for the proper handling and disposal of biomedical waste.

The Plastic Waste Management Rules, 2016 mandate the responsible handling, segregation, recycling and disposal of plastic waste, promoting extended producer responsibility. Given the quantum of plastic packaging associated with the pharmaceuticals and medical devices industry, these rules are increasingly significant.

Similarly, the E-Waste Management Rules, 2016 are vital for the pharmaceutical and medical devices industries, which utilise electronic equipment in manufacturing, diagnostics and research. These rules regulate the collection, storage, recycling and disposal of electronic waste, including computers, lab instruments and medical electronic devices.

Biological Diversity Act, 2002

The Biological Diversity Act, 2002 aims to conserve biological diversity, ensure the sustainable use of its components, and promote the fair and equitable sharing of benefits arising from the use of biological resources, knowledge and related matters.

Important Regulatory Bodies

Central Drugs Standard Control Organisation (CDSCO) and Drugs Controller General of India (DCGI)

Responsibility for the implementation of the DCA, Drugs Rules and MDR is split between regulatory agencies at the central (ie, federal)

and state levels. The CDSCO, led by the DCGI (or CLA), is the apex regulatory body for pharmaceuticals and medical devices in India. The DCGI is responsible for overseeing imports, clinical trials and investigations, the approval of new drugs, the issuing of marketing authorisations, risk classification of medical devices, etc.

State Licensing Authorities

Every state in India has a state-level food and drug administration, which serves as the State Licensing Authority (SLA). The SLA is responsible for granting manufacturing licences, granting licences for the sale and distribution of drugs and devices, inspections and quality testing, etc.

Department of Pharmaceuticals

The Department of Pharmaceuticals, under the Ministry of Chemicals and Fertilizers, plays a role in promoting the pharmaceutical industry, ensuring drug availability at affordable prices, and encouraging research and development. It also oversees the implementation of the UCPMP and UCMPMD.

National Pharmaceutical Pricing Authority

The NPPA functions under the Department of Pharmaceuticals and is responsible for the implementation of the DPCO. It is primarily responsible for ensuring the affordability and availability of drugs and medical devices.

Indian Pharmacopoeia Commission

The Indian Pharmacopoeia Commission (IPC) is an autonomous institution that is responsible for setting standards for drugs in the country, with the objective of ensuring their quality, safety and efficacy. The IPC also oversees the Pharmacovigilance Programme of India and the Materiovigilance Programme of India, and is responsible for laying down the National Formulary of India to guide HCPs on rational prescription practices.

Bureau of Indian Standards

The Bureau of Indian Standards (BIS) is the standards-setting body across products and services in India. Any standards laid down by the BIS are binding for medical devices.

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

An order or decision of a CLA or SLA, as the case may be, can be challenged before the appellate board through the appeal process enumerated under the Drugs Rules and the MDR.

Manufacturers or their authorised agent can appeal a decision related to registration certificates, import licences and manufacturing licences. If an application is denied or a licence is suspended or cancelled, the aggrieved party can appeal to the Central or State Government, against the decision of a CLA or SLA, respectively, within the specified time period. The appeal is reviewed through an inquiry, with the appellant being given the opportunity to present their case before a final decision is made.

The timeline for appealing an order or decision of the CLA or SLA varies based on the appeal process outlined in the Drugs Rules and the MDR.

The appeal process delineated in the regulatory framework governing drugs and medical devices is not applicable to other regulated products, such as food products, which are governed by their own regulatory frameworks.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

The Drugs Rules contain schedules that classify drugs as:

- biological and special products;
- other special products;
- drugs required to be taken under medical supervision;
- prescription drugs;
- prescription drugs requiring a separate register; and
- psychotropic drugs.

Depending on which schedule the drug is under, there may be distinct licensing requirements, record keeping requirements or specific restrictions.

At present, the Drugs Rules do not expressly recognise any drugs as being *"over the counter"* (OTC) drugs, but a proposed draft amendment included a list of common drugs that may be sold by a licensed pharmacy without a prescription from a registered medical practitioner, such as paracetamol, calamine lotion, sodium chloride sprays, diclofenac ointment/cream/gel and clotrimazole cream and dusting powder.

In addition, certain drugs have been exempted from the requirement that they only be sold under a valid sale licence (oral rehydration salts, nicotine gums and lozenges, certain chemical contraceptives, etc).

Medical Devices

In India, medical devices and in vitro diagnostic medical devices are classified based on their risk level, as follows:

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

The DCGI is responsible for classifying medical devices based on their intended use and other factors. The list containing the classification of the medical devices is published by the CLA on the CDSCO's website. This list is of a dynamic nature, and the DCGI may add/remove devices therefrom. Typically, medical devices that are invasive are classified as moderate to high risk or high risk, while non-invasive devices like oxygen masks and atomisers are categorised as low risk medical devices.

The classification process is detailed in the schedule of the MDR, and manufacturers or importers must follow the classification determined by the DCGI. Unlike some other countries, where manufacturers can self-classify their products, India requires adherence to the classification set by the DCGI, and this classification is non-appealable.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Pharmaceuticals

Clinical trials in India are governed under the NDCTR., and are critical for ensuring that any new drug introduced in the Indian market is both safe and effective for its intended population. A clinical trial is necessary in India when a company seeks to introduce a new drug (including novel formulations or delivery mechanisms), conduct bioavailability or bioequivalence studies, or develop biosimilars and orphan drugs. It is also required for global clinical trials (GCTs) conducted in India as part of multinational research. However, under the NDCTR, exemptions from trial requirements may be granted for drugs approved in certain foreign jurisdictions, or in the case of drugs intended for life-threatening or rare diseases, under specific conditions.

Medical Devices

The regulation of clinical investigations for medical devices is governed by the MDR. Investigations are conducted for novel medical devices (ie, a device that does not have a predicate device) that are being introduced into the market, to assess their safety, performance and effectiveness before they are approved for sale in India. Clinical investigations are generally required for Class C and D devices, but may also be required for Class B devices.

The MDR outlines two types of clinical investigations:

- Pilot Clinical Investigations – exploratory studies that evaluate the device's performance and safety; and
- Pivotal Clinical Investigations – larger studies to gather evidence supporting the device's safety and effectiveness.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Pharmaceuticals

Registration of Ethics Committee

An Ethics Committee must have at least seven members, as required by the NDCTR. It applies for permission to register with the CLA, supplying the necessary documents. If the CLA is satisfied with the documents, it will grant approval to the Ethics Committee. The registration of the Ethics Committee is valid for five years, unless suspended or cancelled by the CLA. A person or institution intending to conduct a clinical trial must obtain approval from the duly registered Ethics Committee, which is responsible for overseeing the working of the clinical trial before initiation and throughout the duration of the conduct of the clinical trial.

Application for clinical trial permission

The person or institution intending to conduct a clinical trial must seek approval of their clinical trial protocol from the Ethics Committee. After securing such approval, the applicant applies for permission from the CLA.

The CLA reviews the application along with the necessary documents and information. For new drugs or investigational new drugs discovered or developed in India, the CLA must grant or reject the application within the prescribed time period. If the CLA is satisfied with the documents and information, permission to conduct the clinical trial is granted. If no communication is received within the prescribed time, permission is automatically granted.

Conditions of permission

Clinical trials can only start once the trial protocol is approved by the Ethics Committee at each site. The trial must be registered with the Clinical Trial Registry of India (CTRI) before enrolling participants. Regular updates, such as quarterly enrolment status and bi-annual status reports, must be submitted to the CLA.

If the clinical trial is terminated, the detailed reasons for such termination must be communicated to the CLA within the prescribed time period.

The CLA, the Ethics Committee and the institute where the trial is conducted must be notified of any serious adverse events within the prescribed time period. The sponsors must provide medical management and compensation for injuries, deaths or permanent disabilities during the trial. The premises of the sponsor and the clinical trial sites must be open for inspection by the officers of the CLA or SLA, or authorised outside experts, to verify compliance.

Medical Devices

Clinical investigation for investigational medical devices – approval and application

The Ethics Committee must be duly registered as per the provisions of the Drugs Rules to review and accord approval to a clinical investigation plan. The Ethics Committee shall apply for registration to the CLA, supplying the necessary information and documents. If the CLA is satisfied with the documents after scrutinisation thereof, the registration will be granted. The person or institution intending to conduct a clinical investigation must obtain approval for the clinical trial protocol from the duly registered Ethics Committee.

Application for permission from CLA

An application must be submitted to the CLA for the conduct of the clinical investigation, along with the necessary documents and information. The CLA grants permission for two types of clinical investigations: pilot clinical investigations or pivotal clinical investigations.

It reviews the application and, if satisfied with the information and documents, grants the applicant permission to conduct the clinical investigation.

Conditions for permission

The investigation can only begin after the Ethics Committee approves the investigation plan. It must be conducted in compliance with the approved clinical investigation plan and the Good Clinical Practice Guidelines. The investigation must be registered with the CTRI before enrolling participants. The sponsor must submit annual reports on the status of the investigation, and notify the CLA if the investigation is terminated, including the reasons for doing so. Any suspected serious adverse events must be reported to the CLA within the prescribed time period, and medical management and compensation must be provided for any injuries or death during the investigation.

The investigation sites and premises of the sponsor are subject to inspection by CLA officers, to ensure compliance with the rules. The investigation must begin by enrolling the first participant within one year from the grant of permission. If not, prior permission from the CLA is required to initiate the clinical investigation.

Failure to comply

Failure to comply with the conditions of the permission could result in the suspension or cancellation of said permission by the CLA.

2.3 Public Availability of the Conduct of a Clinical Trial

The CTRI serves as a central repository for clinical trials in India, and registration must be completed before enrolling the first participant. Clinical trials, academic clinical trials, clinical investigations and clinical performance evaluations of new drugs, investigational medical devices or new in vitro diagnostic medical devices conducted in India must be registered with the CTRI. While registration is mandatory for all clinical trials, it is also recommended as a best practice to register all types of studies.

Following competition of each phase of the clinical trial, a Subject Expert Committee examines the data and takes a decision on whether to grant approval for the next phase and/or grant approval. The minutes of these meetings are uploaded to the public domain, but do not contain proprietary details of the clinical trial and its findings.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The regulatory framework governing clinical trials of drugs and medical devices does not explicitly prohibit the use of online tools to support clinical trials. The applicable laws, rules and guidelines do not delineate a procedure for the use of online tools in clinical trials.

However, the permission to conduct a clinical trial under the NDCTR or the MDR requires the approval of the clinical trial protocol from the duly registered Ethics Committee. The proposed protocol includes information about the study design, study monitoring and supervision procedures, and the process of data/statistical analysis during the clinical trial. The use of online tools and the purpose thereof may be included in the proposed protocol to ensure that they are reviewed by the Ethics Committee and receive approval in compliance with the NDCTR or MDR.

2.5 Use of Data Resulting From Clinical Trials

The data protection framework in India is governed by the Information Technology Act, 2000, along with the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (*"SPDI Rules"*). These rules provide the legal foundation for the protection of personal and sensitive data in India.

Health-related information – such as medical records, biometric data or details of a participant's physiological and mental health condition – falls squarely within the definition of SPDI. Therefore, the collection, processing and transfer of such data require explicit, informed consent from the participant, along with clear disclosure of the purpose of collection and how the data will be used or shared. The transfer of data to a third party or affiliate, whether in India or abroad, is only permitted under the SPDI Rules if the participant has given consent to such transfer and the recipient ensures the same level of protection.

However, the data protection landscape is undergoing significant transformation. The Digital Personal Data Protection Act, 2023 (DPDPA) is in the process of being implemented, with the associated Draft Digital Personal Data Protection Rules, 2025 (*"DPDP Rules"*) currently under finalisation. Once the DPDPA comes into full force, it will supersede the SPDI Rules and establish a more comprehensive and robust data protection framework for India. The DPDPA gives the Central Government the power to restrict the transfer of personal data for processing to a country on *"negative list"*.

2.6 Databases Containing Personal or Sensitive Data

A database containing the personal data of persons would be subject to both statutory and contractual requirements. Express informed consent would have to be sought from the data subjects, and reasonable cybersecurity measures would have to be put in place.

3. Marketing Authorisations for Pharmaceuticals or Medical Devices

3.1 Product Classification: Pharmaceuticals or Medical Devices

The assessment process for determining whether a product should be regulated as a pharmaceutical or a medical device for the purpose of the DCA would be two-fold.

First, it would be essential to determine whether the product would satisfy the conditions for a pharmaceutical drug or a medical device, thereby triggering the DCA framework. This assessment would largely be based on the intended use of the product. In principle, if the product is intended to be used for the diagnosis, prevention, monitoring, treatment, mitigation or alleviation of a disease or disorder, it is likely to trigger the applicability of the DCA.

Subsequently, the categorisation into a pharmaceutical or a medical device would depend on the mode of action: if the intended action is achieved through pharmacological, immunological or metabolic means, it would likely be regulated as a pharmaceutical drug. In contrast, if the intended action is achieved through other means, such as physical, mechanical or electronic modes, it would likely be a medical device.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

There are no distinct or additional obligations under the NDCTR that must be fulfilled in order to obtain a marketing authorisation for biological medicinal products. Similar to other drugs that are classified as *"new drugs"* and have not previously been marketed in India, there is a requirement for local clinical trials to demonstrate the product's safety and efficacy to be conducted, unless a waiver is granted by the CLA. However, if the drug involves any hazardous micro-organisms and/or genetically engineered organisms, additional approval from the Review Committee on Genetic Manipulation would also be required.

Pertinently, for the purpose of the NDCTR, biological medicinal products (ie, vaccines, recombinant Deoxyribonucleic Acid (r-DNA) derived products, living modified organisms, monoclonal anti-bodies, cell or stem cell derived products, gene therapeutic products or xenografts, intended to be used as drugs) are considered *"new drugs"* in perpetuity, and remain subject to oversight from the CLA indefinitely. Unlike small molecule drugs, which cease to be *"new drugs"* after a period of four years, any new iteration of the biological medicinal product may trigger the requirement for clinical trials to be conducted.

Furthermore, the process of bringing a similar biologic (ie, biosimilars) to market requires the conduct of pharmacokinetic and pharmacodynamic studies, as well as confirmatory clinical trials evidencing the safety and efficacy.

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

The period of validity for marketing authorisations for pharmaceuticals and medical devices is not explicitly stated under the NDCTR, Drugs Rules, DCA or MDR.

A marketing authorisation can be revoked or suspended by the CLA – as they deem fit – if the authorisation holder fails to comply with any provisions of the DCA or NDCTR, or the conditions of the licence, including:

- failure to place the drug on the market;
- non-conformity with the approved specifications;
- non-adherence to the stipulated labelling requirements;
- failure to submit Periodic Safety Update Reports (PSURs);
- failure to submit reported adverse reactions, etc.

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

Pharmaceuticals

Application for marketing permission

The manufacturer or importer of a new drug must submit an application for marketing permission under the NDCTR to the CLA. This application must include:

- preclinical and clinical trial data – the manufacturer must submit evidence of the safety, efficacy and quality of the drug, including data from clinical trials if required; and
- detailed documentation – the application must include details of the formulation, therapeutic indications and other relevant information of the product.

Review and evaluation

The CLA reviews the submitted documentation, including the clinical trial data, to ensure that the drug meets safety and efficacy standards. The CLA may request additional data if necessary.

Granting of marketing permission

If the CLA is satisfied with the application, the marketing authorisation is granted, allowing the manufacturer or importer to market the drug in India. The manufacturer must then apply for a manufacturing licence or an import licence. The licence requirements for the new drug are governed by the DCA and Drugs Rules.

If a new drug that has already been approved for certain claims is later proposed to be marketed for new claims, indications, dosage forms, routes of administration or strengths, a new application would have to be filed with the CLA for marketing permission, and the applicant would have to include the required data and other particulars. The marketing permission is granted to the applicant and includes the requisite details and contact information of the applicant and the organisation applying for the marketing permission. This marketing permission is non-transferrable; a person or entity wishing to obtain marketing permission for said new drug would have to file a fresh application for marketing permission with the CLA.

Medical Devices

Application for marketing authorisation

The manufacturer or importer of an investigational medical device or new in vitro diagnostic medical device must submit an application for marketing permission to the CLA under the MDR. The grant of the permission is a prerequisite to obtaining the licence to manufacture or import any class of medical device into India. The applicant must provide comprehensive information about the class of medical device, including its intended use, safety and performance.

Granting of marketing authorisation

After reviewing the application and the necessary documents and information, the CLA may grant the marketing permission, if it finds them satisfactory. The permission holder can then apply for a manufacturing or import licence for sale and distribution in India.

The licence holder is obliged to obtain prior approval from the CLA for any major change carried out in the medical device. As per the MDR, any change affecting the qualify, safety or performance of the medical device is a major change, including any changes to the construction material, design (affecting the quality in respect of its specifications, indication for use, performance and stability) and intended use or indication for use. Any such change requires the prior approval of the CLA, which has discretion to approve or reject such change depending on its impact on

the quality, safety and performance of the medical device.

Furthermore, the marketing permission is granted to the applicant and their organisation, and is non-transferable. A person or entity that wants to obtain marketing permission for said medical device must file a fresh application with the CLA to obtain the marketing permission, supplying the requisite details and documents.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Any drug or medical device must obtain a licence for manufacturing or importing, sale and distribution, to ensure compliance with the regulatory framework established under the DCA, Drugs Rules and MDR. However, there are specific exceptions within the regulatory system designed to assist individuals in need of life-saving drugs that may not otherwise be authorised for use in India. These routes may or may not be linked to a compassionate use programme.

A new drug that has not been approved for use in India but is authorised for marketing in the country of origin may be imported by a government hospital or medical institution if it is needed to treat patients suffering from life-threatening diseases, serious permanent disabilities or unmet medical needs.

A small quantity of an investigational medical device that is not otherwise permitted for import under the MDR but has been approved in its country of origin may be allowed to be imported by the CLA. The investigational medical device may be imported for the treatment of a patient suffering from a life-threatening disease, a disease causing serious permanent disability or a condition requiring therapy for an unmet medical need.

Small quantities of drugs (including unapproved drugs) may be imported for personal use upon seeking approval from the CLA. The quantity imported must be reasonable in the opinion of the CLA, and should be supported by a prescription from a registered medical practitioner.

3.6 Marketing Authorisations for Pharmaceuticals and Medical Devices: Ongoing Obligations

Pharmacovigilance for Pharmaceuticals in India

In India, the licence or marketing authorisation for pharmaceuticals imposes ongoing obligations and pharmacovigilance requirements on the holder to ensure that the drug maintains its safety, efficacy and quality after it has been approved for sale and distribution.

Post-Marketing Trials (Phase IV Trials)

Phase IV trials or post-marketing surveillance are conducted after the drug is approved by the CLA. They are designed to evaluate the new drug's interaction with other drugs, its safety in broader patient populations, or its effectiveness in the long term.

The NDCTR also mandates the reporting of serious adverse effects to the CLA, and regulatory actions resulting from these reports must be followed to maintain the marketing authorisation. The authorisation holder must submit PSURs as part of post-marketing surveillance. These reports must include relevant new information, patient exposure data, significant safety variations and any changes needed to optimise the use of the drug. The PSURs must be submitted within the prescribed timeline.

Technovigilance of Medical Devices

The MDR under the DCA also impose similar ongoing obligations and technovigilance requirements on the licence or holders of marketing authorisation for medical devices.

Post-Marketing Surveillance for Medical Devices

After receiving the marketing permission and approval, the manufacturer must conduct post-marketing surveillance. This involves submitting PSURs that contain relevant new safety information, patient exposure data and any significant variations in the device's safety profile. In addition, the device master file, which is required for Class B, C and D medical devices, must include information about serious adverse effects, risk analysis and post-marketing surveillance data, such as complaints and corrective actions.

If the device has no predicate in India, the permission holder must also conduct a post-marketing clinical investigation as per the approved protocol, ensuring the device's continued safety and performance in the market. The PSURs must be submitted within the prescribed timeline.

The manufacturer must also report any serious adverse effects to the CLA within 15 days of becoming aware of such.

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

Third parties can access the general information about pending applications for broad categories of drugs, new drugs, medical devices and investigational medical devices on the CDSCO's website. However, while the details of a pending application can be tracked by the applicant, the details of the drugs or medical devices associated with pending applications are not available to third parties.

The CDSCO publishes a list of approved drugs and medical devices on its website, which includes the name of the drug and its indication, and this information is accessible to third parties as it is in the public domain.

India does not have specific rules governing or protecting commercially confidential information or information related to individuals. As for regulatory authorities, the information in an application for approval for a new drug, investigational medical device or new in vitro diagnostic medical device is not made public until the licence is granted to the entity.

4. Regulatory Reliance and Fast Track Registration Routes

4.1 Fast Track Registration Routes

The regulatory framework in India foresees the abbreviation, modification or relaxation of the clinical trial and/or data requirements for new drugs and medical devices under certain circumstances.

Medical Devices

Under the MDR, the CLA is permitted to abbreviate, defer or waive clinical performance evaluations for medical devices in the interest of public health.

For medical devices indicated for life-threatening diseases, serious health conditions, national emergencies, extreme urgency or epidemic scenarios, the clinical data or animal data requirements may be abbreviated, deferred or omitted, at the discretion of the CLA.

Similarly, the CLA may, in public interest, abbreviate, defer or waive the requirements of conducting clinical performance evaluation for a new in vitro diagnostic medical device, along with the reasons for the same.

Waiver of Local Clinical Trials for New Drugs

The NDCTR gives the CLA discretionary power to permit the waiver of local clinical trials in certain situations – for instance, if the drug has been approved and is being marketed in the USA, Canada, the UK, the EU, Japan or Australia and no major unexpected serious adverse events have been reported, or if there is evidence indicating that the drug will function differently in the Indian population. However, the waiver is applicable for specific categories of new drugs only, including orphan drugs, gene and cellular therapy products, new drugs used in a pandemic, new drugs used in special defence purpose, and new drugs representing asignificant therapeutic advance over the current standard of care.

4.2 Regulatory Reliance

The notion of regulatory reliance has not been fully and formally embraced in India. The DCA, Drugs Rules and MDR do not provide for an automatic waiver or fast tracking of the approval process based on approval conferred by the regulatory agency of a foreign jurisdiction. However, the CLA has been granted discretionary power to waive certain requirements, thereby expediting the process, when the drug or device has been approved and is being marketed in countries such as the USA, UK, EU and Japan.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceuticals and Medical Devices

Pharmaceuticals

A separate authorisation is not required for manufacturing plants per se. However, in order to obtain either an import licence or a manufacturing licence, the applicant is required to furnish a certificate evidencing that the manufacturing unit – whether based in India or overseas – complies with Good Manufacturing Practices (GMPs). This may be the GMP standards prescribed in the Drugs Rules, the WHO-GMP or equivalent international GMP standards.

Domestic manufacturing

For domestic manufacturing, the applicant is required to demonstrate compliance with the GMP prescribed under the Drugs Rules, and must obtain a certificate from the SLA to that effect. Typically, the SLA conducts a prior inspection of the manufacturing premises to verify compliance with Schedule M before issuing the certificate. In certain cases, such as for the renewal of licences or for lower-risk categories, a post-approval inspection may be conducted, or reliance may be placed on previous inspection records. However, for new manufacturing sites, major modifications or critical categories of drugs (eg, injectables or high-risk products), a pre-licensing inspection is generally mandatory to ensure adherence to GMP norms.

Import

To obtain an import licence, an overseas manufacturing site must comply with GMPs equivalent to WHO-GMP standards or those recognised by leading regulatory agencies, such as the US FDA

or EMA. A GMP certificate issued by the competent regulatory authority of the exporting country must be submitted along with the import licence application to the CDSCO. While the submission of this certificate is generally sufficient, the CDSCO may require an inspection of the foreign manufacturing site in certain circumstances – such as when the drug is newly introduced in India, when the manufacturing site has not been previously approved by the CDSCO, or when there are concerns about compliance or product quality. Inspections may also be triggered for high-risk drug categories or on a risk-based approach. In such cases, the CDSCO may coordinate or conduct a pre-approval or post-approval inspection, either directly or through appointed experts, to verify GMP compliance.

Medical Devices

For medical devices, it is necessary to demonstrate compliance with the Quality Management Systems specified in the MDR. Furthermore, every applicant is required to obtain a certification of compliance with ISO 14385 as a prerequisite.

The requirements in terms of inspection vary based on the class of the device.

Domestic manufacturing

For non-sterile and non-measuring Class A and B medical devices, an inspection is typically not required, and the licence is issued based on a documentary review.

For Class A devices, a prior audit of the manufacturing site is not required, and a post-facto audit may be carried out by a registered notified body (ie, not directly by the SLA).

For Class B devices, a prior audit of the manufacturing site is to be conducted by a notified body.

For Class C and D devices, the CLA conducts an inspection of the premises prior to issuing the licence.

Import

For Class A and B devices, a review of the documentation (including a free sale certificate or equivalent issued by the national regulatory authority in the country of origin) is generally sufficient, and inspections of foreign manufacturing sites are not usually required. However, for Class C and D devices, which carry higher risk, the CLA may require a pre- or post-approval inspection of the overseas manufacturing site, especially if the site is not already approved, or if deemed necessary based on risk assessment.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

The sale, stock, exhibit or offer for sale by wholesale of drugs or medical devices requires a wholesale licence in India. The wholesale licence for drugs and medical devices is granted by the respective SLAs.

If the applicant intends to sell or store drugs at multiple locations, a separate application must be submitted for each premises, and a separate licence will be issued for each location.

Depending on the category(ies) of drugs that are to be sold, an application would need to be made to the SLA in the stipulated form, along with the requisite documents. Upon submis-

sion of the application, the SLA will scrutinise the documents and ensure that the premises in respect of which the licence is to be granted is equipped with adequate space, proper storage conditions to preserve the drugs, and competent staff. If the SLA is satisfied with the necessary documents and compliances, the wholesale licence will be granted.

An entity holding a wholesale licence under the Drugs Rules is also entitled to stock and sell medical devices. However, if an entity intends to sell only medical devices, they may seek a registration certificate under the MDR. The procedure for obtaining a registration certificate is similar, but there are fewer prerequisites for the premises associated with it.

Validity of Authorisation

The wholesale licence is valid indefinitely once granted and requires the submission of a retention fee, every five years from the date of issuance, to maintain its validity.

6.2 Different Classifications Applicable to Pharmaceuticals

Please see **1.3 Different Categories of Pharmaceuticals and Medical Devices** regarding the different classifications of pharmaceuticals in India.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies

Legal Framework

DCA, Drugs Rules and MDR

The DCA and Drugs Rules are the primary framework regulating the import of drugs in India, and the DCA and MDR form the primary regulatory framework for the import of medical devices. In terms of procedural requirements, a registration certificate and import licence must be obtained for the import of a drug. Similarly, for medical devices, an import licence must be obtained. There are no licensing requirements triggered under the DCA framework for the export of drugs from India.

If the drug being imported or exported is narcotic or psychotropic in nature, the Narcotic Drugs and Psychotropic Substances Act, 1985 may also be triggered.

Foreign Trade (Development and Regulation) Act, 1992

The import and export of goods and services in India is regulated by the Foreign Trade (Development and Regulation) Act, 1992, which provides a legal framework for issuing licences, restrictions on trade, controls on export of certain goods and penalties for violation of the provisions of the Act.

Customs Act, 1962

The Customs Act, 1962 governs the import/export-related procedures and customs clearance at ports. Under the Customs Act, importers and exporters in India are obliged to truthfully

declare goods, ensure correct classification, valuation and duty payment, and comply with all applicable prohibitions or restrictions. They must also submit the required documentation (like the Bill of Entry or Shipping Bill), co-operate with customs authorities and follow procedures for clearance, warehousing and inspection.

Key Regulatory Authorities

CLA

As previously discussed, the CLA is tasked with granting import licences for the import of drugs and medical devices.

Central Bureau of Narcotics

The Central Bureau of Narcotics (CBN), operating under the Ministry of Finance, is involved in the import and export of narcotic drugs, psychotropic substances and controlled precursors in India. The CBN issues import/export authorisations and monitors licensed use of narcotic substances.

Director General of Foreign Trade

The Director General of Foreign Trade (DGFT) is responsible for formulating and implementing foreign trade policies and issuing Importer-Exporter Code (IEC) numbers and licences for the import and export of goods in India.

Central Board of Indirect Taxes and Customs

The Central Board of Indirect Taxes and Custom manages the implementation of trade facilitation measures, combats smuggling and duty evasion, and co-ordinates with other agencies (including the CDSCO) to enforce import/export regulations and restrictions.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

The foreign manufacturer must apply for an import licence for drugs or medical devices through an authorised agent in India. The authorised agent is typically a third-party entity or an Indian subsidiary of the foreign manufacturer, is the importer of record for the purposes of importing the drug or medical device into India.

The importer of record must have a presence in India and must be licensed to either manufacture or sell drugs or medical devices by wholesale, as the case may be, in India. In addition, the authorised agent is responsible for the foreign manufacturer's business and any resulting liabilities in India, and the appointment must be documented by a power of attorney from the foreign manufacturer.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

Pharmaceuticals

The DCA and Drug Rules require foreign manufacturers or their authorised agents to obtain a registration certificate and an import licence in order to import drugs into India. However, the import of small quantities of drugs for bona fide personal use, for donation to charitable hospitals or in emergency situations without a registration certificate is permitted in India.

Medical Devices

A licence to import medical devices is granted based on an application and the submission of required documents by the foreign manufacturer or their authorised agent in India. However, the import of medical devices for personal use, custom-made devices, donations to charitable hospitals, or for government hospitals and statutory medical institutions treating life-threatening diseases is permitted without a licence. Class A medical devices may be imported if properly registered under the MDR.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Non-tariff regulations and restrictions on the import of drugs and medical devices into India are imposed by the regulatory framework for drugs and medical devices, and by general trade laws.

For both drugs and medical devices, the Indian Trade Classification (Harmonised System) (ITCHS) Code is used to classify the products for import or export. The list of ITCHS Codes is maintained by the DGFT.

In order to import and/or export any goods – including drugs and medical devices – an IEC must be obtained from the DGFT. The IEC must be mentioned in the documents submitted to customs for clearing the imported goods.

The DCA and Drugs Rules impose non-tariff regulations on the import of drugs by requiring the foreign manufacturer or their authorised agent (who holds a valid wholesale licence or a manufacture licence) to obtain a registration certificate and import licence from the CLA for the import of drugs intended for sale and distribution in India.

Similarly, under the MDR, the import of medical devices requires the procurement of an import licence. The foreign manufacturer's authorised agent must submit the required documents to the SLA or CLA, depending on the class of the medical device, to obtain the necessary import licence for the sale and distribution of the device in India.

Please see **7.1 Governing Law for the Import and Export of Pharmaceuticals and Medical Devices and Relevant Enforcement Bodies** regarding the regulatory framework governing the import of pharmaceutical products and medical devices.

7.5 Trade Blocs and Free Trade Agreements

India is a member of several international organisations, including the World Trade Organization, and is actively involved in regional trade blocs such as the South Asian Association for Regional Cooperation. India is also a signatory to free trade and preferential trade agreements, including the ASEAN-India Free Trade Area, the Asia-Pacific Trade Agreement and the India-MERCOSUR Preferential Trade Agreement. Significantly, the India–UAE Comprehensive Economic Partnership Agreement contains a separate annex for bilateral co-operation on pharmaceutical products, which aims to facilitate access to finished pharmaceutical products and certain marketed biologics. It provides for fast track approvals of products that have received approval from certain national regulatory agencies, amongst other provisions aimed at facilitating trade.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

In India, the pricing of drugs and medical devices is subject to substantial oversight, with the price at which drugs and devices can be sold to the ultimate consumer being specifically regulated.

India has a price control regime – the DPCO – which either dictates or regulates the maximum retail price (MRP) of drugs and medical devices. Broadly, this is done under the following two mechanisms.

Price Control

Pharmaceuticals and medical devices listed in the National List of Essential Medicines (NLEM) are subject to a ceiling price, which is specified by the NPPA. The MRP for that drug or device would be the ceiling price plus applicable taxes. Manufacturers, importers and dealers are prohibited from charging a price higher than the MRP.

Price Monitoring

The NPPA is not involved in setting the MRP of pharmaceuticals and medical devices that do not form part of the NLEM. However, the NPPA monitors these prices and restricts manufacturers and importers from increasing the MRP by more than 10% within a 12-month period.

The NPPA also has the power to fix prices of medicines and medical devices in public interest in extraordinary circumstances in India. This is generally done for a fixed period, after which the NPPA reviews the situation.

Distributor Margins

The NPPA factors in a retailer margin – typically 16% – while calculating the ceiling price for drugs and medical devices that is subject to price controls.

The NPPA has also been increasingly employing the Trade Margin Rationalisation approach for fixing prices. Essentially, the NPPA caps the trade margin – ie, the difference between the price that a manufacturer charges for a product and the MRP of the product. This approach has been adopted for several anti-cancer drugs and medical devices.

8.2 Price Levels of Pharmaceuticals or Medical Devices

The price of a pharmaceutical product or medical device in India is independent of the same product in other countries.

8.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

India is at a nascent stage of establishing universal health coverage, and most insurance plans (both public and private) do not cover the cost of medicines and medical devices when required independently of hospitalisation; the cost of medicines and medical devices is overwhelming borne directly by patients out-of-pocket.

The reimbursement of the costs for pharmaceuticals and medical devices from public funds is limited, and is achieved primarily through government schemes aimed at the economically vulnerable populations in India, such as the Ayushman Bharat Scheme and Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana, and Central Government Health Scheme. The reimbursement is typically tied to hospitalisation, where expenses for medicines, diagnostic services and medical devices related to treatments are covered. Reimbursement may occur for outpatient services in limited public healthcare settings, but it is more common for the medicines and medical devices to be supplied at a subsidised or very low cost.

8.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

At present, Health Technology Assessment (HTA) is not being formally used in India for determining the price of pharmaceuticals and medical devices. The DPCO does not currently recognise HTA, and the NPPA still relies exclusively on market data when determining ceiling prices for

drugs and medical devices and imposing prices in extraordinary circumstances.

There is a shift towards incorporating HTA into public health programmes. To support this, the government set up the Health Technology Assessment in India (HTAIn), the objectives of which are to inform decision-making, ensure the optimal use of the limited healthcare budget, improve access to quality healthcare and reduce out-of-pocket expenses for the public. However, it is still at a preliminary stage of integration into the policy-making systems.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

As discussed in **8.1 Price Control for Pharmaceuticals and Medical Devices**, the MRP of medicines and medical devices is regulated in India primarily at the manufacturer level, and the DPCO prohibits any person from selling them at a price higher than the MRP. Therefore, there is limited focus on controlling spending at the prescription and dispensing stages. That being said, the code of ethics that governs the conduct of medical practitioners in India does require that they prescribe drugs with their generic names, and ensure that there is a rational prescription and use of drugs. However, there is currently limited enforcement of this requirement.

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