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PHARMA & MEDICAL DEVICE REGULATION

India

LEXOLOGY

Pharma & Medical Device Regulation

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REGULATORY FRAMEWORK

Competent authorities for authorisation

Identify the competent authorities for approval of the marketing of medicinal products and medical devices. What rules apply to deciding whether a product falls into either category or other regulated categories?

The Drug Controller General of India (DCGI) administers and approves the manufacturing, importing or marketing of medicinal products and medical devices in India.

The Drugs and Cosmetics Act 1940 (DCA), the Drugs and Cosmetics Rules 1945 (DCR) and the Medical Devices Rules 2017 (MDR) govern approvals and decide whether a product is categorised as a drug or any other category (eg, cosmetics or dietary supplements).

Law stated - 28 October 2024

Approval framework

Describe the general legislative and regulatory framework for approval of marketing of medicinal products and medical devices.

The DCA, the DCR and the MDR regulate approvals regarding marketing medicinal products and medical devices in India. The approval process in India involves two phases: Phase I (approval for clinical trials) and Phase II (marketing authorisation). The DCGI approves the drug only if it is safe and effective in human beings. The conditions listed below must be satisfied for approval or permission under the DCR to be granted:

- The formulation must conform to the specifications approved by the licensing authority.
- The proper name of the drug must be printed or written in indelible ink and must appear more conspicuously than the trade name, if any, which must be shown immediately after or under the proper name on the label of the innermost container of the drug or every other covering in which the container is packed.
- The label of the innermost container of the drug and every other covering in which the container is packed must bear a conspicuous red vertical line on the left side running throughout the body of the label that shall not be less than 1mm in width and that shall not disturb the other conditions printed on the label to depict it as a prescription drug.
- The label on the immediate container of the drug as well as the packing in which the container is enclosed should contain the following warning: 'WARNING: To be sold by retail on the prescription of a . . . only.'
- Post-marketing surveillance studies must be conducted for two years after the new drug formulation is marketed after the licensing authority approves the protocol and the investigator's names.
- All reported adverse reactions related to the drug must be disclosed to the licensing authority and the DCGI, and regulatory action resulting from their review must be complied with.

- No claims except those mentioned in the points above must be made for the drug without the prior approval of the licensing authority.
- Specimens of the cartons, labels and package inserts that will be adopted for marketing the drug in the country must be approved by the licensing authority before a drug is marketed.
- Each consignment of an imported drug must be accompanied by a test or analysis report.

The DCA and the MDR also govern labelling requirements for different medicines and medical devices. Some of the basic labelling requirements include the name of the product, the name and address of the manufacturer, the lot or batch number, and the expiry date. The DCR also lays down specific rules for leaflets for different medicinal products, such as including special instructions regarding storage wherever applicable, and a cautionary legend.

According to the Legal Metrology (Packaged Commodities) Amendment Rules, 2017 (brought into force in 2018) and a notification dated July 2023, the provisions of the Legal Metrology (Packaged Commodities) Rules, 2011 (the LM Rules) also apply to the labelling of medical devices declared as drugs. The label of any commodity covered by the LM Rules must include the following information:

- maximum retail price;
- name and address of the manufacturer or importer;
- net quantity;
- common or generic name of the commodity;
- country of origin;
- month and year in which the commodity was manufactured, packed or imported;
- name, address, telephone number and email address of the person or office that can be contacted for consumer complaints; and
- corporate name and complete address of the domestic manufacturer, importer or packer.

In January 2024 the Central Drugs Standard Control Organisation (CDSCO) launched the National Single Window System portal for medical device management, to streamline the process of approvals, licences, registrations and clearances for medical devices.

Law stated - 28 October 2024

CLINICAL PRACTICE

Applicable rules

What legislation controls and which rules apply to ethics committee approval and performance of clinical trials in your territory for medicinal products and medical devices?

The Drugs and Cosmetics Act 1940 (DCA), the Drugs and Cosmetics Rules 1945 (DCR), the Medical Devices Rules 2017 (MDR) and the New Drugs and Clinical Trials Rules 2019 (the NDCT Rules) regulate ethics committee approval and the performance of clinical trials for medicinal products and medical devices in India.

Law stated - 28 October 2024

Reporting requirements

What requirements exist for reporting the commencement of a trial and its results to the competent authorities or the public?

The NDCT Rules prescribe that six monthly status reports of each clinical trial, in respect of whether it is ongoing, completed or terminated, must be submitted to the Drug Controller General of India (DCGI). Additionally, serious adverse events, including death during the trial, must be reported to the DCGI and the ethics committee within 24 hours of occurrence.

Law stated - 28 October 2024

Consent and insurance

Are there mandatory rules for obtaining trial subjects' consent to participate? Must sponsors arrange personal injury insurance to a particular limit?

Yes. The NDCT Rules mandate that in all clinical trials, freely given, informed and written consent must be obtained from each study subject in the prescribed informed consent form, after providing information about the study to the subject verbally, as well as using a patient information sheet, in a language that is non-technical and understandable by the study subject.

It is not mandatory for the sponsors to arrange personal injury insurance for the subjects. The NDCT Rules provide that the sponsor must either arrange an insurance policy or compensate the trial subject in the event of any injury or death resulting from the clinical trial.

Law stated - 28 October 2024

MARKETING AUTHORISATION

Time frame

How long does it take, in general, to obtain an authorisation from application to grant, what fees are payable and what is the normal period of validity of the authorisation?

The Drugs and Cosmetics Rules 1945 (DCR) do not prescribe a specific timeline for granting marketing approval for a drug. However, the table below outlines the key applications to be filed for the import of drugs and marketing, the applicable fees, the validity periods, and approximate timelines. The actual time taken depends on various factors, such as the amount and effectiveness of follow-up with the authorities concerned.

Application	Form No.	Fees	Validity	Approximate timeline*
Import, manufacture of new drug and permission to undertake a clinical trial	Form 44	50,000 rupees	–	180 days
Registration for the import of a single drug into India	Form 40	US$1,000 (or equivalent value in rupees)	3 years	270 days
Import licence	Form 8	1,000 rupees	3 years	45 days
Licence to sell, stock or exhibit	Form 19	1,500 rupees	5 years	30 days
* The timelines will also vary depending on the state licensing authorities.				

Law stated - 28 October 2024

Marketing exclusivity

What protections or exclusivities apply to the marketing period of an approved medicinal product or variation?

A new drug is eligible for data exclusivity in India for a period of four years from the date of its approval. A new drug is defined as a drug that has not been significantly used in India.

Law stated - 28 October 2024

Protecting research data

What protections or exclusivities apply to the data submitted by originators to gain initial approval and, on variation or new application, to add indications or pharmaceutical forms?

There are no statutory provisions in India that protect the research data submitted to regulatory authorities for testing, nor for data exclusivity.

Law stated - 28 October 2024

Freedom of information

To what extent and when can third parties make freedom of information applications for copies of research data submitted by applicants for authorisation to market medicinal products or medical devices?

Currently, no Indian laws allow third parties to make freedom of information or right to information applications to obtain copies of applicants' research data submitted to the government for authorisation to market medicinal products or medical devices.

Law stated - 28 October 2024

Regulation of specific medicinal products

What are the specific requirements and processes for marketing approval of the major categories of regulated products?

The DCR lays down rules in respect of all drugs, including Ayurvedic (traditional medicines), homeopathic and biological drugs, and those for paediatric use.

The Ministry of Health and Family Welfare (MOHFW) issued separate guidelines for similar biological products in 2016, which contain guidelines for the manufacture and quality of similar biologicals, requirements for clinical trial applications and requirements for market authorisations, among others. Further, the Narcotic Drugs and Psychotropic Substances Act 1985 governs controlled drugs in India.

The New Drugs and Clinical Trials Rules 2019 (DCT Rules) define an 'orphan drug' as a drug intended to treat a condition that affects not more than 500,000 persons in India. The clinical trial of an orphan drug is similar to that of other drugs. However, the Central Drugs Standard Control Organisation (CDSCO) has the discretion to expedite the approval of an orphan drug. Further, no application fee is required to be paid for conducting a clinical trial of an orphan drug in India.

For homeopathic medicines, the quality standards of identity, purity and strength specified in the Homoeopathic Pharmacopoeia of India must be complied with.

The processes pertaining to traditional herbal medicines are overseen by the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board and the Ayurvedic, Siddha and Unani Drugs Consultative Committee.

The MDR lays down rules and requirements pertaining to the clinical study, approval, marketing etc of medical devices.

Law stated - 28 October 2024

Rewards and incentives

What rewards or incentives for approval are applicable to the major product categories, including orphan drugs, drugs for paediatric use, generic drugs and biosimilars?

Regulatory

A fast-track approval process and special status for orphan drugs, including a complete fee waiver for filing clinical trials, are available.

There is also a provision for an expeditious review process even if the drug has not completed all clinical trial phases. The sponsor or applicant may apply to the Central Licensing Authority (CLA) for expedited review.

At the discretion of the CLA, local clinical study and Phase IV requirements can be waived.

Financial benefits

No application fee is charged for conducting clinical trials for orphan drugs.

The central government has introduced a production-linked incentive scheme for eight years starting from 2020 in respect of pharmaceutical products including orphan drugs, autoimmune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs, anti-retroviral drugs and in vitro diagnostic devices, among others.

Law stated - 28 October 2024

Post-marketing surveillance of safety

What pharmacovigilance or device vigilance obligations apply to the holder of a relevant authorisation once the product is placed on the market?

Schedule Y under the DCR prescribes that, after a product's approval, the new drug must be closely monitored for its clinical safety. The applicant must provide periodic safety update reports to report all relevant new information from appropriate sources, relate the data to patient exposure and summarise the marketing authorisation statuses in different countries and any significant variations related to safety. The applicant must also indicate whether changes will be made to the product information to optimise the product's use.

Law stated - 28 October 2024

Other authorisations

What authorisations are required to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices? What type of information needs to be provided to the authorities with an application, what are the fees, and what is the normal period of validity?

A person who intends to manufacture, import, export or conduct wholesale distribution and storage of medicinal products and medical devices in India must obtain a licence from the licensing authority appointed by the CDSCO.

The DCR prescribes rules for the manufacture, import and sale of drugs in India.

Importing drugs

To import a drug into India, a registration certificate must be obtained from the licensing authority for registration of the premises of manufacture, the means for import into India and the means of use in India. The fee applicable for registration is US$1,000 (or its equivalent value in Indian rupees) and the registration is valid for three years.

After obtaining the registration certificate, the importer must provide the following information to the licensing authority to obtain the import drug licence:

- the name, full address, telephone number, fax number and email of the applicant;
- the name of the drug to be imported; and
- a copy of the registration certificate obtained from the licensing authority.

The fee to obtain a licence to import a new drug and for permission for clinical trials is 50,000 rupees. The validity period for the licence to import drugs, including new drugs, is three years.

The fee to obtain an import licence is 1,000 rupees. This licence is valid for three years.

To obtain a licence to sell, stock, exhibit or distribute drugs, the following information must be provided to the licensing authority:

- the name of the applicant; and
- the names of the qualified persons under whose personal supervision the drugs will be sold.

The fee to obtain a licence to sell or distribute drugs is 1,500 rupees. The licence is valid for five years.

To obtain a licence to manufacture drugs, the following information must be provided to the licensing authority:

- the name of the applicant;
- the address of the premises where manufacturing activities will take place;
- the name of the drug; and
- the names, qualifications and experience of the technical staff employed for manufacturing and testing.

The fee to obtain a licence to manufacture drugs is 50,000 rupees. The validity period for the licence is five years.

Importing medical devices

The MDR prescribes the conditions for the manufacturing and import of medical devices in India.

To obtain a manufacturing licence for medical devices, the following information must be provided:

- the name of the applicant;
- the nature and constitution of the manufacturer;
- the registered office address, telephone number, fax number and email; and
- details of the medical devices to be manufactured.

The fee to obtain a licence for manufacturing medical devices ranges from 5,000 rupees to 50,000 rupees, depending on the nature of the medical device and the manufacturing site. The licence is valid indefinitely subject to payment of a licence retention fee that ranges from 5,000 rupees to 50,000 rupees before the completion of five years from the date of issue.

To obtain a licence to import medical devices into India, the following information must be provided:

- the name of the authorised agent;
- the nature and constitution of the authorised agent;
- the registered office address, telephone number, fax number and email;
- the name and address of the manufacturer;
- the name and address of the manufacturing site; and
- details of the medical device to be imported.

The fee to obtain a licence to import medical devices ranges from US$1,000 to US$3,000 (or its equivalent value in Indian rupees), depending on the nature of the medical device. The licence is valid indefinitely subject to the payment of a licence retention fee that ranges from US$1,000 to US$3,000 (or its equivalent value in Indian rupees) before the completion of five years from the date of issue.

Exporting drugs

The DCR prescribes that a manufacturer with a valid licence to manufacture drugs may obtain a no objection certificate (NOC) from the DCGI to export the drugs from India.

The Guidelines for the Export of Drugs issued by the MOHFW prescribes detailed guidelines for applicants for the export of drugs outside India. The two primary conditions to obtain the NOC from the DCGI are that the applicant:

- must have a copy of the valid export order; and
- must identify the premises where the drug will be manufactured.

Exporting medical devices

A person must file an application with the CLA and pay a fee of 1,000 rupees to obtain a certificate to export a medical device outside India.

The applicant must also request a free sale certificate or a quality, safety and performance certificate in respect of the medical device from the concerned authority of the importing country.

Law stated - 28 October 2024

Sanctions

What civil, administrative or criminal sanctions can authorities impose on entities or their directors and officers for breach of the requirements concerning controlled activities?

The DCA prescribes criminal sanctions for violations of its provisions.

The import of adulterated or spurious drugs is punishable with imprisonment for a maximum of three years and a maximum fine of 5,000 rupees.

Further, the DCA prescribes that the sale or manufacture of adulterated or spurious drugs that are likely to result in death or grievous harm are punishable with imprisonment for a minimum term of 10 years and a maximum term of life imprisonment, as well as a minimum fine of 1 million rupees or three times the value of the drugs confiscated, whichever is higher.

The DCA also prescribes that a drug that is manufactured or sold without a valid licence is punishable with imprisonment for a minimum term of three years and a maximum of five years, as well as a minimum fine of 100,000 rupees or three times the value of the drugs confiscated, whichever is higher.

The DCA prescribes that if the DCR is violated, action can be taken against the company and all the persons responsible for such conduct within the company and who knew of the offending act.

Law stated - 28 October 2024

Exemptions

What, if any, manufacture and supply of medicinal products is exempt from the requirement to obtain an approval to market?

The DCR prescribes that the following drugs will be exempted from the provisions of the DCA and the DCR:

- drugs not intended for medicinal use, in which case they should be labelled as 'NOT FOR MEDICINAL USE';
- quinine and other antimalarial drugs; and
- drugs supplied by a registered medical practitioner to his or her own patient, or any drug supplied by a registered medical practitioner at the request of another practitioner, provided it is specifically to treat a condition and for the use of an individual patient.

Law stated - 28 October 2024

Parallel trade

Are imports allowed into your jurisdiction of finished products already authorised in another jurisdiction, without the importer having to provide

the full particulars normally required to obtain an authorisation to market? What are the requirements?

No. The DCA prohibits the import of any medicines and medical devices into India without a licence. To import a drug into India, a registration certificate must be obtained from the licensing authority for registration of the premises, the drugs manufactured, the means of import and the means of use in India. After obtaining the registration certificate, the importer must also obtain an import drug licence from the licensing authority.

Law stated - 28 October 2024

AMENDING AUTHORISATIONS

Variation
What are the main requirements relating to variation of authorisations for medicinal products and medical devices?

Medical products

The Drugs and Cosmetics Act (DCA) provides that a licensee must inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and the existing registration will be valid only for three months from the date on which the change has taken place.

If there is a change in the indication or intended use of a registered new drug, the applicant must file a fresh application for approval reflecting the changes and modifications.

Medical devices

The Medical Devices Rules 2017 (MDR) provide that the licensing authority must be informed of any changes in the licensee's constitution within 180 days of the change, in the case of an import licence holder, and within 45 days, in the case of a manufacturing licence holder. The existing licence will be valid only until a fresh licence with the changes incorporated is issued.

Law stated - 28 October 2024

Renewal
What are the main requirements relating to renewal of authorisations for medicinal products and medical devices?

The requirements for renewal of authorisations for medical products and medical devices are the same as those for filing fresh applications.

Applications for re-registration and renewal should be submitted a minimum of nine months before the expiry of the registration.

To obtain or import a drug licence, the importer must provide the following information to the licensing authority:

- the name, full address, telephone number, fax number and email of the applicant;
- the name of the drug to be imported; and
- a copy of the registration certificate obtained from the licensing authority.

To obtain a licence to sell, stock, exhibit or distribute drugs, the following information must be provided to the licensing authority:

- the name of the applicant; and
- the names of the qualified persons under whose personal supervision the drugs will be sold.

To obtain a licence to manufacture drugs, the following information must be provided to the licensing authority:

- the name of the applicant;
- the address of the premises where manufacturing activities will take place;
- the name of the drug; and
- the names, qualifications and experience of the technical staff employed for manufacturing and testing.

To obtain a manufacturing licence for medical devices, the following information must be provided:

- the name of the applicant;
- the nature and constitution of the manufacturer;
- the registered office address, telephone number, fax number and email; and
- details of medical devices to be manufactured.

To obtain a licence to import medical devices into India, the following information must be provided:

- the name of an authorised agent;
- the nature and constitution of the authorised agent;
- the registered office address, telephone number, fax number and email;
- the name and address of the manufacturer;
- the name and address of the manufacturing site; and
- details of the medical device to be imported.

Law stated - 28 October 2024

Transfer

How easy is it to transfer the existing approvals or rights to market medicines and medical devices? How long does this take in general?

Indian law currently does not have any provisions regarding the transfer of existing approvals or rights to market medicines and medical devices.

Law stated - 28 October 2024

RECALL

Defective and unsafe products

What are the normal requirements for handling cases of defective or possibly unsafe products, including approvals required for recall and communication with health professionals?

Medical products

In India, the Drugs and Cosmetics Act 1940 (DCA) contains provisions relating to drug recall, complaints and adverse reactions, and licence conditions for defective product recall in India. Based on the DCA provisions, the Central Drugs Standard Control Organisation (CDSCO) issued the Guidelines on Recall and Rapid Alert System for Drugs in 2017 (the Recall Guidelines). The Recall Guidelines apply to all quality-defective drugs, including biologicals and vaccines.

The Recall Guidelines classify drug recall into three categories: Class I (for drugs likely to cause serious health consequences or death); Class II (drugs that are likely to cause temporary adverse health consequences); and Class III (drugs that are unlikely to cause any adverse health consequences). The recalls are further classified into the following levels: consumer or user; retail; and wholesale.

The recall procedure must be initiated upon receipt of the information from the relevant manufacturer or the authority within 24 to 72 hours for Class I drugs, within 10 days for Class II drugs and within 30 days for Class III drugs. The timeline for stopping the sale and distribution of defective drugs under Class I must be ensured within 24 hours (with physical recall being completed within 72 hours). The sale and distribution of Class II and Class III defective drugs must be stopped within 10 and 30 days, respectively.

As soon as the defective product or batch is identified, the manufacturer or licensee must review the information at hand and decide within 24 to 72 hours (in the case of Class I products) and, thereafter, communicate the recall decision to the entire supply chain, including the warehouse, depot, distributors, retailers, exporters, hospitals, healthcare professionals, and consumers and users. The communication regarding the recall must specify the severity of the defect, using the fastest mode of communication, including email, telephone, fax and SMS.

The manufacturer or licensee must inform the concerned regulatory authority immediately after the recall decision is taken. Other duties of the manufacturer or licensee include informing the personnel involved at the retail level and informing the stock position to the immediate supplier, manufacturer and the local drug inspector.

The manufacturer, licensee or quality head must enter the details in the recall log prescribed under the Recall Guidelines and issue the product or batch recall notice to the distributor or marketing company. The Recall Guidelines also prescribe procedures regarding follow-up actions for recalled goods.

Medical devices

The Medical Devices Rules 2017 (MDR) provide that, if a manufacturer or an authorised agent has reasons to believe that a medical device (imported, manufactured, sold or distributed) is likely to pose a risk to the health of a user or patient during its use, the medical device must be recalled, indicating the reasons for its withdrawal, and the competent authority must be informed of the relevant details thereof.

The manufacturer should immediately inform the relevant authority of the occurrence of any recall within 15 days of the event coming to the attention of the manufacturer.

Law stated - 28 October 2024

ADVERTISING AND PROMOTION

Regulation

Summarise the rules relating to advertising and promotion of medicinal products and medical devices, explaining when the provision of information will be treated as promotional. Do special rules apply to online advertising?

Pharmaceutical advertising is governed by the following legislation:

- the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 (the DMR Act), which controls the advertising of drugs;
- the Drugs and Cosmetics Rules 1945, which regulate the labelling and branding of pharmaceutical products, cosmetics and homeopathic medicines in India;
- the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 (the IMC Regulations), relating to ethical conduct that may affect the relationship of medical practitioners with the pharmaceutical industry;
- the Uniform Code of Pharmaceutical Marketing Practices 2024 (the UCPMP Code), a self-regulatory code adopted by the Indian pharmaceutical industry; and
- the Code of Pharmaceutical Marketing Practices of the Organisation of Pharmaceutical Producers of India.

Medicinal products

The promotion of medicinal products in India is primarily regulated by the DMR Act and its associated Rules. The DMR Act stipulates that any advertisement of a drug that suggests or leads to the use of a drug for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in its schedule is prohibited in India. At the

time of writing, the schedule under the DMR Act contains 54 diseases. A recently proposed amendment to the DMR Act proposes to expand the list to 78 diseases.

The DMR Act provides exceptions where the advertisement of drugs is allowed, including:

- where a registered medical practitioner's signboard on his or her premises indicates treatment for any disease, disorder or condition;
- any treatise or book dealing with diseases from a ***bona fide*** scientific or social standpoint;
- any advertisement sent confidentially to a registered medical practitioner; and
- any government advertisement, or an advertisement by any government-sanctioned person.

Corporate or financial information describing a company's area of business and progress in research falls outside the purview of the DMR Act's definition of advertisement, as it does not constitute promotional claims on drugs as such. Further, it is common practice in India for pharmaceutical companies to advertise their area of business, infrastructure and research capabilities, among others.

In respect of online advertising, the DMR Act defines an 'advertisement' as 'any notice, circular, label, wrapper, or other document, and any announcement made orally or by any means of producing or transmitting light, sound or smoke.' These regulations are technically applicable to online advertising as well.

Another recent development in this regard is that the Ministry of Health and Family Welfare (MOHFW) introduced the Draft DMR Act (Amendment) Bill 2020 (the DMRA Bill) in February 2020, which proposes to include online advertising under the definition of advertisement under the DMR Act. In particular, the DMRA Bill proposes to include the following means of promotion under the definition of advertisement: 'any audio or visual publicity, representation, endorsement or pronouncement made by means of light, sound, smoke, gas, print, electronic media, internet or website and includes any notice, circular, label, wrapper, invoice, banner, poster or such other documents'.

Medical devices

The MOHFW issued a notification on 11 February 2020 (the MOHFW Notification), specifying that the medical devices listed in the MOHFW Notification shall be treated as drugs as of 1 April 2020. Therefore, all the regulations and compliance requirements applicable to the advertising of drugs are also applicable to medical devices. The MOHFW Notification stipulates that medical devices include instruments, apparatuses, appliances, implants, materials or other articles, including software or accessories, for the purposes of:

- diagnosing, preventing, monitoring, treating or alleviating any disease or disorder;
- diagnosing, monitoring, treating, alleviating or providing assistance for any injury or disability;
- investigating, replacing, modifying or supporting the anatomy or a physiological process;
- supporting or sustaining life;
- disinfecting medical devices; or

- controlling conception.

Law stated - 28 October 2024

Inducement

What regulations exist to discourage the provision of inducements to healthcare professionals to prescribe, sell, supply or recommend use of a particular medicinal product or medical device?

The legal framework surrounding inducements to healthcare professionals in India is covered under the IMC Regulations and the UCPMP Code. The IMC Regulations and the UCPMP Code prohibit any inducements to healthcare professionals to prescribe, sell, supply or recommend the use of a particular medicinal product and, under the MOHFW Notification, these restrictions apply to medical devices as well.

Further, the UCPMP Code prohibits pharmaceutical companies from extending to healthcare professionals any travel facilities inside or outside the country, including rail, air, ship and paid vouchers, among others, as well as any hospitality services, accommodation, or cash or monetary grants.

Additionally, the standard Indian laws against corruption and bribery will apply to violations of the IMC Regulations and other legislation, such as the DMR Act and the Drugs and Cosmetic Act 1940 (DCA) and will also apply to healthcare professionals. Further, healthcare professionals in violation of these laws will be prosecuted under the applicable penal laws in India.

Law stated - 28 October 2024

Reporting transfers of value

What requirements apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices?

There are no specific statutory requirements that apply to recording and publishing details of transfers of value to healthcare professionals and organisations by companies marketing medicinal products or medical devices in India.

Law stated - 28 October 2024

Enforcers

Describe the bodies involved in monitoring and ensuring compliance with advertising controls for medicinal products and medical devices, distinguishing between any self-regulatory framework and control by the authorities.

The food and drug administration authority in each Indian state is responsible for enforcing the DCA and the DMR Act.

Further, compliance under the UCPMP Code is enforced by the Ethics Committee for Pharmaceutical Marketing Practices (ECPMP). The ECPMP has three to five members who will preside over a complaint. In case a party is dissatisfied with the ECPMP's decision, it may file an appeal before the Apex Committee for Pharmaceutical Marketing Practices (ACPMP), the decision of which will be final. The appeal must be filed within 15 days, with an additional 15 days of reasonable time delay permitted for reasons to be recorded in writing.

Law stated - 28 October 2024

Sanctions

What are the possible financial or other sanctions for breach of advertising and promotional controls for medicinal products or medical devices?

Breach of the DMR Act provisions is punishable by up to six months' imprisonment and/or a fine. There is up to one additional year of imprisonment for a repeated offence.

The UCPMP Code, which is a self-regulatory code, prescribes any of the following penalties in the event of a breach:

- suspension or expulsion of the company from the pharmaceutical association;
- reprimand of the company and publishing of the details of the reprimand;
- requirement of the company to issue a corrective statement in the media used for promotion; or
- requirement of the company to recover items given in violation of the UCPMP Code from the concerned persons and provide details of the action to the ECPMP or the ACPMP.

Law stated - 28 October 2024

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

May health professionals prescribe or use products for 'off-label' indications? May pharmaceutical companies draw health professionals' attention to potential off-label uses?

Although off-label drugs are very common in medical practice in India, there is currently no law in India that governs the prescription or use of off-label drugs. The Indian Medical Association (IMA), a voluntary association formed in the interest of medical practitioners, attempted to officially permit the use of off-label drugs in India. However, the IMA's attempts have faced strong opposition in the past.

Law stated - 28 October 2024

Unlicensed products

What rules apply to the manufacture and importation and supply to healthcare providers of unlicensed medicines or medical devices?

The Drugs and Cosmetics Act 1940 (DCA) prohibits the manufacturing, sale, distribution and import of medicines and medical devices without a licence.

A person who manufactures, sells, distributes or imports drugs into India without the prescribed licence will be punished with a minimum term of imprisonment of three years and a maximum term of imprisonment of five years, as well as a fine of 100,000 rupees or three times the value of the drugs confiscated, whichever is higher.

Law stated - 28 October 2024

Compassionate use

What rules apply to the establishment of compassionate use programmes for unlicensed products?

Indian law does not prescribe any rules for the compassionate use of unlicensed products.

However, the DCA and the Drugs and Cosmetics Rules 1945 (DCR) permit the import of small quantities of new drugs by a government hospital or an autonomous medical institution to treat patients suffering from life-threatening diseases, diseases resulting in a serious permanent disability or who have extreme medical needs.

Law stated - 28 October 2024

SALE AND SUPPLY

Regulation

Are there special rules governing the dispensing or sale of particular types of medicinal products or medical devices?

The Drugs and Cosmetics Act 1940 (DCA) and the Drugs and Cosmetics Rules 1945 (DCR) govern the sale of all kinds of drugs, including Ayurvedic (traditional medicines), Siddha and Unani (herbal medicines), and homoeopathic drugs in India.

Law stated - 28 October 2024

Online supply

What laws and guidelines govern online dispensing, sale and supply of medicinal products and medical devices?

There is no Indian law that regulates the online sale and supply of medicines and medical devices.

However, the Ministry of Health and Family Welfare (MOHFW) has issued a draft notification to amend the DCR to regulate the online sale of drugs, which, as of October 2024, is pending approval from the government. The draft notification prescribes a procedure for e-pharmacy registration for the sale and distribution of drugs through the e-pharmacy portal, a procedure for sale and distribution by verification of e-prescriptions, e-pharmacy portal monitoring and similar provisions.

The draft Drugs, Medical Devices and Cosmetics Bill 2022 introduces guidelines governing the online sale and supply of drugs.

Law stated - 28 October 2024

Pricing and reimbursement

What are the controls imposed on pricing of medicines and medical devices and reimbursement by national social security systems that are applicable to manufacturers, distributors and pharmacists?

The pricing of medicines in India is controlled by the Drug (Price Control) Order 2013 (DPCO). These pricing regulations are also applicable for medical devices in accordance with the MOHFW's notification issued on 11 February 2020.

The following are some of the key pricing obligations under the DPCO on the importers, manufacturers and marketers of medicines and medical devices:

- The maximum retail price (MRP) of the product must not be increased by more than 10 per cent within 12 months. If the MRP of the product has been increased by more than 10 per cent, the importer, manufacturer or distributor will be liable to pay the overcharged amount along with penalty and interest thereon from the date of the price increase.
- All importers, manufacturers and distributors must submit the price revision of the product to dealers, retailers, hospitals and the government in Form V, prescribed under the DPCO.
- The National Pharmaceutical Pricing Authority (NPPA) has the authority to fix the ceiling prices of medicines and medical devices under extraordinary circumstances and in the public interest. Once the price is fixed, importers, manufacturers or distributors must fix the MRP to a price equal to or below the ceiling price.
- The ceiling price for the medicines and medical devices listed in the National List of Essential Medicines (NLEM) is fixed by the NPPA. In 2022, NLEM revised the list of essential medicines that are covered by the price ceiling.

Further, there is an institutional arrangement, the Health Technology Assessment in India under the Department of Health Research, which is responsible for compiling evidence related to the cost-effectiveness of medicines and medical devices, using the Health Technology Assessment approach. This helps the government in decision-making for efficient use of the health budget, and in increasing access to quality health care, thereby reducing the expenditure of consumers.

India does not have a mechanism for the reimbursement of drugs.

Law stated - 28 October 2024

UPDATE AND TRENDS

Forthcoming legislation and regulation

Is there any current or foreseeable draft legislation or other rules that will affect the regulation of pharmaceuticals and medical devices? What is likely to change, and what steps need to be taken in preparation?

The Ministry of Health and Family Welfare (MOHFW) released the draft Drugs, Medical Devices and Cosmetics Bill 2022 (the DMDC Bill) in July 2022, inviting public comments.

The DMDC Bill intends to bring out a comprehensive regulatory mechanism for drugs, medical devices, cosmetics, clinical trials and e-pharmacies, among other things, in India. Although the DMDC Bill does not substantially deviate from the existing drug regulatory mechanism except to enhance the penalties for violation, notable changes have been introduced to regulate medical devices independently from drugs in India. The DMDC Bill provides a new definition for 'medical device', and includes provisions to control medical devices' quality, manufacture and import in India. Further, the DMDC Bill proposes to establish independent authorities (such as medical devices officers and a medical devices technical advisory board, among others) to regulate medical devices, in contrast with the current regime where the authorities for drugs also regulate medical devices. Additionally, the DMDC Bill proposes to, among other things:

- introduce relevant provisions for clinical trials under the New Drugs and Clinical Trials Rules 2019;
- establish the DMDC Consultative Committee; and
- mandate licence requirements for the sale of drugs and medical devices by e-pharmacies.

The draft e-pharmacy rules regulating the online sale of medical products and devices are expected to be finalised soon. The government issued the draft notification in this regard in August 2018.

The draft New Drugs and Clinical Trials (Amendment) Rules 2023 were notified in May 2023, to amend the New Drugs and Clinical Trials Rules 2019. A noteworthy amendment proposes to introduce new provisions to govern the registration and functioning of clinical research organisations.

The government published a draft amendment to the Cosmetic Rules 2020, which proposes to grant state licensing authorities the authority to cancel or suspend licences issued under the rules.

The Ministry of Ayush, the ministry responsible for developing education, research, and propagation of traditional medicine systems in India, notified the Drugs and Cosmetics (Draft Amendment) Rules 2021 in September 2021. These new rules provide for revised import standards for homeopathic medicines.

The MOHFW released the draft National Digital Health Blueprint Report, which identifies the deployment of digital tools and technological advancements to enhance the healthcare system in India.

The National Medical Commission Act 2019 (NMCA) was notified in September 2020. The NMCA replaced the Indian Medical Council Act 1956 and the National Medical Commission has now replaced the Indian Medical Council. Currently, the NMCA governs the medical education system in India and provides for the adoption of the latest medical research by medical professionals, high-quality health and medical professionals, and periodic assessments of medical institutions, among others.

The government is in the process of setting up a fund of 1 trillion rupees to boost the manufacturing of pharmaceutical ingredients domestically by 2023.

The Drugs (Prices Control) Amendment Order, 2022, and the Drugs (Prices Control) Second Amendment Order, 2023, have amended Schedule I and Schedule II of the DPCO, respectively, which introduced a revised National List of Essential Medicines (NLEM).

With effect from October 2023, class C and class D medical devices (moderate high-risk and high-risk devices) that were earlier under mandatory registration, were brought under a licensing regime. For obtaining the grant of manufacturing licences for class C and class D medical devices, an inspection must take place within 60 days from the date of application by the medical devices officers of the Central Licensing Authority, as per the Medical Devices Rules 2017.

The National Medical Devices Policy 2023 aims to streamline the regulatory mechanism and licensing framework for medical devices and enable an infrastructure that enhances the quality and production of medical devices.

In January 2024, the CDSCO launched the National Single Window System portal for streamlining the process of approvals, licences, registrations and clearances for medical devices.

In March 2024, the Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers released the revised Uniform Code of Pharmaceutical Marketing Practices 2024 and circulated it to pharmaceutical associations requesting strict compliance.

The Jan Vishwas (Amendment of Provisions) Act, 2023, is set to increase the penalty for any person who uses a test report or analysis made by the Central Drugs Laboratory or by a government analyst, to advertise any drug or cosmetic, to a fine of up to 100,000 rupees.

The CDSCO, via a notification dated 7 August 2024, waived the clinical trial requirement for certain categories of new drugs approved in the USA, UK, Japan, Australia, Canada, and the European Union. These categories include orphan drugs for rare diseases, gene and cellular therapy products and new drugs used during the covid-19 pandemic, etc.

On 28 December 2023, the MOHFW released a notification of the Drugs (Amendment) Rules, 2023, which amended Schedule M of the DCR. These amendment rules introduce a pharmaceutical quality system, quality risk management, product quality review and reinforce goods manufacturing practices for pharmaceutical manufacturing units, including detailed specifications for manufacturing premises, plants and equipment under Schedule M. Large manufacturers with a turnover exceeding 2.5 billion rupees must comply with the amendment rules, within six months from the date of publication, whereas small and medium manufacturers with a turnover of less than 2.5 billion rupees are given 12 months.

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