Pharma & Medical Device Regulation 2021

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LEXOLOGY
Getting The Deal Through

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Lexology Getting The Deal Through is delighted to publish the second edition of *Pharma & Medical Device Regulation*, which is available in print and online at www.lexology.com/gtdt.

Lexology Getting The Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique Lexology Getting The Deal Through format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Brazil, China, France, India, Italy and New Zealand.

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Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Lexology Getting The Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editors, Alexander Ehlers of Ehlers, Ehlers & Partner and Ian Dodds-Smith of Arnold & Porter Kaye Scholer LLP, for their continued assistance with this volume.

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India

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ANA Law Group

HEALTH SERVICES FRAMEWORK AND COMPETENT AUTHORITIES

Healthcare bodies

1 Describe the bodies and their responsibilities (public and private sector) concerned with the delivery of healthcare and appropriate products for treatment.

In India, healthcare is a responsibility of the state. At the national level, the Ministry of Health and Family Welfare (MoHFW) is the apex authority in the organisational structure of the healthcare system. It comprises two departments:

- the Department of Health and Family Welfare, which is responsible for organising and delivering all national health programmes; and
- the Department of Health Research, which is responsible for the promotion of health and clinical research, the development of health research and ethics guidelines, grants for research trainings, etc.

The Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy develops and promotes research in alternative medicine practices.

The central government's responsibilities include policymaking, planning, guiding, assisting, evaluating and coordinating the work of the various state-level health authorities, as well as providing funding to implement national health programmes.

The Central Drugs Standard Control Organisation (CDSCO) is the National Regulatory Authority of India and is responsible for approval of drugs, conducting clinical trials, laying down the standards for drugs and controlling the quality of imported drugs in India. The Drug Controller General of India (DCGI) is the head of the CDSCO and is responsible for the licensing and control functions of the CDSCO.

The National Pharmaceuticals Pricing Authority is the authority for controlling and monitoring the prices and availability of medicines.

At the state level, each state has separate Ministries of Health and Family Welfare, Directorates of Healthcare Services and Departments of Health and Family Welfare, which are responsible for organising and delivering healthcare services and include persons from both the public and private sectors. The State Drug Standard Control Organisation is responsible for the regulation of the manufacture, sale and marketing of drugs in each Indian state.

The organisational structure comprises an administrative subordinate office at the regional or zonal, district and subdistrict level. The public healthcare system comprises primary (community health centres), secondary (subdistrict hospitals) and tertiary (district hospitals and medical colleges) care centres. Primary and secondary care hospitals are in the public sector, whereas tertiary care hospitals are in either the public or private sector. Apart from these, there are several clinics and diagnostic centres set up by individual medical practitioners.

The services provided by the private sector are registered and regulated under national and state councils constituted under the Clinical Establishment (Registration and Regulation) Act 2010, while the public sector comes under the authority of the MoHFW and state health ministries. At the district level, Panchayati Raj institutions (local self-government bodies) are responsible for establishing primary health centres in rural areas.

Competent authorities for authorisation

2 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 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).

Approval framework

3 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 the marketing of medicinal products and medical devices in India. The approval process in India involves two phases: Phase 1 (approval for clinical trials) and Phase 2 (marketing authorisation). The Drug Controller General of India (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 in a more conspicuous manner 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 during an initial period of two years of marketing the new drug formulation, after obtaining approval of the protocol and the names of the investigator duly by the licensing authority.
- 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 from the licensing authority before a drug is marketed.
- Each consignment of an imported drug must be accompanied by a test or analysis report.

Labelling requirements for different medicines and medical devices are also governed under the DCA and the MDR. 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.

CLINICAL PRACTICE

Applicable rules

4 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, the Drugs and Cosmetics Rules 1945, 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.

Reporting requirements

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

Yes. 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.

Consent and insurance

6 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.

MARKETING AUTHORISATION

Time frame

7 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 of 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 drugs into India	Form 40	US$1,000	3 years	270 days
Import license	Form 8	1000 rupees	3 years	45 days
Licence to sell, stock or exhibit	Form 19	1500 rupees	5 years	30 days

* The timelines will also vary depending on the state licensing authorities.

Protecting research data

8 What protection 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.

Freedom of information

9 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?

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.

Regulation of specific medicinal products

10 Are there specific rules for approval, and rewards or incentives for approval, of particular types of medicinal products, such as traditional herbal and homeopathic products, biologicals and biosimilars, controlled drugs, orphan drugs and those for paediatric use?

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, requirements for market

authorisations, etc. Further, the Narcotic Drugs and Psychotropic Substances Act 1985 governs controlled drugs in India.

The New Drugs and Clinical Trials Rules 2019 define '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.

Post-marketing surveillance of safety

11 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, 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.

Other authorisations

12 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.

To import a drug in 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 use in India. The fee applicable for registration is US$1,000, 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 drug, including new drug 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 fees to obtain a licence to manufacture drugs is 50,000 rupees. The validity period for the licence is five years.

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 fees to obtain a licence for manufacturing medical devices range 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 a five-year period 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 fees to obtain a licence to import medical devices range from US$1,000 to US$3,000, 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 before the completion of a five-year period from the date of issue.

Requirements for exporting drugs from India

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

The 'Guidelines for the Export of Drug' 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.

Export of medical devices

A person must file an application with the Central Licensing Authority 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.

Sanctions

13 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 Drugs and Cosmetics Act 1940 (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 sale or manufacture of adulterated or spurious drugs that is likely to result in death or grievous harm is 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 in the case of a violation of the DCR, action can be taken against the company and all the persons responsible for the conduct of the company's business who had knowledge of the offending act.

Exemptions

14 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.

Parallel trade

15 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 for import and use in India. After obtaining the registration certificate, the importer must also obtain an import drug licence from the licensing authority.

AMENDING AUTHORISATIONS

Variation

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

Medical products

The Drugs and Cosmetics Rules 1945 provide 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 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.

Renewal

17 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 prior to the expiry of the registration.

To obtain 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 manufacturing licence of 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 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.

Transfer

18 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 does not have any provision on the transfer of existing approvals or rights to market medicines and medical devices.

RECALL

Defective and unsafe products

19 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 recalls in India. Based on the DCA provisions, the Central Drugs Standard Control Organisation issued the Guidelines on Recall and Rapid Alert System for Drugs in 2017 (the Recall Guidelines). The Recall Guidelines are applicable 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 consequence); and Class III (drugs that are unlikely to cause any adverse health consequence). The recalls are further classified into the following levels: consumer or user; retail; and wholesale.

The recall procedure must be initiated on 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 drug 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 make a decision 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 Guidelines also prescribe procedures on follow-up actions for recalled goods.

Medical devices

The Medical Devices Rules 2017 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 notice of the manufacturer.

PROMOTION

Regulation

20 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 (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 the DMR 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 the 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, research capabilities, etc.

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 Notification shall be treated as drugs as of 1 April 2020. Therefore, all the regulations and compliance requirements applicable for the advertising of drugs are also applicable for 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 or modifying or supporting the anatomy or a physiological process;
- supporting or sustaining life;
- disinfecting medical devices; or
- controlling conception.

Inducement

21 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 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, paid vouchers, etc, 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 Cosmetics Act 1940, and will also be applicable to healthcare professionals. Further, healthcare professionals in violation of these laws will be prosecuted under the applicable penal laws in India.

Reporting transfers of value

22 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.

ENFORCEMENT OF ADVERTISING RULES

Enforcers

23 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 Drugs and Cosmetics Act 1940 and the Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 (the DMR Act).

Further, compliance under the Uniform Code of Pharmaceutical Marketing Practices (the UCPMP Code) is enforced by the ethics committee for pharmaceutical marketing practices (ECPMP). The ECPMP has three members who will preside over a complaint. In the case of a review, there will be a five-member review committee named apex ethics committee for pharmaceutical marketing practices (AECPMP) whose decision will be final.

Sanctions

24 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 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 AECPMP.

PRICING AND REIMBURSEMENT

Pricing

25 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 Drug (Price Control) Order 2013 (DPCO). These pricing regulations are also applicable for medical devices in accordance with the Ministry of Health and Family Welfare'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 any 12-month period. 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 the dealers, retailers, hospitals and the government in the 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 is fixed by the NPPA.

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

OFF-LABEL USE AND UNLICENSED PRODUCTS

Off-label use

26 | 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 to govern, prescribe or use off-label drugs. The Indian Medical Association (IMA), a voluntary association formed in the interest of medical practitioners, has been attempting to officially permit off-label use of drugs in India; however, the IMA's attempts have faced strong opposition in the past.

Unlicensed products

27 | 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 manufacture, 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 imprisonment of three years and a maximum imprisonment of five years, as well as and a fine of 100,000 rupees or three times the value of the drugs confiscated, whichever is higher.

Compassionate use

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

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

However, in light of the covid-19 pandemic, in June 2020 the Ministry of Health and Family Welfare proposed to amend the New Drugs and Clinical Trials Rules 2019 (the NDCT Rules) through the draft New Drugs and Clinic Trials (Amendment) Rules 2020 (the NDCT Draft Rules). The NDCT Draft Rules propose to permit compassionate use of unlicensed drugs. However, for compassionate use, the drug must be in a Phase III clinical trial in the country from where it is imported. The NDCT Draft Rules lay down rules for the application for a licence to import a new drug for compassionate use by a hospital or medical institution.

In addition, the DCA and the Drugs and Cosmetics Rules 1945 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 or diseases resulting in a serious permanent disability, or for extreme medical needs.

SALE AND SUPPLY

Regulation

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

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

Online supply

30 | 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 has issued a draft notification to amend the DCR to regulate the online sale of drugs, which, at the time of writing, 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, etc.

UPDATE AND TRENDS

Forthcoming legislation and regulation

31 | 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?

Current and foreseeable draft legislation and rules include the following.

- The draft e-pharmacy rules regulating the online sale of medical products and devices are expected to be finalised soon. The draft notification in this regard was issued by the government in August 2018.
- The draft New Drugs and Clinic Trials (Amendment) Rules 2020 intending to permit compassionate use of unlicensed drugs is pending approval from the government.
- The Ministry of Health and Family Welfare (MoHFW) issued a notification regarding the Drugs and Cosmetics (Amendment) Rules 2020 on 11 February 2020, which will come into effect from 1 March 2021. The Rules provide the definitions, responsibilities and labelling requirements that are to be complied with by the marketer of the drugs. Further, under the Rules, any marketer who sells or distributes any drug is, along with the manufacturer, responsible for the quality of the drug as well as other regulatory compliances.
- In November 2019, the government approved the extension and renewal of the Pharmaceuticals Purchase Policy while adding one additional product (alcoholic hand disinfectants) to the existing list of 103 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) received presidential assent in 2019 and is in the process of being notified and implemented in India. The NMCA will replace the Indian Medical Council Act 1956, and the National Medical Commission will replace the Indian Medical Council. The NMCA will govern 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, periodic assessment of medical institutions, etc.

- The government plans to set up a fund of almost US$1.3 billion to boost the manufacturing of pharmaceutical ingredients domestically by 2023.

Coronavirus

32 What emergency legislation, relief programmes and other initiatives specific to your practice area has your state implemented to address the pandemic? Have any existing government programmes, laws or regulations been amended to address these concerns? What best practices are advisable for clients?

The government has taken many steps to combat the covid-19 pandemic, including steps in respect of legislation, schemes and programmes in the pharmaceutical sector, some of which are outlined below.

- The MoHFW notified the draft New Drugs and Clinic Trials (Amendment) Rules 2020 to permit compassionate use of unlicensed drugs.
- The MoHFW issued a notification on 26 March 2020 permitting retailers to sell and deliver drugs to the doorsteps of consumers within the geographical boundaries of the retailer.
- To ensure sufficient supply of safety equipment for healthcare professionals and the availability of drugs, the Directorate General of Foreign Trade and the Ministry of Commerce and Industry issued various notifications restricting the export of personal protective equipment, ventilators, sanitisers, diagnostic kits and certain essential drugs.

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