# Commercialisation of healthcare in India: overview

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A Q&A guide to the commercialisation of healthcare in India.

This Q&A provides an overview of the regulatory framework for the commercialisation of medical products in India. It covers the key requirements for manufacturing, marketing and advertising medicines, biological medicines, medical devices, combination products and natural health products.

## Medicines

1. What is the definition of medicine (or equivalent) in your jurisdiction?

In India, medicines are regulated as “drugs” under the Drugs and Cosmetics Act 1940 (D&C Act), which is the umbrella legislation regulating all medicinal products in India. The definition of “drug” under the D&C Act is wide enough to include any medical product that makes a medicinal claim or a claim to diagnose, treat, mitigate, or prevent a disease or disorder in human beings or animals. More specifically, drugs include:

- All medicines for internal or external use in human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on the human body for the purpose of repelling insects such as mosquitoes.
- Substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects that cause disease in human beings or animals, as may be specified from time to time by the central government by notification in the *Official Gazette*.
- All substances intended for use as components of a drug, including empty gelatin capsules.
- Devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the central government by notification in the *Official Gazette*.

 

2. What authorities are responsible for regulating the manufacture, marketing and advertising of medicines?

The main regulatory authorities are the:

- Drugs Controller General of India (DCGI).
- Central Drugs Standard Control Organisation (CDSCO) (also referred to as the Central Licensing Authority). The DCGI is the head of the CDSCO.
- State drug licensing authorities (also referred to as the state licensing authorities).
- Gazetted officers authorised by the state governments to enforce drug advertising regulations.
- National Pharmaceutical Pricing Authority (NPPA).
- Department of Pharmaceuticals (DOP).
- Review Committee on Genetic Manipulation (RCGM).
- Genetic Engineering Appraisal Committee (GEAC).

The authorities above are part of the following ministries:

- Ministry of Health and Family Welfare: DCGI and CDSCO.
- Ministry of Chemicals and Fertilisers: NPPA and DOP.
- Ministry of Science and Technology: RCGM.
- Ministry of Environment and Forests: GEAC.
- State-level ministries, such as the public health department: state drug licensing authorities.

3. What notifications, registrations, approvals and licences are required to manufacture and market medicines and their active pharmaceutical ingredients?

## Manufacturing

The basic minimum requirement is that a manufacturer must have a drug manufacturing licence from the drug licensing authority of the state where the manufacturing premises are located. A licence must be obtained for each plant. The licence is granted following an inspection conducted by the CDSCO. The manufacturing premises must comply with the Good

 

Manufacturing Practices set out in Schedule M to the D&C Act.

For new drugs that are manufactured for use in clinical trials, a separate test manufacturing licence must be obtained from the drug licensing authority of the state where the manufacturing premises are located. This licence can only be issued after obtaining prior permission from the CDSCO to manufacture the new drug for the purposes of examination, test and analysis.

## Marketing

The DCGI grants marketing authorisations for new drugs (that is, drugs that do not have a history of safe and efficacious use in India). A marketing authorisation is granted on the successful completion of a clinical trial in India.

Without a marketing authorisation from the DCGI, the state drug licensing authority will not accept an application for a drug manufacturing licence (for sale and distribution purposes) for a new drug.

A drug that has been approved and marketed in India for more than four years ceases to be a new drug. During the four-year period, any person wishing to market the same drug cannot rely on the clinical data generated by the original marketing authorisation holder and must conduct clinical trials and obtain a fresh marketing authorisation from the DCGI.

However, vaccines and drugs derived from recombinant DNA (r-DNA) derived product are considered new drugs indefinitely. As a result, any subsequent person wishing to market a vaccine or other biological products must conduct clinical trials in India regardless of whether the product has already been approved.

New drugs that have not been approved in India but have been approved in their country of origin can be imported or manufactured in India by government hospitals or government medical institutions for the treatment of:

- Life-threatening diseases.
- Diseases causing permanent disability.
- Diseases that require therapies for unmet medical needs.

Further, drugs that cannot generally be imported into India (including unapproved drugs) can be imported in small quantities for the personal use of a patient (*see Question 7*).

4. What are the differences between the regulation of new innovative medicines and generic or biosimilar versions of those medicines?

The same requirements apply to generic and biosimilar medicines, except for the requirement to conduct clinical trials.

Manufacturers and importers of generic drugs are not required to conduct clinical trials in India and can rely on the clinical data relating to the innovator drug, provided the generic drug is released after four years from the date on which the innovator drug was granted a marketing authorisation in India. This is because the innovator drug is no longer considered to be a new drug after the four-year period lapses (*see Question 3, Marketing*).

However, manufacturers and importers of biosimilars must conduct clinical trials in India regardless of whether the original biologic has received approval. This is because biological products (including biosimilars) are considered new drugs indefinitely. The procedure for clinical trials of biosimilars and the data package requirements are more specifically outlined in the Guidelines on Similar Biologic: Regulatory Requirements for Marketing Authorisation in India 2016 (Biosimilar

 

Guidelines). For recombinant biologic products, the Department of Biotechnology (DBT) has issued the Regulations and Guidelines for Recombinant DNA Research and Biocontainment 2017 (rDNA Guidelines), which cover pre-clinical trial submissions.

5.What are the differences between the regulation of prescription and over-the-counter medicines?

There are no differences between the regulation of prescription and over-the-counter medicines with respect to manufacturing and marketing authorisation. However, there are differences in the requirements that apply to the sale of different categories of medicines.

In India, all medicines can only be sold on the basis of a sale licence, which can be either a wholesale licence or a retail licence. Certain drugs, such as aspirin and paracetamol tablets, can be sold without a sale licence, subject to prescribed conditions. The classes of drugs as well as conditions for the exemption are set out in Schedule K to the Drugs and Cosmetics Rules 1945 (D&C Rules).

6. Are there fewer or different requirements for the approval of medicines that have already been licensed or approved in another jurisdiction?

The CDSCO has discretion to waive local clinical trial requirements or expedite the approval of medicines that have been approved in other jurisdictions. The CDSCOO exercises its discretion on a case-by-case basis.

The New Drugs and Clinical Trial Rules 2019 (CT Rules) regulate the process for the approval of medicines. Under the CT Rules, all drugs sought to be marketed in India must undergo local clinical trials as a pre-requisite. However, the CDSCO can:

- Waive local clinical trial requirements if a medicine has been approved in any country notified by the Ministry of Health and Family Welfare under Rule 101 of the CT Rules. No such countries have been notified to date.
- Expedite the approval of a medicine (including by taking into consideration pre-clinical data generated in other jurisdictions) that are intended to treat serious or life-threatening or rare diseases. For example, the CDSCO released an office memorandum outlining the relaxations on clinical trial requirements available for 2019 novel coronavirus disease (COVID-19) vaccines. The memorandum states that pre-clinical trial data generated in other jurisdictions can be included as part of regulatory submissions to conduct clinical trials in India. Further, the memorandum states that the CDSCO is willing to consider an abbreviated pathway for approval of COVID-19 vaccines “based on scientific rational and level of completeness of data in human trials in addition to satisfactory pre-clinical data”.

 

7. Is it possible to sell medicines to or buy medicines from other jurisdictions?

## Import

An import licence from the DCGI is required to import drugs from other jurisdictions. An import licence can only be obtained after receipt of:

- Marketing approval from the DCGI for the drug (for new drugs only).
- A registration certificate from the DCGI by the foreign manufacturer.

Importing new drugs for use in clinical trials requires a separate test import licence from the DCGI.

A new drug can be imported into India under a specific import licence granted to government hospitals and autonomous medical institutions in exceptional cases for the treatment of patients suffering from:

- Life-threatening diseases.
- Diseases causing serious permanent disability.
- Diseases requiring therapies for unmet medical needs.

This specific import licence does not require marketing approval and foreign manufacturer registration. However, the new drug must be approved for marketing in the country of origin.

A patient can also import a new drug into India for their personal use under a personal use permit based on a prescription issued by a registered medical practitioner. In this case, a drug can be imported either:

- As part of the patient's baggage. The drug must be declared to the customs authorities if so directed. The quantity of a single drug must not exceed 100 doses, unless special permission is obtained from the CDSCO.
- By making an application to the CDSCO to import drugs for personal use. The CDSCO can approve such an import by granting a licence if it believes the quantity of the drug to be imported is reasonable and is covered by a prescription issued by a registered medical practitioner.

Indian law recognises the principle of international exhaustion (that is, medicines can be imported into India if they have already been lawfully placed on the market anywhere in the world). Therefore, parallel imports have not raised any significant issues to date.

## Export

No special permission is required to export domestically manufactured drugs to other jurisdictions. Manufacturers seeking to export drugs must have a manufacturing licence from the state drug licensing authority (and licence approval from the DCGI in certain cases).

 

8. How is medicine promotion and advertising activity regulated, and what are the general requirements to advertise medicines?

The advertising of drugs is heavily regulated in India. The Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 (DMRA) is the primary legislation regulating advertisements of drugs in India. The DMRA applies to advertisements made through all types of medium, including online advertisements.

Prescription drugs cannot be advertised to consumers except with specific authorisation of the central government. Generally, prescription drugs are drugs that are listed in Schedules H, H1 and X to the D&C Rules. Additionally, drug labels cannot claim to prevent or cure diseases listed in Schedule J to the D&C Rules.

The DMRA prohibits advertisements that suggest or are intended to lead to the use of a drug for the:

- Procurement of miscarriage in women.
- Maintenance or improvement of sexual pleasure.
- Correction of menstrual disorders in women.
- Diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule to the DMRA.

It is possible to advertise drugs to healthcare practitioners, provided that the advertisement is made directly to the healthcare practitioner with the following statement printed on top of the advertisement in indelible ink: “for the use only of registered medical practitioners or a hospital or a laboratory”.

The marketing and promotion of drugs to healthcare practitioners is also specifically regulated by the Uniform Code of Pharmaceutical Marketing Practices (UCPMP), which prohibits pharmaceutical companies from providing healthcare practitioners:

- Travel facilities for attending conferences, seminars, workshops and so on as delegates.
- Hospitality under any pretext.
- Any cash or monetary grants in an individual capacity.

However, the UCPMP is a voluntary code and does not have the force of law. The government has proposed to make the UCPMP mandatory, although it is currently uncertain when this will be the case.

9. Are there additional or alternative regulations for special types of medicines or medicines intended for particular types of patients or diseases?

 

The following additional guidelines apply to vaccines and stem cell therapies:

- Stem cell research: National Guidelines for Stem Cell Research 2017 released by the Indian Council for Medical Research (ICMR) and the DBT.
- Vaccines: Draft Regulatory Guidelines for Development of Vaccines with Special Consideration for COVID-19 Vaccine released by the CDSCO.

These guidelines are intended to supplement the D&C Act and Rules.

10.What controls apply to medicines or components of medicines that derive from humans or animals or incorporate modified genetic material?

The conduct of research into, and commercialisation of, medicines that contain components derived from humans or animals and modified genetic material are subject to the following additional guidelines:

- Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989 (GEM Rules), notified under the Environment (Protection) Act 1986. The GEM Rules regulate the manufacture, import and storage of micro-organisms and gene-technological products as well as genetically engineered micro-organisms and cells. Research into, and industrial use of, micro-organisms require permission from the RCGM and GEAC.
- The rDNA Guidelines, which regulate the biosafety of rDNA research and the handling of hazardous micro-organisms and genetically engineered organisms or cells.
- Guidance Document for Industry: Submission of Stability Data and Related Documents for Review and Expert Opinion for Granting Post-approval Changes in Shelf Life of Recombinant Biotherapeutic Products and Therapeutic Monoclonal Antibodies, published by the National Institute of Biologicals 2016 (Post-Approval Guidelines). The Post-Approval Guidelines provide guidance and recommendations to marketing authorisation holders for biologics who intend to make post-approval changes to the shelf life of the product.

## Biological medicines

11. What is the definition of biological medicines in your jurisdiction and what are the main laws that specifically apply to them (if any)?

The law does not specifically define biological medicines. However, the website of the CDSCO refers to biologics as medical products made from a variety of natural sources (human, animal or micro-organism) which are intended to prevent, diagnose or treat diseases and medical conditions. See: *https://cdsco.gov.in/opencms/opencms/en/biologicals*.

 

12. Are there any additional or alternative regulations that apply specifically to biological medicines?

The regulatory framework outlined in *Question 2 to 10* generally apply to biological medicines. In addition, the following instruments regulate the research into and industrial use/commercialisation of biological products:

- Biosimilar Guidelines.
- rDNA Guidelines.
- GEM Rules.
- Post-Approval Guidelines.

The key differences in the regulation of biological medicines include the following:

- There are specific pre-clinical trial requirements for biological products.
- Research into and commercialisation of biological medicines requires permission of the RCGM and GEAC, in addition to the other approvals generally applicable to drugs.
- Unlike other drugs, biological products are considered new drugs indefinitely (*see Question 3, Marketing*).

## Medical devices

13. What is the definition of medical device (or equivalent) in your jurisdiction? What is the significance of any legal classifications?

Medical devices are regulated by the Medical Device Rules 2017 (MDR), which were issued under the D&C Act. The MDR classifies medical devices into four categories:

- Class A: low risk.
- Class B: low-moderate risk.
- Class C: moderate-high risk.
- Class D: high risk.

The MDR only regulates certain categories of medical devices specifically notified for regulation by the Ministry of Health

 

and Family Welfare. Until 2019, 29 categories of medical devices had been notified for regulation under the MDR.

On 11 February 2020, the Ministry of Health and Family Welfare published a notification (which came into force on 1 April 2020) effectively bringing all medical devices within the scope of the MDR (Definition Notification). Rather than notifying each individual medical device, the Definition Notification includes an expansive and catch-all definition of medical devices. A medical device is now defined as any device, including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which can be assisted in its intended function by such means, for one or more of the following purposes:

- Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder.
- Diagnosis, monitoring, treatment, alleviation of, or assistance for, any injury or disability.
- Investigation, replacement, modification or support of the anatomy or of a physiological process.
- Supporting or sustaining life.
- Disinfection of medical devices.
- Control of conception.

To allow manufacturers/importers of newly notified medical devices sufficient time to ensure compliance with the MDR, the Health Ministry introduced a temporary exemption from compliance requirements for a period of 30 months for Class A and B devices and 42 months for Class C and D devices (Exemption Notification). The exemption commenced on 11 February 2020 and is conditional on manufacturers/importers registering their devices on the Online System for Medical Devices established by the CDSCO for this purpose.

The CDSCO also released a draft risk classification list of devices that have come under regulation following the adoption of the Definition Notification. The draft classification list contains preliminary guidance for manufacturers/importers seeking to register their medical devices.

A manufacturer/importer can apply to the CDSCO for a clarification on how a specific product should be regulated. There is no prescribed procedure to seek clarification.

### 14. What authorities are responsible for regulating the manufacture, marketing and advertising of medical devices?

The main authorities regulating medical devices are the same as for medicines (*see Question 2*).

### 15. What notifications, registrations, approvals and licences are required to manufacture and market medical devices?

 

## Manufacturing

The manufacture of regulated medical devices requires a manufacturing licence from the relevant state drug licensing authority or from the DCGI, depending on its risk classification. The state licensing authorities issue licences for lower-risk devices (that is, class A and class B devices), while the DCGI issues licences for higher-risk devices (that is, class C and class D devices).

For investigational medical devices that are manufactured for use in clinical trials, a separate test manufacturing licence must be obtained from the DCGI. An investigational medical device is a regulated medical device the safety and efficacy of which have not been established by clinical investigations in India.

## Marketing

A marketing authorisation is required for investigational medical devices. The CDSCO grants marketing authorisation on successful completion of the clinical investigation. The clinical investigation must be conducted locally and carried out in two phases (referred to as the pilot and pivotal phase).

Medical devices that are not considered to be investigational medical devices do not require a marketing authorisation. However, the other manufacturing and import requirements apply.

16. Are there fewer or different requirements for medical devices that have already been licensed or approved in another jurisdiction?

The requirement to conduct local clinical investigations can be waived for medical devices that have been granted a free sale certificate in Australia, Canada, Japan, the EU and the US. The other requirements under the MDR otherwise apply.

17. Is it possible to sell devices to or buy devices from other jurisdictions?

## Import

An import licence from the DCGI is required to import medical devices from other jurisdictions. For investigational medical devices, an import licence can only be obtained after receipt of marketing approval from the DCGI.

For investigational medical devices that are imported for use in clinical investigations, a separate test import licence must be obtained from the DCGI.

An investigational medical device that has been approved in its country of origin can be imported for the treatment of patients suffering from:

- Life-threatening diseases.

 

- Diseases causing serious permanent disability.
- Diseases requiring therapies for unmet medical needs.

A patient can also import an investigational medical device for their personal use based on the prescription of a registered medical practitioner. In this case, the investigational medical device must be imported as part of the patient's personal baggage.

## Export

The export of medical devices from India is not specifically regulated. However, devices manufactured in India for export are subject to the general manufacturing requirements under the MDR.

18. What are the general requirements to advertise medical devices?

The DMRA and the UCPMP apply to the advertising of medical devices. Therefore, the restrictions on the advertising and promotion of drugs also apply to medical devices (*see Question 8*).

19. What product marking is required for authorised medical devices?

The following must be specified on the label of a medical device:

- Name of the medical device.
- Details necessary for the user to identify the device and its use.
- Name of manufacturer and address of manufacturing premises.
- Statement on net contents (in terms of weight or measure).
- Date of manufacture.
- Date of expiry (or shelf life).
- Storing and handling conditions, warnings and precautions.
- Batch number.
- Manufacturing licence number (if manufactured in India).

(*MDR*.)

Imported products must display the:

 

- Import licence number.
- Name and address of the importer.
- Address of the manufacturing premises.
- Date of manufacture.

(*MDR*.)

The Legal Metrology (Packaged Commodities) Rules 2011 (LM Rules) also apply to the labelling of medical devices. 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.
- Corporate name and complete address of the domestic manufacturer, importer or packer.

Labels of medical devices registered on the Online System under the Exemption Notification (*see Question 13*) must indicate the registration number.

## Combination products

20. Does your jurisdiction recognise combination products? What are the main laws that specifically apply to them (if any)?

There are no specific regulations on combination products. A product that has both drug/biological aspects and medical device aspects will be regulated either as a drug or a medical device. To know whether a product should be subject to the drug or medical device regulatory framework, the manufacturer/importer can apply for clarification to the CDSCO.

21. Are there any additional or alternative regulations that apply specifically to combination products?

 

There are no additional or alternative regulations specifically applicable to combination products.

## Natural health products

22.Is there a category for natural health products (or equivalent) (including, for example, traditional medicines, homeopathic medicines, supplements, vitamins and minerals)?

There is no official category of natural health products under Indian law. Natural health products can be either:

- Drugs. Products that make a medicinal claim are categorised as drugs and governed by the same regulatory framework as drugs.
- Food. Products that do not make a medicinal claim are categorised as food and governed by the regulatory framework that applies to food products.

Traditional medicines, homeopathic medicines, unani medicines and ayurvedic medicines are categorised as drugs under the D&C Act. Foods for special dietary uses, functional foods, nutraceuticals and health supplements are categorised as food under the Food Safety and Standards Act 2006 (FSS Act), provided that they do not make a medicinal claim.

23. What authorities are responsible for regulating the manufacture, marketing and advertising of natural health products?

For natural health products regulated as drugs, the main regulatory authorities are the:

- DCGI.
- CDSCO.
- State drug licensing authorities.

The Food Safety and Standards Authority of India (FSSAI) is the primary regulatory authority for natural health products regulated as food.

 

24. What notifications, registrations, approvals and licences are required to manufacture and market natural health products?

## Manufacturing

Natural health products categorised as drugs. A manufacturer must have:

- A drug manufacturing licence from the drug licensing authority of the state in which the manufacturing premises are located.
- Licence approval from the DCGI.

For new natural health products that are manufactured for use in clinical trials, a separate test manufacturing licence must be obtained from the drug licensing authority of the state in which the manufacturing premises are located. This licence can only be issued after receipt of a no-objection certificate from the DCGI to manufacture the new product.

Natural health products categorised as food. A manufacturer must have a food manufacturing licence from the food licensing authority of the state in which the manufacturing premises are located. In certain cases, depending on the nature of the health product and scale of operations, the manufacturing licence may be issued by the FSSAI.

## Marketing

Natural health products categorised as drugs. Products that may be considered new drugs must:

- Undergo clinical trials in India.
- Obtain a marketing authorisation from the DCGI on successful completion of such trials.

Natural health products categorised as food. No specific approval is required for products that are specified in the schedules to the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food) Regulations 2016. However, a food business operator wishing to launch a new nutrient without history of safe or beneficial use in India must apply to the FSSAI for approval.

25. Are there fewer or different requirements for natural health products that have already been licensed or approved in another jurisdiction?

There are no fewer or different requirements for the manufacture or marketing of natural health products that have already been licensed or approved in another jurisdiction.

 

26. Is it possible to sell natural health products to or buy natural health products from other jurisdictions and/or electronically?

It is possible to sell natural health products to or buy natural health products from other jurisdictions and/or electronically.

See *Question 7* for details on the requirements that apply to products categorised as drugs.

27. What are the general requirements to advertise natural health products?

## Natural health products categorised as drugs

Over-the-counter natural health products can be advertised to consumers if they do not claim to treat, prevent or mitigate certain diseases and conditions specified in Schedule J to the D&C Rules.

It is prohibited to advertise any natural health product in a manner that suggests, or is calculated to lead to, the use of that product for the:

- Procurement of miscarriage.
- Prevention of conception for women.
- Correction of menstrual disorders.
- Maintenance or improvement of sexual pleasure.
- Diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule to the DMRA.

## Natural health products categorised as food

Advertisements of natural health products are permitted subject to certain restrictions. The advertisement of a natural health product must not be misleading or deceiving, and must not in particular:

- Falsely represent that the foods are of a particular standard, quality, quantity or composition.
- Make a false or misleading representation concerning the need for, or the usefulness of, the product.
- Give to the public any guarantee of efficacy that is not based on an adequate or scientific justification.

Further, the general advertising regulations applicable to all goods and services in India, that is, the Code for Self-Regulation of Advertising Content in India issued by the Advertising Standards Council of India (ASCI Code) also apply to the

 

advertising of natural health products. The ASCI Code is a non-binding code (except for advertisements made on cable television) regulating the content of advertisements. The ASCI Code generally provides that advertisements should:

- Be truthful.
- Not be offensive to generally accepted standards of public decency.
- Not advertise harmful products.
- Ensure fairness of competition (when comparing similar products).

The above regulatory framework also applies to advertisements made on the internet.

## Data

28. What data and information laws must be complied with by life sciences businesses that collect, use or otherwise deal in patient data (including through health apps)?

The Information Technology Act 2000 and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011 (Data Protection Rules) regulate the collection, storage, processing and transfer of sensitive personal data or information (SPDI), which include:

- Medical records and history.
- Physical, physiological and mental health conditions.

Entities involved in the collection, storage, processing and transfer of SPDI must comply with certain requirements under the Data Protection Rules, including:

- The publication of a privacy policy on their website.
- Obtaining consent from the provider of the data to collect, transfer or disclose SPDI.

The Government is currently in the process of enacting the Personal Data Protection Bill 2019, which is a more comprehensive data protection legislation.

## Research

29. What restrictions and regulatory requirements apply to the testing of life sciences products on human and animal subjects?

 

### Human clinical trials

Human clinical trials are regulated by the:

- CT Rules.
- National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, issued by the Indian Council for Medical Research in 2017.

A clinical trial must be conducted in accordance with a clinical trial protocol. The protocol must be approved by both:

- An ethics committee constituted for overseeing the clinical trial.
- The DCGI.

### Pre-clinical trials

Pre-clinical trials (including studies on animals) are regulated by the:

- Prevention of Cruelty to Animals Act 1960 (PCA Act).
- Breeding of and Experiments on Animals (Control and Supervision) Rules 1998 (BEACS Rules).

Any protocol for pre-clinical studies must comply with the following requirements:

- First considering animals lowest on the phylogenetic scale which may give scientifically valid results.
- Using the minimum number of animals to give statistically valid results at 95% degree of confidence.
- Giving due and full consideration of alternatives not involving experiments on animals.
- Providing sound justification for not using available alternatives not involving experiments on animals.

(*BEACS Rules*.)

Experiments on animals require a specific permission of either the Committee for Purpose of Control and Supervision of Experiments on Animals (CPCSEA) or an Institutional Animals Ethics Committee (IAEC) recognised by CPCSEA. The CPCSEA or IAEC will review each protocol for compliance with the requirements outlined above, among other things.

## Reform

30. Are there any plans to reform the rules on the development, manufacture, marketing and advertising of life sciences products and services?

### Amendments to D&C Rules

 

The D&C Rules have been amended so that, from 1 March 2021, entities marketing a drug are responsible for the quality of the drug and regulatory compliance.

Under the amendments, a "marketer" is any person who adopts a drug manufactured by another manufacturer for sale and distribution, by affixing or labelling their name on the drug. The amendments also require manufacturers and marketers to enter into an agreement for marketing the drug as a pre-condition to such activity. Once an agreement is in place, the name of the marketer must be displayed on the label of the drug. The manufacturer and the marketer will share liability for any defect in the drug or any regulatory non-compliance.

Previously, only manufacturers were liable for defects and failure to comply with regulatory requirements. As a result, many pharmaceutical companies have entered into manufacturing agreements with third parties under which the pharmaceutical company only markets the drug and the contract manufacturer is solely responsible for the quality of the drug and other regulatory compliance. The amendments aim to encourage pharmaceutical companies in ensuring that contract manufacturers comply with the D&C Rules.

## Proposed amendments to CT Rules

The Ministry of Health and Family Welfare has published a set of draft rules amending the CT Rules permitting hospitals and medical institutions to import or have manufactured certain unapproved drugs for the treatment of patients suffering from:

- Life-threatening diseases.
- Diseases causing serious permanent disability.
- Diseases requiring therapy for unmet medical need.

Under the draft amendments, hospital/medical institution would be able to import an unapproved drug or have it manufactured after obtaining permission from the CDSCO, provided the unapproved drug is undergoing phase-III clinical trials in India or in any other country. The hospital/medical institution importing the drug or the manufacturer engaged by the hospital/medical institution would be required to comply with certain obligations (for example, not selling the drug in the open market and maintaining records of import/manufacture).

Currently, the D&C Act allows patients to import small quantities of drugs for their personal use and government hospitals/medical institutions to import drugs that have been approved in other countries. There is no provision for importing drugs that have not been approved in other countries. If notified and brought into force, the draft amendments would bridge this gap and permit patients suffering from life-threatening diseases to undergo experimental treatment.

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