Drugs and Cosmetics

1. What are drugs and cosmetics?

'Drugs' include all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation, or prevention of disease or disorder in human beings or animals. 'Cosmetic' means any article intended to be rubbed, poured, sprinkled or sprayed on or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic. The pharmaceutical industry in India is currently valued at $50 Bn. The pharmaceutical industry in India is expected to reach $65 Bn by 2024 and $130 Bn by 2030. This indeed attracts the need to be stringently regulated because of the sheer nature of the product and its use.

2. How are drugs and cosmetics regulated in India?

The pandemic also saw a rise in the development of the pharmaceutical sector in India. With programmes like Pharma Vision 2020, which aims to make India the most desirable location for the creation of new drugs, it is obvious that the size of this industry will only increase.

To address medical conditions, people use drugs and cosmetics. The creation and approval of drugs for human consumption must therefore ensure that the drugs are of an acceptable quality and do not have any side effects. Additionally, medication costs must be kept under control to ensure that everyone has access to healthcare.

3. What are the grounds for consumer complaints about drugs and cosmetics?

1. If drug or cosmetic is adulterated:
    a. if it consists of any filthy or decomposed substance
    b. if it is prepared, packed, or stored under insanitary conditions.
    c. if the container is composed of any poisonous substance
    d. if it contains any harmful or toxic substances.
    e. if any substance is mixed so as to reduce its quality or strength.
    f. if it bears any colour for the purpose of colouring only, a colour which is not prescribed
2. Overcharging

3. Selling of untested drugs/drugs of poor quality.
4. Overcharging of medical devices.
5. Refusal to sell drugs.
6. Shortage or non-availability of drugs.
7. Allergic reactions or harmful side effects not adequately disclosed.
8. False or exaggerated claims about product benefits.
9. Missing or unclear information on ingredients/ Insufficient usage instructions.
10. Claims about the product's effectiveness that are not substantiated.
11. Poor product quality or defects.
12. Selling products beyond their expiration date.
13. Lack of proper warnings for potential risks associated with product use.

4. What are the modes or methods of complaint available?

1. The first step is to approach the manufacturing company through their customer care to register the grievance.

2. The consumer can also approach the drug controller of the concerned state in case of a banned drug, side effects, adulteration- https://cdsco.gov.in/opencms/opencms/en/State-Drugs-Control/

State Drugs Helpdesk- helpdesk.statedrug@cdsco.nic.in

If not satisfied with the response, approach the Drug Controller General of India- https://cdsco.gov.in/opencms/opencms/en/About-us/who/

3. Register complaint with CDSCO- https://cdsco.gov.in/opencms/opencms/en/About-us/contact-us/

Telephone directory, CDSCO- https://cdsco.gov.in/opencms/opencms/en/About-us/Telephone_Directory/

4. Approaching any other appropriate judicial or quasi-judicial body:

The complainant is free to take the service provider to a court or any other suitable venue (judicial or quasi-judicial). The proceedings in consumer commissions are not mired by the niceties of procedure, allowing the complainant to file a complaint for himself. As a consumer, the aggrieved party can take the service provider to the appropriate consumer commission, based on the pecuniary and territorial jurisdiction. The jurisdictions of the various consumer commissions are as follows-

a) District Commission: The aggrieved consumer can reach out to the District Commission under section 34 of the CPA, 2019, which provides that the district commission shall entertain matters where the value of the goods or services paid as consideration does not exceed more than one crore rupees.

b) State Commission: In cases where the value of the goods or services paid as consideration is more than one crore, but less than 10 crores, the consumer can approach the State Commission. Moreover, in cases of unfair contracts, the State Commission has original jurisdiction and the consumer can be directly approached. An appeal against the order of the District Commission can also be made under section 47 of the CPA, 2019.

c) National Commission: The National Commission can entertain matters where the value of goods or services paid as consideration exceeds 10 crores. Section 58 also provides that complaints against unfair contracts can be entertained by NCDRC when the amount of value paid exceeds 10 crores. The NCDRC also has appellate jurisdiction against the orders of any State Commission and Central Authority. http://www.ncdrc.nic.in/districtlist.html

Moreover, it must also be kept in mind that section 100 of the CPA, 2019 provides that the remedy under CPA is in addition and not in derogation of other available remedies.

5. Central Consumer Protection Authority

If the commission finds violations of rights of consumers or in notice of trade practices which is unfair it can inquire or cause an inquiry, either on receipt of complaint or suo moto or as directed by Central Government. If the commission finds, after preliminary inquiry, of an existence of a prima facie case of consumer rights violation or it is in notice of any unfair trade practice or any wrong or inaccurate advertisement which is prejudicial to public interest or to the interests of the consumers,it can order an investigation by the District Collector or by Director General. The consumer can complain to the District Collector of the respective district for investigation and subsequent proceedings by the CCPA. He/she/they can also submit a complaint via email, at com-ccpa@nic.in.

5. When would complaints not be accepted?

There are various situations which might cause the complaint to be rejected. These include situations where the consumer is unable to file an appeal against an order within a period of three months, where the complaint is based on a frivolous cause of action, where the complaint falls

outside the jurisdiction of the authority approached, and when the complaint has been filed under wrong sections of the act, and other such situations. This requires careful reading of all acts and regulations.

6. What are some Sample consumer complaints on drugs and cosmetics?

https://cdrc.gujarat.gov.in/images/pdf/1-CC-Eng.pdf - DCDRC format.

https://cdrc.gujarat.gov.in/images/pdf/1-CC-Eng.pdf - SCDRC format.

https://ncdrc.nic.in/cc.html - NCDRC format.

7. What are the regulatory bodies in this sector?

Central Drugs Standard Control Organization (CDSCO) Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India regulate the approval of any drugs in India.

The National Pharmaceutical Pricing Authority is a government body that regulates the price of drugs in India.

8. What are the rules, Acts, and Guidelines that govern this sector?

The Drugs and Cosmetics Act, 1940 (As amended up to the 30th June, 2005)
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf

The Drugs and Cosmetics (Amendment) Act, 2008
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/DC_ACT_AMENDMENT_2008_file.pdf

The Drugs and Cosmetics Rules, 1945 (As amended up to the 30th June, 2005)
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf

New Drugs and Clinical Trials Rules, 2019
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

The Cosmetic Rules, 2020

https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Cosmetics-Rules/

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954

https://cghealth.nic.in/CFDA/Doc/Acts&Rules/Drugs%20and%20Magic%20Remedies%20(Objectionable%20Advertisement)%20Act,%201954.pdf

The Drug Price Control Order, 2013

https://www.nppaindia.nic.in/wp-content/uploads/2018/12/DPCO2013_03082016.pdf

9. What are the landmark judgements in this sector?

Dinesh B. Patel v. State of Gujarat

The dispute arose from the sale of medicines by M/s. Denis Chemical Lab. Ltd., which were later found to contain fungus. The legal issue focused on whether the manufacturer could be held liable under Section 34 of the relevant act, which holds the entire company and associated individuals responsible for offenses committed by the company. The court, considering the severity of the allegations and the direct impact on public health, opted not to take a strictly technical view based solely on the complaint's pleadings. The court rejected the argument that specific averments about the active role of directors, as required in other legal contexts, should apply in this case. Emphasizing the unique language of Section 34(2) of the Act and the gravity of offenses affecting public health, the court upheld the High Court's order. The directors were granted the opportunity to demonstrate to the Trial Court that they were not involved in the manufacturing process and, therefore, should not be held liable under Section 34(2) of the Act. The appeal was dismissed with these observations.

Common Cause v. Drug Controller of India and Others

In the case of Common Cause v. Drug Controller of India and Others (1991), a complaint was made to the National Consumer Disputes Redressal Commission under Section 2(1)(f) of the Consumer Protection Act (defective goods) of the lack of adequate quality control in the manufacturing and bottling of intravenous fluids given to patients, leading to defects in the fluids. In this case, the defect was the presence of fungus due to the poor quality of the fluid itself and the inadequate cleaning and sealing of the bottle containing it. The Drug Controller was ordered by the Commission to constitute an expert committee to review the provisions of the existing legislation regulating quality control and make recommendations. The Committee made

certain recommendations for protecting the public against the possibility of contamination of I. V. fluids. This case reiterates the fact that the rational drug policy must be accompanied by sustained campaign to enhance awareness of consumers. The literate and enlightened consumers have a greater role and responsibility for materialising the above objective as they can amplify the process of educating and enlightening the illiterate and ignorant consumers.

10. What are the important links and resources?

INGRAM- https://consumerhelpline.gov.in/faq-details.php?fid=Drugs%20and%20Cosmetics
Consumer Guide, CDSCO- https://cdsco.gov.in/opencms/opencms/en/consumer/
Pharma Jan Samadhan scheme-
https://www.nppaindia.nic.in/wp-content/uploads/2018/07/Online-Complaint-System.pdf

Generic Drugs — FAQs

11. What is generic medicine?

According to WHO, A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights . A generic drug is identical -- or bioequivalent -- to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.

12. What is theDrug development process for generic drugs?

Whenever a new potential pharmaceutical product is identified, the inventor (individual or company) files for protection of their intellectual property. This pharmaceutical product is now patent protected and no one can produce it without permission (or license) from a patent holder. Patents are transferable following a legal process involving payment of royalty. Innovator Company is the first one to identify or develop and market the pharmaceutical product. Once the duration of patent protection expires (usually 20 years unless specified), the product can be

manufactured and marketed by anyone without permission from the innovator provided it shows bioequivalence with the innovator's product. These products are called generics and manufacturers are called generic manufacturers while those from innovator companies are called branded.

13. What are branded generics?

Once the patent period of a drug is over, any company can manufacture and market the drug without the permission of the innovator company , as long as it shows bioequivalence, that is, prove to the drug regulator that the copy releases the same amount of the active ingredient and is absorbed by the body in the same way as the original or innovator drug. Such a proven copy of a drug is called its generic version.

14. What is the difference between branded generics and generic generics?

The difference is in the name. One is sold under a brand name and the other is sold under a generic name. But both are generic drugs, that are their patent has expired. Generic drugs are sold by the non-proprietary name or generic name instead of a brand name. The international non-proprietory name (INN) is a unique name given to identify pharmaceutical substances or active pharmaceutical ingredients. INN is globally recognised and is public property unlike a brand name that belongs to a particular company. A nonproprietary name, also known as generic name, is the simplified name for a chemical product. Since it is impossible to remember the chemical name for most people, the INN for this is pioglitazone. So, this chemical can be sold by its INN or generic name, as pioglitazone, or it can be given a brand name (Pioglar from Ranbaxy , Pioz by USV , Pioped by Torrent) and sold as a branded generic.

15. Why are generic prescriptions preferred?

Companies spend huge amounts of money on promoting their branded generics and that cost is added to the drug’s price, making them much more costly than generic named drugs. To bring down the cost of prescription drugs, most health systems opt for generic named drugs and ensure that the quality of generic drugs are maintained. Only generic names are used in medical and pharmacological textbooks. It is expected that the use of generic names will ensure production, sale, and dispensing of more rational, single ingredient drugs.

16. Why do doctors in India object to prescription using generic names?

Doctors are often influenced by the marketing practices of pharmaceutical companies and believe that drugs being sold under trade names are of better quality. There are also genuine concerns about the quality of many of the branded generic drugs and the generic name drugs. With very high margins for retailers on generic drugs, both branded as well as generic name drugs, doctors fear that their generic prescriptions will be used by pharmacists to push the products of companies that give them the highest margins. Doctors fear that while they are directly held responsible to the patient for treatment, the pharmacists would not be held liable for dispensing poor quality drugs.

17. What is the status of generic prescriptions in developed countries?

Since the economic crisis of 2008, most developed nations have taken several measures to push the prescription of generic drugs. In 2013, generics accounted for more than three-quarters of the volume of pharmaceuticals sold in the US, UK, Chile, Germany and New Zealand. Generics accounted for well over one quarter of the market in Italy , France and Japan. Prescribing in INN is permitted in two thirds of OECD countries and mandatory in France, Spain, Portugal and Estonia. Many developed countries have also fixed price caps for generic drugs, either by bulk procurement through tenders or by fixing it as a certain percentage of the brand-name's price.

18. Are generic drugs as effective as brand-name drugs?

Yes. A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used.

Not every brand-name drug has a generic drug. When new drugs are first made they have drug patents. Most drug patents are protected for 20 years. The patent, which protects the company that made the drug first, doesn't allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug. But, first, they must test the drug and the concerned authority must approve it.

Creating a drug costs lots of money. Since generic drug makers do not develop a drug from scratch, the costs to bring the drug to market are less; therefore, generic drugs are usually less

expensive than brand-name drugs. But, generic drug makers must show that their product performs in the same way as the brand-name drug

19. What standards do generic drugs have to meet to be available for public consumption?

Before marketing the drug, generic manufacturers need to obtain permission from relevant drug regulatory authorities.

First, any drug manufactured should follow good manufacturing practices guidelines, the enforcement of which is the responsibility of drug regulators. The manufacturing units should obtain certification in this regard from drug regulators of the respective Country.

Second, there is a requirement for in-vitro dissolution and in-vivo bio-availability and bio-equivalence (BA-BE) testing of new brand (from generic manufacturer) which compares the release of active pharmaceutical ingredient (API) on certain dissolution and liberation characteristics and pharmacokinetic parameters (Cmax, Tmax, and area-under-the-curve) with those from reference standard. If dissolution and BA-BE of API is within acceptable range only then, the new brand is approved for marketing. This ensures that the quality of drugs marketed by generic manufacturers is as good as the one marketed by the innovators. In-vivo BA-BE studies are required only at the time of seeking approval for marketing and not after that while in-vitro studies can be performed anytime.

Health professionals and consumers can be assured that approved generic drugs have met the same rigid standards as the innovator drug.

contain the same active ingredients as the innovator drug(inactive ingredients may vary)

be identical in strength, dosage form, and route of administration

have the same use indications

be bioequivalent

meet the same batch requirements for identity, strength, purity, and quality

be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products

20. How are Generics similar to Brand-Name Drugs?

The law requires a generic drug to meet standards that ensure it's the same basic product as the brand-name drug. That means the generic drug is safe and can be taken:

The same way as a brand-name drug

For the same reason as a brand-name drug

To approve a generic drug, it must be the same as the brand-name product in:

- Active ingredient
- Strength
- Use and effect
- How you take it (for example as a pill, inhaler, or liquid)
- Ability to reach the required level in the bloodstream at the right time and to the same extent
- Testing standards

21. How Are Generics Different From Brand-Name Drugs?

Some differences between generics and brand-name drugs are allowed. These may change the look of the drug. But they dont affect how it works or its safety.

Generic drugs may differ in:

Shape

Color

Packaging

Labeling (minor differences)

Generic drugs are allowed to have different inactive ingredients than brand-name drugs. For example, they may have a different:

Flavoring

Preservative

The inactive ingredients in a generic, though, must be considered safe by the approving authority.

Generic drugs may also have a different expiration date than brand-name drugs. But even so, the generic must keep its effectiveness until its expiration date, just like a brand-name product.

22. Why Are Generic Drugs Cheaper Than Brand-Name Drugs?

You may be wondering how a generic drug can be sold at a much lower price than a brand-name drug.

The difference in price has to do with the different costs drug makers have in bringing generics and brand-name drugs to the pharmacy shelf.

23. Are There Situations That Require Special Consideration Before Choosing a Generic?

Some drugs -- known as NTI (narrow therapeutic index) drugs -- may need special consideration if you are thinking of using the generic version. NTI drugs have a narrow margin between the amount that is safe and effective and the amount that is toxic.

These generic drugs include:

warfarin (a blood thinner)

digoxin (treats certain heart conditions)

theophylline (treats asthma, COPD, and other lung diseases)

Your doctor should tell you if you are taking an NTI drug and what type of monitoring you need.

24. Should I Be Taking Generic Medication?

Generics are not available for all medications. The best way to find out if a generic is available for a medication you are taking -- and whether or not you should take it -- is to ask your doctor and pharmacist.

Some health insurance providers require you to use a generic drug, if available. If you choose to purchase the brand-name product, you may end up paying on your own or have a larger co-pay.

Generally, your pharmacist can substitute a generic drug for a brand-name drug. If a generic is available, but for some reason your doctor thinks you should still take the brand-name drug, he'll write "Do Not Substitute" on the prescription.

If your pharmacist for some reason does not substitute a generic for a brand-name drug, you can ask your doctor to indicate on the prescription that substitutions are acceptable. That way, you can get the same drug for a lot less money.

It can get confusing. Don't be afraid to ask your pharmacist if the medication you received is the generic form of the medicine you are used to taking.

Tell your doctor if you notice any change in your condition or have any unusual side effects when changing from a brand-name to a generic drug.

25. What are the Indian laws and policy on generic drugs?

The regulation of manufacture, sale and distribution of drugs is primarily the concern of state authorities while central authorities are responsible for approval of new drugs and clinical trials, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of State Drug Control Organizations providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act.

Central Drugs Standard Control Organization (CDSCO) under Ministry of Health and Family Welfare is the pivotal agency dealing with all drug related issues. This organization deals with all new drug approvals, review of new safety information regarding approved drugs, approval and safety review of fixed-dose combinations, medical devices, and implants. All endocrine and metabolic drugs are covered by these organizations and acts. Food supplements (including many herbal products) are regulated by separate laws since they are legally not considered drugs

26. What are the relevant Regulation for generic drugs in India?

In India, the approval, production, and marketing of quality drugs at reasonable prices is ensured by the following regulatory bodies,

The Central Drug Standards and Control Organization (CDSCO),

CDSCO functions under the Ministry of Health and Family Welfare

Prescribes standards and measures for ensuring the safety, efficacy, and quality of drugs, cosmetics, diagnostics and devices in the country;

Regulates the market authorization of new drugs and clinical trials standards;

Supervises drug imports and approves licenses to manufacture the above-mentioned products;

The National Pharmaceutical Pricing Authority (NPPA),

The NPPA functions under the Department of Chemicals and Petrochemicals.

fixes or revises the prices of decontrolled bulk drugs and formulations periodically

updates the list under price control through inclusion and exclusion of drugs in line with prescribed guidelines priodically;

maintains data on production, exports and imports and market share of pharmaceutical firms;
monitors the shortage of medicines in addition to providing inputs to Parliament in issues pertaining to drug pricing.

The Ministry of Health and Family Welfare examines pharmaceutical issues within the larger context of public health while the focus of the Ministry of Chemicals and Fertilizers is on industrial policy.

27. How did the government create a body to better regulate the pharmaceutical sector?

In July 2008,the cabinet Secretariat, created a new department under Ministry of Chemicals and Fertilisers the Department of Pharmaceuticals, with the objective of giving greater focus and thrust on the development of Pharmaceutical Sector in India and to regulate various complex issues related to pricing and availability of affordable medicines, research & development, protection of intellectual property rights and international commitments related to pharmaceutical sector which require integration of work with other ministries.
All the drugs and pharmaceuticals, unless specifically allotted to any other department, would come under the purview of the department of pharmaceuticals. the main functions and responsibilities of the department are as follows,

All matters relating to NPPA including its functions of price control and monitoring.
Responsible for the drugs and pharmaceuticals, excluding those specifically allotted to other departments, and for the development of infrastructure, manpower and skills for the pharmaceutical sector
Work for the promotion and coordination of basic, applied and other research in areas related to the pharmaceutical sector and for international co-operation in pharmaceutical research.
Entrusted with the task of maintaining inter-sectoral coordination between organizations and institutes, both under Central and State Governments, related to areas concerning the subject.
To deal with all matters relating to planning, development, and control of, and assistance to, all industries in the pharmaceutical segment.
Promotion of Public Private Partnership (PPP) in pharmaceutical related areas.

18. How do other ministries play a role in the regulation process?

The Ministry of Environment and Forests, Ministry of Finance, Ministry of Commerce and Industry and the Ministry of Science and Technology also have a part to play in the regulation process. The process for drug approval requires the coordination of different departments, in addition to the DCGI, depending on whether the application in question is a biological drug or one based on recombinant DNA technology.

The Department of Industrial Policy and Promotion and Directorate General of Foreign Trade, both under the aegis of Ministry of Commerce and Industry and the Ministry of Chemicals and Fertilizers, look into matters related to industrial policy such as the regulation of patents, drug exports, and government support to the industry.

Licensing, quality control issues, market authorization is regulated by the Central Drug Controller, Ministry of Health and Family Welfare, Department of Biotechnology, Ministry of S Science and Technology (DST) and Department of Environment, Ministry of Environment and Forests.

State drug controllers have the authority to issue licenses for the manufacture of approved drugs and monitor quality control, along with the Central Drug Standards Control Organization (CDSCO).

19. What are the other legislations that are present and govern the pharmaceutical practice in India?

Drugs and Cosmetics Act of 1940 and Rules 1945

In India, drug manufacturing, quality and marketing is regulated in accordance with the Drugs and Cosmetics Act of 1940 and Rules 1945. Over the last few decades, this act has undergone several amendments. The Drugs Controller General of India (DCGI), who heads the Central Drugs Standards Control Organization (CDSCO), assumes responsibility for the amendments to the Acts and Rules. Other major related Acts and Rules include the Pharmacy Act of 1948, The Drugs and Magic Remedies Act of 1954 and Drug Prices Control Order (DPCO) 1995 and various other policies instituted by the Department of Chemicals and Petrochemicals.

Some of the important schedules of the Drugs and Cosmetic Acts include:
Schedule D: dealing with exemption in drug imports,
Schedule M: to control spurious drugs, incorporated in 1995 that lays down Good Manufacturing Practices(GMP) at par with WHO standards.involving premises and plants
Schedule Y: which, specifies guidelines for clinical trials, import and manufacture of new drugs

In accordance with the Act of 1940, there exists a system of dual regulatory control or control at both Central and State government levels. The central regulatory authority undertakes approval of new drugs, clinical trials, standards setting, control over imported drugs and coordination of state bodies activities. State authorities assume responsibility for issuing licenses and monitoring manufacture, distribution and sale of drugs and other related products.

Narcotic Drugs And Psychotropic Substances Act

The Narcotic Drugs and Psychotropic Substances Bill, 1985 was introduced in the Lok Sabha in August 1985 and subsequently passed by both the Houses of Parliament.It came into force on 14 November 1985 as The Narcotic Drugs And Psychotropic Substances Act, 1985 (shortened to NDPS Act). Under the NDPS Act, it is illegal for a person to produce/manufacture/cultivate, possess, sell, purchase, transport, store, and/or consume any narcotic drug or psychotropic substance. Under one of the provisions of the act, the Narcotics Control Bureau was set up with effect from March 1986. The Act is designed to fulfill Indias treaty obligations under the Single Convention on Narcotic Drugs, Convention on Psychotropic Substances, and United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. The Act has been amended three times in 1988, 2001, and most recently in 2014.

Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act

The Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act is a drug control law passed in 1988 by the Parliament of India. It was established to enable the full implementation and enforcement of the Narcotic Drugs and Psychotropic Substances Act of 1985.

The Narcotics Control Bureau (NCB) is the chief law enforcement and intelligence agency of India responsible for fighting drug trafficking and the abuse of illegal substances. It was created on 17 March 1986 to enable the full implementation of the Narcotic Drugs and Psychotropic Substances Act (1985) and fight its violation through the Prevention of Illicit Trafficking in Narcotic Drugs and Psychotropic Substances Act (1988).

There exists a published list that mentions the names of all substances banned or controlled in India under the NDPS Act 237 line items. The list uses the International Nonproprietary Name (INN) of the drugs but in some cases mentions drugs by their chemical name also widely known drugs such as ganja, cocaine, heroin etc. are mentioned as such. Cultivation/production/manufacture, possession, sale, purchase, transport, storage, consumption or distribution of any of the following substances, except for medical and scientific purposes and as per the rules or orders and conditions of licenses that may be issued, is illegal and a punishable offense.

The Patents Act

The Patent Act of 1970 recognized only process patents. The life of the patent was also reduced significantly from 16 to 5 years from the date of sealing or 7 years from the date of filling a complete application, whichever is shorter; in other words, the maximum period of patent was 7 years. Further, in the amended Act an MNC could patent only one process.

The Patent Act of 1970 and the changes in domestic regulation virtually curbed the monopoly of MNCs. Adopting the flexible provisions of the amended patent act, indigenous companies started imitating the patented product and could eventually come out with better processes for the same product.

The industry also embarked on the path of high growth during this period. The other significant outcomes were fall in the prices of the medicines and the introduction of a large number of generic versions of patented products.

The drug policy of 1978 was, however, revised in 1986 to dilute the mechanism of check and control with respect to the production of certain categories of drugs. NDP 1986 also regularized the production of a large number of drugs that were earlier questionable on regulatory grounds.

The Patent Law was amended under the WTO compulsion to recognize product patent from 2005 onward. This was implemented in a staggered manner in three phases. The first phase of it was implemented in 1995 in which the mail-box system was recognized.

On January 1, 2000, a Second Amendment was introduced where the salient features were re-defined patentable subject matter, extended the term of patent protection to 20 years and amended the compulsory licensing system.

A third amendment of patent law was made on January 1, 2005 to introduce product patent regime in areas, including pharmaceuticals that were hitherto covered by process patents only.

20. How are pricing and tax policies made for drugs and pharmaceuticals? What are DPCO and NPPA and what role do they play in making policy for drugs and pharmaceuticals?

Price control on medicines was first introduced in India in 1962 and has subsequently undergone evolution through the Drug Price Control Order (DPCO). As per the directive of NPPA, the criterion for price regulation is based on the nature of the drug in terms of whether it enjoys mass consumption and in terms of whether there is lack of adequate competition for the drug.

In 1978 selective price controls based on disease burden and prevalence was brought about by the Government. Thereafter, the list of prices under DPCO underwent a gradual decrease over a period of time. Around 80% of the market, with 342 drugs, was under price control in 1979. The number of drugs under DPCO decreased from 142 drugs in 1987 to 74 in 1995.

The major objective of DPCO 1995 was to decrease monopoly in any given market segment, further decrease the number of drugs under price control to 74 and the inclusion of products manufactured by small scale producers under price control list.

In 1997, the National Pharmaceutical Pricing Authority [NPPA] was constituted in order to administer DPCO and deal with issues related to price revision.

The NPPA also regulates the prices of bulk drugs or pharmaceutical actives. The MRP excise on medicines was levied by the Finance ministry in 2005 with the objective of increasing revenue and lowering prices of medicines by using fiscal deterrent on MRP. This change may have had some impact in terms of magnifying the advantage to industries located in the excise free zones.

Drugs with high sales and a market share of more than 50% are part of the price regulation exercise. These drugs are referred to as scheduled drugs. Historically the NPPA would intervene only if the annual price increases were more than 20%.

However, post-2007, the NPPA intervenes in cases where drugs have significant sales and where the annual price increases by 10%.

The National Pharmaceuticals Policy 2006, proposed various measures such as increasing the number of bulk drugs under regulation from 74 to 354, regulating trade margins and instituting a new framework for drug price negotiations so as to make drugs more affordable for the Indian masses, to name a few.

21. Good Manufacturing Practices and policies

World Health Organization GMP guidelines were instituted in 1975 in order to assist regulatory authorities in different countries to ensure consistency in quality, safety and efficacy standards while importing and exporting drugs and related products. India is one of the signatories to the certification scheme.

The WHO-GMP certification, which possesses two-year validity, may be granted both by CDSCO and state regulatory authorities after a thorough inspection of the manufacturing premises.

WHO defines Good manufacturing practice (GMP) as a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production be it manufacturing, packaging, testing, labeling, distributing and importing, that cannot be eliminated through testing the final product drug or device or any formulation. The GMP protocols are largely concerned with parameters such as drug quality, safety, efficacy and potency.

India has made progress in the domain of GMP through the enforcement of Schedule M Compliance. The requirements specified under the upgraded Schedule M for GMP have become mandatory for pharmaceutical units in India from July 1, 2005. Schedule M classifies the various statutory requirements mandatory for drugs, medical devices and other categories of products as per the current Good Manufacturing Practices (cGMP). Schedule M contains various regulations for manufacturing, premises, waste disposal, and equipment.

Schedule M protocols have been revised to harmonize it along the lines of WHO and US-FDA protocols. These revised protocols include detailed specifications on infrastructure and premises, environmental safety and health measures, production and operation controls, quality control and assurance and stability and validation studies.

Schedule M compliance is the next thing, smaller pharmaceutical units may take longer to be compliant whereas large-scale firms have shown greater willingness to comply with the revised norms in order to increase their competitiveness in the global arena. According to state regulatory sources, units in states like Gujarat, Karnataka, Maharashtra and Andhra Pradesh have achieved a high percentage of Schedule M compliance in comparison to units in other states.

Export of drugs, devices, and formulations to developed countries from India requires that Regulators from these countries visit Indian manufacturers to carry out a thorough inspection of their manufacturing units before registering the concerned product.

A large number of domestic players are seeking international regulatory approvals from agencies like US-FDA, MHRA UK, TGA Australia and MCC South Africa in order to export their products, mostly generic medicines, in these markets. Indian drug makers have the largest number of FDA-approved plants outside the US and accounted for 39 per cent of all approvals for generic drugs during 2013.

The cost of production has been a leading source of Indias industry strength, as India is 60% cheaper than the U.S. and 50% cheaper than Europe in terms of drug production costs.

22. What are the Policies relating to clinical trials in India?

Till about a decade ago, there was little or no visibility with regard to the conduct of quality clinical trials in India-compliant to regulatory standards and ethics. The Central Drugs Standards Control Organization (CDSCO) has played a critical role in bringing about a positive change in

the clinical trials landscape for India.The progression towards Good Clinical Practice (GCP) has largely been a gradual and slow process.

In 1988 local clinical trials for new drug introductions were first made mandatory in India. Along with the changeover to product patents in January 2005, India also amended the schedule Y of the Drugs and Cosmetics Rules to allow drug trials without a phase lag in the country, that is, Phase II and Phase III trials were permitted only after these had been carried out elsewhere in the world.

The new rule permitted conducting the concurrent trials of the same phase in India. Also Drugs Technical Advisory Board (DTAB) made GLP practices mandatory for all laboratories and in-house units of pharmaceutical firms and Contract Research Organizations (CROs).

Reports of incidents of ethical violations related to informed consent and conduct of trials by multinational and domestic organizations were known prior to the year 2000. In 2000, the regulators the Central Ethics Committee on Human Research (CECHR) and Indian Council of Medical Research (ICMR) took proactive initiative to conceptualize and issue the Ethical Guidelines for Biomedical Research on Human Subjects.

The Good Clinical Practice (GCP) guidelines were developed in line with the latest WHO and ICH guidelines in 2001 by Central Expert Committee -set up for the purpose by Central Drugs Standards Control Organization (CDSCO)

Subsequently in 2005, the requirements of data submission on animal testing for permission to undertake Phase I, Phase II and Phase III clinical trials were laid down in the revised Schedule Y of the Drugs and Cosmetics rules.

Clear responsibilities for investigators; and sponsors were specified and notifying changes in the protocol were made mandatory. Expert clinicians & scientists from the industry assist the evaluation of the relevant data submitted to the Drugs Control General of India (DCGI)

Similarly, for registration and approval of new drugs, which have already been registered and used in the country of origin, The DCGI mandates Phase II trials in about 100 prior to allowing such products to be marketed in India. Normally, new drug approval is usually granted for a period of about two years. The trials are conducted only after clearances are obtained from the Institutional Ethics Committees. Consent of patients for participation in such trials is an integral part of the regulatory framework.

However, there remains a need for the establishment of pharmacovigilance centers at national, zonal and regional levels to monitor adverse drug reactions to be met.

23. What are the policies and guidelines on medical devices and biotechnology in India?

Medical devices

In June 2007, the DCGI introduced a new set of guidelines for the import and manufacture of medical devices in the country.

The Mashelkar Committee subsequently recommended the creation of a specific medical devices division within the CDSCO in order to address the management, approval, certification and quality assurance of all medical devices.

This essentially consisted in alteration of the status of sterile medical devices, intended for internal or external use to medical drugs and creation of suitable provisions and amendments to the Drugs and Cosmetics Act of 1940.

The Drugs Consultative Committee approved these recommendations in 2005, ensuring that in future all devices would be licensed for manufacture, distributed and sold by the CDSCO, with special evaluation committees in order to ensure that the concerned manufacturing units complied with the requisite GMP requirements.

24. Biotechnology and related products

The Department of Biotechnology [DBT] constituted under the Ministry of Science and Technology is the parent body for policy, promotion of R&D, international cooperation and manufacturing activities.

Together with DBT, Genetic Engineering and Approval Committee [GEAC] constituted under Ministry of Environment and Forests [MoEF] is the key regulatory body in Biotechnology in India. Several committees have also been constituted under the said ministries to regulate the activities involving handling, manufacture, storage, testing, and release of genetic modified materials in India.

The Institutional BioSafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) and the Genetic Engineering Approval Committee (GEAC) to monitor rDNA research, product development and commercialization. The ISBC functions as the nodal point for

interaction within the institution for the implementation of the rDNA Biosafety guidelines. The RCGM essentially monitors the safety related aspects of activities involving genetically engineering organisms or hazardous microorganisms.

The GEAC undertakes the responsibility of approval of activities involving large-scale use of genetically modified/hazardous microorganisms and products thereof in research and industrial production and their safety in terms of environmental protection. In addition, the DCGI and state drug controllers as per the Drugs and Cosmetics Act 1945 and its subsequent amendments regulate biologicals

Drugs and Cosmetics FAQs

1. What is a drug?

All medicines for internal or external use of 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 human body for the purpose of repelling insects like mosquitoes

2. What is Cosmetic?

Cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic.

3. Under which act is the import of cosmetics regulated?

Import of cosmetic is regulated in India under the provisions of the Drugs & Cosmetic Act,1940 & Rules,1945.

4. What is the significance of the Act?

The primary objective of the Act is to ensure that the drugs and cosmetics sold in India are safe, effective and conform to quality standards. The related Drugs and Cosmetics Rules, 1945

contains provisions for classification of drugs under given schedules and there are guidelines for the storage, sale, display and prescription of each schedule.

5. Which department regulates the approval of any drugs to be used in India?
Central Drugs Standard Control Organization (CDSCO) Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.

6. What is the role of CDSCO?
Central Authorities are responsible for approval of New Drugs, Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs, coordination of the activities of State Drug Control Organizations. For more information, refer the following link:- https://cdsco.gov.in/opencms/opencms/en/About-us/Functions/

Import of cosmetics in India is regulated to ensure quality of cosmetics being imported into India and safety of consumers using these cosmetics.

7. What are the Essential/ mandatory information that is required to be printed on the label of the medicine pack?
The following information is required to be printed on the label of a medicine under the Drugs and Cosmetics Act and DPCO, 1995.

- Name of the formulation
- Composition of the formulation
- Pack Size
- Address of the manufacturer

- Manufacturing License Number
- Date of manufacture
- Expiry Date
- Maximum Retail Price

8. Where can a consumer register a grievance for the selling of medicines higher than the one printed?
Complaints on prices as well as quality of medicines can be lodged with the Drugs Inspector of the District or the State Drug Controller:

https://cdsco.gov.in/opencms/opencms/en/State-Drugs-Control/

9. How can a consumer get a product tested if he thinks it is fake or spurious?
By submitting the product to the government analyst and following the prescribed process of the same:
https://cdsco.gov.in/opencms/opencms/en/About-us/Laboratories/

10. Can a consumer lodge a grievance for the shopkeeper who is not taking the medicine back?
No, the consumer cannot lodge the grievance as it is the decision of the shopkeeper to take it back or not.

11. What is the role of NPPA?
The National Pharmaceutical Pricing Authority is a government body that regulates the price of drugs in India.

12. If any banned drug is being used in any state, where can the consumer register his grievance?
The consumer can register the grievance with the drug controller of the state and can also approach the Drug Controlle General of India.

https://cdsco.gov.in/opencms/opencms/en/State-Drugs-Control/

12. If a consumer uses a cosmetic product and faces irritation, then what he can do?
Consumer can register the grievance with the manufacturing company and with the drug controller of the concerned state and get the product checked by the government analyst. For more information, refer the following link:-
https://cdsco.gov.in/opencms/opencms/en/State-Drugs-Control/

13. If a consumer received adulterated or spurious drug, where he can complain?
Consumer can register the grievance with the manufacturing company and with the drug controller of that concerned state and get the product checked by the government analyst. For more information, refer the following link:-
https://cdsco.gov.in/opencms/opencms/en/State-Drugs-Control/

14. Is a bill necessary for any grievance registration related to drug and cosmetics?
Yes, a receipt or bill is mandatory.

15. Tier wise escalation level for consumer complaints handling.
Tier 1

Send first written complaint to the Company Customer Care by email, website or by post

Tier 2

If consumer does not receive any reply or is not satisfied with the response, he/she can file complaint to the Controller of Drugs & Cosmetic of the State/ Union territory.

Tier 3

In case the consumer is not satisfied with the resolution provided, he/she may file case with Consumer Dispute Redressal Commission, following the procedure prescribed by them. For more information, you may visit http://www.ncdrc.nic.in/districtlist.html