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Review Article

THE INDIAN PHARMACEUTICAL INDUSTRY; EVOLUTION OF REGULATORY SYSTEM AND PRESENT SCENARIO

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ABSTRACT
Indian pharmaceutical industry evolved in true sense only after independence. Government provided the impetus to growth with the establishment of few public sector units. Healthcare facilities in India are still below standard as compared to most developed nations. Indian government is stringent on price control of Pharmaceuticals and this becomes a major hurdle for global players to enter in India but Indian patent act and new drug policy has bought a new dimension to Indian Pharmaceutical Industry. Some of the Indo-global industries like Cipla, Ranbaxy and Dr .Reddy's are showing rapid and consistent growth with their impact worldwide. India is also turning out to be a prime destination for clinical trials. Industry today is governed by wide range of regulations and different regulatory bodies. Current article focuses on all these aspects along with regulations for new drugs, medical devices, imports etc.

KEYWORDS: Pharmaceutical industry, Regulations, Regulatory bodies, Clinical trials, Manufacturing, Imports.

INTRODUCTION:

The Indian pharmaceutical sector has come a long way, being almost a small sector before 1970 to a vital supplier of healthcare products, serving almost 95 per cent of the country's pharmaceuticals needs. It ranks 3rd in the world in terms of production volume and 13th in domestic consumption value. Indian Pharmaceutical industry grew at 15.7% during December 2011. The Industry today is in the front rank of India's science based industries with wide ranging capabilities in the complex field of drug manufacture and technology.[1, 11]

At the time of independence, the total drug production in our country was around Rs. 10 crores. At that time the Multinational companies (MNCs) taking the advantage of the colonial Patent and Designs Act, 1911 exploited the drug market of our country. They were engaged mainly in the import of drugs from their country of origin. Even 10 years after the independence 99% of about 1700 drugs and pharmaceutical patents in India were held by these MNCs. However, MNCs who were controlling more than 80% of the market stake did not come forward with financial investment and technological help to establish drug production centers in India. Drug prices in India were amongst the highest in the world. Thus, five public sector drug manufacturing units under the Ministry of Chemicals and Fertilizers were started. They are Indian Drugs and Pharmaceutical Limited (IDPL), Hindustan Antibiotics Limited (HAL), Bengal Immunity Limited (BIL), Bengal Chemicals and Pharmaceutical Limited (BCPL) and Smith Stanistreet Pharmaceutical Limited (SSPL). The establishment of these large public sector units and the coming into force of the Drug Policy of 1978 had been mainly responsible for the availability of drugs and medicines at relatively lower prices in India.[2]

HEALTHCARE FACILITY IN INDIA:

Healthcare facility in India is poor as compared to many developed countries, still various attempts made by government are found to be insufficient to ever increasing population in India.

Table 1: Statistics of healthcare facility in India.[3, 4, 5, 6]

Doctors	60 per 100,000 people
Nurses	80 per 100,000 people
Pharmacies	367,000 (urban),183,000 (rural)
Hospitals	30,000 (67% public, 23% private)
Hospital beds	1.7 million (one per 1,000 people)

Large proportion of Indian population resides in villages, which has contributed to lack of healthcare facilities to about 67 % population and confinement of modern healthcare facilities to 33% population in cities and towns only.

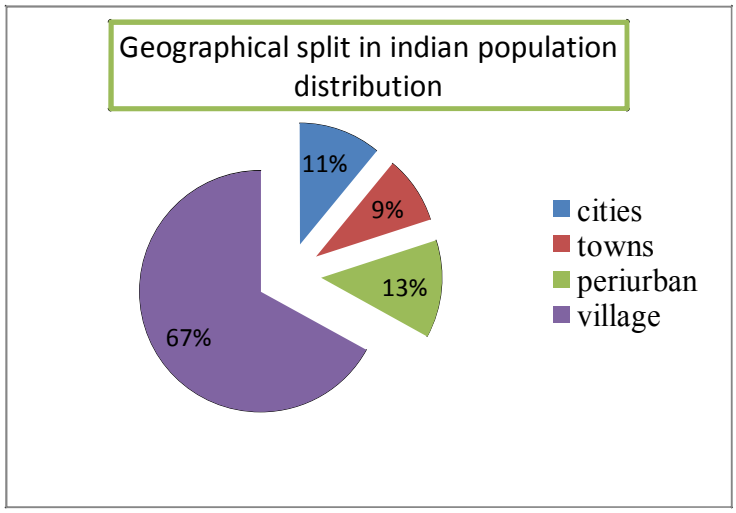

Figure 1: Geographical split in Indian population.[7]

FACTORS INVOLVED IN THE GROWTH AND CHALLENGES FACED BY INDIAN PHARMACEUTICAL MARKET: [1, 7]

India is known today for producing high quality generic medicines that are sold globally. Further, India is known to be one of the fastest growing pharmaceutical markets in the world. The following factors have fuelled the growth for the drugs and pharmaceutical market;

- The growing population of over a billion;
- Growing Indian economy with Increasing incomes;

- Changing Disease Profile. An increase in lifestyle-related diseases such as diabetes, cardiovascular diseases, and central nervous system;
- A huge patient base;
- Improving healthcare infrastructure;
- Penetration of health insurance;
- Adoption of patented products;
- Patent expiries and aging population in the US, Europe, and Japan.

The following challenges faced by the global pharmaceutical industry also open up a number of opportunities for the Indian Pharmaceutical Industry:

- Higher healthcare costs;
- Competition from generics;
- Patent expiries of blockbuster drugs;
- Increasing R&D costs;
- Poor all-round infrastructure is a major challenge;
- Stringent price controls;
- Lack of data protection.

Many Indian Pharmaceutical firms are major market players in Indian and global market and following Figure no. 2 is enough to show this.

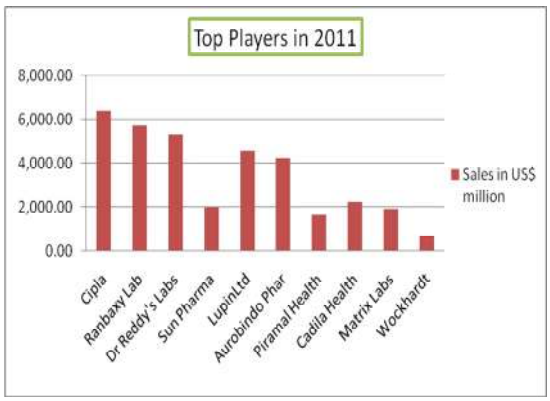

Figure 2: Indian Pharmaceutical industry top 10 players in 2011.[1,8]

LAWS AND REGULATIONS GOVERNING INDIAN PHARMACEUTICALS:

The Drugs and Cosmetics Act, 1940: [9]

This Act regulates the import, manufacture, distribution and sale of drugs in India.

It contains in detail the regulations divided in different schedules A to Y, Schedule I and Schedule II. Some very important schedules are as follows:

Schedule M of the Drugs and Cosmetics Act specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs. Part I describes good manufacturing practices for premises and materials. Part II deals with requirements of equipments.

Schedule T of the Drugs and Cosmetics Act prescribes Good Manufacturing Practices (GMP) specifications for manufacture of Ayurvedic, Siddha and Unani medicines. It is divided in two parts. Part I deals with Good Manufacturing Practices, while Part II deals with list of machinery, equipment and minimum manufacturing premises required for their manufacture.

Schedule Y of the Drugs and Cosmetics Act specifies about the requirement and guidelines on clinical trials for import and manufacture of new drug.

Additionally this act provides for construction and functioning of various regulatory bodies like Drug Technical Advisory Board, Drug consultative Committee, Central Drugs Laboratory etc.

The Pharmacy Act, 1948: [10, 11]

Indian market is 13th in domestic consumption value. Such a big market is regulated by this act. This legislation regulates the profession of Pharmacy in India. Under the provisions of this act the Central Government constitutes a Central Pharmacy Council of India and the State Governments constitute State Pharmacy Councils. Provisions regarding Joint State Pharmacy Council are also mentioned to the states who agree to share these services jointly. The composition, structure and function of councils are also described. These councils control provisions regarding registration of Pharmacists, Education Regulations, Removal of name from register etc.

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954:[12]

An Act to control the advertisement of drugs in certain cases, to prohibit the advertisement for certain purposes of remedies alleged to possess magic qualities and to provide for matters connected therewith.

The Narcotic Drugs and Psychotropic Substances Act, 1985:[13, 14, 15]

This is an Act to consolidate and amend the law relating to Narcotic Drugs, to make stringent provisions for the control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances and for matters connected therewith.

The Medicinal and Toilet Preparations (Excise Duties) Act, 1956:[16]

This act lay down the regulations for the levy and collection of duties of excise on medicinal and toilet preparations containing alcohol. It also specifies the manufacturing conditions to be maintained for such products.

Good Clinical Practice (GCP) Guidelines: [17]

For any type of clinical study involving human volunteers it is mandatory to follow these guidelines. These are draft guidelines for research in human subjects. These GCP guidelines are essentially based on Declaration of Helsinki, World Health Organization (WHO) guidelines and International Conference on Harmonization (ICH) requirements for good clinical practice.

Good Laboratory Practice (GLP) Guidelines: [18]

Good Laboratory Practice is defined in the OECD Principles as *"a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported."* The purpose of the Principles of Good Laboratory Practice is to promote the development of quality test data and provide a tool to ensure a sound approach to the management of laboratory studies, including conduct, reporting and archiving

Indian Patent Act 1970:[11, 19, 20, 21]

The Act's stated objective was to foster the development of an indigenous Indian pharmaceutical industry and to guarantee that the Indian public had access to low-cost drugs. The Patent Bill was first introduced in Parliament in 1967, but the Patent Act, 1970 came into force only in 1972. It does not allow product patents on medicines, agricultural products and atomic energy. Process patents were allowed for 5-7 years. Indian scientists developed new processes for 107 drugs. Indian companies are now among the world leaders in the production of bulk drugs from basic stages. Today, the prices of drugs in India are very economic as compared to many other nations. Table no.2 shows various acts and amendments made related to patent laws in India.

Table 2 Indian patent laws prior to and after independence. [22]

Year	Act/ Amendment in Patent System
1856	Protection of inventions based on the British patent law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.
1859	Patent monopolies called exclusive privileges (making. Selling and using inventions in India and authorizing others to do so for 14 years from date of filing specification).
1872	The patents & designs protection act.
1883	The protection of inventions act.
1888	Consolidated as the inventions & designs act.
1911	The Indian patents & designs act.
1972	The patents act (act 39 of 1970) came into force on 20th April 1972.
1999	On march 26, 1999 patents (amendment) act, (1999) came into force from 01/01/1995.
2002	The patents (amendment) act 2002 came into force from 20th may 2003
2005	The patents (amendment) act 2005 effective from January 2005

Attempts to change the Indian Patent Act 1970 are a part of this globalization programme. The imposition of an unequal trade treaty like the World Trade Organization (WTO) is a step towards globalization in favour of the MNCs of rich nations. With its help, the market of the developing nations is forced open for the developed countries. Most of the developing countries were forced to sign the WTO agreement without realizing its implication. As a result, the developed countries are the gainers. As per the requirement of WTO guidelines for the product patent regime, the availability of new drugs in our country may be delayed depending on the desire of the patent holders.

The Indian parliament approved India's product patent legislation in March 2005. The Indian Patents Third Amendment Bill, 2005, establishes product patent protection for pharmaceuticals in India. Manufacturers of new drugs can apply for product patents. The Act allowed for only two types of generic drugs in the Indian market: off-patent generic drugs and generic versions of drugs patented before 1995. At present, nearly 97 percent of all drugs manufactured in India are off patent and therefore will not be affected by this Act. As per the guidelines, a product patent is granted for 20 years and a process patent for another 20 years.

In March 2006, Roche became the first company in India to receive a patent under the product patent regime. The product patent has been granted for Pegasys (peginterferon alfa-2a) for the treatment of hepatitis C, under the country's "mailbox" facility for post-1995 inventions. The patent is valid for 20 years from May 15, 1997. Prices of drugs will go up by 5 to 10 times as it is evident from the prices of drugs in India and other countries like Pakistan, U.K. and U.S.A. where product patents are in force. Ranitidine is sold by Glaxo in India at Rs. 7.20. The same product is sold by the same company in Pakistan at Rs. 65 and in the U.S.A. at Rs. 545.

The Drugs Price Control Order (DPCO), 1995: [23, 24, 25, 26]

This is an order issued by the Government of India under the Essential Commodities Act, 1955 to regulate the prices of drugs. The Order provides the list of price controlled drugs, procedures for fixation of prices of drugs, method of implementation of prices fixed by Government and penalties for contravention of provisions among other things. For the purpose of implementing provisions of DPCO, powers of the Government have been vested in the National Pharmaceutical Pricing Authority (NPPA). Following is the general criteria employed to include the drug under DPCO.

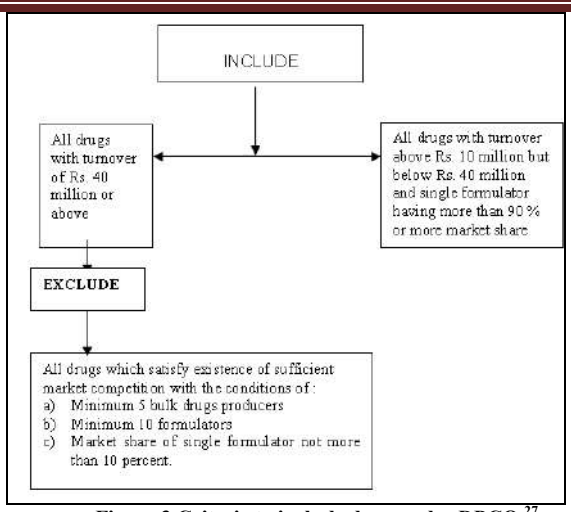

Figure 3 Criteria to include drug under DPCO.[27]

Drug prices in India are among the lowest in the world (and imports are therefore negligible). This is because of several reasons. Indian labour costs are low compared to overseas levels. India also has a large pool of technical and managerial personnel and does not need management skills from overseas. Most of the plant and equipment required is made locally.

Most importantly a measure of statutory price control for bulk drugs and formulations operates in India. Certain drugs (known as scheduled drugs, as they are listed in the First Schedule to the DPCO), the recent policy changes have enormous implications for drug prices in India. As of today, only one-tenth of drug market is price controlled as against nearly 90 percent during the late 1970s. Non-scheduled drugs can be priced freely, subject to some restrictions. The price control regime is administered by the National Pharmaceutical Pricing Authority (NPPA). The Government can exempt certain products from price control if they are new drugs discovered in India or bulk drugs produced from the basic stage by a new process discovered in India or drugs manufactured by small-scale industries (capital investment below a certain level) and sold under their own brand names. Price control does not apply to formulations under the Indian system of medicine or homeopathic medicines or items to which the DCA does not apply.

The Government of India announced in February 2002, the Pharmaceutical Policy 2002, in which it is proposed to make changes in the method of detaining price controlled drugs and also in the pricing formula.

The Department of Pharmaceuticals has recently released the draft note on the National Pharmaceutical Pricing Policy (2011), which if accepted would replace the present Drug Policy introduced back in 1994. In its proposed form, the policy framework aims at widening the ambit of medicines under price control as it proposes to include all of the 348 essential drugs listed in the National List of Essential Medicines (NLEM) as compared to the 74 bulk drugs, which forms part of the present policy regime.

The following are some of the other laws which have a bearing on pharmaceutical manufacture, distribution and sale in India:

- The Industries (Development and Regulation) Act, 1951.
- The Trade and Merchandise Marks Act, 1958
- The Indian Patent and Design Act.
- Factories Act.

THE REGULATORY SYSTEM: [28, 29, 30]

India's federal regulatory structure has been plagued by some of the classic problems of developing countries, including red tape and corruption. India has a federal form of government and the medical regulatory structure is divided between national and state authorities. The principal national drug authority based in New Delhi is the Central Drug Standards Control Organization (CDSCO). CDSCO is controlled by the Drug Controller General India (DCGI). There are also 35 state-level Food and Drug Administrations, one for each of India's states and territories.

Following figure no.4 shows important factors which must be considered while deciding regulatory policies for pharmaceuticals.

Figure 4 What decides the regulatory policies?

The DCGI registers all imported drugs, new drugs, biological and drugs in selected categories. It also has responsibility for medical devices, clinical trials and quality standards. The state FDAs register all other products, accredit manufacturing plants, and conduct the bulk of quality monitoring and inspections. The drug regulatory system structure as a whole is shown in Figure no. 5 including all the departments and ministries related to it.

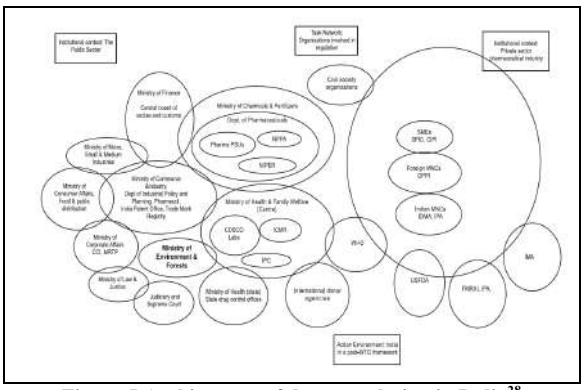

Figure 5 Architecture of drug regulation in India[28]

REGULATORY BODIES: [30, 31]

The Ministry of Health & Family Welfare and the Ministry of Chemicals and Fertilisers of the Government of India play a major role in regulating the pharmaceutical sector in the country. In India, state authorities are responsible for licensing a drug maker's research and manufacturing facilities. But the federal Central Drugs Standard Control Organization (CDSCO) and the drugs controller general of India (DCGI) have been responsible for approvals of preclinical and clinical trials, new drug applications, and the importation of drugs from abroad. But, problem lies in state authorities. India's state drug regulatory authorities (DRAs) often lack the staff to monitor their work. This staffing problem, combined with their relatively poor technical experience in such issues worsens the problem. The DRAs have been susceptible to influence by local political authorities, and thus unable to prevent illegal drug manufacturing and marketing activities. Manufacturers that set up operation in states where regulatory oversight and enforcement are weakest can then market their drugs in the rest of the country. Figure no. 6 shows of regulatory bodies and under whom they work.

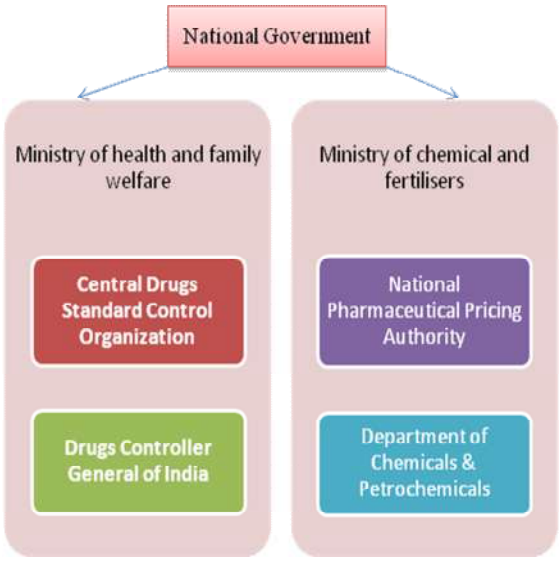

Figure 6 Regulatory bodies in India

Ministry of Health & Family Welfare (Department of Health):

Central Drugs Standard Control Organization (CDSCO): As an agency of the Department of Health, the CDSCO works both at the Central and the State level and is responsible for ensuring safety, efficacy and quality of drugs supplied to the public. The agency performs the above mentioned functions with the Drugs Controller General of India (DCGI) as the executive head.

Drugs Controller General of India (DCGI): The DCGI is an apex body in the pharmaceutical industry governing issues such as Approval/NOC for Clinical trials, Bioequivalence studies and Marketing permission in India. Along with it is also responsible for approval for Test License, Testing of Drugs, Registration for Import and Licensing, Export NOCs-Biological samples, Drugs, etc., Licensing of Blood Banks, r-DNA products, Vaccines and Medical Device, Amendment in Drugs And Cosmetics Acts and Rules from time to time

Ministry of Chemicals and Fertilisers:

The Ministry of Chemicals & Fertilizers constitutes bodies such as the Department of Chemicals & Petrochemicals (DCP) and the National Pharmaceutical Pricing Authority (NPPA). These departments are entrusted with the responsibility of policy making, planning, development and regulations relating to Chemicals, Petrochemicals and Pharmaceuticals.

NEW DRUG REGISTRATION: [19, 29, 32, 33]

Medicinal products count as 'new drugs' in India if they fall into one of the following categories:

- Drugs not previously available in Indian market.
- Drugs with new therapeutic indications or dosages that have not been marketed in India
- New fixed-dose combinations of two or more drugs.

- Any drug which was first approved in India less than four years ago, unless it is included in the Indian Pharmacopoeia
- All vaccines are treated as new drugs, unless notified otherwise by the DCGI.

For permission to import or manufacture of new drug substances and its formulations for marketing in the country, applicant is required to file application in Form 44 along with prescribed fees in the form of treasury challan and all relevant data as per Schedule Y to Drugs and Cosmetics Rules which include chemical & pharmaceutical information, animal pharmacological & toxicological data, clinical data of safety & efficacy regulatory status in other countries etc and results of clinical trials on local population. New drug registration carries a fee of 50,000 rupees. There is no fixed time frame in which the application has to be reviewed, but a typical range is around 12-18 months.

There is need for approval from the DCI to import, market, or manufacture a "new drug." All new drugs (drugs not previously used in India or in use for less than four years) proposed to be introduced must be approved for import or manufacture in India by the DCI.

Data requirements

The document design is as per the International submission requirements of Common Technical Document (CTD) and has five Modules.

Module I: Administrative/Legal Information

Module II: Summaries

Module III: Quality Information (Chemical, Pharmaceutical and Biological)

Module IV: Non-Clinical Information

Module V: Clinical Information

All items above may not be required for all drugs. In case the drug is already approved and marketed abroad, then only Phase III trials may be required in India. Further, such trials would need to be conducted on at least 100 persons spread over 3-4 locations in the country. However, the DCI may agree to dispense with the need for local clinical trials, if it is in the public interest and if it can use the data of trials carried out in other countries. Similarly, the submission of data related to animal toxicology, reproduction studies, teratogenic studies, prenatal studies, mutagenicity and carcinogenicity may be relaxed or modified in case the drugs are in use overseas for several years and there is adequate published evidence regarding the safety of the drug.

However, In case the new drug is a fixed dose combination (FDC) of existing approved active ingredients, and combined for convenience and not likely to have interactions, then no additional animal or human data are generally required and marketing permission may be given. However, if the combination is being done for the first time, and a claim is being made, and/or the combination is likely to result in a significant interaction of a pharmacodynamic or pharmacokinetic nature, then it is treated in the same way as any other new drug.

There is no specific timeline laid down for approval. But, usually three months after dossier filing is usual period required.

MANUFACTURING: [9, 19]

License to Manufacture Drugs

Most manufacturing is licensed by state FDAs, but new drugs, blood products, sera, and vaccines require approval from the DCGI. Manufacturing permission is fairly simple compared to new drug approval. Besides basic information on the site, information must be furnished that the drug is being made to therapeutically justified specifications, and has new drug approval if appropriate. A GMP standard has also been recently implemented, under the name of "Schedule M." This may drive out many smaller drug manufacturers as it is enforced more strictly.

All manufacturing of drugs in India requires a license. Manufacturing is defined by the DCA as including any process or part of a process for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug with a view to its sale or distribution. It does not include dispensing or packing at the retail sale level. A license is required for each such location at which drugs are to be manufactured, and also for each drug to be manufactured. The license has to be renewed periodically. It is also possible to obtain a license to manufacture a product in the factory premises owned by another party, a practice called "loan licensing."

The good manufacturing practices and requirements of premises, plant and machinery are provided in the schedule M. The items covered are: locations and surroundings, buildings, water supply, disposal of waste, requirements for sterile products manufacturing areas, working space and storage areas, health clothing and sanitation of workers, medical services and equipment standards. With respect to plant and machinery, the Drug and Cosmetics act provides for recommended equipment for all product forms including syrups, elixirs, pills, compressed tablets and capsules as well as repacking installations.

The D and C act also specifies other conditions for the grant or renewal of a license, competent technical staff, qualification with experience in drug manufacture, requirements of the testing laboratory and qualifications of the head of the testing unit. The applicant must also show (in case of patent or proprietary medicines), that the medicines contain the constituent ingredients in the therapeutic/ prophylactic quantities as determined in relation to the claims or conditions for which the medicines are to be used, that the medicines are safe for use in the context of the vehicles, excipients, additives and pharmaceutical aids used in the formulation, are stable in the conditions of storage recommended, and contain such ingredients and in such quantities for which there is therapeutic justification.

Industrial Licensing

Besides the drug manufacturing license as above, for certain drugs there is need for a manufacturing license from the Central Government, in accordance with the Drug Policy and the Industrial Policy. The legal basis for this is the Industries (Development & Regulation) Act, 1956 (IDR). However, the list of such drugs has been reduced substantially and the only drugs now requiring a license are: those involving use of recombinant DNA technology, those involving use of nucleic acids as the active principles and formulations based on use of specific cells/ tissue - targeted formulations. The applicant in these cases has to apply for an industrial license.

IMPORTS: [19, 29, 34]

Registration of imported drugs

All drugs to be imported require their own import registration. This is independent of new the required drug registrations. Foreign manufacturers must apply for registration certification for their manufacturing premises and for the individual drugs to be imported. Applications can be made by authorized agents of foreign firms in India.

According to recent new legislation, import licenses will be required for all types of drugs, rather than the existing import license requirements for Schedule C and C (1) and Schedule

X drugs only. Import license applications should be made using Form 40, and information and undertakings specified in Schedule D(I) and Schedule D(II) should duly signed by the manufacturer. Schedule D(I) and D(II) should comprise actual plant and drug data, such as the plant master file; the manufacturing license in country of origin; a GMP certificate; a Certificate of Pharmaceutical Products (CPP) issued by the regulatory authority of the country of origin; drug substance information; finished formulation information; clinical documentation, and packaging and labeling information.

The process of receiving import registration can take up to a year, and it must be done after new drug registration. Once you have import registration for a drug, you can apply for a simple import license, which is needed to actually let the drug in through customs.

Import Licensing:

India does not permit the free import of all goods. While India is a signatory to the World Trade Organization (WTO), it has been given time to remove its quantitative restrictions on imports (QRs) in a phased manner, with QRs to be totally lifted by 2002 or earlier. At present most non-consumer goods items are permitted to be imported freely, while some consumer goods are permitted to be imported freely, and others are prohibited for import. Most items are classified under the International Harmonized System (IHS or BTN) and categorized for import accordingly. Imports and exports are regulated by the Foreign Trade (Development and Regulation) Act, 1992.

Pharmaceutical Imports:

Most pharmaceuticals are still freely importable under the foreign trade law. Certain drugs may not, however, be imported except under a license given by the Drug Controller of India. Such products cannot be imported after the date shown on the label as being that on which the potency would reduce or toxicity would increase beyond the standard permitted.

The foreign manufacturer would have to appoint an Indian agent to apply for the import license. The agent would be responsible for fulfilling all the terms of the license. An agent has to be an entity (individual, partnership or company) registered in India. A license is valid for a year, up to December 31st of the year following the year in which the license was granted, and has to renew thereafter. The importer must have a license to stock and sell drugs. In case there is any repacking or labeling to be done, then the importer must also have a drug manufacturing license. A single license may be applied to all drugs imported from one manufacturer, provided that the drugs are manufactured at one factory or more than one factory functioning conjointly as a single unit. If the drugs are made in two separate factories, a separate license is required for drugs manufactured by each such factory.

REGISTRATION FOR A MEDICAL DEVICE: [19, 29]

CDSCO regulates medical devices registration and import. The health ministry in 2005 declared the following sterile devices to be considered as drugs: cardiac stents; drug eluting stents; catheters; intra-ocular lenses; intravenous cannulae; bone cements; heart valves; scalp vein sets; orthopedic implants; internal prosthetic replacements. Various other sterile medical devices such as spinal needles, insulin syringes, cardiac patches and many others were added to this category in March 2009.

Registration applications should be submitted via Form 40 and as under Rule 24A of the Drugs and Cosmetics Rules. The product information and undertakings should be submitted under Schedule D (I) and D (II) – these schedules are modified to suit the requirements of devices, such as category of device, intended use and method of use, qualitative and quantitative particulars of the constituents, contraindications, and lists of accessories.

APPLICATION AND APPROVAL PROCEDURES FOR CLINICAL TRIALS: [29, 34, 35, 36]

Efforts in India to improve the regulatory environment for developing and licensing pharmaceuticals shifted up a gear in 2008, as the country pressed on with its bid to maximise opportunities in both domestic and international sectors. India now participates in over 7% of all global Phase III and 3.2% of all global Phase II trials. Apart from specific elements of the Indian market that attract global players, the main aspect that has put the country at an advantage is the notable momentum adopted by the Indian Council of Medical Research and the CDSCO in tandem with global regulatory guidelines – considering India's involvement in global GCP has only happened in the past decade. With the number of clinical trials being conducted in India increasing rapidly, the regulatory bodies recognised the need to frame guidelines and regulatory approval processes on a par with international standards.

Clinical trials are applied for via Form 44, the same form used for new drug approvals. Data should be submitted along with the application in Schedule Y of the Drugs and Cosmetics Act 1940, and the rules therein. CDSCO decided to make registration of clinical trials in the Indian Council of Medical Research (ICMR) clinical trial registry mandatory in June 2009, applicable for clinical trials initiated after 15 June 2009

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