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Development of Innovative Standards for the Registration of Drugs in India Based Upon International Norms

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A B S T R A C T
The regulatory landscape in India can be challenging, with multiple agencies involved in the drug approval and registration process. India is increasingly becoming the preferred destination for foreign pharmaceutical companies due to its vast population, expanding healthcare infrastructure, and rising demand. With a well-established regulatory framework and lower production costs, India offers opportunities for market expansion and access to a diverse patient population, making it an attractive choice for pharmaceutical companies. Drug License is imperative for establishments involved with the manufacturing, distribution, and procurement of the drug. The Registration Process to Obtain Drug License may seem plain and simple on the surface, but it is a lot more complicated in the real-world scenario. India's pharmaceutical industry ranks third in production volume, growing steadily at about 9.43% annually for nine years. Key segments include generics, over-the-counter medicines, and vaccines. India supplies more than half of the world's vaccine demand, 40% of the US generic demand, and a quarter of the UK's medicine supply. With a vast pool of scientists and engineers, India plays a vital role in the global pharmaceutical industry. The regulated market involves those countries where there are defined regulatory requirements set by the regulatory bodies of that country and the emerging market countries are those who still lag behind in putting forward the well-defined regulations for drugs.
Keywords: Manufacturing, distribution, UK's medicine supply, Drug License

A R T I C L E I N F O

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Contents

1. Introduction

Indian drug market

The Indian pharmaceutical market is projected to grow to US$ 65 billion by 2024, US$ 130 billion by 2030, and US$ 450 billion by 2047. Currently valued at around US$ 50 billion, with over US$ 25 billion from exports, and India supplies 20% of global generic drugs.

The following pointed details give a clearer idea of the Indian drug market.

- India ranks among the top 12 biotechnology destinations globally and aims for a US$ 300 billion economy by 2030. The biosimilar market is expected to reach US$ 12 billion by 2025,

comprising 20% of India's pharmaceutical market.

- India is the 3rd largest API producer globally, contributing 8% to the industry.
- The medical devices sector is valued at US$ 11 billion, with plans to reach US$ 50 billion by 2030.
- India dominates the global pharmaceutical sector, supplying 20% of generics and 60% of vaccines[1-7].

India is increasingly becoming the preferred destination for foreign pharmaceutical companies due to its vast population, expanding healthcare infrastructure, and rising demand. With a well-established regulatory framework and lower production costs, India offers opportunities for market expansion and access to a diverse patient population, making it an attractive choice for pharmaceutical companies.

Below are some reasons why you should choose India as the market for your drug. India is one of the largest pharmaceutical markets in the world, home to over 1.3 billion people. Rising healthcare expenditure- As India's economy grows, so does its healthcare expenditure. The government's efforts to modernize the healthcare system and the rise in disposable income present numerous opportunities for the pharmaceutical industry. India's strategic location makes it an ideal hub for pharmaceutical companies looking to expand their presence in Asia. With a well-established network of suppliers, distributors, and contract manufacturing organizations, India offers access to neighboring markets.

Challenges in the Indian drug market

Regulatory complexity: The regulatory landscape in India can be challenging, with multiple agencies involved in the drug approval and registration process. Affordability: Balancing the need for affordable drugs with maintaining profitability is a constant challenge, particularly in a market with diverse socio-economic segments, impacting accessibility to essential medications. Quality control: While India has made significant strides in improving the quality standards of its pharmaceutical products, concerns about product quality and counterfeit drugs persist.

Import registration certificate and license

In India, importing drugs necessitates acquiring both an Import Registration Certificate and an Import License. The Import Registration Certificate, obtained from the DCGI, is linked to the drug's manufacturing site and may prompt site inspections. While the DCGI typically trusts GMP certification from advanced countries, inspections are more common for drugs from low-cost countries. The Import License, essential for customs clearance, varies based on the drug type and to ensure compliance with shipment testing requirements before entry through designated ports.

Regulatory information and compliance

The CDSCO, under the Ministry of Health and Family Welfare, is the primary regulatory authority responsible for drug approval and registration in India. Additionally, state drug control authorities oversee regulatory compliance at the regional level. The Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945 govern the regulation of pharmaceuticals in India. These laws outline the drug registration, manufacturing, distribution, and sale. Drug manufacturers must comply with regulatory requirements, including GMP guidelines, product labeling regulations, and pharmacovigilance obligations. Non-compliance can result in regulatory sanctions, including product recalls and fines.

Timeline and fees

The Indian drug registration timeline can vary. The following table gives a general idea of the timeline. Fees depend on factors such as the drug type and clinical trial phases, ranging from thousands to lakhs of rupees. The healthcare imperatives and the resultant laws and regulations around health in India are unique. In the absence of any significant reimbursement or insurance system in place, the focus of successive Indian governments has been on achieving significant reductions in out-of-pocket expenditure on healthcare and drugs. Drug prices and affordable healthcare have been an integral part of campaign rhetoric in general and state elections since 2014. The issue of affordable healthcare and the disproportionate focus on prices of drugs and devices have been occupying a progressively larger space in the political and media arena. Since 2014, the current government has not only increased the scope of price control of drugs and devices that have been notified as drugs (stents, orthopaedic knee implants) but is now proposing significant legal and regulatory changes. The establishment of public pharmacies dispensing generics and the policy and regulatory measures discussed below are part of a push to make India an overwhelmingly generic-generic market.

Globally, the Indian pharmaceutical industry is ranked third largest in volume terms and tenth largest in value terms.1 It is expected to grow at a compound annual growth rate (CAGR) of 15.92 percent to reach a turnover of INR 3.53 trillion (US$ 55 billion) by 2020. By 2020, India is likely to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size. However, the market is predominantly a generic one and therefore the laws and regulations of the country, including intellectual property, drug regulatory, drug pricing, prescriptions, etc., are geared towards governing and strengthening a generic market. Measures in the pipeline will push it further in this direction[16-20].

Pricing

Since the 1970s, India has had some form of price control. The Drug Price Control Order (DPCO) is issued under the Essential Commodities Act, 1955 and all drugs under the National List of Essential Medicines (NLEM) are under the purview of the DPCO. Currently there are 376[2] drugs in NLEM 2015, which includes a couple of patented drugs as well. The National Pharmaceutical Pricing Authority (NPPA) is the price regulator. Price controls over pharmaceuticals, which are often arbitrary and unpredictable, have been a challenge for the industry in

doing business in India. Irrational and overly steep price cuts have been acting as a de facto trade barrier to doing business in India. Over the last couple of years, the Indian Government has expanded the scope of such arbitrary price controls that were hitherto restricted to drugs to the field of medical devices; these measures are considerably more stringent and devoid of rationale when compared to drugs.

Regulatory changes

Heralding these regulatory changes, the CDSCO claimed[8] that it had initiated various measures in the last two years to streamline the regulatory procedures by relaxing, rationalizing, and modifying the existing provisions of the DCR, which has resulted in accelerating the regulatory approvals without compromising the safety, quality, and performance of medical products. A separate, simplified, and extensive New Drugs and Clinical Trials (CT) Rules under the Drugs and Cosmetics Act, 1940 (DCA) that will codify all amendments to date is in the planning stages. In its efforts toward digitization and implementation of the e-governance scheme, MoH launched its online licensing system called SUGAM, which is being continuously expanded in a phased manner. In order to give impetus to the Government's "Make in India" initiative, emphasis is being placed on ensuring safety, efficacy, and quality of drugs manufactured in India by requiring submission of stability data and compliance of GMP/GLP practices. Additionally, there are deliberations for plugging the gaps in the sale of drugs including internet sales and for OTCs[31-38].

Medical Devices Rules

The Government is simultaneously in a process of streamlining the medical device industry, which has seen a paradigm shift this year with notification of separate and distinct Medical Devices Rules, 2017 (MDR) effective from January 2018. The MDR has been notified with an aim to bring within its purview the entire universe of devices by notifying them as "drugs" (as defined in the DCA) in a phase-wise manner thereby bringing them within the jurisdiction of CDSCO, the drug regulator. Currently, only 22 types of medical devices are regulated in India as "drugs" under Section 3(b) (iv) of the DCA and all other non-notified medical devices do not require any registration certificate or other regulatory approvals. With the MDR and the subsequent notification of medical devices, regulatory approvals would be required. CDSCO has already circulated a draft list of 462 medical devices and 250 in vitro diagnostics (IVDs) along with their risk classification to encourage importers, manufacturers, distributors, and supply chain personnel to voluntarily adhere with the safety, performance, and quality aspects as stated in the MDR for creating the proper ecosystem for its effective implementation.[12] Further, deliberations are underway for developing a detailed guidance on essential principles for safety and performance to be followed in the manufacturing process of medical devices intended to be sold in India.

Enforcing One Company, One Brand, One Molecule

The issue of the sale of the same drug under multiple brand names and different prices was first taken up in the 50th meeting of the Drug Consultative Committee held on November 4, 2016. Concerns were raised over multiple brands of the same drug (manufactured by one company and marketed by multiple companies) available at different prices. It was recommended that a separate committee be constituted to suggest measures to prevent the misuse of current practice with respect to third-party manufacturing of drugs wherein a product manufactured by a single company is marketed by multiple companies. The current draft NPP proposes to put a restraint on multiple brand names and implement the principle of one manufacturer, one salt, one brand name, and one price. In addition, the draft NPP proposes to prohibit third-party manufacturing that companies use for brand variation of the same formulation.

Marketing Code

One of the noteworthy pieces of legislation that the Department of Pharmaceuticals (DoP) is spearheading is the Uniform Code of Pharmaceutical Marketing Practices (UCPMP). UCPMP was implemented effective January 1, 2015 as a voluntary code. The Code has provisions on gifts, hospitality, and travel that the industry allegedly extends to doctors as well as provisions on claims and comparisons, textual and audio-visual promotional material, and the conduct of sales representatives and the samples they provide to doctors. The Department is now proposing to make UCPMP statutory and mandatory under the Essential Commodities Act, 1955 along with penal provisions for companies violating the Code.

Biosimilars

There have also been some key changes in regulations relating to Similar Biologics. On August 16, 2016, the MoH released a new Guidelines on Similar Biologics. The change to the Guidelines on Similar Biologics, 2012 seems to have been initiated in light of a suit filed in Delhi High Court by Roche against Biocon, Mylan, and the DCGI. Roche challenged the approval process followed during the grant of approvals for the biosimilar of Herceptin, alleging it was not in accordance with the process laid down in the Guidelines on Similar Biologics, 2012. Roche sought injunctions against Biocon and Mylan on account of imminent threat and credible apprehension of the introduction of the purported biosimilar version of the drug *Trastuzumab*. The case has seen many twists with the interim order of the Single Judge of the Delhi High Court favoring Roche. The Single Judge stressed compliance of the Guidelines for Similar Biologics. After a detailed hearing, the Single Judge on April 25, 2016 partially allowed an interim injunction sought by Roche wherein Biocon and Mylan could market their product for only one indication even though approval was granted by CDSCO for three.

2. Methodology

Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will probably want to ship the investigational drug to clinical

investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA. During a new drug's early preclinical development, the sponsor's primary goal is to determine if the product is reasonably safe for initial use in humans, and if the compound exhibits pharmacological activity that justifies commercial development. When a product is identified as a viable candidate for further development, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies.

FDA's role in the development of a new drug begins when the drug's sponsor (usually the manufacturer or potential marketer) having screened the new molecule for pharmacological activity and acute toxicity potential in animals, wants to test its diagnostic or therapeutic potential in humans. At that point, the molecule changes in legal status under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system.

The IND application must contain information in three broad areas: Animal Pharmacology and Toxicology Studies - Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experience with the drug in humans (often foreign use). Manufacturing Information: Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product. This information is assessed to ensure that the company can adequately produce and supply consistent batches of the drug.

Clinical Protocols and Investigator Information - Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks. Also, information on the qualifications of clinical investigators--professionals (generally physicians) who oversee the administration of the experimental compound--to assess whether they are qualified to fulfill their clinical trial duties. Finally, commitments to obtain informed consent from the research subjects, to obtain review of the study by an institutional review board (IRB), and to adhere to the investigational new drug regulations. Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials. During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

Procedure for new drug approval in India

The Drug and Cosmetic Act 1940 and Rules 1945 were passed by the India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO), and the office of its leader, the Drugs Controller General (India) [DCGI] was established.

In 1988, the Indian government added Schedule Y to the Drug and Cosmetics Rules 1945. Schedule Y provides the guidelines and requirements for clinical trials, which was further revised in 2005 to bring it at par with internationally accepted procedure. The changes includes, establishing definitions for Phase I–IV trials and clear responsibilities for investigators and sponsors.

The clinical trials were further divided into two categories in 2006. In one category (category A) clinical trials can be conducted in other markets with competent and mature regulatory systems whereas the remaining ones fall in to another category (category B) Other than A. Clinical trials of category A (approved in the U.S., Britain, Switzerland, Australia, Canada, Germany, South Africa, Japan and European Union) are eligible for fast tracking in India, and are likely to be approved within eight weeks. The clinical trials of category B are under more scrutiny, and approve within 16 to 18 weeks.

An application to conduct clinical trials in India should be submitted along with the data of chemistry, manufacturing, control and animal studies to DCGI. The date regarding the trial protocol, investigator's brochures, and informed consent documents should also be attached. A copy of the application must be submitted to the ethical committee and the clinical trials are conducted only after approval of DCGI and ethical committee. To determine the maximum tolerated dose in humans, adverse reactions, etc.

On healthy human volunteers, Phase I clinical trials are conducted. The therapeutic uses and effective dose ranges are determined in Phase II trials in 10-12 patients at each dose level. The confirmatory trials (Phase III) are conducted to generate data regarding the efficacy and safety of the drug in ~ 100 patients (in 3-4 centers) to confirm efficacy and safety claims. Phase III trials should be conducted on a minimum of 500 patients spread across 10-15 centers, If the new drug substance is not marketed in any other country.

The new drug registration (using form # 44 along with full pre-clinical and clinical testing information) is applied after the completion of clinical trials. The comprehensive information on the marketing status of the drug in other countries is also required other than the information on safety and efficacy. The information regarding the prescription, samples and testing protocols, product monograph, labels, and cartons must also be submitted.

The application can be reviewed in a range of about 12-18 months. Figure 10 represents the new drug approval process of India. After the NDA approval, when a company is allowed to distribute and market the product, it is considered to be in Phase IV trials, in which new uses or new populations, long-term effects, etc. are explored.

The drug approval process varies from one country to another. In some countries, only a single body regulates the drugs and responsible for all regulatory task such as

approval of new drugs, providing license for manufacturing and inspection of manufacturing plants e.g. in USA, FDA performs all the functions. However in some counties all tasks are not performed by a single regulatory authority, such as in India, this responsibility is divided on Centralised and State authorities. Other issues where the difference appears are, time taken for the approval of a CTA application, time taken in evaluation of marketing authorization application, registration fee, registration process and marketing exclusivity.

Some counties have two review processes as normal review process and accelerated review process as in USA, China etc. and some countries have only a single review process as in India. Similarly, the format used for the presentation of dossier submitted for approval of drug is also different. In some countries like as in USA, EU, and Japan, it is mandatory that the dossier prepared in CTD format, however, in some countries it is optional such as in India.

3. Results and Discussion

CTD guideline in India:

Scope: This guideline applies to import / manufacture and marketing approval of new drugs including new chemical entity, new indication, new dosage forms, modified release form, new route of administration etc. under the definition of new drug under Rule 122E of Drugs & Cosmetics rules as a finished pharmaceutical product. Difference in organization of data in each application has made reviewing more difficult and can also lead to omission of critical data or analysis so unnecessary delay in approval. Thus common format of submission will help. Through the ICH process, CTD guidance developed for japan, EU & US. CDSCO also adopted the CTD.

Documents To Be Submitted For Grant Of Permission To Conduct Bioequivalence Studies For Export Purpose: A large number of applications are being filed to the office of DCG (I) at CDSCO (HQ) by Pharmaceutical companies, both manufacturers and importers as well as CRO's on behalf of them, requesting for the approval to carry out BE studies with various pharmaceutical dosage formulations on Indian subjects.

In light of the above, for easy processing of such applications and to bring uniformity in decision making all stake holders of the afore mentioned activities are hereby advised to submit their applications with following documents. All applications should accompany the documents with proper index & page number.

The new regulations cover provision for promoting clinical research as well as complex topics such as orphan drug, post-trial access, and pre and postsubmission meeting. The new rules appear comprehensive, well-balanced, and likely to improve the ethical and quality standards of clinical trials in India, which will further benefit patients and industry. The conditions of waiving local clinical trials under these rules will help provide patients with earlier access to drugs. The approval for clinical trials in 30 working days for indigenous drugs will also speed up the trial process and encourage local drug development. Provision for accelerated product approval under some conditions, especially pre and postsubmission meetings with authorities, may add increased predictability and confidence in the system.

The new regulations also are aimed at promoting clinical research in the country by implementing time-bound review of applications, allowing increased predictability and transparency of regulatory pathway and providing clarity on many complex subjects, including post-trial access. In 2013, after a series of media allegations of unethical practices, the CDSCO office made stricter regulations for conducting clinical trials. Many new regulations were introduced, many of which led to degrees of confusion and uncertainty among sponsors who conduct Global Clinical Trials (GCT) in India. Despite changes implemented to overcome challenges in those regulations, much work was still required, evidenced by the fact that the number of clinical trials approved by the Indian regulator has still not yet reached the levels existing prior to 2013.

Regulations on Biomedical and Health Research (BHR)

Previously, studies other than clinical and bioavailability and bioequivalence (BA/BE) studies were not regulated in the Drug and Cosmetic Rules and, consequently, there was insufficient control on the conduct of these studies. These types of studies were covered by the Indian Council of Medical Research (ICMR) in the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (released initially in 2000, amended in 2006 and 2017). Since these were covered only under Indian Council of Medical Research (ICMR) Guidelines and not under the Drugs and Cosmetics Rules, these studies were unregulated and there was no clarity on the approval mechanism and or compensation process. In New Rules, 2019, such research has been defined to include "studies on basic, applied and operational research or clinical research designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioral), their detection and cause and evolving strategies for health promotion, prevention or amelioration of disease and rehabilitation but does not include CT."

Presubmission Meeting

CDSCO decided in January 2015 to introduce a system of formal presubmission meetings between applicants, CDSCO officers and subject experts to discuss a regulatory pathway for a specific application. The resulting document was published, but never implemented as this was not part of the rules and, subsequently, there were no follow up actions. However, New Rules, 2019 has included a provision for presubmission meetings with the CLA or any other officer authorized by the CLA for seeking guidance about the requirements of laws and procedures for obtaining license or permission of manufacturing processes, clinical trials and other requirements**.** The application for a presubmission meeting should be accompanied by documents referred to in the Second Schedule, as available with the applicant to support their proposal along with a fee

specified in the Sixth Schedule. CLA, within a period of 30 days, will relate the facts to the applicant in writing and direct them to provide further information or documents as necessary[64-68].

New drugs are classified into two categories. The first category would convert to an old drug after four years of its approval; the second category has always been considered 'new drugs,' irrespective of the period since they were first approved by the CLA. Class (i) is part of first category and Class (ii) and (iii) are part of second category. Sustained release and modified release dosage forms have been moved from the first category to the second.

For products in the second category, CTs and marketing approvals undertaken with these products would legally come under the control of CLA. Even for generic products (after four years of innovator approval) companies first need to take approval from CLA, followed by State FDA, for local manufacturing. For sustained and modified release dosage forms, there would be additional timelines for generic product approval, as this would be first approved by CLA.

Import and Manufacture of Unapproved new Drug

Under the Rule 36 of *Drug and Cosmetic Rules, 1945*, provision was made for patients to apply for a license to import an unapproved new drug. The applicant is required to apply using Form 12A, along with the prescription of the Registered Medical Practitioner (RMP) indicating the quantity of drug required for treating the patient. So long as the application is submitted as per required documents and on satisfaction of Licensing Authority (LA), the permission Form 12B is issued on priority basis. Now, under *New Rules, 2019*, a medical officer from a government hospital also may import unapproved drugs approved for marketing in a country of origin. This provision is for patients suffering from a life-threating disease or a disease causing serious permanent disability or for an unmet medical need. There is also provision to manufacture an unapproved new drug in India, in limited quantity, one currently in clinical trials and only used to treat a patient with a life-threatening disease.

New clinical trial approval timelines also have been included. For the clinical trial of drugs developed outside of India, there is a 90 working-day limit for the CLA to respond. However, this timeline for review may be further reduced to 30 working-days if the drug was discovered in India or research and development of the drug are being carried out in India, and the drug is proposed to be manufactured and marketed in India. In the event no communication is received from the CLA, permission to conduct a clinical trial shall be deemed to have been granted for BA/BE studies of new drugs or investigational new drugs within 90 working days of receipt of application.

Overall, the new rules are comprehensive, well-balanced and will likely improve the ethical and quality standards of clinical trials in the country, which also will further benefit patients and industry. Waiving local clinical trial under these rules will help provide earlier access to drugs for patients in India. The deemed approval for clinical trials in 30 working days for indigenous drugs also will speed up the clinical trial process and encourage local drug development. Provision for accelerated product approval under some conditions, along with provision of pre and postsubmission with the CDSCO office, would add predictability and confidence in the system. The shortened review timelines would clearly require additional manpower at CDSCO to ensure timely disposal of applications[71-78]. The government has already planned an expansion of CDSCO strength and it is expected that additional revenue generated through increased application fees will help ensure adequate human resources are available at CDSCO.

4. Conclusion

The study concluded that drug License is imperative for establishments involved with the manufacturing, distribution, and procurement of the drug. The Registration Process to Obtain Drug License may seem plain and simple on the surface, but it is a lot more complicated in the real-world scenario. The rejection rate of the drug license is relatively higher than any other license since it is associated with human life in one way or another. The issuance authority might cancel your request for a license even if it got a negligible disparity. Therefore, the individual must be spot on with the documentation work and meet the remaining prerequisite against the prescribed norms. Registration and approval phase is very crucial part in commercialization of the pharmaceutical products. As per the regulatory point of view, one has to prepare and compile the documents as per CTD module. The new rules have been revised keeping various issues in mind. The most important among those issues are those aimed at reviving the clinical research industry in India, bringing more global clinical studies to India and promoting to the drug development process.

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