Review Article

# Overview on Current Regulatory Requirements for Non-Proprietary (Generic Drugs) in United States and BRICS Nations

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**ABSTRACT**

A generic medication is defined as "a medication product that is equivalent to a brand/reference listed medication product in terms of dosage form, strength, quality, and intended use."It is a less expensive, safer, and more effective substitute for the original branded medication available, hence these should be made easily accessible across the whole world. Each country has its own registration process for getting approval to market the generic medication. The study aims to evaluate the registration processes for generic drugs and identify any discrepancies or gaps in the guidelines in various countries including the BRICS countries. Commonly Brazil, Russia, India, China, and South Africa are collectively termed as "the BRICS" or "the BRICS economies". Ensuring that drug development, manufacture, and testing have been completed in compliance with rules and guidelines and that everything has been properly documented is one of the regulatory authorities' primary responsibilities. The International Conference on Harmonisation (ICH) developed a uniform application format for the registration of pharmaceutical products to minimize some of the challenges being faced during registration. This paper addresses the need for generic drug registration and the processes.

**Keywords:** BRICS, Generic, CTD, NDA, Regulatory, Guidelines, Approval.

## INTRODUCTION

A generic drug is one that functions, is taken as directed, and has a dosage that is comparable to that of a branded drug but does not have the brand name. The generic medication may contain different inactive ingredients (texture, smell, and taste) in addition to the same active ingredient as the branded medication. It is inappropriate to draw comparisons between illegally produced counterfeit medications and generic drugs. A generic version of the medication may be sold after the patent for the brand-name drug expires. Before a generic drug can be sold as a brand-name drug, the FDA must first approve it.[1]

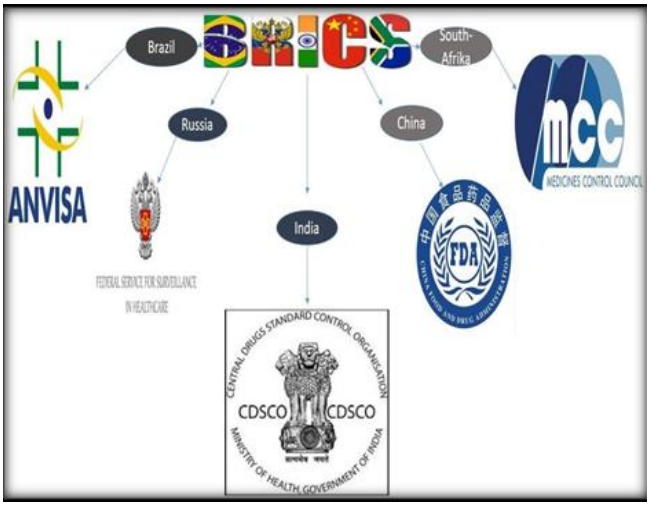
### Need For Generics/Rationale

Generic medications are necessary because branded ones are too costly for the average person to afford. The high cost of medications prevents almost 2 billion people from having access to life-saving treatments. Compared to branded medications, generic drug prices aresignificantly lower since the producers of generic drugs do not have to pay for the expensesassociated with creating a new drug from the scratch or with marketing it. Because of this, generic medications are 30% to 70% less expensive than branded ones.[2]

BRICS is an alliance, which stands for Brazil, Russia, India, China, and South Africa, composed of five important developing markets. The emerging markets of Brazil, Russia, India, South Africa, and China are collectively referred to as BRICS[3], and they are all thought to be in a comparable stage of their recent economic development. Typically, it is presented as "the BRICS" or "Economies of BRICS."

### Aim of BRICS

Cooperation, development, and influence in international affairs are the main objectives ofthe BRICS. In more detail, the BRICS aim to foster technological and innovative advancement, sustainable development, political coordination, social and cultural exchanges, economic cooperation, and peace and security.




### Global Drug Market

A key component of giving patients access to cheap medications is generic medication. The United States of America, the European Union, Canada, Japan, and Australia are the world's top generic marketplaces. China and India, the two main exporters of generic medications, are experiencing phenomenal expansion in the generic drug market.[5] The use of generic products is associated with legal and regulatory complexities, as well as quality

concerns. The generic medication sector has recently suffered greatly from bilateral international agreements known as free trade agreements, as well as from originator corporations' delaying strategies such strategic patenting and lawsuits against generic manufacturers. These difficulties need to be solved to optimize the usage of generic drugs. Foreveryone on the planet to have better access to important medications, the generic medicine industry must be sustainable.[6] The majority of necessary medications are less readily available and far more expensive in thepublic sector in India. The retail price of the drug is significantly greater than the procurement price because of the restricted control mechanisms; also, the cost of branded medication is morethan 20 times that of generic medication.[7]

At a compound annual growth rate (CAGR) of 13.3%, the domestic pharmaceutical business, which was valued at $15.4 billion in 2014, is predicted to reach $32.7 billion by 2020. motivated by favourable factors such as the ageing population, rising rates of lifestyle diseases,sharp rises in disposable incomes, and the expanding encroachment of Indian pharmaceutical companies in the international market. By 2020, generic pharmaceuticals will hold an 85% market share in the domestic pharmaceutical industry, with a 75% value share. These medications are widely available on the international market and are used for lipid regulators, respiratory problems, liver illnesses, pain management, anticoagulants, and cholesterol control.[8]

**Current Scenario of Generics**

Generic pharmaceutical drugs are bioequivalent versions of innovator products that are available at much lower costs, primarily because accompanying bioequivalency studies are waived and research and clinical trial expenses are decreased.[9] But up to now, the solid oral dose forms have been better served by the bioequivalency idea. The current regulatory criterionto show bioequivalence in the case of topical medicines that operate locally rather than systemically is clinical end-point trials. To attain statistical significance, evaluating the therapeutic equivalency of these drugs through these studies is costly, intricate, and necessitatesthe participation of multiple patients.[10]

**Current Scenario in India**

In India, ANDA should be submitted by the companies to regulatory bodies in order to obtain a generic drug approval. This is the prerequisite for approval of generic drugs. The ANDA procedure spares the company from having to conduct time-consuming, repeated animal testing of generics because their branded versions have already undergone safety and efficacy testing. They are created after the inventor's patent and other exclusivity rights have run out. The second-largest pharmaceutical sector in India is found in ANDAs and holds the top position globally in Drug US applications for Master Files (DMFs). It is evidence for this that Indian304 ANDAs have been approved by corporations in 2017 by the US Food and Drug Administration (USFDA). The nation is home to around. In the US $ 70–80 billion generics market there is 30% (by volume) and roughly 10% (by value) marketplace.[11] As stated in the 2017 National Health Policy, the government is dedicated to ensuring that healthcare is cheap. The cost of healthcare is predicted to push 94 million people into povertyin India. Approximately two-thirds of the money is spent on medications. All brands of medications work just as well as generic versions. Many questions concerning the availability and quality of generic drugs have been highlighted by the government's and the Medical Council of India's initiative to make it necessary for physicians to write prescriptions for generic medications. The case for generic medications is supported by experiences in the United States and Canada. Physicians won't be able to persuade patients—including the wealthy—to take generic medications until the real-time efficacy of these medications has been shown and reported. If the regulator continues to hold generic medicine reviews to strict criteria for quality, safety, and efficacy, our government will be able to accomplish this goal. Effective collaboration between sponsors, healthcare providers, and regulators can result in cost savings for patients and high-quality treatment alternatives through the efficient use of generic pharmaceuticals.[12]

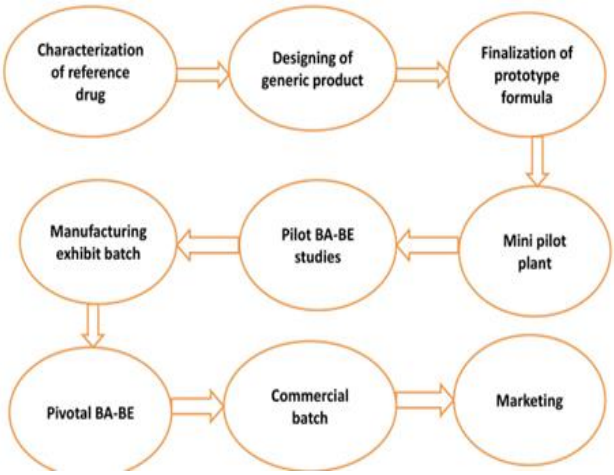
**Other Major Nations**

**US-** The USFDA is a Health organisation whose purview extends to the majority of food products (apart from meat and poultry), pharmaceuticals for humans and animals, biologically derived therapeutic agents, medical devices, radiation-emitting consumer goods, medical equipment, cosmetics, and animal feed. The institution is led by the Office of the Commissioner, which is responsible for four departments that oversee regulatory issues, international activities, management, health, and science. They have a number of centres for the regulation of food, veterinary products, medical equipment, pharmaceuticals, and toxicological research.[13]

**EUROPE-** The EU has one of the most highly regarded regulatory systems in the world. The system comprises of European parliament, the council of ministers, and the European Commission. EU consists of 27 member states: Austria, Belgium, Bulgaria, , Estonia, Finland, France, Germany, Greece, , Ireland,Italy, Latvia, Denmark, , Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden,etc and the United Kingdom and three countries which are member of European Free Trade Agreement (EFTA) Iceland, Norway, and Liechtenstein.[14] The Agency oversees the centralized system for the scientific examination of pharmaceutical company-developed drugs intended for use in the EU as well as applications for European marketing authorizations of drugs intended for use in humans and animals. By means of the centralized approach, businesses send the Agency a single application for marketing authorization.[15]

**Generic Drugs Registration/Approval**

The registration procedure for generic products corresponds to the registration procedure for new chemical entities. A corporation creates a dossier for a new generic product that is mostly composed of information concerning the product's medicinal chemistry. It is assumed that a novel product already exists (often within the same market) and has demonstrated clinical efficacy and safety (though this may not hold true in unregulated markets). Because of this, the generic product's data is intended to demonstrate that, in terms of both efficacy and safety, it is clinically equivalent to the innovator medicine.[16]




**Generic drug Approval Process**

**Generic Drug Approval Process:**

Once a drug's patent expires, anyone can produce and market it. However, in order to market the drug, generic manufacturers must obtain approval from the regulatory body of the relevantstate. Initially, all manufactured drugs must adhere to good manufacturing practices and obtain certification from drug-related regulatory authorities (Schedule M. Drugs and Cosmetics Act of India, 1940).[18] Subsequently, bioavailability and bioequivalence (BA-BE) testing of thenew brand must compare it to other active pharmaceutical ingredients and its reference standards. If the results are satisfactory, the drug can then be marketed. Indian generic products will profit if they are approved by the USFDA and the ANDA. The United States is currently the top exporter of generic products, with a 35% global share. For exporting to developed countries, a comprehensive description together with a set of lawsand regulations is necessary. Promoting generic medicine is more dependent on the ANDA review procedure. Following extensive evaluations of the branded medication's microbiology, chemistry, and product labelling, the relevant FDA grants approval. Only after passing rigoroustesting in terms of identification, strength, quality, purity, and potency has the FDA authorized generic products.[19]

**Regulatory Requirements in Various Countries:**

**1.USA:**

US requirements for the registration of generic drug products:

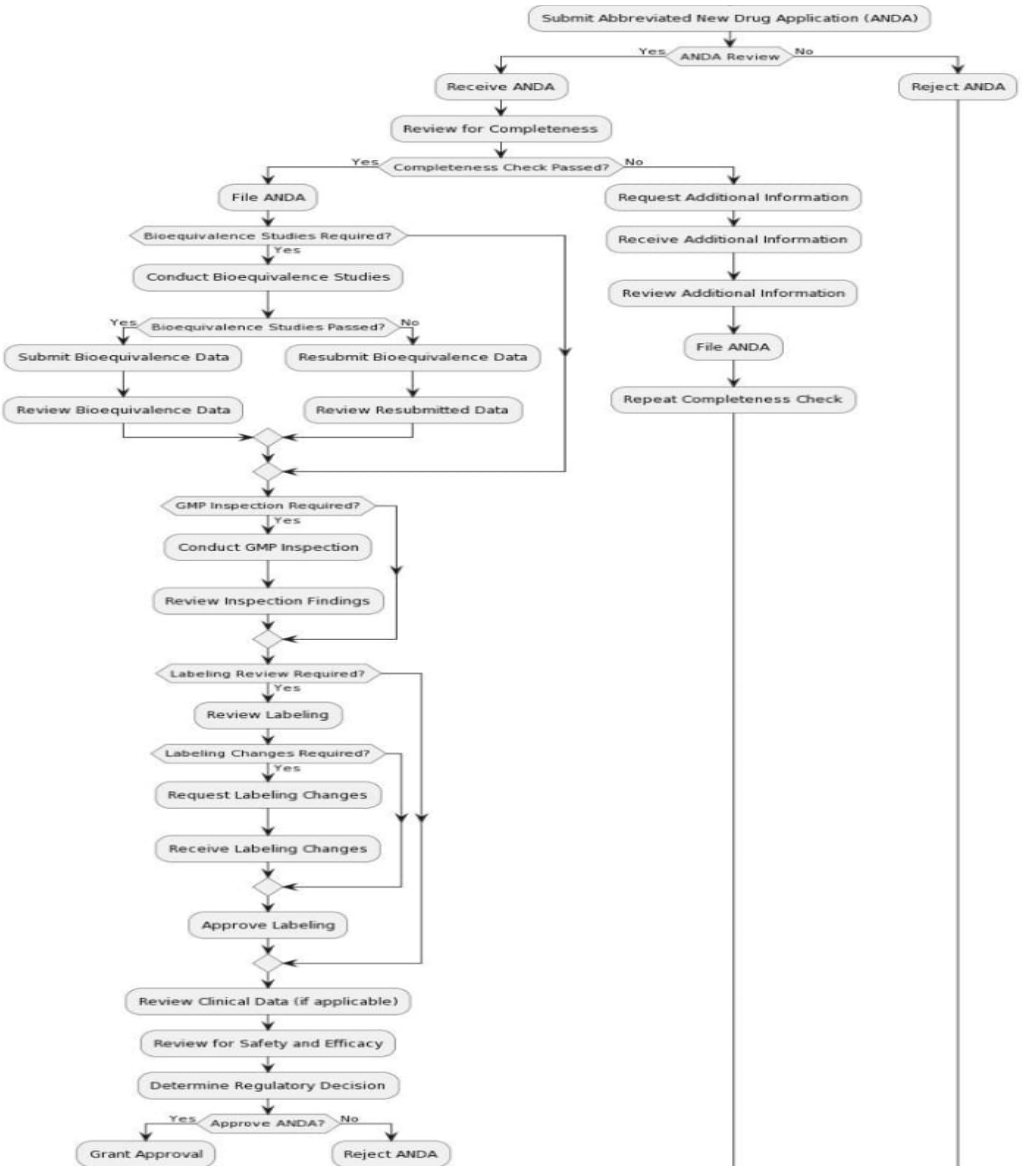
The submission of drug applications (NDA/ANDA) requires the eCTD.

The FDA sections (such as 505(b) for NDAs and 505(j) for ANDAs) and USFDA guidelines (CFR) publications are complied with while creating the dossier for drug approval applications.

1) Here are the ways in which the applications differ:
   - NDA for novel drugs
   - ANDA : for generic medication
   - BLA for use in biological applications
2) The application may be sent directly to the FDA by the applicant or a GDEA
3) A cover letter, forms (356h), field copy certification, financial certification, patent information, and exclusivity are not the same as administrative information .
4) The contribution is being made on letter-sized paper (8.5 x 11 inches) with a font size of 12in Times New Roman. The font size in the tables and figures is modest, ranging from 8 to 10.
5) Drug product labeling includes package inserts.
6) Provided are suggested labels and cartons that match the Reference Listed Drugs labels interms of dimensions.
7) The financial disclosure Statement part of this module and Module 5 both contain information about the clinical investigators.
8) A request to for in-vivo BE research is made.
9) Proper annotation is provided along with annotated draft labeling for labels and cartons thatare compared with the RLD[20]

**Generic Drug Approval Process In USA**

The world's strictest regulations for filing generic medication applications are found in the United States. The FDA's rules and standards should be followed by pharmaceutical businesses, according to the regulatory bodies. Regulations and guidelines aid in the development, production, and safety testing of drugs to ensure that they are effective and safeand do not jeopardize patient health. It is not necessary to create separate registration dossiers for various regulatory bodies because CTD offers a globally standardized format that is recognized in many areas. The main goal of the regulations controlling pharmaceuticals in the US is to ensure that medications are produced in compliance with the standards, ensuring patient safety.




**Generic Drug Approval Process in USA**

**2.BRAZIL**

ANVISA: (ANVISA) AGENCIA NACIONAL DE VIGILANCIA SANITARIA and a new system of user fees for products and companies were established on December 31, 1998, when the Brazilian President put temporary legislation into operation. applying. New certification standards and fees affect devices and equipment used in the medical field. items of food and drugs.

**Drug Product Registration[22]**

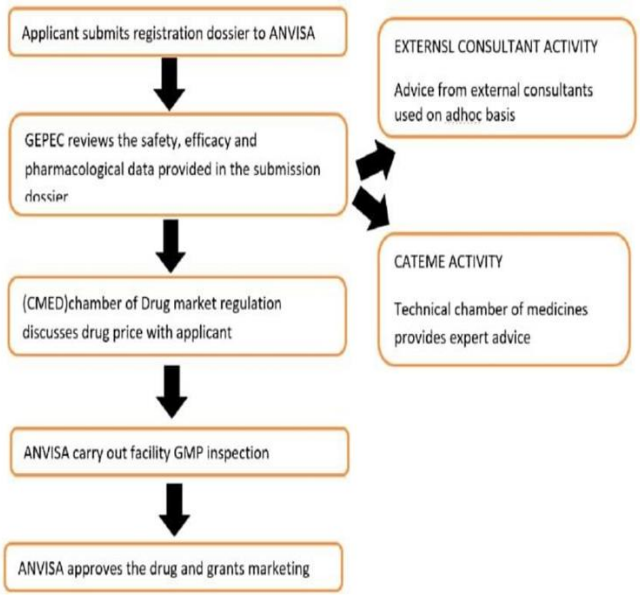
**Generic Medicine:** A medicine that is equivalent to a reference or innovator product and is said to be replaced with it; usually manufactured following the expiry of patent protection or other exclusive rights; its efficacy, safety, and quality have been established; and provided the CBD (Common Brazilian Denomination) designations, or in the event that this is not achievable, the CID (Common International Denomination).

- The foreign company's local office or its authorised representative (distribution) must request authorization of a drug product in Brazil.
- Five years validation is present for registered product, following which it may be alwaysextended.
- The legislation specifies that the process for registration must be completed in 180 days.
- When verifying the documentation provided for, alteration, or registration, ANVISA will publish its conclusions in the Federal Gazette.
- The evaluation of the documentation will be conducted within the time frames and legal parameters set forth in Brazilian sanitary laws.
- The manufacturer or importer must provide the completed documentation outlined in Resolution-RDC nº185/01 together with all other documents necessary for the product's original registration whose information has been changed in order to request a modification to the authorization of the medicinal product.

**After publication of the product generic manufacturer should supply ANVISA with:** 1. evidence demonstrating the first three batches developed, in order to enable ANVISA to get samples for control investigation if required; 2. Outcomes and conclusion assessment of the first three batches' sustainability investigated in compliance with the ANVISA-approved schedule. If a registered medicine's stability study does not follow the guidelines in the handbook on conducting stability studies, a new study needs to be submitted; 3. Publish current information on the occurrence of adverse reactions and inefficiency of medicine; 4. The company must update the list of drugs, which must be present at drug stores in accordance with particular regulations, by providing bills of sale to as evidence of the initial stage of sales of this pharmaceuticals, preferably within a year of thedate of publication of the registration of the generic medicine in the DOU; 5. Authorised laboratories do not have to supply bills of sale, but they have to provide verification of the pharmaceuticals' manufacturing and distribution.[23]

**Registration Requirements**

1. Information about the API's technical aspects.
2. Pharmacodynamic; Pharmacokinetics.
3. Management on the quality of all utilising raw materials.
4. The technician in in charge of the company's affairs should initial each page of every document and sign the last page in hard copy. Provide a copy of every technical report which was saved to a diskette, CD-ROM, or other format the ANVISA acknowledges, beginning in"doc."




**Approval Process of ANVISA**

**3.RUSSIA**

**Drug Regulatory Authorities of Russia-**

- Ministry of health and social services (MOH)
- Federal service for surveillance in healthcare and social development (Roszdrvanadzoror Federal Service)
- Ministry of industry and trade (MIT)

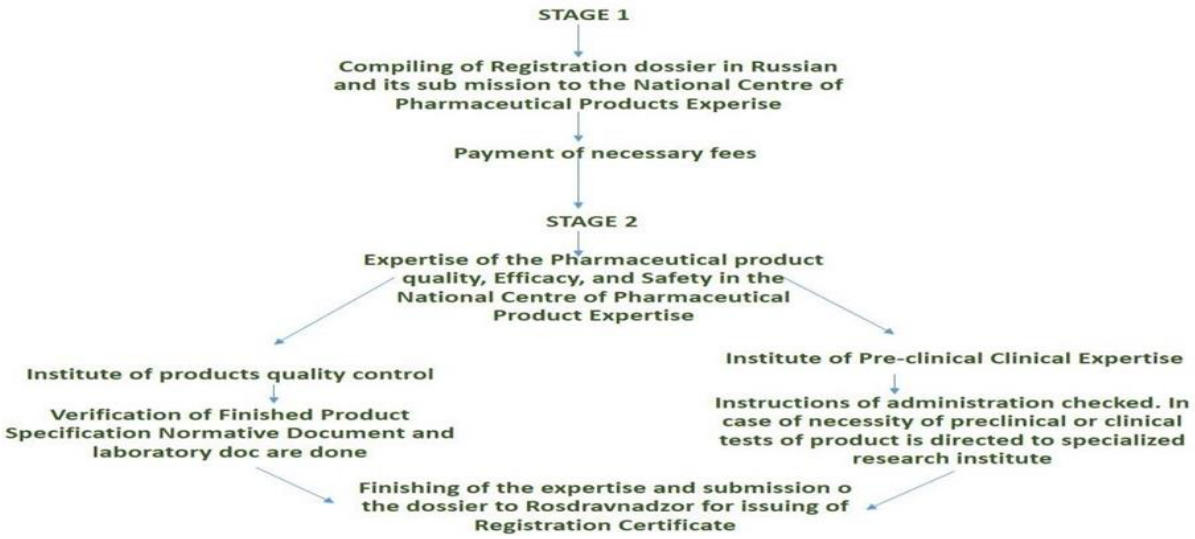
In recent years, Russia's pharmaceutical business has grown at double-digit rates, marking a significant expansion. Market analysts predict that the increasing trend will continue at an even faster rate in light of recent developments. As previously stated, the market was valued at USD 8.6 billion in 2010 and had grown at a compound annual growth rate of 14.2 percent during theprevious four year. In contrast, the compound annual growth rates of the pharmaceutical markets in France and Germany between 2006 and 2010 were just 1.8% and 3.4%, respectively. Although those markets have a greater value ($36 billion and USD 37.9 billion, respectively) than the Russian pharmaceutical industry, Russian producers of pharmaceuticals are steadily working to overtake their European competitors.

Probably, In the next coming years, Russia's pharmaceutical market is expected to rank amongthe top five worldwide in terms of value, according to some estimates. Russia is currently on the verge of emerging as a significant player in the world pharmaceutical industry. Russia is amember of the Commonwealth of Independent States (CIS), a regional organization whose members were former Soviet Republics established following the disintegration of the Union of Soviet Socialist Republics (USSR). The CIS was established in 1991.[25] Regulatory Agencies that work closely with or inside the different Ministries of Health overseeand manage the regulatory procedures in the CIS nations. The entire process might take up to 24 months. The documentation is completed in Russian and follows Russian format specifications. The Russian Federation's certified research organizations conduct the recommended submission of a bioequivalence study. Products that are original and generic both complete the same registration phases. While generic products are free from some registration requirements, original products must go through all of them. For instance, clinicalstudies for the original product are required in Russia.[26]

**Highlights of Russian Pharmaceutical Market-**

The total value of the Russian pharmaceutical market is 15 billion USD.80% of the items in the Russian pharmaceutical market are imported, whereas 20% are produced locally, with lessthan 1% of those being novel. There are 15280 registered pharmaceutical products, of which 13850 are completed goods. A 26% increase in local currency was seen in 2008.OTC productsmake up 70% of the market, while prescription drugs make up 30%. Foreign businesses such as Novartis, J&J, Novo Nordisk, Roche, Sanofi-Aventis, and Nicomed, as well as generic companies like Gedeon Richter and Lek, dominate the industry.

**Chart Shows Schemes of the Registration Process[27]**




## 4. INDIA

### Regulatory requirements for registration of generic drugs in India

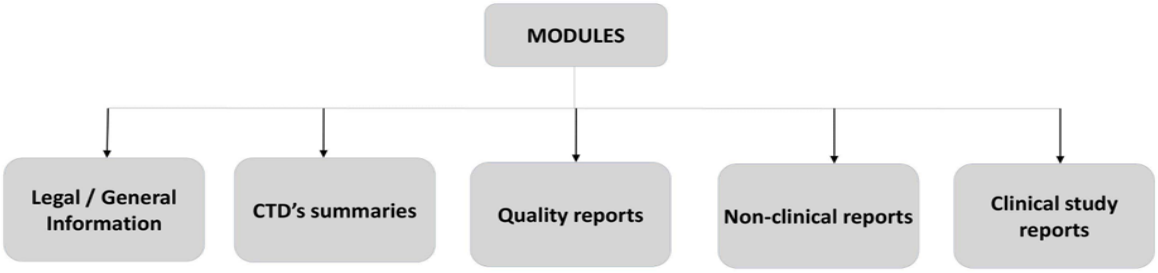
The Central Drug Standards and Control Organisation is under the direction of the Ministry ofHealth and Family Welfare. (CDSCO), administers drug tests; defines standards and procedures to ensure that the nation's supply of medications, cosmetics, devices, and diagnostics is secure, efficient, and of superior quality; The departments of science and technology, commerce and industry, environment and forestry, and finance are also engaged in the regulatory-making process. The drug approval process requires cooperation from other departments in addition to the DCGI, depending on whether the request is for a biological therapy or one based on recombinant DNA technology.[28]

### Registration of Drugs

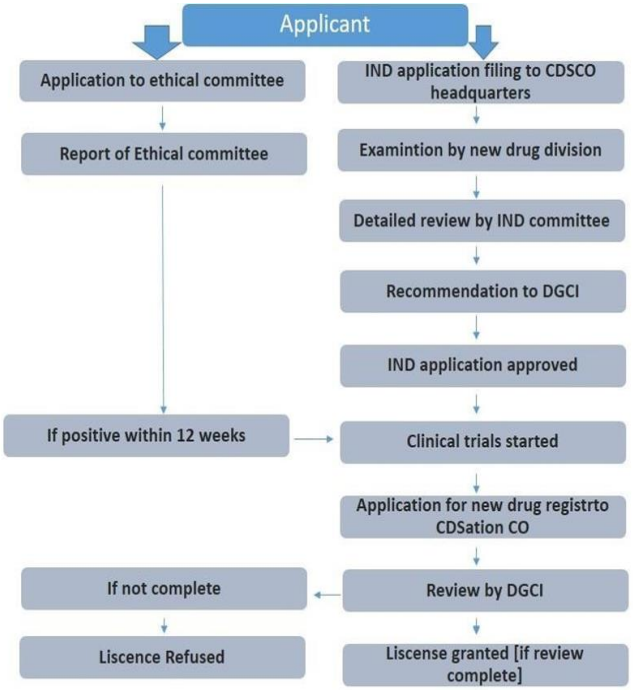
1. In accordance with Schedule Y of the Drugs and Cosmetics Act, 1940, an application has been submitted in Form 44 to the Licensing Authority seeking permission to manufacture thenovel medicine.
2. The information listed in Appendix 1a to Schedule Y, which includes the outcomes of clinical studies conducted in the nation in compliance with the guidelines mentioned in Schedule Y, must be submitted by the manufacturer of a new medication. Once the licensing authority is satisfied that the medicine, if authorised for manufacturing as a finished formulation or as a raw material (bulk drug substance), will be safe and effective for use in thenation, it will issue an approval in Form 46 and/or Form 46A, as the case might be, provided the following requirements are met. As long as the applicant complies with the requirements, which must be met before license is granted, the Licensing Authority will notify them in writing when the data created or supplied about the medicine is insufficient.
3. The applicant needs to show documentation showing the drug for which the application is being submitted has prior authorization. from licensing authority when requesting a license tomanufacture a novel drug or its preparations to the State Licensing Body, from the licensing authority. If the treatment is of a nature that allows the licensing body to decide to issue such clearance in the public interest based on information from other countries, it might not be necessary to submit the results of local clinical trials.[29]

### Registration Requirements for Generic Drugs

Copies of the documentation provided for the registration to the Central Drug Standard Control Organisation are contained in the registration file (or dossier). Beginning in November 2010, India has been creating dossier files in compliance with the globally recognised ICH M4 Common TechnicalDocument (CTD) standard.




**Modules for registering Generic drugs[30]**




**Procedure for generic drug approval in India**.

**5.CHINA**

**Drug Regulatory Authority: State Food and Drug Administration (SFDA)**

China's government declared in March 1998 that the State Pharmaceutical Administration of China (SPAC) and the Ministry of Health's Department of Drug Administration will combineto form the State Drug Administration (SDA). SDA is in charge of all drug production, trade, and registration as a result.[31]

**SFDA:**

The SDA was reorganized in 2003 and is now known as the State Food and Drug Administration (SFDA). Other former ministry responsibilities have been delegated to other governmental entities. One of the most significant of them was the assignment of medical insurance duties to the recently established Ministry of Labor and Social Security. However, the Department of Health maintains its their primary duties like creation and supervision of regulations, the distribution of healthcare resources, and the promotion of medical research andinstruction. Because it eliminated the inconsistent standards that existed among provincial government agencies, centralized the Chinese healthcare regulatory system, and increased transparency, the Chinese government's establishment of a single drug regulatory authority was a significant step toward foreign access. Modern-day SFDA is in charge of advertising and all pharmaceuticals, Western and TCM.

**Drug Registration Procedures**

The papers that are submitted to the State Food and Drug Administration for registration are referred to as the registration file (or dossier). China uses the ICH CTD format for preparing registration files. There are 5 modules in it.

1) Information about administration and prescriptions
2) Standard Technical Document Synopses
3) Superior Reports
4) Reports of nonclinical studies
5) Reports on Clinical Studies.[32]

**6. SOUTH AFRICA**

**Drug Regulatory Authority:** Medical Control Council (MCC)

South Africa has established a globally recognized pharmaceutical regulatory body since the mid-1970s. The Medicines and Related Substances Control Act, 101 of 1965, established the MCC as a legal entity to oversee the guidelines for drugs in South Africa. Its primary goal is to safeguard and protect the public by guaranteeing that all medications that are used and soldin South Africa are safe, therapeutically effective, and continuously satisfy acceptable standards of quality. It is chosen by the Ministry of Health. The MCC employs outside experts who are members of Council Board organizations.[33]

**Process of Registering Drugs**

*It is necessary to submit an application on MRFI for the registration of medications.

*Every page in the application needs to be numbered, printed in a font size that is at least as readable as Arial 10-point dark on white, and copies of all the materials—including tables andphotos—need to be easily readable.


**Medical control Council South Africa**

**Generic drug registration requirements**

Module 1 – Administrative Information

Module 2 - CTD Summaries

Module 3 – Quality

Module 4- Non clinical Study Reports

Module 5 - Clinical Study Reports [34]

## CONCLUSION

The research findings indicate that the global pharmaceutical industry, specifically the fastest-growing and largest emerging markets economies - Brazil, Russia, India, China, and South Africa (BRICS) - is exhibiting positive growth and attracting a growing amount of direct foreign investment. The drug registration process in India is streamlined, and compared to other countries, there are significant differences in the requirements for bioavailability and bioequivalence studies. The disadvantage of Brazil, Russia, and China is that their regulations are written in their native tongues, and the paperwork needed to register drugs should also be translated into those languages. Gaining knowledge of the guidelines and registering requires time. Our best option is to harmonise the guidelines in order to address their disparities. so that a global set of guidelines can be anticipated. Harmonising the guidelines is going to take sometime. But emerging nations like the BRICS will profit once the rules are harmonised. The industry anticipates regulatory harmonisation with ICH formation, making filing simpler.

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