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REGULATORY REQUIREMENTS FOR REGISTRATION OF GENERIC DRUGS IN "BRICS" COUNTRIES

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Abstract:

The purpose of the study was to compare generic drug registration process and to find out the differences, lacunae among the guidelines. Brazil, Russia, India, China and South Africa are typically rendered as "the BRICS" or "the BRICS economies". The registration process for Brazil and Russia are completely different. Even though India, China and South Africa follow the CTD format the requirements for Module 1 are different. It can be concluded that the world pharmaceutical economy, the fastest growing and largest emerging markets economies of Brazil, Russia, India, China and South Africa (BRICS) countries are showing positive growth and increasing direct foreign investment by creating significant opportunities for pharmaceutical companies to expand into these markets. They would be the largest entity on the global stage. To rectify the differences of the guidelines, we need to go for harmonization. So that we can expect a common guideline worldwide. It will take time to harmonize the guidelines. But once harmonized the guidelines, emerging countries like BRICS will get benefit. With ICH formation, the industry foresees harmonization of regulations, so that we can do filing easily. In the interest of industry, we are opinion that all regulations are harmonized and unified regulations are emerged.

Keywords: *Regulatory Requirements, Registration Process, Brazil, Russia, India, China and South Africa (BRICS), Generic Products.*

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INTRODUCTION:

A Marketing authorization (MA) is a Process of reviewing and assessing the dossier to support a medicinal product which is approved by the regulatory authority of a country. A Marketing Authorization, which has been issued by regulatory authority for a product, allows the holder to sale the product in the market. Medicines meeting the standards of Safety, Quality and Efficacy are granted "Marketing Authorization" in order to be prescribed or sold. This authorization covers all the main activities associated with the marketing of a medicinal product. The drug that is granted by marketing authorization is then said to be "licensed", "approved" or "registered [1]".

Why Drug Registration is required [2]?

- The primary aim of drug regulation and registration is to protect public health.
- Medicines are not normal "commodities"; they meet fundamental health needs, and access to essential medicines, according to the World Health Organization, is a fundamental human right. Thus, medicines have additional social value.
- In addition to the quality, safety and efficacy requirements, therefore, these are the arguments for regulating the pharmaceutical industry more generally, and controlling what it supplies.

Process of drug registration for Generic products

The process of registration for generic products is similar to, the process of registration of New Chemical Entities (NCEs). For a new generic product, a company develops a dossier that contains data primarily about the pharmaceutical chemistry of the product. The assumption is that an innovator product exists (usually in the same market) and that the innovator has been shown to be clinically effective and safe (although in poorly controlled markets this may not be the case). The data for the generic product is therefore designed to establish that it is clinically interchangeable with the innovator in terms of efficacy and safety [3].

BRICS countries [4]

BRICS comprises the developing markets of Brazil, Russia, India, China and South Africa which are all deemed to be at a similar stage of newly advanced economic development. It is typically rendered as "the BRICS" or "the BRICS economies"

Reasons for the emergence of BRICS market:

- Decline in the growth rate of the developed pharmaceutical market in developed nations.
- Decline in R & D productivity.
- Availability of patient population in emerging markets.
- R & D resources availability.
- Changing regulatory and investment environment for the research.

The BRICS are both the fastest growing and largest emerging markets economies. As of 2012, the five BRICS countries represent almost 3 billion people, with a combined nominal GDP of US$13.7 trillion, and an estimated US$4 trillion in combined foreign reserves. Presently, India holds the chair of the BRICS group. On almost every scale, they would be the largest entity on the global stage. These five countries are among the biggest and fastest growing emerging markets.

Generic drug [5]

Generics are defined as "a drug product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use".

- A generic medicine contains the same active ingredient as a prescription medicine that is no longer protected by patent.
- Generic drug is bioequivalent to that of brand drug.

METHODOLOGY:

Criteria for selection of study parameters: As the generic drug registration in BRICS countries is a sequential process, four parameters are selected for the understanding and studying the regulatory requirements.

Part-I: Requirement for filing application:

Application for generic drug registration should be in local language of country in which we need registration of generic drug.

Part-II: Documents and study information required for submission:

To collect the information about the extent of information and data is one of the most important parts of any kind of regulatory submission.

a) Legal documents: GMP certificate, Letter of Authorization, Certificate of Pharmaceutical product (COPP), Free Sale Certificate (FSC) should be notarized.

b) Pharmaceutical information: Normative documentation contains main pharmaceutical information in BRICS countries dossier, which needs to be filed in local language only.

c) Bioequivalence study information: Literature search have to be included.

Part-III: Dossier compilation and submission:

During compilation and submission, certain parts needs to be filed in local languages or translated to the local language from original documents as per country regulatory requirements. After translation the documents should be notarized.

Part-IV: Bioavailability and Bioequivalence study information:

During conducting Bioequivalence study, it should be conduct in according to their national regulatory legislations and the various differences like statistical application, study population, the fasting and fed conditions, etc. in the study pattern of the Bioequivalence study in BRICS countries.

DISCUSSION OF VARIOUS REGULATORY REQUIREMENTS:

BRAZIL: (ANVISA) Agencia Nacional de Vigilancia Sanitaria

On December 31, 1998 the Brazilian President signed a provisional measure that created ANVISA and established a new user fees structure for companies and products registration. The user fees and new certification rules affect medical devices and equipment, pharmaceuticals and food products.

DRUG PRODUCT REGISTRATION [5,6]

Generic Medicine- a medicine similar to a reference or innovator product which is claimed to be interchangeable with it, generally produced after the expiration or waiver of patent protection or of other exclusiveness rights, its efficacy, safety and quality being proven, and designated by CBD (Common Brazilian Denomination) or, failing this, by the CID (Common International Denomination).

- For registering a drug product in Brazil, one has to be requested by the local office of the foreign company, or its agent (distributor).
- The product registration is valid for five years and can be renewed continuously for the same period.
- According to the law, the registration process shall be complete within 180 days.
- The documentation presented for registration, alteration or revalidation of the registration will be assessed by ANVISA, which will issue its decision through publication in the Federal Government Gazette (DOU – Diario oficial da Uniao).
- The assessment of the documentation will be undertaken within the legal conditions and periods stipulated in Brazilian sanitary legislation.
- In order to request an alteration to the registration of the medical product, the manufacturer or importer should submit at least the documentation stipulated in Resolution-RDC nº185/01, completed, together with the other documents required for the original registration of the product whose information has been modified Drug Registration Requirements.

POST-REGISTRATION MEASURES [6]

After publication of the registration, the generic medicine manufacturer must supply ANVISA with:

1. Proof of distribution of the first three batches manufactured, to allow ANVISA, if it wishes, to collect samples for control analysis;
2. Results and final evaluation of the long-duration stability study of the first three batches produced, in accordance with the timetable approved by ANVISA. In the case of registered medicines, whose stability study does not conform to the description in the guide to the carrying out of stability studies, a fresh study must be presented;
3. Report on the incidence of adverse reactions and therapeutic inefficacy;
4. The company must produce evidence of the start of sales of this medicine, by submitting a copy of three bills of sale to ANVISA, preferably within 1 year of thedate of publication of registration of the generic medicine in the DOU, in order to update the list of generic medicines sold, which must be available at pharmacies and drug stores, in accordance with specific legislation;

5. Official laboratories are exempted from presentation of the bills of sale, but they must produce evidence of production and distribution of the medicines.

REGISTRATION REQUIREMENTS

- Technical information of the API.
- Pharmacodynamic; Pharmacokinetics.
- Quality control of all raw materials used.
- Quality control of finished product.
- All documents should be addressed in hard copy signed on the final page and initialed on every page by the technician responsible for the company. Add a copy of all technical reports recorded on diskettes or CD-ROM in doc extension files or in any extension acceptable to ANVISA.
- Transfer of methodology to execute local product release.

RUSSIA: (ROSZDRAVNADZOR)

(Federal Service on Healthcare and Social Development Supervision) [6,7]

Russian federal government, healthcare issues fall within the competence of the Ministry of Healthcare and Social Development (Ministry of Health) and subordinated to it, the Federal

Service on Healthcare and Social Development Supervision (Federal Health Service or Roszdravnadzor). The Ministry of Health defines state policy and issues administrative healthcare regulations relating to the production, quality and distribution of pharmaceuticals. The Federal Health Service (Roszdravnadzor) performs the control and supervisory functions of this process. In accordance with the Federal Law on Pharmaceuticals No. 86-FZ of June 22, 1998, which later became known as the Pharmaceutical Law, as amended on December 18, 2006, the Federal Health Service has primary responsibility for the administrative aspects of medicinal product registration as well as for coordinating the activities of specialized departments and committees within the department [8].

This federal regulation over the production and distribution of pharmaceuticals is performed by:

- State registration of pharmaceuticals.
- Licensing of certain activities related to the distribution of pharmaceuticals.
- Review of experts engaged in the sphere of circulation of pharmaceuticals.
- Expert review and certification of certain activities related to pharmaceutical product development and distribution.
- State control over the production, preparation, quality, safety and effectiveness of pharmaceuticals.
    - State regulation of pharmaceutical pricing

State Russian Regulatory Authorities

State Regulatory Authority is called Federal Service on Supervision in Sphere of Public Health Services and Social Development (Roszdravnadzor). Roszdravnadzor takes the decision to register the product and issues Registration Certificate. The expertise of all pharmaceutical products quality, efficacy and safety is done by National Center of Pharmaceutical Products Expertise (FGU). Only this National Center is authorized to execute independent expertise especially for Roszdravnadzor.

National Center of Pharmaceutical Products Expertise consists from different Sections and Institutes. Applicants for products registration submit registration documents directly to National Center. The registration procedure is organized in the way that regulatory affairs specials must communicate with experts every week.

DRUG REGISTRATION-CONCEPTION

To enter into Russian market all pharmaceutical products must be registered.

The Registration Certificate is issued on the basis of quality, efficacy and safety then the product is introduced in the database of registered products in Russian Federation. From 2008 Registration Certificate is unlimited. But before this date Registration Certificates were issued only for 5 years. A big number of already registered products must pass re-registration. Registration Certificate is the same document as Marketing Authorization.

"Administrative Regulations of the Roszdravnadzor on execution of the state function of pharmaceutical products registration" approved by order of Ministry of Health and Social Development of Russian Federation No. 736 dated 30.10.2006.

Pharmaceuticals are produced, imported, sold and used in the Russian Federation only if they are registered with the state authority exercising control over the quality of pharmaceuticals. Presently, these control functions are exclusively in the Federal Health Service, which is an agency subordinate to the Ministry of Health. Domestic and foreign pharmaceuticals enjoy the same treatment for the purposes of registration.

Specifically, the following types of pharmaceuticals are subject to state registration:

- New pharmaceuticals.
- Pharmaceuticals previously registered but produced in other medical forms, in new doses or with other compositions of supplementary substances; and
- Generic pharmaceutical products.

Pharmaceuticals that meet all necessary requirements for registration are entered into the State Register of Pharmaceuticals. The information on registered pharmaceuticals is placed at the official website of the Federal Health Service and is thus in the public domain.

REGISTRATION OF ORIGINAL AND GENERIC PHARMACEUTICAL PRODUCT – STAGES [8]

Registration process conditionally can be divided into 3 basic stages:

Stage I:

Compiling of Registration dossier in Russian and its submission to the National Center of Pharmaceutical Products Expertise (FGU).

Stage II:

Expertise of the pharmaceutical product Quality, Efficacy and Safety in the National Center of Pharmaceutical Products Expertise (FGU).

- Institute of Products Quality Control - ***Quality Control Expertise***
- Institute of Preclinical and Clinical Expertise - ***Efficacy and Safety Expertise***

Stage III:

Finishing of the expertise and submission of the

dossier to Roszdravnadzor for issuing of Registration Certificate [15].

The following information must be presented in the Russian language:

- ✓ Data about the manufacturer (including the organization authorized to accept claims from consumers)
- ✓ Country of origin
- ✓ Trademark
- ✓ Net weight or quantity
- ✓ Composition
- ✓ Nutritional value based on the specificity of the product
- ✓ Storage conditions
- ✓ Use-by date or shelf-life expiration date
- ✓ Regulatory or technical documents with which the products can be identified[16]

INDIA: Central Drug Standard Control Organization (CDSCO)

DRUG REGULATORY AUTHORITY [9,10]

It is governed by both Centre and State Governments under the Drugs & Cosmetics Act, 1940.

Under the Drugs and cosmetics act, the regulations of manufacture, sale and distribution of drugs is primarily concern of the state authorities while the central authorities are responsible for approval of new drug, clinical trials in the country, laying down the standards for drugs, control over the quality of imported drugs, coordination of the activities of state drug control organizations and providing expert advice with a view of bringing about uniformity in the enforcement of Drugs and Cosmetics act.

Drugs controller general of India is responsible for approval of licenses of specifies categories of drugs such as blood products, IV fluids, Vaccines and Sera.

Central Drug standard Control Organization (CDSCO) is located at the Nirmalbhawan, Newdelhi, 110011 and functions under Directorate General of Health Services.

DRUG REGISTRATION

1) An application for the grant of approval to manufacture the new drug and its formulations or to undertake clinical trial have be made in Form 44 to the Licensing Authority as per Schedule Y of the Drugs and Cosmetics Act, 1940.

- ➢ Provided that where the application is for permission to import a new drug (bulk drug substance) and grant of approval to manufacture its formulation/s.

- ➢ Provided further that where a subsequent application by the same applicant for that drug, whether in modified dosage form or with the new claims, is made.

2) The manufacturer of a new drug shall submit data as given in Appendix 1a to Schedule Y including the results of clinical trials carried out in the country in accordance with the guideline specified in Schedule Y and submit the report of such clinical trials in the same format given in Appendix II to the said Schedule.

The Licensing authority after being satisfied that the drug if approved to be manufactured as raw material (bulk drug substance) or as finished formulation shall be effective and safe for use in the country, shall issue approval in Form 46 and/or Form 46A, as the case maybe, subject to the conditions stated therein:

Provided that the Licensing Authority shall, where the data provided or generated on the drug is inadequate, intimate the applicant in writing, and the conditions, which shall be satisfied before permission could be considered.

3) When applying for approval to manufacture a new drug or its preparations, to the State Licensing Authority, an applicant shall produce along with his application, evidence that the drug for the manufacture of which application is made has already been approved by the Licensing Authority.

Submit the results of local clinical trials may not be necessary if the drug is of such nature that the Licensing Authority may, in public interest, decide to grant such permission on the basis of data available from other countries: Provided further that the submission of requirements relating to Animal Toxicology, Reproduction studies, Teratogenic studies, Perinatal studies, Mutagenicity and Carnicogenicity may be modified or relaxed in case of new drugs approved and marketed for several years in other countries if he is satisfied that there is adequate publish evidence regarding the safety of the drug, subject to the other provisions of these rules.[18]

GENERIC DRUG REGISTRATION REQUIREMENTS

Registration file (or dossier) represents the documents submitted to Central Drug Standard Control Organization for registration. India began to follows the international acceptance format of ICH M4 Common Technical Document (CTD) for compilation of dossier file from November 2010. [10]

It contains 5 modules.

- ➢ General Information
- ➢ Common Technical Document Summaries
- ➢ Quality Reports
- ➢ Nonclinical study Reports

Table 1: Labeling of Specific Parameters:

Specific Parameters	Instructions
If it contains a substance specified in Schedule G	—Caution: It is dangerous to take this Preparation except under medical supervision‖
For Narcotic Drugs and Psychotropic Substances	With the symbol of NRx
If it contains a substance specified in Schedule X	—Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only‖. With the symbol of XRx. The symbol XRx should be in red conspicuously displayed on the left top corner of the label.
If it contains a substance specified in Schedule H.	—Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only‖, with the symbol of Rx on the left top corner of the label.
If the Formulation contains Nimesulide	—Box Warning: Use of Nimesulide should Ordinarily be restricted to 10 days. If longer clinical use is warranted, liver function test Should be assessed periodically.

CHINA: State Food and Drug Administration (SFDA)

DRUG REGULATORY AUTHORITY [11]

In March 1998 the government of China was announced the Ministry of Health's Department of Drug Administration merged with the State Pharmaceutical Administration of China (SPAC) to become the State Drug Administration (SDA). As a result, SDA oversees all drug manufacturing, trade, and registration.

SFDA:

In 2003, the SDA was restructured to become the State Food and Drug Administration (SFDA). Other former functions of the ministry have been assigned to different government bodies. The most important of these was the transfer of medical insurance responsibilities to the new Ministry of Labor and Social Security. Nonetheless, the Ministry of Health retains its other main functions-regulatory development and oversight, healthcare resource allocation, and medical research and education. The Chinese government's establishment of a single drug regulatory authority was an important step toward foreign access, because it eliminated the conflicting standards that prevailed among provincial government agencies, centralized the Chinese healthcare regulatory system, and made it more transparent. SFDA now oversees all medications-both Western and TCM-as well as advertising [22].

DRUG REGISTRATION REQUIREMETNS

Registration file (or dossier) represents the documents submitted to State food and drug administration for registration. China for preparation of registration files it follows ICH CTD format. It contains 5 modules[12]:

1) Administrative information and prescribing information
2) Common Technical Document Summaries
3) Quality Reports
4) Nonclinical study Reports
5) Clinical study Reports

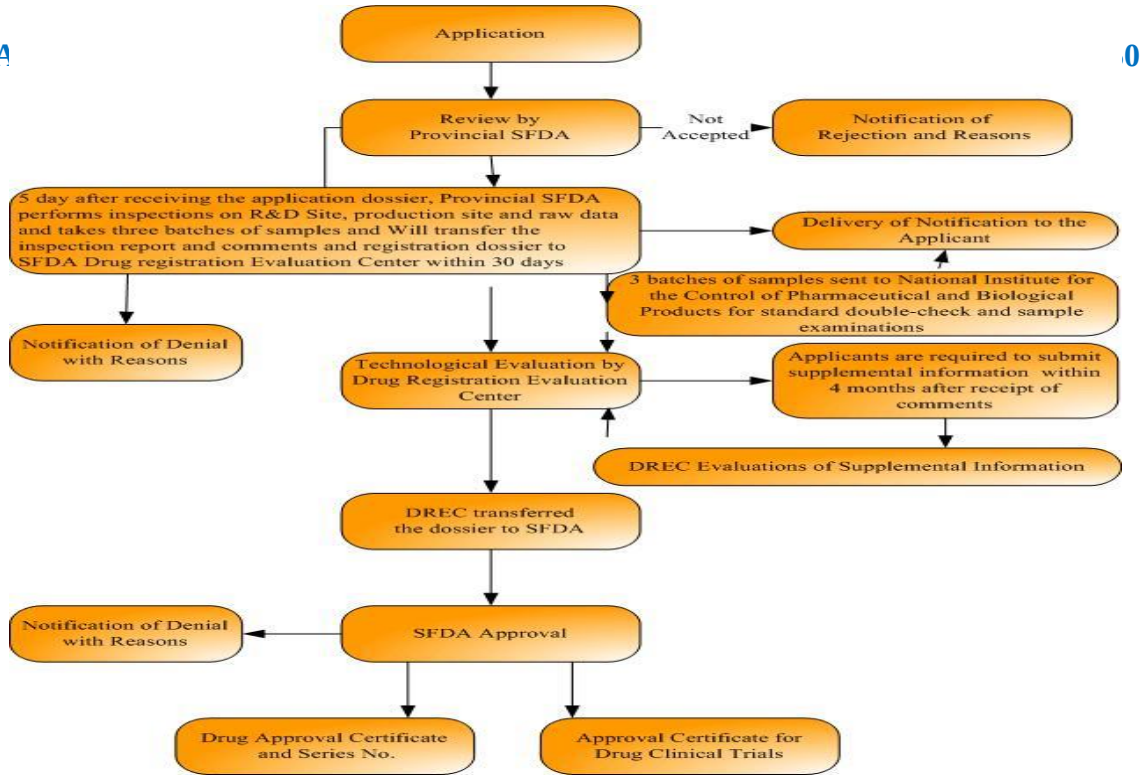

Fig 1: Flow Chart for Generic Drug Registration [16]

SOUTH AFRICA :(MCC) (MEDICINES CONTROL COUNCIL)
DRUG REGULATORY AUTHORITY [13]

Since the early 1970"s South Africa has developed a medicines regulatory authority that is internationally recognized. The MCC is a statutory body that was established in terms of the Medicines and Related Substances Control Act, 101 of 1965, to oversee the regulation of medicines in South Africa. It is appointed by the minister of Health and its main purpose is to safeguard and protect the public through ensuring that all medicines that are sold and used in South Africa are safe, therapeutically effective and consistently meet acceptable standard of quality. The MCC operates through external experts who are members of Council Committee structures. Most experts evaluate data sets submitted by the pharmaceutical industry for purposes of registration [28].

Fig 2: MCC Structure

GENERIC DRUG REGISTRATION REQUIREMENTS [13]

Module 1 – Administrative Information
Module 2 - CTD Summaries
Module 3 - Quality
Module 4- Non clinical Study Reports
Module 5 - Clinical Study Reports

RESULTS AND DISCUSSION:

The critical relationship between evolving BRICS healthcare climates and pharmaceutical markets; and the best strategies to boost growth in each of the emerging markets.

The generics share has increased to over 70% and growing, while CAGR (Compound Annual Growth Rate) in developed countries for Pharmaceuticals has flattened. In order to drive or even maintain profit margins, manufacturers must therefore seek new opportunities elsewhere.

This leads us to a new trend: the growth of emerging markets, particularly in the BRICS countries (Brazil, Russia, India, China and South Africa). Part of this is driven by demand as a burgeoning middle class emerges.

Brazil offer incentives for the registration of generics and it discount the registration application fee for generic drugs and in addition Brazil offers a shorter evaluation time for generic and similar product.

In India the drug registration process is simplified procedure and the Bioavailability and Bioequivalence study requirements are too different from other country requirements.

On July 10, 2007, China's State Food and Drug Administration (SFDA) promulgated the amended Measures on the Administration of Drug Registration. The Amended Measures are to improve registration procedures by upgrading drug appraisal and approval standards to enhance the focus on drug safety in China. The Amended Measures also call for tighter supervision during the application process, both for products and on-site production.

By 2017 South Africa Regulatory Authority, Medicines Control Council (MCC) going to be replaced with the **South African Health Products Regulatory Authority (SAHPRA).** The arrival of SAHPRA is being viewed positively by industry organizations as this will lead to expediting drug approvals that translates to faster commercialization and speedier returns on investments.

The major challenges in generic drug registration in BRICS Countries are Language barrier and understanding of their regulations.

Language barrier: In case of Russia, Brazil and China total dossier and labeling information has to submit local language only (Russian, Portuguese and Chinese) it would be extra administrative burden for foreign manufacturers.

The future trends of emerging markets of BRICS Countries are rapidly growing and cross the developed countries market share in economy after 2045, so that the new opportunities for pharmaceutical manufacture to invest the money in these countries are very beneficial to improve their global market share.

CONCLUSION:

The purpose of the study was to compare generic drug registration process and to find out the differences, lacunae among the guidelines. Brazil, Russia, India, China and South Africa are typically rendered as "the BRICS" or "the BRICS economies". The registration process for Brazil and Russia are completely different. Even though India, China and South Africa follow the CTD format the requirements for Module 1 are different. It can be concluded that the world pharmaceutical economy, the fastest growing and largest emerging markets economies of Brazil, Russia, India, China and South Africa (BRICS) countries are showing positive growth and increasing direct foreign investment by creating significant opportunities for pharmaceutical companies to expand into these markets. They would be the largest entity on the global stage. The drawback in Brazil, Russia and China are the regulations are in their local languages and the documents required for registration of drugs should translate into their local languages. It takes time to understand the rules and regulations and for registration. To rectify the differences of the guidelines, we need to go for harmonization. So that we can expect a common guideline worldwide. It will take time to harmonize the guidelines. But once harmonized the guidelines, emerging countries like BRICS will get benefit. With ICH formation, the industry foresees harmonization of regulations, so that we can do filing easily. In the interest of industry, we are opinion that all regulations are harmonized and unified regulations are emerged. The information provided above is satisfactorily translated from different languages like Portuguese, Russian and Chinese and compiled in a sequence as a part of my dissertation work.

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