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Original Article

Comparative Overview of Regulatory Pathways for Generic Drug Approval in BRICS Nations

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ABSRACT

Background: The pharmaceutical industry is highly regulated to ensure that the drugs delivered to the public are safe, effective and of good quality of the emerging economies in the world's major economies, BRICs countries, including Brazil, Russia, India, China and South Africa, have an important position in the pharmaceutical industry and the regulations associated with the pharmaceutical industry. **Materials and Methods:** Each country has its own National Regulatory Authority (NRA) that is responsible for laying down and enforcing regulations and guidelines to ensure the safety of public health. The regulatory bodies are responsible for the management and supervision of manufacturing and research activities of pharmaceuticals, approval and authorisation of pharmaceutical products and their regulations by various regulatory mechanisms applied to their day-to-day operations. **Results:** In view of the different regulations and requirements of submitting dossiers and evaluating in different countries, pharmaceutical companies face the challenges of getting simultaneous market approval of the same drug in different countries. Regulatory each drug must meet the regulatory requirements of the country where the drug is made or to be supplied. In Brazil, in order to comply with the regulations and needs of the ANVISA authority, Bioequivalence studies need to be conducted with Brazilian investigators from clinical trial that are approved and recognized by the authority. Nevertheless, it has been seen that the regulatory processes are slowly developing towards harmonization. **Conclusion:** For example, Russia has adopted the European Union-like procedures regarding dossier submission. South Africa has implemented the electronic version of the Common Technical Document (eCTD). It has been noticed that there is a constant change in the regulatory processes, which could open up opportunities in future.

Keywords: Bioequivalence Studies, BRICS Countries, Dossier Submission, Generic Drugs, National Regulatory Authorities, Regulatory Framework.

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INTRODUCTION

Generic medicines play a crucial role in enhancing access to affordable healthcare across the world, especially in emerging economies. Generic drugs are pharmaceutical products with the same strength, active ingredient, dosage form, route of administration and intended use as an innovator (reference) drug, and are approved based on demonstrated efficacy, quality, safety and bioequivalence. Regulatory frameworks governing generic drugs ensure that these medicines meet internationally accepted standards while remaining cost-effective alternatives to branded products.

The BRICS nations (Brazil, Russia, India, China, and South Africa) are among the largest pharmaceutical markets in the world, and they are also some of the largest producers and consumers of generic medicines. Each country has developed its own regulatory system for approving, manufacturing, and monitoring generic drugs, taking into consideration the country's health care needs with international standards of regulation, including the International Council for Harmonization (ICH) and the World Health Organization (WHO).

Overall, the generic drug frameworks in BRICS countries aim to balance drug quality, patient safety, regulatory efficiency, and affordability. Continuous regulatory reforms, harmonization initiatives, and adoption of international best practices have strengthened the role of BRICS nations in supporting global access to essential medicines through high-quality generic drug production.

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The BRICS Nations Each country has a main regulatory authority that oversees pharmaceutical regulations (Table 1). They act as gatekeepers to provide you with access to the market.[1,2]

GENERIC DRUG APPROVAL PROCESS IN BRAZIL (ANVISA)

The Agência Nacional de Vigilância Sanitária (ANVISA), which was founded on 26 January 1999, acts as the main regulator under the supervision of Brazil, with its main office being based in Brasília and employing over 2200 staff, with a huge budget. As the main regulatory body for the country, the drug approval process for pharmaceutical drugs entails the submission of comprehensive documentation regarding the pre-clinical, clinical, and quality data before a stringent scientific evaluation (Figure 1). ANVISA inspects the manufacturing plant and ensures that it meets the Good Manufacturing Practices (GMP). In addition, once the drug has been approved, pharmacovigilance activities, which involve the continuous monitoring of the ADRs, is carried out by the regulatory agency. At an international level, the agency is one of the renowned agencies and works alongside other organizations such as the WHO and ICH of Technical Requirements for Pharmaceuticals for Human Use.[3,4]

LEGAL AND REGULATORY BASIS

Generic drugs in Brazil are regulated under the Law No. 3,960/1976 (Vigilância Sanitária Law), which requires all pharmaceutical products to be listed with the Ministry of Health before commercialization. ANVISA, created by Law No. 9,782/1999, is the authority responsible for evaluating and granting marketing authorizations. The current main regulatory standard for generic drug registration is Resolution RDC No. 753/2022**,** which sets out requirements for synthetic and semi-synthetic medicines, including generics.

SEP-BY-STEP APPROVAL PROCESS

Pre-Submission Preparation

The applicant (local company or authorized partner of a foreign holder) needs to be registered with ANVISA to apply for the electronic Peticionamento system. Determine if the reference (innovator) drug is listed in ANVISA's database with the same strength and form. If the drug is not listed, the company may apply for the selection of a reference drug prior to submitting the application. Prepare the application using ANVISA's checklist for generic drug applications, as defined under RDC No. 753/2022.

Dossier Submission (Peticionamento)

The marketing authorization application (Dossier) needs to be submitted electronically using ANVISA's Peticionamento System with the correct "Código de Assunto" for generic applications. The application should include all necessary documents (quality, safety, identity, and efficacy) such as certificates, labeling, and studies, as per the checklist (Table 2). Foreign documents should include sworn translations if necessary. The regulatory fees (TFVS - Taxa de Fiscalização de Vigilância Sanitária) should be paid, generated at the end of the submission process. The application is then protocolized with ANVISA after payment is made.

Technical Evaluation

After filing the dossier, ANVISA undertakes a technical evaluation on the following

Quality and Pharmaceutical Documentation:

- Chemistry, manufacturing, and controls are reviewed, including the formulation, specifications, stability, and manufacturing process (Table 3).

Bioequivalence and Therapeutic Equivalence:

- For generic products, bioequivalence with the reference product is necessary, and this is done through *in vivo* and *in vitro* studies. Bioequivalence studies are done in certified centers and are part of the submitted dossier.

Labeling and Package Review:

- Product information, labeling, and packaging artwork are reviewed and must comply with the regulations, which include the mandatory identification of the generic product with the phrases "Medicamento Genérico" and the yellow stripe (Table 6).

CLARIFICATIONS AND DEFICIENCY RESPONSES

During the process, ANVISA may issue a list of requirements or a clarification in the following situations: If the submitted dossier is incomplete with regard to the necessary documentation and study data. The applicant is required to respond within the given time period set by ANVISA. Only one clarification is issued in the process to facilitate the applicant and the agency. The applicant is required to respond within the given time period set by ANVISA.

FINAL DECISION AND PUBLICATION

After technical review and resolution of questions: If approved, ANVISA issues the marketing authorization, allowing the product to be marketed.the approval is published in the Diário Oficial da União (DOU), which is the official federal gazette; publication in the DOU is the formal confirmation that the generic can be commercialized nationwide. If ANVISA determines the dossier does not meet requirements, the application may be denied.[5-7]

RUSSIA

Drug Registration in Russia is administered by the Ministry of Health, which is responsible for issuing of the Final Marketing Authorizations (FMAs). Roszdravnadzor (Federal Service of Surveillance for Healthcare), an independent federal service under

the Ministry of Health is responsible for conducting inspections and post-market follow-up for drugs once they are on the market. To these ends, Russia's regulatory system has harmonised with the Eurasian Economic Union's (EAEU) Harmonisation of Drug Regulations initiative (Figure 2). The purpose of this initiative is to develop a common market for pharmaceuticals within the EAEU.[8,9]

Generic Drug Approval Process in Russia

INDIA

India's regulatory agency for drug and device regulation is the Central Drugs Standard Control Organisation (CDSCO), located within the Indian Ministry of Health and Family Welfare. The CDSCO is headed by the Drug Controller General of India (DCGI), who has the final authority for approving new medicines and conducting clinical trials (Figures 3, 4). The CDSCO has joint responsibility for decision-making for drug regulation along with the state-level drug control authorities.

This submission is quite dissimilar from the new drug application. In the present application, CDSCO and DCGI may allow the candidate and the controlling authorities to rely on some part of the safety and/or efficacy data for the formerly permitted drug. Additional non-clinical and/or clinical data are required for the assessment of the safety and efficacy of the approved drug for the new claims (Table 4).

The additional data that are required for the evaluation of the safety and efficacy of the new generic drug are determined based on the new claim if the drug is already agreed by various agencies and is marketed in the major countries for the proposed new claim.

However, if the generic drug is able to establish the bio-equivalence and pharmaceutical equivalence of the drug with the approved drug and if the metabolism of the drug is not affected due to ethnic differences (Table 5). The need for reduced or relaxed data for the animal toxicology and clinical data may be reduced or relaxed if the proposed new claim is for a life-threatening disease or a disease of special importance. CDSCO will examine the reasonableness of the application for the granting of permission for the import of these new drugs. The case may be referred for expert or expert committee opinion, if required.[10-12]

Approval process for Drug Substance /Drug Product approved by DCG(I)

CHINA

The National Medical Products Administration (NMPA) is the Chinese regulatory authority for drug, medical devices and cosmetics. The NMPA was previously named the China Food and Drug Administration (CFDA). The NMPA has undergone significant changes since 2015 and has developed new guidelines based on the same objectives that are creating many business opportunities for drug access with the help of the Chinese government.

NMPA is the main regulatory authority for the management of drug registering, the formulation of drug registering conditions, and the organization of drug registration review and sanction.

The Drug Evaluation Center of NMPA (CDE) is responsible for the evaluation of drug clinical trial submissions, drug marketing authorization, supplementary requests, and drug re-registration for abroad manufactured drugs (Figure 5).

In China, who is eligible to register drugs?

The Marketing Authorization Holder (MAH) can apply for drug clinical trials, drug marketing authorization, re-registration and additional requests. Along with these responsibilities, the MAH can perform many other responsibilities.

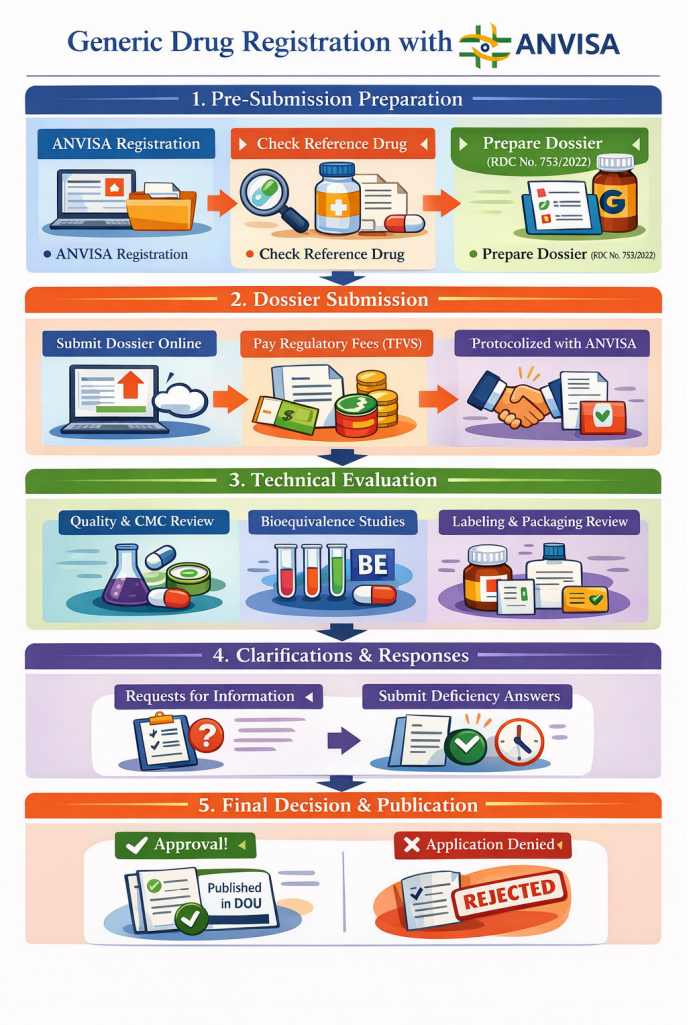

Figure 1: Generic Drug Approval Process in Brazil (ANVISA).

Table 1: Comparative study of bricks region according to regulation.

Parameter	Brazil	Russia	India	China	South Africa
Regulatory Authority	Agência Nacional de Vigilância Sanitária (ANVISA)	Ministry of Health of the Russian Federation / Roszdravnadzor	Central Drugs Standard Control Organization (CDSCO) / Drug Controller General of India (DCGI)	National Medical Products Administration (NMPA)	South African Health Products Regulatory Authority (SAHPRA)
Drug Regulatory Law	Law No. 6,360/1976	Federal Law on Circulation of Medicines	Drugs and Cosmetics Act, 1940 and Rules, 1945	Drug Administration Law of China	Medicines and Related Substances Act
Established Year (DRA)	1999	2004	2009	2018 (restructured as NMPA)	2017
Head of DRA	Director-President	Head / Director	DCGI	Commissioner	CEO
Official Language	Portuguese	Russian	English	Chinese (Mandarin)	English
Marketing Authorization Validity	10 years	5 years	Perpetual (subject to retention fee)	5 years	5 years
Application Form	ANVISA Electronic Petition Form	State Registration Application	Form CTD / Online Form (SUGAM)	NMPA Electronic Application	SAHPRA Application Form
Approval Timeline	9-15 months	12-18 months	12-15 months	12-24 months	12-24 months
Submission Format	CTD / eCTD	CTD	CTD / eCTD	CTD / eCTD	CTD / eCTD
Authorization Holder	Brazilian MAH / Local company	Local MAH	Indian MAH / Authorized Agent	Chinese MAH / Local agent	Local applicant / Authorized representative

Table 2: Comparison of administrative documents in BRICS countries.

Document	Brazil	Russia	India	China	South Africa
Cover Letter	Required	Required	Required	Required	Required
Application Form	ANVISA Electronic Petition Form	State Registration Application Form	Form CTD / Online SUGAM	NMPA Electronic Application	SAHPRA Application Form
Power of Attorney (PoA)	Yes	Yes (Notarized)	Yes	Yes	Yes
CPP (Certificate of Pharmaceutical Product)	Yes	Yes	Yes	Yes (or equivalent Free Sale Certificate)	Yes
GMP Certificate	ANVISA / WHO-GMP	EAEU / WHO-GMP	WHO-GMP	Chinese GMP or WHO-GMP	WHO-GMP
Labels / Artwork	Portuguese	Russian	English	Chinese	English
Package Insert / PIL	Portuguese	Russian	English	Chinese	English
Manufacturing License	Yes	Yes	Yes	Yes	Yes
Site Master File (SMF)	Yes	Yes	Yes	Yes	Yes
Stability Data	Yes	Yes	Yes	Yes	Yes
Bioequivalence Study Report	Mandatory	Mandatory	Mandatory	Mandatory	Mandatory
Local Agent / MAH Authorization	Brazilian MAH	Local MAH	Indian Agent / MAH	Chinese MAH / Local agent	Local applicant

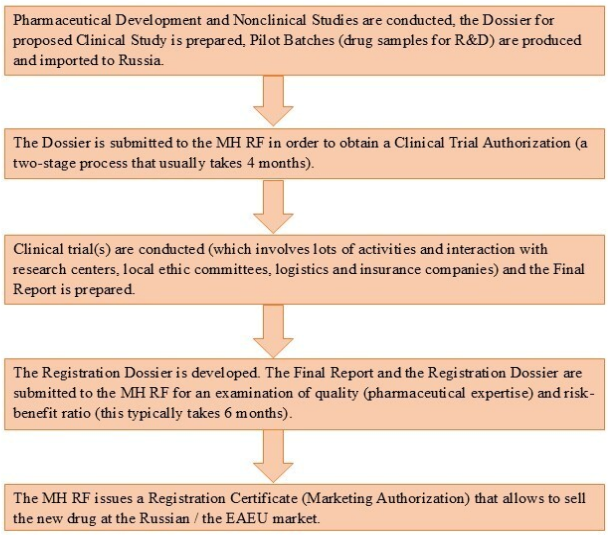

Figure 2: Generic Drug Approval Process in Russia.

Figure 3: Cental Drugs Standard Control Organisation.

Medicinal product registration categories in China

The necessities for the development and registration of the medicinal product in China are further classified into the following categories as Chemical medicine, biological products, Traditional Chinese medicine.

Each of these medicinal product categories is classified into three registration classes, which define the application materials that the candidate must deliver for the registration of the medicinal product, for example, a clinical trial submission, marketing authorization submission, etc.

For the chemical medicines, the registering groups are classified as Innovative drugs, improved new drugs, Generics. For the biologics, the registering groups are classified as Innovative biological products, improved new biological products, marketed biological products (including biosimilars).

The requirements for the submission materials are based on the features of the registered medicinal product, the level of innovation and the administration necessities for the registered medicinal product. The type of drug that a candidate selects in the drug category determines the review and sanction course of the clinical trial application. NMPA is responsible for the review of the clinical trial submission.

The review process of the drug marketing authorization application

The applicant has to submit the application for the drug marketing authorization in accordance with the application requirements after the pre-clinical studies and clinical studies in support of the drug registering. The application materials will be subject to the formal examination. After that, the application will be accepted if it meets the application necessities. The Drug Evaluation Center (CDE) will arrange pharmacy, medical and relevant technical personnel to review the accepted application of drug marketing authorization. The application will be issued with a registration certificate after the conclusion of the comprehensive review. However, if the application fails in the conclusion of the comprehensive review, it will be disapproved.[13]

Table 3: Comparison of technical documents in MENA countries and India

Technical Document Category	Brazil	Russia	India	China	South Africa
CTD Format	CTD / eCTD	CTD	CTD / eCTD	CTD / eCTD	CTD / eCTD
Drug Substance (API) DMF / ASMF	Required	Required	Required	Required	Required
Manufacturing Process (API and FPP)	Required	Required	Required	Required	Required
Specifications and COA (API and FPP)	Required	Required	Required	Required	Required
Pharmaceutical Development (QbD)	Required	Required	Required	Required	Required
Stability Studies	Zone IVb	Zone II / IVb	Zone IVb	Zone II / IVb	Zone IVb
Process Validation	Required	Required	Required	Required	Required
Analytical Method Validation	Required	Required	Required	Required	Required
Bioequivalence Study Report	Mandatory	Mandatory	Mandatory	Mandatory	Mandatory
Dissolution Profile Comparison	Required	Required	Required	Required	Required
Impurity Profile (ICH Q3A/B/C)	Required	Required	Required	Required	Required
Excipients Compatibility Study	Required	Required	Required	Required	Required
Packaging Material Data	Required	Required	Required	Required	Required
Labeling and PIL (Local Language)	Portuguese	Russian	English	Chinese	English
Risk Management Plan (if applicable)	Sometimes	Sometimes	Sometimes	Sometimes	Sometimes
Clinical Study Reports (for Generics)	Not required (BE only)	Not required	Not required	Not required	Not required

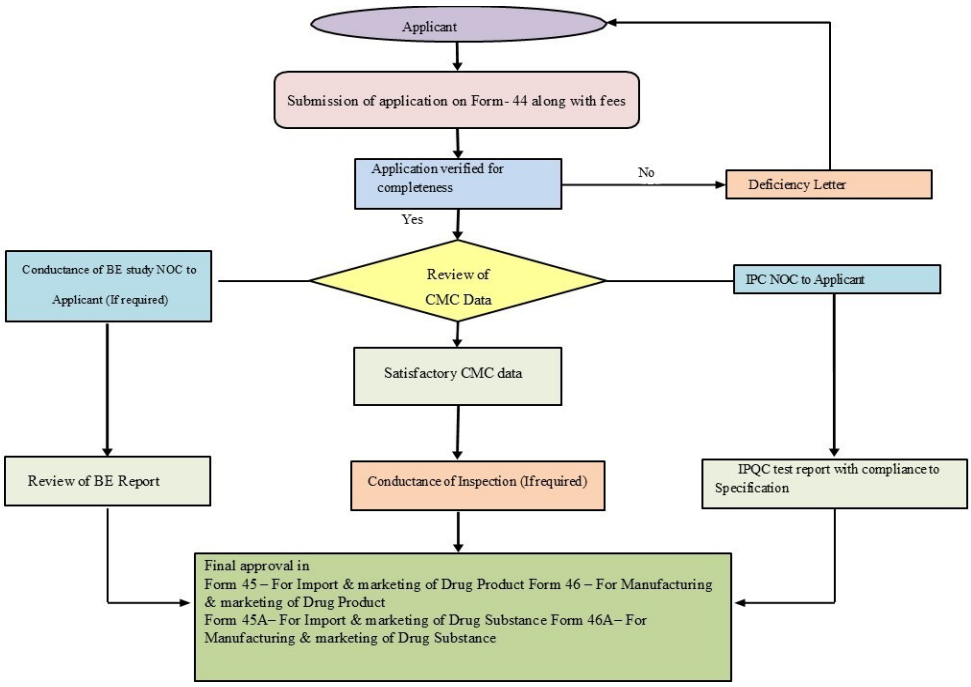

Figure 4: Flow Chart of CDSCO Generic Drug Approval Processes.

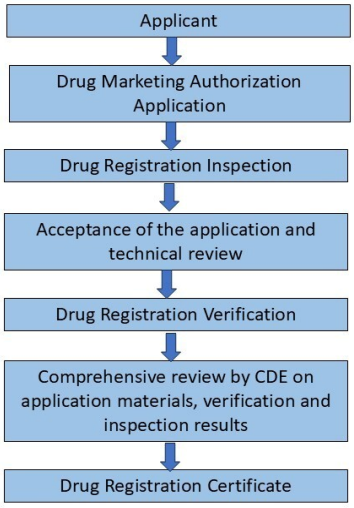

Figure 5: Generic drug approval process in China.

SOUTH AFRICA

The South African Health Products Regulatory Authority (SAHPRA) will supervise the regulation of health products in South Africa, including medicine, medical devices, and IVDs. It is responsible for making FDA-supported fast-tracked approvals. It was founded in 2018 as an authority that replaced the Medicines Control Council (MCC). It is currently busy with the task of catching up on the Application backlog that has been created over the years.

CLASSIFY THE APPLICATION AND SELECT A REVIEW PATHWAY

Determine if it is an NCE, Biological, Generic, Line Extension, or Duplicate

Decide if it will be a Full, Reliance (Abridged), or Precedence review based on existing data and previous sanctions from standard authorities.

Appoint the local authorization holder (HCR) and confirm licences

Propose your South African Legal Entity as Holder of Certificate of Registration. Confirm that relevant manufacturing/wholesale licenses and GMP documentation are in place.

Map your data strategy

NCEs/Biologics: Align nonclinical/clinical data to CTD. Generics: Define your BE plan (design, endpoints) and Stability Program (Long Term/Accelerated) in line with ICH aligned practice referenced in SAHPRA guidelines.

Choose the format: eCTD + ZA Module 1

SAHPRA eCTD + ZA-specific Module 1 and regional sections 2.3R/3.2R. Build the full CTD package:

Module 1 (ZA): forms, fee payment proof, HCR details, labeling (PI/PIL), risk management, PV details.

Module 2: QOS and overviews.

Module 3-5: CMC, non-clinical/clinical or BE.

Authoring and publishing

Use the ZA level of detail, nomenclature convention and life cycle terminology. Build the clean order with the proper proposal type and submission details. Use the latest General/Module 1 direction to avoid directorial screen-outs.

026538/Validation of the eCTD package technically

Use the ZA eCTD Validation Criteria in your validator and resolve all critical/major issues. For Variations and follow-up sequences, use the SAHPRA Validation Template as a guide, mirroring the verification the regulator performs upon receipt of the application.

Payment of fees and electronic submission

Pay the application fee applicable. Insert this in the eCTD in Module 1. Submit the application through the SAHPRA eSubmission channel according to the ZA eCTD specification.

Administrative screening

SAHPRA checks the format, completeness, forms, fees, labelling and existence of the Module. This leads to screening questions, which are cleared through a new order using the question log.

Table 4: Non-clinical document comparison in BRICS countries.

Non-Clinical Document Requirement	Brazil	Russia	India	China	South Africa
Pharmacology (General and Safety)	Usually not required for generics	Not required for generics	Required	Not required for generics	Not required for generics
Pharmacokinetics (ADME)	Not required for generics	Not required for generics	Required	Not required for generics	Not required for generics
Toxicology (Single / Repeated Dose)	Not required for generics	Not required for generics	Required	Not required for generics	Not required for generics
Genotoxicity / Carcinogenicity	Not required for generics	Not required for generics	Required	Not required for generics	Not required for generics
Reproductive Toxicity	Not required for generics	Not required for generics	Required	Not required for generics	Not required for generics
Non-Clinical Summary (CTD Module 4)	Not required	Not required	Yes	Not required	Not required
Local Language Summary (Module 2)	Portuguese (if submitted)	Russian (if submitted)	English	Chinese (if submitted)	English
Acceptance of Foreign Non-Clinical Data	ICH / SRA accepted	ICH / EAEU / OECD accepted	ICH / SRA accepted	ICH / SRA accepted	ICH / SRA accepted
Animal Species / Study Standards	ICH / OECD	ICH / OECD	OECD	ICH / OECD	OECD

Table 5: Clinical documents comparison in BRICS countries.

Clinical Document Requirement	Brazil	Russia	India	China	South Africa
Clinical Overview and Summary (CTD Module 5)	Required mainly for NCEs / complex generics	Required mainly for NCEs	Yes	Required mainly for NCEs / complex generics	Required mainly for NCEs
Clinical Study Reports (CSR)	Required for NCEs; not for simple generics	Required for NCEs; not for generics	Yes	Required for NCEs; not for simple generics	Required for NCEs; not for generics
Bioavailability / Bioequivalence (BA/BE)	Required (BE mandatory)	Required (BE mandatory)	Required (BE mandatory)	Required (BE mandatory)	Required (BE mandatory)
Foreign Clinical Data Acceptance	ICH / SRA accepted	ICH / EAEU / SRA accepted	ICH / SRA accepted	ICH / SRA accepted	ICH / SRA accepted
Local Clinical Trials for Generics	Not required	Not required	Not required	Not required	Not required
Ethics Committee Approval (for BE studies)	Yes	Yes	Yes	Yes	Yes
Informed Consent Forms (ICF)	Yes	Yes (Russian)	Yes (English)	Yes (Chinese)	Yes (English)
Patient Information Leaflet (PIL)	Portuguese	Russian	English	Chinese	English
Good Clinical Practice (GCP) Compliance	ICH-GCP	ICH-GCP	ICH-GCP	ICH-GCP	ICH-GCP

Table 6: General requirements for labelling in BRICS countries.

Labeling Parameter	Brazil	Russia	India	China	South Africa
Brand / Proprietary Name	Yes	Yes	Yes	Yes	Yes
Generic / INN Name	Yes	Yes	Yes	Yes	Yes
Pharmacological Category	Required	Required	Required	Required	Required
Dosage Form	Yes	Yes	Yes	Yes	Yes
Strength	Yes	Yes	Yes	Yes	Yes
Route of Administration	Yes	Yes	Yes	Yes	Yes
Batch / Lot Number	Yes	Yes	Yes	Yes	Yes
Manufacturing Date	Yes	Yes	Yes	Yes	Yes
Expiry Date	Yes	Yes	Yes	Yes	Yes
Storage Conditions	Required	Required	Required	Required	Required
Warnings / Precautions	Yes	Yes	Yes	Yes	Yes
Manufacturer's Name and Address	Yes	Yes	Yes	Yes	Yes
Importer / MAH Information	Yes	Yes	Yes	Yes	Yes
Product Registration Number	Yes	Yes	Yes	Yes	Yes
Barcode / Serialization	Required (Brazilian track and trace system)	Required for certain products	Optional (moving toward serialization)	Required for certain product classes	Optional / recommended
Mock-up / Artwork Approval	Required	Required	Required	Required	Required
Language Requirements	Portuguese	Russian	English	Chinese	English

Figure 6: Generic drug approval process in South Africa.

Scientific assessment

Full review: CMC, nonclinical, clinical, etc.

Proof of sanction and arrangement of the reference authority is required; SAHPRA is concerned with the local context.

Queries and responses

Quality, clinical, BE, labelling, etc., questions are expected. Response is required within time limits; only modified or new docs are submitted with a summary of the response, and the lifecycle is followed.

Approval and certification

A Certificate of Registration is issued by SAHPRA upon approval (Figure 6), the final PI/PIL and scheduling are included. Only the registered info is marketed.[14,15]

DISCUSSION

Each of the BRICS countries has its own way of regulating generic drug approval, making it difficult to simultaneously enter these markets. The drug companies must strictly adhere to these specific regulations of each country, including Good Manufacturing Practices and bioequivalence study requirements. For example, in Brazil, bioequivalence studies must be conducted among Brazilian subjects at ANVISA-approved clinical trial

centers. The regulations in BRICS countries' jurisdictions are slowly moving towards harmonization. For example, Russia has adopted dossier submission regulations as per European Union regulations, whereas South Africa has adopted the electronic Common Technical Document (eCTD) format.

CONCLUSION

The drug registration process is an important aspect that guarantees the efficacy, safety and quality of drugs before they finally reach the market. The sanction process and the components of the drug dossier are vital aspects that need to be understood before the approval process is a success. Although the ICH CTD format has made the drug registration process easier, the country's regulatory bodies have their own set of rules, including GMP certification, labeling, stability, and pricing issues, which need to be taken into account during the approval process. Thus, a well-prepared drug dossier is the only way to success in the drug registering process. Better coordination between the country's regulatory bodies and the pharmaceutical industry will also help the approval process in the future. Although BRICS routes all have a similar scientific basis, the disparities in their approval processes, use practices, and domestic guidelines pose both obstacles and benefits. Successful management hinges on timely regulatory intelligence, dossier preparation consistency, and flexible submission strategies, thereby reducing time to market and ensuring adherence to regulations within these rapidly developing economies.

ABBREVIATIONS

ADRs: Adverse Drug Reactions; **ANVISA:** Agência Nacional de Vigilância Sanitária; **API:** Active Pharmaceutical Ingredient; **BRICS:** Brazil, Russia, India, China, and South Africa; **CDE:** Drug Evaluation Center; **CDSCO:** Central Drugs Standard Control Organisation; **CPP:** Certificate of Pharmaceutical Product; **CTD:** Common Technical Document; **DCGI:** Drug Controller General of India; **EAEU:** Eurasian Economic Union; **eCTD:** electronic Common Technical Document; **FMAs:** Final Marketing Authorizations; **GMP:** Good Manufacturing Practices; **ICH:** International Council for Harmonization; **MAH:** Marketing Authorization Holder; **NRA:** National Regulatory Authority; **NMPA:** National Medical Products Administration; **PIL:** Patient Information Leaflet; **SAHPRA:** South African Health Products Regulatory Authority; **TFVS:** Taxa de Fiscalização de Vigilância Sanitária; **WHO:** World Health Organization.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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