

Navigating Global Regulatory Requirements for Generic Drugs: A Comparative Study of MIST, BRICS, and ICH Countries

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ABSTRACT

Bringing a new healthcare product to market can be challenging, especially when navigating the complex regulatory requirements of different countries. The approval process can be a maze of differing regulations, but this study provides a roadmap to success. This study aims to provide a clear and concise comparison of the regulatory dossier requirements of MIST and BRICS with ICH countries. The results of this study highlight key similarities and differences in their standards for quality, safety, efficacy, preclinical and clinical trials, and more. Whether you're looking to meet stringent requirements or find areas of alignment, this study offers valuable insights to help you bring your product to market with confidence. This comprehensive comparative analysis helps in succeeding in today's rapidly evolving pharmaceutical market.

Keywords: Generic drugs, Regulatory requirement, Dossier requirement, MIST, BRICS, ICH.

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INTRODUCTION

Regulatory affairs play a crucial role in the pharmaceutical industry as they ensure the safety and efficacy of medicines for human use. The regulatory authorities of different countries have different requirements for the development, registration, and post-approval of pharmaceutical products. To ensure a consistent and harmonized approach to the regulatory affairs of pharmaceuticals, global organizations such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) have been established. The ICH brings together regulatory authorities and the pharmaceutical industry from around the world to develop and implement guidelines and standards that support the development of safe and effective medicines.¹

The regulatory requirements of the countries under the MIST (Mexico, Indonesia, South Korea, and Turkey) and BRICS (Brazil, Russia, India, China, and South Africa) are different

from those of ICH countries (Australia, Brazil, Canada, China, European Union, India, Japan, Russia, South Africa, South Korea, Singapore, Switzerland, Taiwan, United Kingdom, United States). These countries have their own unique regulations and guidelines, which may vary in terms of stringency, documentation requirements, and the length of the approval process. As a result, it is important for pharmaceutical companies to understand the specific requirements of each country to ensure a smooth and efficient regulatory process.²

In this study regulatory dossier requirements of MIST and BRICS countries with those of ICH countries are reviewed and compared. The comparison will provide an insight into the similarities and differences between the requirements of the different regions and help pharmaceutical companies to better understand the regulatory landscape in each country.

MIST countries have made significant progress in recent years in terms of regulatory reform and harmonization, but there is still a long way to go before they can be considered fully harmonized with ICH guidelines. In many MIST countries, there is still a lack of clarity and consistency in the regulatory requirements, which can result in longer approval times and higher costs for pharmaceutical companies.³



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On the other hand, the BRICS countries have some of the largest pharmaceutical markets in the world and are of strategic importance to the pharmaceutical industry. In recent years, the BRICS countries have made significant efforts to improve their regulatory systems and harmonize their requirements with those of ICH. However, there are still significant differences between the regulations in each country, which can make it challenging for pharmaceutical companies to navigate the regulatory landscape. Understanding the specific requirements and challenges of each country can help companies to develop a successful regulatory strategy, reduce the risk of regulatory delays and costs, and ultimately bring safe and effective medicines to patients more quickly.⁴

ICH

The ICH guidelines and standards are developed through a collaborative process involving regulatory authorities and the pharmaceutical industry and are designed to be adaptable to changing circumstances and to reflect the specific needs and regulatory practices of each country.⁵

BRICS

The BRICS countries are major players in the global economy and are home to some of the fastest-growing pharmaceutical industries in the world. The dossier requirements for BRICS countries are designed to ensure the safety and efficacy of new drugs for human use, and to provide a framework for the development and registration of pharmaceuticals in these countries. The dossier requirements for BRICS countries are designed to reflect the specific needs and regulatory practices of each country. For example, the requirements in Brazil, Russia, and South Africa may be influenced by local laws and regulations, as well as cultural and medical practices. In India and China, the requirements may be influenced by the large and rapidly growing populations, as well as the need to ensure access to essential medicines. The dossier requirements for BRICS countries are developed through a collaborative process involving regulatory authorities and the pharmaceutical industry. This collaboration helps to ensure that the requirements are relevant, practical, and responsive to the needs of both regulators and industry. The dossier requirements for BRICS countries are designed to be adaptable to changing circumstances. The guidelines and standards are regularly reviewed and updated to ensure that they remain relevant and up to date with the latest advances in scientific and medical knowledge. The introduction of dossier requirements for BRICS countries is also intended to help these countries become more competitive in the global pharmaceutical industry. The harmonization of requirements and the development of a robust regulatory framework can help to attract investment and innovation to these countries and support the growth of their pharmaceutical industries.⁶

MIST

The MIST countries are rapidly developing economies with growing pharmaceutical industries. The primary purpose of the dossier requirements for MIST countries is to ensure the safety and efficacy of new drugs for human use. The requirements provide a framework for the development and registration of pharmaceuticals and help to ensure that the drugs meet the same high standards for safety and efficacy in different countries. Also, it is designed to reflect the specific needs and regulatory practices of these countries. The requirements may be influenced by local laws and regulations, as well as cultural and medical practices. These are developed through a collaborative process involving regulatory authorities and the pharmaceutical industry. This collaboration helps to ensure that the requirements are relevant, practical, and responsive to the needs of both regulators and industry. The guidelines and standards are regularly reviewed and updated to ensure that they remain relevant and up to date with the latest advances in scientific and medical knowledge.³

This also intended to help these countries become more competitive in the global pharmaceutical industry. The harmonization of requirements and the development of a robust regulatory framework can help to attract investment and innovation to these countries and support the growth of their pharmaceutical industries. As the MIST countries are important players in the global pharmaceutical industry, and the introduction of dossier requirements is a critical step in ensuring the continued growth and development of their pharmaceutical sectors. The requirements help to ensure that new drugs are safe and effective, and that the regulatory approval process is predictable and transparent.⁷

Regional harmonization of the MIST countries is in different regions of the world, and the introduction of dossier requirements is intended to help promote regional harmonization in the regulatory approval process for pharmaceuticals. The harmonization of requirements can help to reduce the regulatory burden for the pharmaceutical industry and promote cross-border trade and investment in the pharmaceutical sector.⁸

The regulatory authorities in the MIST countries may provide technical assistance and support to the pharmaceutical industry in developing and submitting dossiers. This can help to ensure that the requirements are practical and easy to implement, and that the industry is able to take full advantage of the opportunities provided by the new requirements and are responsible for monitoring and enforcing compliance with the dossier requirements. This helps to ensure that the safety and efficacy of new drugs are protected, and that the regulatory approval process is transparent and predictable.⁷

DISCUSSION

The Common Technical Document (CTD) is a standardized format for the submission of regulatory applications for pharmaceutical products. The CTD is divided into five modules, each with specific sections that provide detailed information about the product being submitted for approval with respect to ICH guidelines.

Module 1 – Administrative Information and Prescribing Information

This module provides an overview of the product, including its name, formulation, and intended use. It also includes information on the manufacturer, the marketing authorization holder, and the relevant regulatory submissions.

Module 2 – Quality Overall Summaries

This module provides a summary of the quality-related information for the product, including the results of stability studies and an overview of the manufacturing process.

Module 3 – Quality

This module provides detailed information on the quality aspects of the product, including the active pharmaceutical ingredient, the finished product, and the manufacturing process. It includes information on the controls and specifications used to ensure the quality of the product.

Module 4 – Non-Clinical Study Reports

This module provides information on the pre-clinical studies conducted to evaluate the safety of the product. It includes information on the study design, methods, and results, as well as an evaluation of the product's safety profile.

Module 5 – Clinical Study Reports

This module provides information on the clinical trials conducted to evaluate the efficacy and safety of the product in human subjects. It includes information on the study protocols, results, and statistical analysis, as well as a summary of the overall clinical benefit-risk assessment.⁹

Dossier requirement comparison of BRICS countries with ICH countries (Table 1)

Clinical trial requirements

BRICS countries: The clinical trial requirements for BRICS countries vary widely. For example, in Brazil, clinical trials may be conducted in two phases (I and II) before regulatory approval is granted. In Russia, the number of clinical trials required for approval may be higher compared to ICH countries. In India, the clinical trial requirements may be less stringent compared to ICH countries, but they have recently implemented stricter regulations for clinical trials.¹⁰

Table 1: Comparison of MIST and ICH countries dossier requirement.

Dossier Requirements	ICH Countries	BRICS Countries
Clinical trial requirements	Three-phase clinical trial process (I, II, and III) for regulatory approval.	Vary widely regarding clinical trial phases.
Regulatory submissions	Submission of Marketing Authorization Application to the relevant national regulatory agency.	Submission may differ from ICH and approval by respective country regulatory agency.
Data requirements	Data requirements are based on the guidelines set by the ICH.	May be more extensive than those in ICH countries.
Language requirements	Accepted in English.	Some of the countries require that regulatory documents to be submitted in their local language.
Approval timeline	Several months to several years.	Timelines vary from ICH due to difference in regulatory process.

ICH countries: The ICH guidelines recommend a three-phase clinical trial process (Phase I, Phase II, and Phase III) for regulatory approval. The trials must be conducted in accordance with Good Clinical Practice (GCP) guidelines.

Regulatory submissions

BRICS countries: Each of the BRICS countries has its own regulatory agency responsible for approving new drugs. The submissions required for regulatory approval may differ from the ICH guidelines and can include additional data or information specific to the country.¹⁰

ICH countries: In ICH countries, the regulatory submission process typically involves submission of a Marketing Authorization Application (MAA) to the relevant national regulatory agency. The MAA must include data generated from clinical trials and other preclinical studies, as well as information on the manufacturing process and quality control measures.⁴

Data requirements

BRICS countries: The data requirements for BRICS countries may be more extensive than those in ICH countries. For example, in China, submissions may require Traditional Chinese medicine

data, as well as data on pharmacokinetics, pharmacodynamics, and toxicity in specific populations.¹⁰

ICH countries: In ICH countries, data requirements are based on the guidelines set by the ICH. The data submitted must demonstrate the safety and efficacy of the drug for its intended use.⁴

Language requirements

BRICS countries: Some of the BRICS countries require that regulatory documents be submitted in their local language. For example, in Russia, submissions must be made in Russian, while in China, submissions may need to be in both English and Chinese.¹⁰

ICH countries: ICH countries typically accept regulatory submissions in English.¹¹

Approval timeline

BRICS countries: Approval timelines for new drugs in BRICS countries can vary widely and may be longer than in ICH countries due to differences in the regulatory process and requirements. In some cases, the approval process can take several years.

ICH countries: Depending on the country, approval timeline in ICH countries varies as it typically takes several months to several years to obtain regulatory approval.⁴

Comparison of other dossier requirements in BRICS countries with ICH guidelines

Brazil: In terms of quality, safety, and efficacy requirements, ANVISA's guidelines are in line with ICH standards. However, in terms of environmental and social impact assessment, Brazil has more stringent requirements compared to ICH. Additionally, companies must provide information on the raw materials used and the results of environmental and social impact assessments, which are not required by ICH.¹¹

Russia: The Roszdravnadzor's requirements for quality, safety, and efficacy, as well as preclinical and clinical trials, are in line with ICH standards. However, Russia has more stringent requirements in terms of risk-benefit assessment compared to ICH. Additionally, Russia requires a risk management plan, which is not required by ICH.

India: The CDSCO's requirements for quality, safety, and efficacy, as well as preclinical and clinical trials, are in line with ICH standards. However, India has more stringent requirements in terms of manufacturing information and stability data compared to ICH. Additionally, India requires a risk management plan, which is not required by ICH.¹²

China: The NMPA's requirements for quality, safety, and efficacy, as well as preclinical and clinical trials, are in line with ICH

standards. However, China has more stringent requirements in terms of manufacturing information and stability data compared to ICH. Additionally, China requires a risk management plan and information on labeling and packaging, which are not required by ICH.¹³

South Africa: The SAHPRA's requirements for quality, safety, and efficacy, as well as preclinical and clinical trials, are in line with ICH standards. However, South Africa has more stringent requirements in terms of manufacturing information and stability data compared to ICH. Additionally, South Africa requires a risk management plan and information on labeling and packaging, which are not required by ICH.¹⁴

Dossier requirement comparison of MIST and ICH countries (Table 2)

Clinical trial requirements

MIST countries: Clinical trial requirements for the MIST countries vary, but they generally follow the ICH guidelines. In some cases, additional trials may be required to support regulatory approval.¹⁵

ICH countries: The ICH guidelines recommend a three-phase clinical trial process (I, II, and III) for regulatory approval. The trials must be conducted in accordance with Good Clinical Practice (GCP) guidelines.¹⁶

Regulatory submissions

MIST countries: Each of the MIST countries has its own regulatory agency responsible for approving new drugs. The submissions required for regulatory approval may differ from the ICH guidelines and can include additional data or information specific to the country.¹⁷

ICH countries: In ICH countries, the regulatory submission process typically involves submission of a Marketing Authorization Application (MAA) to the relevant national regulatory agency. The MAA must include data generated from clinical trials and other preclinical studies, as well as information on the manufacturing process and quality control measures.

Data requirements

MIST countries: The data requirements for the MIST countries may be more extensive than those in ICH countries. In some cases, additional data may be required to support regulatory approval.

ICH countries: The data requirements in ICH countries are based on the guidelines set by the ICH. The data submitted must demonstrate the safety and efficacy of the drug for its intended use.¹¹

Table 2: Comparison of MIST and ICH countries dossier requirement.

Dossier Requirements	ICH Countries	MIST Countries
Clinical trial requirements	Three-phase clinical trial process (I, II, and III) for regulatory approval.	Clinical trial requirements vary but follow ICH guidelines. Additional trials may be required.
Regulatory submissions	Submission of Marketing Authorization Application to the relevant national regulatory agency.	Submission may differ from ICH and approval by respective country regulatory agency.
Data requirements	Data requirements are based on the guidelines set by the ICH.	May be more extensive than those in ICH countries that demonstrates safety and efficacy. Additional data may require.
Language requirements	Accepted in English.	Some of the countries require that regulatory documents be submitted in their local language. Ex: Turkish.
Approval timeline	Several months to several years.	Timelines vary widely and may be longer from ICH due to difference in regulatory process.

Language requirements

MIST countries: Some of the MIST countries require that regulatory documents be submitted in their local language. For example, in Turkey, submissions must be made in Turkish.

ICH countries: ICH countries typically accept regulatory submissions in English.¹¹

Approval timeline

MIST countries: For new drugs in the MIST countries approval timelines can vary widely and may be longer than in ICH countries due to differences in the regulatory process and requirements. In some cases, the approval process can take several years.

ICH countries: The approval timeline in ICH countries varies depending on the country, but it typically takes several months to several years to obtain regulatory approval.¹⁸

Dossier requirements comparison of MIST with ICH countries

Mexico

Clinical trial requirements: Clinical trials in Mexico are generally conducted in accordance with ICH guidelines. However, some additional trials may be required to support regulatory approval.

Regulatory submissions: The regulatory submission process in Mexico involves submitting a Marketing Authorization Application (MAA) to the Mexican regulatory agency, the Federal Commission for the Protection Against Sanitary Risk (COFEPRIS). The MAA must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: Mexico requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements may be more extensive than those in ICH countries.

Language requirements: Regulatory documents must be submitted in Spanish.

Approval timeline: The approval timeline in Mexico for medicines is 180 days which includes API or therapeutic indications already approved and 240 days for not approved.^{3,19}

Indonesia

Clinical trial requirements: Clinical trials in Indonesia are generally conducted in accordance with ICH guidelines. However, some additional trials may be required to support regulatory approval.

Regulatory submissions: The regulatory submission process in Indonesia involves submitting a Marketing Authorization Application (MAA) to the Indonesian regulatory agency, the National Agency of Drug and Food Control (BPOM). The MAA must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: Indonesia requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements may be more extensive than those in ICH countries.

Language requirements: Regulatory documents must be submitted in Indonesian.

Approval timeline: The approval timeline in Indonesia is 100 working days with electronic standardized information and 150 days without electronic standardized information countries that have been marketed.²⁰

South Korea

Clinical trial requirements: Clinical trials in South Korea are generally conducted in accordance with ICH guidelines.

Table 3: Comparison table for CTD requirements in some ICH countries.²⁶

Details	Countries				
	USA	EUROPE	JAPAN	CHINA	INDIA
Regulatory authority	Food and Drug Administration	European Medicines Agency	Ministry of Health Labour and Welfare	National Medical Product Administration	Central Drug Standard and Control organization
Types of Application	NDA ANDA BLA	Marketing Authorization Application	NDA ANDA BLA	NDA ANDA Supplemental Import Drug application Renewal	Marketing Authorization Application
Types of Registration procedure	Direct submission to FDA or through approved contact agent	CP, DCP, MRP and NP	J-NDA (Japan New Drug Application)	Standard review and Special review procedure	N/A
Administrative and prescribing information	356h FDA form	Notice to Applicant: Volume 2B	Application Approval Form (AAF)	Chinese specific application Form	Form 44
Drug product labeling	Package inserts are provided	SmPL (Summary of Product Labeling)	Draft package inserts	--	Proposed Draft labels and cartoons Provided in Module 1
Information about clinical investigator	In Module 5	In Module 1	In Module 2	--	In Module 1
BE study against	RLD	European reference product	Japan reference product	--	Innovator marketed product
Regulatory approval of CTA/IND application Time	30 days	60 days	30 days	9-10 months	16-18 weeks
MAA Time	180 Days	210 Days	150 Days	180 Days	8-12 weeks

However, some additional trials may be required to support regulatory approval.

Regulatory submissions: The regulatory submission process in South Korea involves submitting a Marketing Authorization Application (MAA) to the Korean regulatory agency, the Ministry of Food and Drug Safety (MFDS). The MAA must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: South Korea requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements may be more extensive than those in ICH countries.

Language requirements: Regulatory documents can be submitted in English or Korean.

Approval timeline: The approval timeline in South Korea can be months or several years.²¹

Turkey

Clinical trial requirements: Clinical trials in Turkey are generally conducted in accordance with ICH guidelines. However, some additional trials may be required to support regulatory approval.

Regulatory submissions: The regulatory submission process in Turkey involves submitting a Marketing Authorization Application (MAA) to the Turkish regulatory agency, the Turkish Medicines, and Medical Devices Agency (TMDA). The MAA must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: Turkey requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements may be more extensive than those in ICH countries.

Language requirements: Regulatory documents must be submitted in Turkish.

Approval timeline: The approval timeline in Turkey is 210 days having addition of 30 days for examining suitability of application.¹⁷

Comparison of other dossier requirements in MIST countries with ICH guidelines

Mexico: The COFEPRIS' requirements for quality, safety, and efficacy, as well as preclinical and clinical trials, are in line with ICH standards. However, Mexico has more stringent requirements in terms of environmental impact assessment compared to ICH. Additionally, Mexico requires a risk management plan and information on labeling and packaging, which are not required by ICH.¹⁵

Indonesia: The BPOM's requirements for quality, safety, and efficacy, as well as preclinical and clinical trials, are in line with ICH standards. However, Indonesia has more stringent requirements in terms of manufacturing information and stability data compared to ICH. Additionally, Indonesia requires a risk management plan, which is not required by ICH.²⁰

Turkey: The Turkish Ministry of Health's requirements for quality, safety, and efficacy, as well as preclinical and clinical trials, are in line with ICH standards. However, Turkey has more stringent requirements in terms of environmental impact assessment compared to ICH. Additionally, Turkey requires a risk management plan and information on labeling and packaging, which are not required by ICH.¹⁷

South Korea: The MFDS' requirements for quality, safety, and efficacy, as well as preclinical and clinical trials, are in line with ICH standards. However, South Korea has more stringent requirements in terms of manufacturing information and stability data compared to ICH. Additionally, South Korea requires a risk management plan, which is not required by ICH.²¹

Dossier requirements of some countries under ICH (Table 3)

United States (US)

Clinical trial requirements: Clinical trials in the US are conducted in accordance with ICH guidelines and are subject to review by the US Food and Drug Administration (FDA).

Regulatory submissions: The regulatory submission process in the US involves submitting a New Drug Application (NDA) to the FDA. The NDA must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: The US requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements are more extensive than those in other ICH countries.

Language requirements: Regulatory documents can be submitted in English.

Approval timeline: The approval timeline in the US can be 180 days or less other times it may take several revisions.¹²

European Union (EU)

Clinical trial requirements: Clinical trials in the EU are conducted in accordance with ICH guidelines and are subject to review by the European Medicines Agency (EMA).

Regulatory submissions: The regulatory submission process in the EU involves submitting a Marketing Authorization Application (MAA) to the EMA. The MAA must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: The EU requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements are more extensive than those in other ICH countries.

Language requirements: Regulatory documents can be submitted in English.

Approval timeline: The approval timeline in the EU is generally 210 days and can vary based on the procedure and revisions.¹²

Japan

Clinical trial requirements: Clinical trials in Japan are conducted in accordance with ICH guidelines and are subject to review by the Japanese Ministry of Health, Labour, and Welfare (MHLW).

Regulatory submissions: The regulatory submission process in Japan involves submitting a Marketing Authorization Application (MAA) to the MHLW. The MAA must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: Japan requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements are more extensive than those in other ICH countries.

Language requirements: Regulatory documents can be submitted in English or Japanese.

Approval timeline: The approval timeline in Japan is generally 150 days to 12 months.²²

Canada

Clinical trial requirements: Clinical trials in Canada are conducted in accordance with ICH guidelines and are subject to review by Health Canada.

Regulatory submissions: The regulatory submission process in Canada involves submitting a New Drug Submission (NDS)

to Health Canada. The NDS must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: Canada requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements are more extensive than those in some other ICH countries.

Language requirements: Regulatory documents can be submitted in English or French.

Approval timeline: The approval timeline in Canada can vary from 6 months to 2 years.²³

Australia

Clinical trial requirements: Clinical trials in Australia are conducted in accordance with ICH guidelines and are subject to review by the Therapeutic Goods Administration (TGA).

Regulatory submissions: The regulatory submission process in Australia involves application submit for Registration of a Therapeutic Goods to the TGA. The application must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: Australia requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements are more extensive than those in some other ICH countries.

Language requirements: Regulatory documents can be submitted in English.

Approval timeline: The approval timeline in Australia can vary widely and may take several months.²⁴

Switzerland

Clinical trial requirements: Clinical trials in Switzerland are conducted in accordance with ICH guidelines and are subject to review by the Swiss Agency for Therapeutic Products (Swissmedic).

Regulatory submissions: The regulatory submission process in Switzerland involves submitting a Marketing Authorization Application (MAA) to Swissmedic. The MAA must include data generated from clinical trials, as well as information on the manufacturing process and quality control measures.

Data requirements: Switzerland requires data that demonstrate the safety and efficacy of the drug for its intended use. The data requirements are more extensive than those in some other ICH countries.

Language requirements: Regulatory documents can be submitted in English, French or German.

Approval timeline: The approval timeline in Switzerland for authorization takes 10 and 12 months or between 4 and 5 months if applicant choose expedited procedure.²⁵

CONCLUSION

The regulatory environment in MIST and BRICS countries continues to evolve, and it is important for pharmaceutical companies to stay informed and adapt their regulatory strategies as needed. While there may be significant differences between the regulatory requirements of each country, the goal of ensuring the safety and efficacy of medicines for human use remains the same. By working closely with regulatory authorities and taking a proactive approach to regulatory affairs, pharmaceutical companies can help to promote greater harmonization and consistency in the regulatory requirements of MIST and BRICS countries.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

AAF: Application Approval Form; **ANDA:** Abbreviated New Drug Application; **ANVISA:** Agência Nacional de Vigilância Sanitária; **API:** Active Pharmaceutical Ingredients; **BE:** Bioequivalence; **BLA:** Biologics Licence Application; **BPOM:** Badan Pengawas Obat dan Makanan; **BRICS:** Brazil, Russia, India, China, and South Africa; **CDSCO:** Central Drugs Standard Control Organisation; **COFEPRIS:** Commission for the Protection Against Sanitary Risk; **CP:** Centralized Procedure; **CTA:** Clinical Trial Application; **CTD:** Common Technical Document; **DCP:** Decentralized Procedure; **EMA:** European Medicines Agency; **EU:** European Union; **FDA:** Food and Drug Administration; **GCP:** Good Clinical Practices; **ICH:** International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; **IND:** Investigational New Drug; **MAA:** Marketing Authorization Application; **MAH:** Marketing Authorization Holder; **MFDS:** Ministry of Food and Drug Safety; **MHLW:** Ministry of Health, Labour, and Welfare; **MIST:** Mexico, Indonesia, South Korea, and Turkey; **MRP:** Mutual Recognition Procedure; **NDA:** New Drug Application; **NDS:** New Drug Submission; **NMPA:** National Medical Products Administration; **NP:** National Procedure; **RLD:** Reference Listed Drug; **SAHPRA:** South African Health Products Regulatory Authority; **SmPL:** Summary of Product Labeling; **TGA:** Therapeutic Goods Administration; **TMDA:** Turkish Medicines, and Medical Devices Agency.

REFERENCES

1. Medicines Agency E. The European regulatory system for medicines. Available from: https://www.ema.europa.eu/en/documents/leaflet/european-regulatory-system-medicines-european-medicines-agency-consistent-approach-medicines_en.pdf. doi: doi.
2. Rahalkar H, Sheppard A, Santos GML, Dasgupta C, Perez-Tapia SM, Lopez-Morales CA, *et al.* Current regulatory requirements for biosimilars in six member countries of BRICS-TM: challenges and opportunities. *Front Med (Lausanne)*. 2021;8:726660. doi: 10.3389/fmed.2021.726660, PMID 34568384.
3. López-Morales CA, Tenorio-Calvo A, Cruz-Rodríguez R, Sánchez Y Tepoz J, Belgharbi L, Pérez-Tapia SM, *et al.* Regulatory pathway for licensing biotherapeutics in Mexico. *Front Med (Lausanne)*. 2018;5:272. doi: 10.3389/FMED.2018.00272/BIBTEX, PMID 30320117.
4. Deore R, H. Patel P. Comparative overview of Registration and Approval process for Generic Drugs in BRICS Countries. *Int J Drug Reg Affairs*. 2022;10(1):40-50. doi: 10.2270/ijdra.v10i1.509.
5. Baber N. International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH). *Br J Clin Pharmacol*. 1994;37(5):401-4. doi: 10.1111/J.1365-2125.1994.TB05705.X, PMID 8054244.
6. Sowmya MV, Bhavana JS, Ramakrishna G, Nagabhushanam v M, Bonthagarala B, Reddy DN. Regulatory requirements for generic and new drug registration in Russia. Sowmya, *et al.* *World Journal of Pharmaceutical Research*. 2019;8. doi: 10.20959/wjpr201910-15639.
7. Annex 11 Good regulatory practices in the regulation of medical products Background WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-fifth report. Available from: https://www.wto.org/english/tratop_e/trips_e/techsymp_290621/gaspar_pres2.pdf. doi: doi.
8. Introduction – international regulatory harmonization amid globalization of drug development – NCBI bookshelf [cited Feb 14, 2023]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK174222/>.
9. Step. Committee for Medicinal Products for Human Use ICH. guideline M4 (R4) on Common Technical Document (CTD) for the registration of pharmaceuticals for human use-organisation of CTD. Published online 2021 [cited Feb 14, 2023]. Available from: <http://www.ema.europa.eu/contact>.
10. Jayalakshmi B, Seetharaman R, Kamaraj R. Registration and regulatory requirements of generic drugs marketing authorization in "BRICS" countries. *Res J Pharm Technol*. 2019;12(3):1403-8. doi: 10.5958/0974-360X.2019.00234.8.
11. Rai K, Potphode P, Gupta C, Rao N. Comparative study between ICH guideline and anvisa guideline. *IJRPC*; 10(2):173-90. doi: 10.33289/IJRPC.10.2.2020.10(31).
12. Am S, Dp M, Da B. Regulatory requirements and drug approval process in India, Europe and US. *Pharm Regul Aff*. 2018;7(2). doi: 10.4172/2167-7689.1000210.
13. Li X, Su Z. A review of the common technical document (CTD) regulatory dossier for generic drugs in China. *Chin Pharm J*. 2016;51(4):329-34. doi: 10.11669/CPJ.2016.04.018.
14. South African good clinical practice: clinical trial guidelines. Published online 2020. Available from: https://www.sahpra.org.za/wp-content/uploads/2021/06/SA-GCP-2020_Final.pdf. doi: doi.
15. Clinical research regulation for Mexico | ClinRegs [cited Feb 14, 2023]. Available from: <https://clinregs.niaid.nih.gov/country/mexico>.
16. Schadt S, Bister B, Chowdhury SK, Funk C, Hop CECA, Humphreys WG, *et al.* A decade in the MIST: learnings from investigations of drug metabolites in drug development under the "metabolites in safety testing" regulatory guidance. *Drug Metab Dispos*. 2018;46(6):865-78. doi: 10.1124/DMD.117.079848, PMID 29487142.
17. Turkish guidelines for generics [cited Mar 16, 2023]. Available from: <https://www.gabionline.net/guidelines/Turkish-guidelines-for-generics>.
18. Tannoury M, Attieh Z. The influence of emerging markets on the pharmaceutical industry. *Curr Ther Res Clin Exp*. 2017;86:19-22. doi: 10.1016/J.CURTHERES.2017.04.005, PMID 29234483.
19. PharmaBoardroom – regulatory. Mexico: Pricing and Reimbursement [cited Mar 16, 2023]. Available from: <https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-mexico/>.

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