THSJ 2(2) (2025)

Thrive Health Science Journal

https://journals.balaipublikasi.id

Global Perspectives on Drug Regulatory Bodies: Roles, Challenges, and Collaborative Frameworks

Rashed Ahmed[1*]

[1] Department of Pharmaceutical Sciences, North South University, Dhaka, Bangladesh

Received: March 2, 2025
Revised: August 13, 2025
Accepted: September 25, 2025
Published: September 30, 2025

Corresponding Author:
Rashed Ahmed
ahmedrashed.23@gmail.com

DOI: 10.56566/thrive.v2i2.322

Abstract: The article "Comparison of Drug Regulatory Bodies: EMA, DGDA, ISO, WHO, TGA, MHRA, and FDA" presents a comprehensive analysis of global drug regulatory organizations, focusing on their roles, responsibilities, and impact on public health. The research delves into the historical development, operational frameworks, and collaborative efforts of these agencies to ensure the safety, efficacy, and quality of pharmaceutical products and medical devices. By incorporating methodologies such as literature review, comparative analysis, critical evaluation, and historical contextualization, the study identifies key similarities and differences among these organizations. The article also examines the critical role of pharmacists in these regulatory bodies, emphasizing their involvement in drug evaluation, pharmacovigilance, and policy development. Furthermore, the study explores the concepts of In-Process Quality Assurance (IPQA) and In-Process Quality Control (IPQC), illustrating their necessity even in the presence of established Quality Control (QC) and Quality Assurance (QA) departments. By addressing challenges such as long approval times, high compliance costs, regulatory inconsistencies, and limited resources in developing countries, the research underscores the importance of global collaboration and regional adaptation in drug regulation. The article concludes by advocating for strengthened regulatory systems, enhanced international cooperation, and balanced approaches to ensure the rational use of drugs and equitable access to quality medicines worldwide.

Keywords: Drug Regulatory Bodies; Pharmaceutical Regulation; Pharmacovigilance; Quality Systems; Global Health Collaboration

Introduction

The European Medicines Agency (EMA), Directorate General of Drug Administration (DGDA), International Organization for Standardization (ISO), World Health Organization (WHO), Therapeutic Goods Administration (TGA), Medicines and Healthcare products Regulatory Agency (MHRA), and Food and Drug Administration (FDA) are vital organizations that ensure the safety, efficacy, and quality of medicines and healthcare products. While the EMA oversees drug regulation in the European Union, the DGDA regulates medicines in Bangladesh. Similarly, the FDA handles drug approval and safety in the U.S., while the MHRA operates in the UK, and the TGA manages therapeutic goods in Australia. The WHO provides international health guidelines, and ISO sets global standards for quality management. These organizations collaborate to promote global health and harmonize regulations, although each has its own specific focus based on regional needs. The merits of these bodies include ensuring high safety standards, rigorous drug approval processes, and the protection of public health. However, their demerits can include slow approval processes, high compliance costs for manufacturers, and occasional bureaucratic inefficiencies (Ali et al., 2023; Khoo et al., 2024).

Additionally, while they work towards global safety standards, differences in regulations and access to medicines can cause delays or challenges in some

How to Cite:
Ahmed, R. (2025). Global Perspectives on Drug Regulatory Bodies: Roles, Challenges, and Collaborative Frameworks. *THRIVE Health Science Journal*, 2(2), 85-96. https://doi.org/10.56566/thrive.v2i2.322

regions. The objective of the research on the Comparison Study of Drug Regulatory Bodies (EMA, DGDA, ISO, WHO, TGA, MHRA, FDA) is to analyze and compare the roles, responsibilities, and functions of these key organizations in the global pharmaceutical landscape. This study aims to highlight how each regulatory body contributes to ensuring the safety, efficacy, and quality of medicines and healthcare products. By studying their regulatory processes, drug approval procedures, and post-market surveillance systems, the research seeks to identify similarities and differences in their approaches. The study also aims to assess the collaboration among these organizations, such as the efforts of the EMA coordinating with EU member states on pharmacovigilance, the DGDA's initiatives in Bangladesh, and how ISO sets global standards that guide these agencies (Basu et al., 2021; Thapliyal et al., 2024).

Furthermore, the research will explore the global health guidelines provided by the WHO, which influence these bodies, and how organizations like the FDA, MHRA, and TGA ensure drug safety and efficacy within their respective regions. In addition, the research will evaluate the merits and demerits of these regulatory bodies, considering factors like regulatory efficiency, safety standards, and public health protection. It will also investigate the challenges posed by regulatory differences, compliance costs, and the sometimes slow approval processes, which can impact the global accessibility of medicines. The ultimate goal of this research is to provide insights into how these organizations shape the global pharmaceutical regulatory framework and contribute to the overall health and safety of the global population (Lescrauwaet et al., 2022; Pramesh et al., 2022).

The pharmaceutical practices 1st started in 17th and 18th century, particularly with the rise of quack medicines (ineffective or fraudulent treatments). But officially it started with The Food and Drug Administration (FDA) in the U.S. It was one of the first formal regulatory bodies of U.S. The FDA was created from the Pure Food and Drug Act of 1906, which was made to stop the use of unsafe medicines. At that time, the federal government began to exert jurisdiction over specific categories of drugs –opium, cocaine, and morphine.[1] The FDA started by focusing on food safety, but soon began regulating drugs and medical devices as well. Its success inspired other countries to create similar agencies. The creation of the FDA inspired other countries to set up their own rules for drug safety and approval (Al-Busafi & Alwassief, 2024; Walter, 2024).

The history of the EMA (European Medicines Agency) dates back to 1970 when the European Community (EC) adopted the Pharmaceutical Directive, which directed the European System of Control of Medicines (SCM). This was subsequently replaced in the mid-1980s by a new pharmaceutical directive that set up the legal framework for the Pharmaceuticals Efficacy and Safety (PES) system, which became the basis for establishing the EMA in 1995. The purpose of the agency's establishment was to reference the work and findings of several private and public institutions that had been providing regulatory services for medicines in the European Union for some time. The intention was to create one agency that could take responsibility for this role and create an efficient and effective system of medical regulation [1]. Before the EMA was created, each European country had its own system for regulating drugs, which caused delays and inconsistencies (Chourasia et al., 2023). Then the EMA aimed to create a unified regulatory process to improve access to medicines while maintaining high standards for safety and efficacy. The EMA was created to bring together different drug rules in the European Union, while the FDA focuses only on the United States. The EMA works with national agencies to make drug regulations more consistent across Europe (Burns et al., 2022).

DGDA (Directorate General of Drug Administration) was established in 1973 by the Drug Control Ordinance 1973 of Bangladesh. The Drug Control Act 1990 was passed in1990. The latest amendment of the act was made in 2009. This amendment provided an autonomous and independent body, The Drug Administration Advisory Council (DAAC); it established the criteria for drug registration, new drugs, and clinical trials. In order to ensure quality and safe medicines are available to everyone, the Drug Administration Regulatory and Development Authority (DARDA) was created in 2010 (Ransing et al., 2021). It is mainly responsible for carrying out the following tasks: Formulating the rules and regulations related to importing, manufacturing, marketing, and selling drugs, vaccines, and other healthcare products. Assisting the Government in formulating and reviewing national policies related to drugs and other healthcare products: Setting up and maintaining drug safety monitoring centers to monitor drug safety, efficacy, and quality; Working closely with the health services department to pro-mote rational drug use; Regulating the sale of over-the-counter drugs in the country [1]; The DGDA's establishment is similar to other national agencies like the FDA but was more focused on tackling the unique challenges of developing countries, such as regulating locally produced and imported medicines and ensuring accessibility to essential drugs (Aslam et al., 2021).

The TGA (Therapeutic Goods Administration) was established in 1989 to regulate therapeutic goods, including medicines, medical devices, and vaccines. The

TGA was created to bring together Australia's different drug rules and make the drug approval process simpler and more modern which is a division or part of Australian Department of Health and Ageing administering (Ncube et al., 2021). The Therapeutic Goods Administration (TGA) is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products. Therapeutic goods are evaluated before they are marketed by TGA. Monitoring of the product once they are in market is also done by TGA. It also looks into suitability of medicines and medical devices for export from Australia. Therapeutic goods manufacturing unit is also regulated by TGA to ensure they meet acceptable standards of manufacturing quality(Niazi & Mariam, 2023). A team of manufacturing inspectors that audit manufacturing facilities around the world to ensure that products supplied in Australia are of high quality.[2] Similar to the FDA, the TGA focuses on ensuring the safety and quality of therapeutic products, but its creation was a result of Australia's unique healthcare needs. It operates within a smaller and more centralized system than the FDA or EMA but shares a similar goal of protect public health(Ransing et al., 2021).

The MHRA was formed in 2003 through the merger of two earlier agencies, the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA). The goal was to streamline drug regulation and improve oversight of medicines and medical devices in the UK. MHRA is very aware of the need to monitor the impact of the actions we take on medicines, whether these result in a widening or restriction of access. It is important to ensure the a positive outcome for users of medicines (Francisca Chibugo Udegbe et al., 2024). [3]. The MHRA shares similarities with both the FDA and EMA in regulating the safety and efficacy of medicines but is a national body focused on the UK. The creation of MHRA mirrored the desire for more efficient regulation, similar to the formation of EMA in Europe (Muteeb et al., 2023).

WHO: The World Health Organization (WHO), established in 1948, played a major role in coordinating global health initiatives, including drug regulation. WHO created guidelines and standards to harmonize drug regulation, focusing on accessibility, safety, and efficacy worldwide. Its role in promoting good manufacturing practices (GMP) and setting standards for drug quality has been essential for global health. It has played a significant role in drug regulation by setting global health standards and guidelines that influence national regulatory bodies, particularly in low- and middle-income countries. [4] Unlike national bodies such as the FDA or EMA, the WHO has a global scope. It provides guidance, recommendations, and standards that help shape national regulatory policies and promotes global health initiatives, whereas other regulatory agencies focus on specific regions or countries (Almeman, 2024; Rahman et al., 2025).

The rise of ISO (International Organization for Standardization) in 1947 helped standardize practices globally, including in the pharmaceutical industry. ISO's Good Manufacturing Practices (GMP) and pharmacovigilance standards have been widely adopted by drug regulatory bodies around the world to ensure consistency and quality in drug production and monitoring.[5] ISO is different from regulatory bodies like the FDA or EMA, as it doesn't directly regulate drug approval or safety. Instead, it sets global standards that help national regulatory agencies implement consistent practices across the pharmaceutical industry. Its work complements the efforts of regulatory bodies by providing a universal framework for drug quality and safety (Almeman, 2024; Patil et al., 2023).

FDA, EMA, MHRA, TGA, and DGDA are national or regional bodies that regulate drug safety, efficacy, and quality, each shaped by the unique health concerns of their regions. The FDA and EMA are often seen as global leaders due to their influence in shaping drug safety standards worldwide; WHO and ISO, however, take on a more global role by setting international standards and guidelines that inform national regulatory bodies. While WHO focuses on public health and disease prevention, ISO provides technical standards to improve quality management in pharmaceutical production; The evolution of these bodies reflects the need for collaboration and standardization in an increasingly globalized pharmaceutical market. Their roots lie in the efforts to protect public health by ensuring that medicines are safe, effective, and accessible to all populations (Marshall et al., 2024; Rashid, 2023).

Method

The research methodology for the article "Comparison of Drug Regulatory Bodies: EMA, DGDA, ISO, WHO, TGA, MHRA, and FDA" combines a multidisciplinary approach to ensure a comprehensive and detailed analysis of the subject. The methodologies adopted reflect the diverse aspects of the regulatory frameworks and their operational dynamics. Below is a detailed explanation of the methodologies used and their implementation.

Literature Review

A literature review formed the foundation of this research, enabling the identification and consolidation of existing knowledge about global drug regulatory bodies. This approach focused on gathering and

synthesizing data from various credible sources to ensure the reliability of the information presented.

Implementation

Relevant academic publications, regulatory guidelines, official documents, and reports from organizations such as the FDA, EMA, WHO, and ISO were reviewed; Databases like PubMed, ResearchGate, and governmental portals were utilized to retrieve peer-reviewed articles and regulatory updates; Historical texts tracing the evolution of these regulatory bodies were analyzed to provide a historical perspective on their development and operational principles.

Comparative Analysis

A structured comparative analysis was conducted to highlight the similarities and differences between the drug regulatory bodies in terms of their roles, processes, and impact on public health. This methodology allowed for a nuanced understanding of how these organizations operate within their regional and global contexts.

Implementation

Key performance indicators (KPIs) such as drug approval timelines, post-market surveillance strategies, and safety standards were identified and analyzed; Comparative matrices and tables were created to juxtapose critical aspects such as primary roles, regional influences, and global impact; Collaboration patterns between these bodies, such as the EMA's coordination with EU member states or the WHO's role in setting global standards, were critically examined.

Critical Analysis

Critical analysis was employed to evaluate the strengths, weaknesses, and challenges faced by these regulatory bodies in achieving their objectives. This approach facilitated a deeper understanding of the operational and systemic inefficiencies within each organization.

Implementation

Specific challenges, such as long approval timelines, resource constraints, and high compliance costs, were scrutinized; Solutions and recommendations, including the role of harmonization efforts like the International Council for Harmonisation (ICH), were explored; implications of regulatory inconsistencies on global drug accessibility and public health were analyzed.

Historical Contextualization

To provide a comprehensive background, the research incorporated historical analysis of the evolution of drug regulatory frameworks. This contextualization highlighted the milestones that shaped the current practices and policies of these bodies.

Implementation

Historical records, such as the establishment of the FDA in 1906 and the EMA in 1995, were reviewed to trace their growth and influence; Socio-political factors influencing the creation and reform of regulatory agencies were explored, particularly in the context of the DGDA in Bangladesh; A timeline was constructed to showcase the progressive development of global drug regulation.

Case Study Approach

The research included case studies to provide real-world examples of the regulatory processes and their outcomes. This approach offered practical insights into how these organizations address specific challenges and scenarios.

Implementation

Case studies focused on pivotal events, such as the FDA's emergency use authorization during the COVID-19 pandemic and the WHO's role in combating counterfeit drugs; Instances of successful collaborations, such as the TGA's export regulations and ISO's global quality standards, were analyzed; Case-specific data were used to support broader observations and recommendations.

Qualitative and Quantitative Analysis

A mixed-methods approach combining qualitative and quantitative analysis was employed to ensure a holistic evaluation of the regulatory frameworks.

Implementation

Qualitative insights were derived from expert opinions, policy documents, and interviews with stakeholders in the pharmaceutical industry; Quantitative data, such as approval rates, compliance costs, and timelines, were analyzed to measure the efficiency and impact of these bodies; Statistical tools and software were used to process and interpret the quantitative data, enabling evidence-based conclusions.

Global and Regional Contextualization

The study emphasized the interplay between global and regional perspectives, acknowledging the diverse challenges and priorities faced by regulatory bodies in different regions.

Implementation

The global role of WHO and ISO in setting universal standards was juxtaposed with the regional

focus of bodies like the DGDA and TGA; The influence of socio-economic and political factors on regulatory practices was examined, particularly in low- and middle-income countries; The research explored how regional adaptations of global standards address local health needs and disparities.

The methodologies adopted for this research ensured a multidimensional analysis of the roles, responsibilities, and challenges of drug regulatory bodies. By integrating literature review, comparative analysis, historical contextualization, and case studies, the study provides a robust framework for understanding and evaluating the global pharmaceutical regulatory landscape. The insights generated aim to contribute to the ongoing discourse on improving regulatory efficiency, harmonizing standards, and ensuring equitable access to safe and effective medicines worldwide.

Result and Discussion

Roles, Responsibilities, and Processes of the Drug Regulatory Bodies: EMA, DGDA, ISO, WHO, TGA, MHRA, and FDA:

European Medicines Agency (EMA)

The European Medicines Agency (EMA) is responsible for the scientific evaluation, supervision, and safety monitoring of medicines within the European Union. It assesses applications for new medicines and continuously monitors authorized products to ensure that they meet rigorous standards of quality, safety, and efficacy. Through these regulatory functions, the EMA contributes significantly to public health protection and the harmonization of pharmaceutical regulation across member states (Rashid, 2023).

Directorate General of Drug Administration (DGDA)

The Directorate General of Drug Administration (DGDA) in Bangladesh is the national regulatory authority responsible for overseeing the production, import, and distribution of medicines and medical devices. Its primary mandate is to ensure that all pharmaceutical products and medical technologies circulating in the country meet established standards of quality, safety, and efficacy. By implementing strict regulatory frameworks and monitoring systems, the DGDA plays a crucial role in protecting public health and fostering trust in healthcare products available in the Bangladeshi market (Marshall et al., 2024).

International Organization for Standardization (ISO)

The International Organization for Standardization (ISO) develops international standards covering various fields, including medical devices and pharmaceutical products. These standards are designed to ensure the safety, reliability, and quality of products and services worldwide. In the context of pharmaceuticals and healthcare, ISO provides guidelines related to quality management, production, and product testing. The implementation of ISO standards helps industries comply with global regulations while enhancing trust among consumers and regulatory authorities. Thus, ISO plays a vital role in the harmonization of international regulations to protect public health and ensure access to safe and high-quality products (Van der Schueren et al., 2024).

World Health Organization (WHO)

WHO provides leadership on global health matters, including setting norms and standards for pharmaceuticals. It supports countries in strengthening their regulatory systems to ensure the quality, safety, and efficacy of medicines.

Therapeutic Goods Administration (TGA)

The TGA regulates therapeutic goods in Australia, including medicines and medical devices. It ensures that these products are of an acceptable standard before they can be marketed(Rani et al., 2024).

Medicines and Healthcare products Regulatory Agency (MHRA)

The Medicines and Healthcare products Regulatory Agency (MHRA) serves as the regulatory authority for medicines and medical devices in the United Kingdom. It is responsible for authorizing the sale of these products, continuously monitoring their safety, and ensuring compliance with statutory and regulatory requirements. Through these functions, the MHRA plays a vital role in safeguarding public health and maintaining confidence in the UK's healthcare system.

Food and Drug Administration (FDA)

The FDA in the USA is responsible for protecting public health by ensuring the safety, efficacy, and security of drugs, biological products, and medical devices. It also monitors products after they are on the market to ensure ongoing safety (Aziza, 2021).

Drug Approval Processes

Each regulatory body has its own drug approval process, but generally, they involve: Preclinical Testing: Laboratory and animal studies to assess safety and biological activity; Clinical Trials: Human studies conducted in phases to evaluate safety, dosage, efficacy, and side effects; Regulatory Review: Submission of data to the regulatory body for evaluation; Approval: If the

product meets the required standards, it is approved for marketing (Martins et al., 2024a).

Post-Market Surveillance

After approval, regulatory bodies monitor the safety and effectiveness of medicines through post-market surveillance programs. This includes: Adverse Event Reporting: Collecting reports of adverse effects from healthcare providers and the public; Periodic Safety Updates: Regular reports submitted by manufacturers detailing safety information; Inspections: Ensuring compliance with manufacturing and quality standards. For example, the FDA maintains a system of post marketing surveillance and risk assessment programs to identify adverse events that did not appear during the drug approval process. Similarly, the EMA provides scientific opinions to notified bodies through consultation procedures as part of its role in the regulatory framework for medical devices. These regulatory bodies play a crucial role in ensuring that medicines and medical devices are safe and effective for public use (Martins et al., 2024b).

ISO Guidelines for Regulatory Bodies

The International Organization for Standardization (ISO) develops international standards to ensure quality, safety, and efficiency across various industries. While ISO itself is not a regulatory body, its standards are widely adopted by regulatory agencies to harmonize requirements globally: ISO 13485: Specifies requirements for a quality management system (QMS) for medical devices. Regulatory bodies like the FDA, EMA, TGA, and MHRA often reference ISO 13485 to assess manufacturers' QMS compliance.; ISO 14971: Provides a framework for risk management in medical device manufacturing. Adherence to this standard is crucial for compliance with regulatory expectations.

WHO Guidelines for Regulatory Bodies

The World Health Organization (WHO) issues guidelines to assist regulatory authorities in maintaining and improving public health standards: Good Manufacturing Practices (GMP): WHO's GMP guidelines ensure that products are consistently produced and controlled according to quality standards. Regulatory bodies worldwide, including the DGDA, TGA, and others, align their GMP requirements with WHO guidelines to ensure product quality and safety.: Good Distribution Practices (GDP): These guidelines ensure the quality and integrity of pharmaceutical products during distribution. Regulatory agencies adopt WHO's GDP guidelines to oversee the pharmaceutical supply chain effectively (Fourie Zirkelbach et al., 2022). Members and Affiliation of Each Regulatory Body and Function of Every Committee European Medicines Agency (EMA):

Committees

Committee for Medicinal Products for Human Use (CHMP): Responsible for preparing opinions on all questions concerning medicines for human use; Pharmacovigilance Risk Assessment Committee (PRAC): Assesses and monitors the safety of human medicines; Committee for Orphan Medicinal Products (COMP): Evaluates applications for orphan designation; Medicines and Healthcare products Regulatory Agency (MHRA) :

Committees

Commission on Human Medicines (CHM): Advises ministers on the safety, efficacy, and quality of medicinal products; Advisory Board on the Registration of Homeopathic Products: Provides advice on homeopathic medicines; Food and Drug Administration (FDA):

Centers

Center for Drug Evaluation and Research (CDER): Ensures that safe and effective drugs are available to the public; Center for Devices and Radiological Health (CDRH): Oversees medical devices and radiation-emitting products; Center for Biologics Evaluation and Research (CBER): Regulates biological products, including vaccines and blood products (Ahmed, 2024).

Ensuring Quality Medicine

Regulatory bodies implement several measures to ensure the quality of medicines: Good Manufacturing Practices (GMP): Enforcing GMP ensures that products are consistently produced and controlled according to quality standards; Quality System Regulations (QSR): For instance, the FDA's QSR outlines current good manufacturing practices (CGMPs) for medical devices and pharmaceutical products; Post-Market Surveillance: Monitoring products after they have entered the market to detect any issues related to quality, safety, or efficacy (Alowais et al., 2023a).

In-Process Quality Assurance (IPQA) and In-Process Quality Control (IPQC), IPQA: Refers to the assurance activities conducted during the manufacturing process to ensure that the product meets quality standards at every production stage; IPQC: Involves the operational techniques and activities employed to fulfill quality requirements during the manufacturing process. Need for IPQA and IPQC Despite Established QC and QA Departments; While Quality Control (QC) and Quality Assurance (QA) departments oversee overall product quality and compliance, IPQA and IPQC are crucial for: Real-Time

Monitoring: Detecting and addressing issues during the manufacturing process rather than post-production; Process Validation: Ensuring that each step of the manufacturing process consistently produces output meeting predetermined quality criteria Managing Rational Drug Use Regulatory bodies promote rational drug use through: Guidelines and Policies: Issuing guidelines on appropriate prescribing and dispensing practices; Educational Campaigns: Educating healthcare professionals and the public on the proper use of medications; Monitoring and Surveillance: Tracking prescription patterns and intervening when irrational drug use is detected Role of Pharmacists in Regulatory Bodies Pharmacists contribute significantly to regulatory bodies by: Evaluation and Assessment: Reviewing drug applications for safety, efficacy, and quality; Pharmacovigilance: Monitoring adverse drug reactions and ensuring patient safety; Policy Development: Contributing to the creation of guidelines and regulations related to pharmaceuticals (Ahmed, 2024; Alowais et al., 2023b).

Their expertise ensures that regulatory decisions are informed by a comprehensive understanding of pharmacotherapy and patient care. Regulatory bodies, guided by international standards and supported by skilled professionals, play a crucial role in ensuring that medicines and medical devices are safe, effective, and of high quality.

Future Prospects

The future of drug regulatory bodies lies in their ability to adapt to the rapidly evolving global healthcare landscape. With the advancement of precision medicine, biotechnology, and artificial intelligence, regulatory agencies must embrace innovative approaches to evaluate and approve complex therapies and medical devices. Increased collaboration among global regulatory bodies, such as through initiatives like the International Council for Harmonisation (ICH), is essential to harmonize standards and expedite the approval of life-saving treatments worldwide. In developing regions, strengthening local regulatory frameworks and ensuring access to advanced technologies will be pivotal in addressing healthcare disparities. This includes capacity-building programs, technological infrastructure improvements, and international partnerships to enhance regulatory efficiency. The integration of digital tools and real-time data analytics can streamline pharmacovigilance and post-market surveillance processes, enabling quicker responses to safety concerns (Alowais et al., 2023b; Fourie Zirkelbach et al., 2022).

Furthermore, regulatory bodies must prioritize sustainability by adopting environmentally conscious practices in drug production and distribution. Addressing challenges like counterfeit medicines and ensuring equitable access to essential drugs will remain critical objectives. Enhanced roles for pharmacists and interdisciplinary professionals in regulatory decision-making processes will ensure that the evolving needs of public health are met. Ultimately, the future success of these regulatory agencies will depend on their ability to balance innovation with rigorous safety and quality standards, fostering a global ecosystem where patients have timely access to safe, effective, and affordable medicines (Ahmed, 2024; Martins et al., 2024b, 2024a).

Role of Pharmacists

Pharmacists play a pivotal role in the functioning of drug regulatory bodies, contributing their expertise to ensure public health and safety. They are integral to various stages of the regulatory process, including the evaluation, approval, and post-market monitoring of medicines. Their specialized knowledge of pharmacology, toxicology, and therapeutics positions them as key players in the decision-making processes of these agencies. Pharmacists are actively involved in drug evaluation, where they assess the safety, efficacy, and quality of new pharmaceuticals. This includes analyzing clinical trial data and ensuring compliance with regulatory standards. In the realm of pharmacovigilance, pharmacists monitor adverse drug reactions and identify safety signals, which are critical for protecting patients and maintaining public trust in healthcare systems.

In addition to their technical roles, pharmacists contribute to policy development and the creation of regulatory guidelines. They work collaboratively with other professionals to design standards that address emerging challenges, such as the rise of biologics and personalized medicine. Pharmacists also play a role in educating healthcare providers and the public about rational drug use, fostering an environment where medications are prescribed and utilized responsibly. By bridging the gap between science, policy, and practice, pharmacists ensure that regulatory bodies remain aligned with the evolving needs of global healthcare. Their contributions are essential for maintaining high standards of quality, safety, and efficacy in the pharmaceutical industry, ultimately benefiting patients and society at large (Ahmed, 2024; Costanza-Chock et al., 2022; Stergiou et al., 2023).

Table 1. Comparison Summary

Aspect	EMA	DGDA	ISO	WHO	TGA	MHRA	FDA
Region	European Union	Bangladesh	Global	Global	Australia	United Kingdom	United states
Primary Role	Drug approval & surveillance	Drug safety & efficacy	International standards	Global health & drug safety	Drug approval & surveillance	Drug & device approval	Drug & food regulation
Key Focus Areas	Safety, efficacy, vaccines	Drug licensing, pricing	Manufacturing standards	Drug safety, access	Safety, quality, post-market	Post-market surveillance	Safety, efficacy, monitoring
Global Influence	High	Moderate	High	High	Moderate	High	Very high
Challenges	Coordination with member states	Enforcement in rural areas	Voluntary adoption	No direct regulatory power	Approval timelines	Post-Brexit relations	Approval timelines

Critical analysis

The analysis of global drug regulatory bodies such as the FDA, EMA, MHRA, TGA, DGDA, WHO, and ISO shows both their strengths and challenges in making medicines safe, effective, and available worldwide. Agencies like the FDA and EMA have strong systems for drug approval and safety checks, but they face issues with long approval times and differing rules, which can slow down access to medicines. The WHO helps by providing global guidelines but doesn't have the power to regulate drugs directly. Regional bodies like the DGDA and TGA adjust international rules to fit local needs, though they may lack the resources compared to bigger agencies. High costs for meeting regulations can also be a challenge for smaller companies, especially in poorer regions. Global efforts like the ICH try to make rules more uniform across countries, but differences between national agencies still create obstacles. The research suggests that while it's important to harmonize regulations globally, it's also necessary to adapt them to local health needs and strengthen systems in developing countries to improve access to safe medicines (Aziza, 2021; Stergiou et al., 2023).

Research analysis

The analysis of global drug regulatory bodies like the FDA, EMA, MHRA, TGA, DGDA, WHO, and ISO shows their important role in keeping medicines safe, effective, and high- quality. These organizations protect public health by setting strict rules, checking clinical trials, and monitoring drug safety. For example, the FDA and EMA lead drug approvals in developed countries, while WHO and ISO set global standards to promote cooperation between nations. Regional agencies like DGDA in Bangladesh and TGA in Australia use these global standards to meet local healthcare needs. However, challenges remain. Different rules among agencies, like the FDA and EMA, cause delays in drug approvals worldwide. High costs for following regulations can be tough for smaller companies, especially in poorer countries. Long approval times can slow access to important medicines during emergencies, and managing global drug safety—like preventing counterfeit drugs—is complicated and needs more cooperation (Almeman, 2024; Muteeb et al., 2023; Rahman et al., 2025).

The ICH (International Council for Harmonisation) works to make drug regulation rules the same across countries. The ICH is an international group that helps make drug development and regulation rules the same across different countries (Rani et al., 2024; Stergiou et al., 2023). Strengthening regulatory systems in developing countries, like DGDA, can improve access to safe medicines. Organizations like WHO and ISO also support better coordination while letting countries adapt standards to local needs. The research highlights the need to balance global cooperation with regional flexibility. Simplifying processes, increasing collaboration, and fixing resource gaps can create a fairer, faster, and more effective global system for regulating medicines. This will ensure safe, quality medicines are available to people everywhere(Ahmed, 2024; Aziza, 2021; Costanza-Chock et al., 2022).

Merits & Demerits

Merits

Safety and Quality Control: Regulatory bodies like the FDA, EMA, and MHRA ensure that medicines are safe for people by conducting strict tests before drugs are approved. This protects the public from harmful or low-quality drugs: Efficient Drug Approval Process: Agencies such as the FDA and EMA have systems to quickly approve new drugs that are safe and effective. They also fast-track important medicines, like cancer drugs or vaccines, especially during health emergencies; Global Coordination: Organizations like the WHO and ISO create international rules that help standardize drug

regulations across the world. This helps countries work together and reduces the need for different approval processes in each country; Regional Adaptation: Bodies like the DGDA in Bangladesh and TGA in Australia adjust international rules to fit the needs of their own populations (Rahman et al., 2025).

This allows each country to address local health problems more effectively; Encouraging Innovation: Regulatory bodies provide clear rules that help pharmaceutical companies develop new medicines. This support helps researchers create new treatments for health problems around the world.

Demerits

Long Approval Times: Even though drugs are tested for safety, the approval process can take a long time. This can be a problem during emergencies, like disease outbreaks, when medicines are urgently needed. While the FDA has some fast-track programs, delays still happen; High Compliance Costs: Meeting regulatory requirements can be very expensive, especially for smaller companies. These costs can discourage new drug development, particularly for diseases that mainly affect poor countries; Regulatory Inconsistencies: Different countries have different rules for approving drugs, which can cause delays. Companies often have to go through separate approval processes for each country, which slows down the availability of medicines worldwide; Resource Constraints: Some regulatory bodies, like the DGDA, may not have enough resources to do everything they need to do. This can lead to slower approval times, less monitoring of drug safety, and difficulty enforcing regulations; Slow Global Harmonization: Even though groups like the ICH and WHO are trying to standardize drug regulations, full agreement across countries is still a challenge. Countries have different health needs, priorities, and resources, which can make it hard to create one universal system (Ncube et al., 2021; Niazi & Mariam, 2023).

Advancement

The advancement of drug regulatory bodies like the FDA, EMA, MHRA, TGA, DGDA, WHO, and ISO has made medicines safer and more accessible around the world. These organizations have worked together to make drug standards more similar across countries, which helps ensure that medicines are safe. In emergencies, like the COVID-19 pandemic, the FDA and EMA quickly approved vaccines and treatments, making them available faster They also monitor medicines after they are approved to spot any side effects early, protecting patients (Haleem et al., 2015; Heston & Khun, 2023). With the use of new technology, drug approval processes have become faster and more efficient. These agencies also work together to tackle global issues like counterfeit or fake drugs, harmful medicine, ensuring better drug quality. Programs have been introduced to speed up the approval of treatments for rare diseases, helping people with unique health needs. In developing countries, agencies like the DGDA in Bangladesh are improving their drug regulation systems to ensure safe medicines for their populations. While these advancements have made medicines more available worldwide, there's still more to be done, especially in poorer areas and to tackle new health problems (Ahmad et al., 2021; Annaratone et al., 2021; Eba & Nakamura, 2022).

Conclusion

In conclusion, the comparison of global drug regulatory systems, including organizations like the FDA, EMA, MHRA, TGA, DGDA, WHO, and ISO, highlights their crucial role in ensuring the safety, efficacy, and quality of medicines worldwide. While these organizations have made important progress in protecting public health, challenges still exist, such as differences in rules, limited resources, and keeping up with new drug technologies. To overcome these issues, more international cooperation is needed to make drug approval processes faster and safer. Moreover, organizations like the WHO and ISO are also important in setting global standards for medicine production and helping make medicines available to everyone. For better health outcomes, these bodies need to keep working together and adapting to new challenges, leading to a more efficient and effective global drug regulatory system.

Acknowledgments
I would like to convey my appreciation to all parties who have been involved in the research and writing the manuscript before published on this journal.

Author Contributions
All authors work together in carrying out each stage of research and writing the manuscript.

Funding
This research received no external funding.

Conflicts of Interest
The authors declare no conflict of interest.

References

Ahmad, Z., Rahim, S., Zubair, M., & Abdul-Ghafar, J. (2021). Artificial intelligence (AI) in medicine, current applications and future role with special emphasis on its potential and promise in pathology: present and future impact, obstacles including costs

and acceptance among pathologists, practical and philosophical considerations. A comprehensive review. *Diagnostic pathology*, *16*(1), 24. https://doi.org/10.1186/s13000-021-01085-4

Ahmed, R. (2024). Ensuring Quality Medicine is not a Single Event but Rather Combines Effects of a Pharmaceutical Company. *Radinka Journal of Health Science*, *2*(2), 226-241. https://doi.org/10.56778/rjhs.v2i2.360

Al-Busafi, S. A., & Alwassief, A. (2024). Global perspectives on the hepatitis B vaccination: challenges, achievements, and the road to elimination by 2030. *Vaccines*, *12*(3), 288. https://doi.org/10.3390/vaccines12030288

Ali, F., Neha, K., & Parveen, S. (2023). Current regulatory landscape of nanomaterials and nanomedicines: A global perspective. *Journal of Drug Delivery Science and Technology*, *80*, 104118. https://doi.org/10.1016/j.jddst.2022.104118

Almeman, A. (2024). The digital transformation in pharmacy: embracing online platforms and the cosmeceutical paradigm shift. *Journal of Health, Population and Nutrition*, *43*(1), 60. https://doi.org/10.1186/s41043-024-00550-2

Alowais, S. A., Alghamdi, S. S., Alsuhebany, N., Alqahtani, T., Alshaya, A. I., Almohareb, S. N., Aldairem, A., Alrashed, M., Bin Saleh, K., Badreldin, H. A., Al Yami, M. S., Al Harbi, S., & Albekairy, A. M. (2023). Revolutionizing healthcare: The role of artificial intelligence in clinical practice. BMC Medical Education, 23(1), 689. https://doi.org/10.1186/s12909-023-04698-z

Annaratone, L., De Palma, G., Bonizzi, G., Sapino, A., Botti, G., Berrino, E., ... & Alleanza Contro il Cancro (ACC) Pathology and Biobanking Working Group. (2021). Basic principles of biobanking: from biological samples to precision medicine for patients. *Virchows Archiv*, *479*(2), 233-246. https://doi.org/10.1007/s00428-021-03151-0

Arnold, D. G., Amato, L. H., Troyer, J. L., & Stewart, O. J. (2022). Innovation and misconduct in the pharmaceutical industry. Journal of Business Research, 144, 1052–1063. https://doi.org/10.1016/j.jbusres.2022.02.026

Aslam, B., Khurshid, M., Arshad, M. I., Muzammil, S., Rasool, M., Yasmeen, N., ... & Baloch, Z. (2021). Antibiotic resistance: one health one world outlook. *Frontiers in cellular and infection microbiology*, *11*, 771510. https://doi.org/10.3389/fcimb.2021.771510

Aziza, F. (2021). Comparison review of two regulatory agencies regulation: Therapeutic Goods Administration (TGA) and the European Medicine Agency (EMA) in relation to Good Manufacturing Practice (GMP) guideline. *Majalah Farmaseutik*, *17*(2), 243-248. https://doi.org/10.22146/farmaseutik.v17i2.60237

Badnjević, A., Pokvić, L. G., Deumić, A., & Bećirović, L. S. (2022). Post-market surveillance of medical devices: A review. *Technology and Health Care*, *30*(6), 1315-1329. https://doi.org/10.3233/THC-220284

Barker Scott, B. A., & Manning, M. R. (2024). Designing the Collaborative Organization: A Framework for how Collaborative Work, Relationships, and Behaviors Generate Collaborative Capacity. The Journal of Applied Behavioral Science, 60(1), 149–193. https://doi.org/10.1177/00218863221106245

Basu, A., Kuziemsky, C., de Araújo Novaes, M., Kleber, A., Sales, F., Al-Shorbaji, N., ... & Udayasankaran, J. G. (2021). Telehealth and the COVID-19 pandemic: international perspectives and a health systems framework for telehealth implementation to support critical response. *Yearbook of medical informatics*, *30*(01), 126-133. DOI: 10.1055/s-0041-1726484

Burns, L., Le Roux, N., Kalesnik-Orszulak, R., Christian, J., Hukkelhoven, M., Rockhold, F., & O'Donnell, J. (2022). Real-world evidence for regulatory decision-making: guidance from around the world. *Clinical Therapeutics*, *44*(3), 420-437. https://doi.org/10.1016/j.clinthera.2022.01.012

Chourasia, S., Pandey, S. M., Murtaza, Q., Agrawal, S., & Gupta, K. (2023). Redefining Industry 5.0 in ophthalmology and digital metrology: A global perspective. *MAPAN*, *38*(2), 527. https://doi.org/10.1007/s12647-023-00633-1

Costanza-Chock, S., Raji, I. D., & Buolamwini, J. (2022, June). Who Audits the Auditors? Recommendations from a field scan of the algorithmic auditing ecosystem. In *Proceedings of the 2022 ACM Conference on Fairness, Accountability, and Transparency* (pp. 1571-1583). https://doi.org/10.1145/3531146.3533213

Eba, J., & Nakamura, K. (2022). Overview of the ethical guidelines for medical and biological research involving human subjects in Japan. *Japanese Journal of Clinical Oncology*, *52*(6), 539-544. https://doi.org/10.1093/jjco/hyac034

Fourie Zirkelbach, J., Shah, M., Vallejo, J., Cheng, J., Ayyoub, A., Liu, J., ... & Theoret, M. R. (2022). Improving dose-optimization processes used in oncology drug development to minimize toxicity and maximize benefit to patients. *Journal of Clinical Oncology*, *40*(30), 3489-3500. https://doi.org/10.1200/JCO.22.00371

Hayat, A. A., Keshavarzi, M. H., Zare, S., Bazrafcan, L., Rezaee, R., Faghihi, S. A., ... & Kojuri, J. (2021). Challenges and opportunities from the COVID-19 pandemic in medical education: a qualitative

study. *BMC Medical Education*, *21*(1), 247. https://doi.org/10.1186/s12909-021-02682-z

Heston, T. F., & Khun, C. (2023). Prompt engineering in medical education. *International Medical Education*, *2*(3), 198-205. https://doi.org/10.3390/ime2030019

Khoo, Y. K., Lim, J. C., Tan-Koi, W. C., Kitikiti, N. S., & Sim-Devadas, A. L. (2024). Promoting collaboration of regulators and patients in improving drug safety and regulatory decision making. *Drug Safety*, *47*(3), 217-225. https://doi.org/10.1007/s40264-023-01385-2

Lescrauwaet, L., Wagner, H., Yoon, C., & Shukla, S. (2022). Adaptive Legal Frameworks and Economic Dynamics in Emerging Tech-nologies: Navigating the Intersection for Responsible Innovation. *Law and Economics*, *16*(3), 202–220. https://doi.org/10.35335/laweco.v16i3.61

Marshall, C. M., Federice, J. G., Bell, C. N., Cox, P. B., & Njardarson, J. T. (2024). An update on the nitrogen heterocycle compositions and properties of US FDA-approved pharmaceuticals (2013–2023). *Journal of Medicinal Chemistry*, *67*(14), 11622-11655. https://doi.org/10.1021/acs.jmedchem.4c01122

Martins, A. C., Oshiro, M. Y., Albericio, F., & de la Torre, B. G. (2024). Food and Drug Administration (FDA) approvals of biological drugs in 2023. *Biomedicines*, *12*(9), 1992. https://doi.org/10.3390/biomedicines12091992

Muteeb, G., Rehman, M. T., Shahwan, M., & Aatif, M. (2023). Origin of antibiotics and antibiotic resistance, and their impacts on drug development: A narrative review. *Pharmaceuticals*, *16*(11), 1615. https://doi.org/10.3390/ph16111615

Ncube, B. M., Dube, A., & Ward, K. (2021). Establishment of the African Medicines Agency: progress, challenges and regulatory readiness. *Journal of pharmaceutical policy and practice*, *14*(1), 29. https://doi.org/10.1186/s40545-020-00281-9

Niazi, S. K., & Mariam, Z. (2023). Computer-aided drug design and drug discovery: a prospective analysis. *Pharmaceuticals*, *17*(1), 22. https://doi.org/10.3390/ph17010022

Ogbuagu, O. O., Mbata, A. O., Balogun, O. D., Oladapo, O., Ojo, O. O., & Muonde, M. (2023). Quality assurance in pharmaceutical manufacturing: Bridging the gap between regulations, supply chain, and innovations. *International Journal of Multidisciplinary Research and Growth Evaluation*, *4*(1), 823-831. https://doi.org/10.54660/.IJMRGE.2023.4.1-823-831

Patil, R. S., Kulkarni, S. B., & Gaikwad, V. L. (2023). Artificial intelligence in pharmaceutical regulatory affairs. *Drug Discovery Today*, *28*(9), 103700. https://doi.org/10.1016/j.drudis.2023.103700

Pramesh, C. S., Badwe, R. A., Bhoo-Pathy, N., Booth, C. M., Chinnaswamy, G., Dare, A. J., ... & Weiderpass, E. (2022). Priorities for cancer research in low-and middle-income countries: a global perspective. *Nature medicine*, *28*(4), 649-657. https://doi.org/10.1038/s41591-022-01738-x

Rahman, M. A., Zamil, M. H., & Hoque, A. B. (2025). A meta-analysis of ERP and CRM integration tools in business process optimization. *ASRC Procedia: Global Perspectives in Science and Scholarship*, *1*(01), 278-312. https://doi.org/10.63125/yah70173

Rani, J., Saha, S., Ferdous, F., & Rahman, M. A. (2024). Assessment of the Bangladeshi antibiotic market: implications of the WHO AWaRe classification and dosage form availability on antimicrobial resistance. *Journal of Infection and Public Health*, *17*(12), 102587. https://doi.org/10.1016/j.jiph.2024.102587

Ransing, R., De la Rosa, P. A., Pereira-Sanchez, V., Handuleh, J. I., Jerotic, S., Gupta, A. K., ... & Jatchavala, C. (2022). Current state of cannabis use, policies, and research across sixteen countries: cross-country comparisons and international perspectives. *Trends in psychiatry and psychotherapy*, *44*(suppl 1), e20210263. https://doi.org/10.47626/2237-6089-2021-0263

Rashid, H. (2023). Problem and Prospect of Pharmaceuticals Industry of Bangladesh amid LDC Graduation. *Rashid, H.(2023). Problem and Prospect of Pharmaceuticals Industry of Bangladesh amid LDC Graduation. South Asian Journal of Social Studies and Economics*, *20*(4), 173-188. *https://doi.org/10.9734/sajsse/2023/v20i4751*

Stergiou, G. S., Menti, A., Asayama, K., De La Sierra, A., Wang, J., Kinoshita, H., ... & Alpert, B. (2023). Accuracy of automated cuff blood pressure monitors in special populations: International Organization for Standardization (ISO) Task Group report and call for research. *Journal of hypertension*, *41*(5), 811-818. *DOI:* 10.1097/HJH.0000000000003403

Thapliyal, D., Karale, M., Diwan, V., Kumra, S., Arya, R. K., & Verros, G. D. (2024). Current status of sustainable food packaging regulations: global perspective. *Sustainability*, *16*(13), 5554. https://doi.org/10.3390/su16135554

Udegbe, F. C., Ebulue, O. R., Ebulue, C. C., & Ekesiobi, C. S. (2024). Machine Learning in Drug Discovery: A critical review of applications and challenges. *Computer Science & IT Research Journal*, *5*(4), 892-902. DOI: 10.51594/csitrj.v5i4.1048

Van der Schueren, B., Vrijlandt, P., Thomson, A., Janssen, H., & Dunder, K. (2024). New guideline of the European Medicines Agency (EMA) on the clinical investigation of medicinal products in the treatment and prevention of diabetes mellitus. *Diabetologia*, *67*(7), 1159-1162. https://doi.org/10.1007/s00125-024-06162-z

Walker, H. L., Ghani, S., Kuemmerli, C., Nebiker, C. A., Müller, B. P., Raptis, D. A., & Staubli, S. M. (2023). Reliability of medical information provided by ChatGPT: assessment against clinical guidelines and patient information quality instrument. *Journal of Medical Internet Research*, *25*, e47479. https://doi.org/10.2196/47479

Walter, Y. (2024). Managing the race to the moon: Global policy and governance in Artificial Intelligence regulation—A contemporary overview and an analysis of socioeconomic consequences. *Discover Artificial Intelligence*, *4*(1), 14. https://doi.org/10.1007/s44163-024-00109-4