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Review Article

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Building Bridges: Harmonization efforts for enhanced collaboration between developed and developing countries

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Abstract

The harmonization efforts among regulatory bodies and stakeholders from developed and developing countries in the global healthcare landscape specifically focus on initiatives taken by CDSCO in India, MHLW in Japan, the TGA in Australia, ASEAN countries, and the US. The objective is to examine the importance of building bridges between these regions and harmonizing regulatory frameworks in the pharmaceutical and healthcare industries. The challenges faced include disparities in resources, technological capabilities, cultural differences, and regulatory frameworks. However, collaboration offers benefits such as increased access to affordable medicines, knowledge sharing, regulatory convergence, and capacity-building programs. International organizations like ICH play a role in facilitating harmonization efforts. Aligning regulatory systems and collaboration can enhance patient safety, facilitate trade, attract investment, and foster innovation. This paper concludes that harmonization efforts among CDSCO, MHLW, TGA, ASEAN countries, and the US can create a more integrated and equitable global healthcare ecosystem, bridging the gap between developed and developing countries.

Keywords: Regulatory bodies, Harmonization, International cooperation, Regulatory Harmonization Steering Committee (RHSC), Asia-Pacific Economic Cooperation (APEC), ASEAN, PAHO, ICMRA, WHO, PANDRH, EMEA, FDA, ICH, ACESS

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1. Introduction

This paper has set out to map the importance of regulatory harmonization between developed and developing countries in the field of pharmaceuticals. Regulatory harmonization refers to the alignment of regulatory standards, processes, and requirements across different countries or regions, with the goal of facilitating the global development, evaluation, and access to safe and effective medicines.(1)

In recent years, the pharmaceutical industry has witnessed a rapid globalization of drug development and market access. However, disparities in regulatory frameworks between developed and developing countries have created challenges for both regions. Developed countries often face obstacles in accessing affordable medicines, while developing countries struggle to ensure timely access to quality drugs and build robust regulatory systems. Bridging these gaps and fostering collaboration can lead to significant benefits for both sides.(1)

The paper also explores the various initiatives and strategies that have been implemented globally to promote regulatory harmonization, such as the ICH, prequalification program, and regional harmonization initiatives. These initiatives aim to streamline regulatory processes, promote information sharing, and enhance capacity building in developing countries.

Regulatory Affairs are a relatively new field that developed as a result of government's efforts to protect public health by regulating the efficacy and safety of goods in industries like pharmaceuticals, veterinary medicines, medical devices, pesticides, and cosmetics by analysing the regulatory documents of developed and developing agencies. For the marketing and distribution of medications for both human and veterinary use, regulated countries have clearly established and more stringent processes. The US, Japan, and TGA are the developed regulated markets. Developing countries markets are those in which some characteristics of developed/regulated market but no harmonized guideline. They can establish their harmonization in

clusters with their mutual situation that regulates the supply of medicines. It may include newly formed nations, those with limited populations, and developing nations such as Asian and AFRICAN nations. A specialized regulatory Affairs department or independent regulatory advisors are necessary for pharmaceutical businesses that are in charge of drug research, development, manufacturing, and marketing in order to meet their needs and comprehend regional concerns about pharmaceutical manufacturing products.(2)

Developed and developing countries face different challenges in pharmaceutical regulatory Affairs due to variations in their healthcare systems, economic conditions, and regulatory frameworks. Here are some of the challenges faced by each group:

1.1 Challenges Faced by Developed Countries

- Stringent Regulatory Requirements: Developed countries often have more complex and stringent regulatory requirements, including extensive clinical trial data, safety and efficacy evaluations, and post-market surveillance. Meeting these requirements can be time-consuming and expensive for pharmaceutical companies.
- Rising Healthcare Costs: Developed countries often struggle with rising healthcare costs, including pharmaceutical expenditures. Balancing access to affordable medicines while maintaining high regulatory standards poses a significant challenge.
- Drug Pricing and Reimbursement: Developed countries face challenges in establishing fair and cost-effective drug pricing and reimbursement policies. Striking a balance between ensuring access to innovative medicines and controlling healthcare costs is a complex task.
- Rapid Technological Advancements: Technological advancements in pharmaceuticals, such as personalized medicine, gene therapies, and digital health solutions, present regulatory challenges in evaluating and approving novel products while ensuring patient safety.(3)

1.2 Challenges Faced by Developing Countries

- Limited Regulatory Capacity: Developing countries often face challenges in building and maintaining robust regulatory systems due to resource constraints, lack of expertise, and inadequate infrastructure. This can result in delays in product registration, weak pharmacovigilance systems, and limited regulatory oversight.
- Access to Essential Medicines: Developing countries often struggle to ensure access to affordable and quality medicines for their populations. Regulatory processes, including lengthy approval timelines, can hinder timely availability of life-saving drugs.
- Counterfeit and Substandard Medicines: Developing countries often face a significant problem of counterfeit and substandard medicines entering their markets. Weak regulatory enforcement and limited surveillance capabilities contribute to this challenge, posing risks to patient safety.
- Technology and Knowledge Gaps: Developing countries may face technology and knowledge gaps in areas such as advanced clinical trial methodologies, data management, and regulatory harmonization. Bridging these gaps is crucial to strengthen their regulatory frameworks.
- Collaboration and Harmonization: Developing countries often struggle with regional and international regulatory harmonization, which can hinder efficient access to medicines. Lack of coordination and varying regulatory requirements can create barriers for pharmaceutical companies seeking to enter multiple markets.(3)

These challenges can vary across individual countries within each category, and efforts are being made globally to address them through collaborations, capacity building, and regulatory reforms. There is a need for harmonization in developed and developing countries with respect to regulatory perspectives to resolve these challenges:

- Globalization and interconnectedness: In today's world, countries are increasingly interconnected through trade, investment, and technology. Products and services flow across borders and regulatory differences can create barriers to market access and hinder economic growth. Harmonization of regulations helps to facilitate international trade, reduce trade barriers, and promote economic cooperation.(4)
- Consumer protection: Harmonization of regulations ensures consistent standards for consumer protection. When regulations are harmonized, consumers can have confidence that products and services meet certain safety, quality, and labeling requirements, regardless of where they are produced or purchased. This enhances consumer trust, promotes fair competition, and safeguards public health.(5)
- Efficiency and cost-effectiveness: Harmonization can lead to increased efficiency and cost-effectiveness for businesses operating in multiple jurisdictions. When regulations are aligned, companies can streamline their operations, avoid duplicative compliance requirements, and reduce administrative burdens. This can result in cost savings and foster innovation by freeing up resources for research and development.(6)

- Regulatory convergence: Harmonization encourages regulatory convergence, where countries adopt similar approaches to address common challenges. This convergence allows for the exchange of best practices, sharing of scientific expertise, and coordination in addressing emerging issues such as environmental protection, public health crises, or technological advancements. It helps countries leverage each other's knowledge and experiences to develop more effective and efficient regulatory frameworks.(7)
- Investment and economic development: Regulatory harmonization can attract foreign direct investment (FDI) and promote economic development. When regulations are consistent and transparent across countries, investors feel more confident in committing their resources to new markets. Harmonization creates a level playing field and reduces uncertainty, which can stimulate investment, create jobs, and spur economic growth, particularly in developing countries.(7)
- International cooperation and standards: Harmonization fosters international cooperation and collaboration among regulatory authorities. It encourages countries to work together in developing common standards, guidelines, and regulatory frameworks. This collaboration promotes the sharing of information, harmonization of testing and certification procedures, and alignment of technical regulations. It also helps countries address transnational issues such as cybersecurity, cross-border data flows, and emerging technologies.

The international regulatory authorities and the pharmaceutical industry are connected via regulatory Affairs professionals. They analyse the regulations of the developed agencies to fill the gap left by the lack of regulation for regional Affairs.(8)

Overall, regulatory harmonization between developed and developing countries can lead to numerous benefits, including improved market access, consumer protection, efficiency, innovation, and economic growth. It is a crucial step towards creating a more interconnected and sustainable global economy. Each nation has a regulatory body that is tasked with enforcing laws and issuing directives pertaining to pharmaceutical product development, licensing, registration, manufacturing, marketing, and labelling. Regulations must be in place for drug manufacture, import, storage, distribution, sales, and supply.(8) Here we have discussed the efforts taken by the various developed and developing countries to harmonized the pharmaceutical world.

REGULATORY HARMONIZATION AND CONVERGENCE

The term "regulatory harmonization" has a wide range of connotations depending on the context. The procedure through which technical suggestions are developed to ensure consistency across participating authorities is one word that refers to CBER's work. Regulatory convergence, on the other side, describes the process through which regulatory requirements throughout all countries or regions progressively become much more equivalent or closely allied over time as a result of the gradual adoption of globally recognized technical guidance documents, and scientific principles, standards, common or similar practices and processes, or the adaptation of regulatory mechanisms that may be specific to a local legal sense but align with common values.(9)

2. Actions in the CBER Harmonization Program

Economic Cooperation in Asia-Pacific Regulatory Harmonization Steering Committee of the Life Sciences Innovation Forum

The Asia-Pacific Economic Cooperation (APEC) organisation is a global, voluntary grouping of Pacific-rim economies. By policy alignment and technical collaboration, APEC supports commerce and sustainable economic growth. APEC works through a number of specialised topic area fora, one of which is the Life Sciences Innovation Forum (LSIF). The LSIF's major purpose is to "bring together representatives from government, industry, and academia to promote life-sciences innovation in support of human health in the area."

The Regulatory Harmonization Steering Committee (RHSC) established in 2008 underneath the jurisdiction of the LSIF to support a strategy and contributing to greater pharmaceutical product regulatory harmonic progression and capacity development initiatives within the APEC continent. The RHSC has established a Managerial Framework that defines major work spaces and implementation strategies in order to foster greater uniformity in medical product regulations, with training playing an important role. The FDA CBER accompanies the Centers for Drug Evaluation and Research and Devices and Radiological Health inside its involvement in the RHSC and its task forces. The worldwide supply chain Fidelity and Quality Of products, Safety monitoring, Good Registration Management, Multi-regional Clinical Testing and Good Clinical Practice Inspection, Advanced Therapies, Medical Devices, and Biotherapeutic Products are all areas where FDA CBER personnel may assist.(9)

3. Regulatory Agencies

3.1 Central Drugs Standard Control Organization (CDSCO)

Leading drug regulators across the world have agreed to collaborate with the CDSCO to investigate regulatory possibilities. As reported by the Pharmaceutical Export Promotion Council of India, stronger relationships with overseas drug regulators are expected to enhance the regulatory environment and promote Indian exports (Pharmexcil). India also contributed immensely to and backed the new South East Asia Regulation Network (SEARN). The Indian national regulatory authority is also a member of the Developing Country Vaccine Regulators' Network (DCVRN); an observer in ICH,

and a Vice-Chair of WHO's Member State Mechanism on substandard and falsified medical products.(10) Mutual agreements and memorandum of understanding have been concluded with the NRAs of the United States, the United Kingdom, Japan, Russia, Sweden and other countries.(11) The Memorandum of Understanding (MOU) in Table 1 will assist in creating a framework for effective communication and information sharing in between CDSCO and various other regulatory organizations.

Table 1. MOU Signed by CDSCO

Sr. No	Name of the MOU/Agreement/Treaty	Description
1	Memorandum of Understanding (MOU) between Ministry of Health and Family Welfare of Republic of India and the Office of Healthcare Policy, Cabinet Secretariat, Government of Japan and the Ministry of Health, Labour and Welfare of Japan in the field of Healthcare and Wellness	To establish a mechanism to identify potential areas for collaboration between India and Japan in common domains of primary healthcare, prevention of non-communicable diseases, maternal and child health services, sanitation, hygiene, nutrition and elderly care
2	Memorandum of Intent between the CDSCO of the Republic of India and the Swedish Medical Products Agency (MPA)	This agreement, complimentary to the on-going cooperation between India and Sweden covering the area of health, is for increasing bilateral cooperation in the fields of pharmacovigilance, electronic submissions in related matter, clinical trials, drugs, medical devices and diagnostic kits, cosmetic and hygiene products and for exchange of information and experiences regarding good manufacturing practice.
3	MOU in pharmaceuticals between CDSCO, GOI, and National Administration of Drugs, Food and Medical Technology, Argentina	The two sides highlighted the importance of concluding enabling instruments such as the MOU on cooperation in the field of Medical Products Regulation, which facilitates, the exchange of information on procedures for inspection and registration of pharmaceutical products and efficient communication channels between their counterpart institutions
4	The MOU between the CDSCO, India and National Agency for Drug and Food Control (BPOM), Indonesia on cooperation in the field of pharmaceutical products, pharmaceutical substances, biological product and cosmetics regulatory functions.	The MOU is expected to forge better understanding about each other's regulatory requirements and would be beneficial to both the countries. It could also facilitate India's export of pharmaceutical products. It will also establish a framework for fruitful cooperation and exchange of information between the two countries in matters relating to pharmaceutical products regulation on the basis for equality, reciprocity and mutual benefit. Further, it will facilitate better understanding between the regulatory authorities of the two countries.

Source*:* List of announcements/agreements signed between regulated and non-regulated countries.

3.2 Association of Southeast Asian Nations (ASEAN)

Indonesia, Malaysia, the Philippines, Singapore, Thailand, Brunei Darussalam, Vietnam, Burma, Laos, and Cambodia comprise ASEAN. Nowadays, various nations have varying regulatory criteria for new medicine approval. The single regulatory method for a new medicinal product's marketing authorization application (MAA) applicable to several countries (based on a single dossier) is extremely complex. As a result, in order to develop an appropriate regulatory approach, each country's specific and thorough regulatory requirements for MAA should be known. The ASEAN Pharmaceutical Product Working Group (PPWG activities) for harmonisation include discussions of current technical needs and recommendations, examination of standardised practises and regulatory frameworks for technical standards and regulatory requirements that are now in use in other locations, creation of CTDs in order to reach a Mutual Recognition Arrangement, and harmonisation of technical principles and regulatory requirements that apply to the ASEAN pharmaceutical industry (MRAs).(12) The ASEAN guidelines which are harmonised with the European Union and ICH as mentioned in the Table 3.

Table 2. ASEAN Guidelines Harmonization

ASEAN Guidelines	Leading Country	Harmonized with Guidelines	Status
Process Validation	Singapore	European Union	Approved and implemented
Analytical Validation	Thailand	ICH	
Bioavailability/Bioequivalence and Variations	Malaysia	European Union	
Stability Studies	Indonesia	ICH Q1A (R2), Q1B, Q1C, Q1D, Q1E, Q1F), EMA Guideline, WHO Guideline	

Safety Studies	Philippines	ICH S1A, S1B, S1C(R), S2A, S2B, S3A, S3B, S4, S5(R2), S6, S7A, M3), without modification	Adopted
Efficacy Studies	Thailand	ICH E1, E2A, E2C, E3, E4, E6, E7, E8, E9, E10, E11	

Source: The Drug Regulatory Landscape in the ASEAN Region; ICH: International Council for Harmonisation.

3.3 Ministry of Health, Labour, and Welfare (MHLW)

The "International Pharmaceutical Regulatory Harmonization Strategy - Regulatory Science Initiative" has been established by the MHLW. The objective of this approach is to highlight Japan's proactive leadership in Asia and other parts of the global community. Pharmaceutical and Medical Device Agency (PMDA) in Japan are currently working to more successfully support global harmonization and collaboration initiatives. The universal coverage scheme guarantees quick insurance reimbursement, which is the main competitive advantage. In addition to providing the technological foundation and other benefits, such as a greater incentive for research and development on age-related medical conditions, the system is highly likely to collect clinical data. The reliability and timeliness of pharmaceutical approvals also have increased as a result of PMDA structural advancements, and data produced in Japan can now be used throughout Asian populations. There are a few concerns in Japan, such as a lesser market size in comparison to the United States, the high cost of conducting clinical research, and the sluggish global action framework of MHLW and PMDA. The infrastructure needed to speed the licencing of cutting-edge medications, technologies, and regenerative medicine products well before rest of the globe is one of the measures Japan should take to build itself as a "global reference country".(13)

SAKIGAKE's Strategy

On June 14, 2013, the Government of Japan (GOJ) issued the 'Japan Revitalization Strategy' and the 'Healthcare and Medical Strategy,' declaring that the GOJ would promote the practical application of pharmaceuticals, medical devices, and regenerative medicines, which are at the heart of medical excellence, and that the GOJ would develop cutting-edge, innovative medical products with the potential to capture a share of the expanding global market. Based on this, the "Act to Promote Healthcare and Medical Strategies" bill was introduced in the current Diet session and was passed on May 23, 2014.(14)

The Ministry of Health, Labour, and Welfare (MHLW) has been exploring strategies to encourage the production of pharmaceuticals, medical devices, and regenerative medicines. In response, the MHLW released the "Vision for the Pharmaceutical Industry 2013" and "vision for the Medical Device Industry 2013," which depicted medium and long-term visions aimed at having the pharmaceutical and medical device industries play a major role in creating innovation with international competitiveness. The revised Pharmaceutical Affairs Act and legislation were enacted to ensure the safety of regenerative medicine and to enhance the development and enhancement of innovative medical product safety measures.(14)

In this regard, in December 2013, the MHLW appointed the Ministerial Secretariat to serve as the leader of the Ministerial Project Team (SAKIGAKE PT), which would endeavour to pioneer the actual use of breakthrough medical goods. It also opted to design plans as a package that included everything from fundamental research through clinical research/trials, approval reviews, safety measures, insurance coverage, infrastructure and environment improvements, and worldwide expansion. SAKIGAKE's approach includes regulations primarily relevant to regenerative medicine and medical devices that were independently studied by SAKIGAKE PT.(14)

3.4 Therapeutic Goods Administration (TGA)

The TGA's 2021–2025 international engagement plan has a number of objectives, such as developing regulatory framework to decrease the burden of regulations on industry while balancing the requirement to ensuring that drugs introduced to the market are of high quality, safe, and effective, to work together with international partners to share data, work, and information in order to facilitate globally uniform decisions about therapeutic products, shorten the period until a product may be released onto the market, and lower product costs, to identify post market issues and to improve regulatory practice which helps in identifying substandard products. It has participated in international forums to optimize the regulatory processes that are ACCESS – Australia, Canada, Singapore, Switzerland and the United Kingdom Consortium and International Coalition of Medicines Regulatory Authorities (ICMRA).(15)

3.5 Indo-Pacific Regulatory Strengthening Program

In October 2018, the Indo-Pacific Regulatory Strengthening Program (RSP) was formally started. The TGA is spearheading technical interaction with counterpart National Regulatory Authorities (NRAs) in Cambodia, Indonesia, Myanmar, Lao PDR, Papua New Guinea, and Vietnam through this programme and working as a partner nation with Thailand. The RSP's mission is to promote health security in the Indo-Pacific region by increasing access to high-quality, safe, and effective products for the diagnosis, treatment, and prevention of infectious disease risks. This aim is being met via two interconnected components: increasing the capabilities of country NRAs to assure timely access to safe, high-quality, and effective medical goods, and ensuring stakeholder coordination to enhance regional collaboration on regulatory practise. The RSP countries have a wide range of priorities, experience, and expertise.

The TGA is putting in place tailored support packages based on mutually agreed-upon workplans derived from country-specific WHO Institutional Development Plans and individual regulator objectives. In Singapore, a Program Management Unit led by a TGA Program Manager has been formed. The Unit promotes the establishment of strong partnership among regional nations as well as partner organisations.(16)

3.6 Program for Pacific Medicine Testing

From September 2017 to June 2021, the Program for Testing of Pacific Medicines operated as a trial programme. This joint programme between the Departments of Foreign Affairs and Trade (DFAT) and Health (facilitated by the TGA) was established to support quality assurance of medicines throughout the Pacific region, with a focus on laboratory testing of medicines for noncommunicable diseases and antibiotics. The pilot Program involved twelve Pacific Island nations (PICs), including the Federated States of Micronesia, Fiji, Kiribati, Nauru, Palau, Papua New Guinea, the Republic of the Marshall Islands, Samoa, the Solomon Islands, Timor Leste, Tonga, Tuvalu, and Vanuatu.(16)

The TGA tested 223 therapeutic goods for participating PICs over a four-year pilot programme, assisting Pacific Island governments in making decisions about upgrading medical storage facilities, recalling medicines, changing suppliers, and notifying other partner governments about product issues. It has also raised awareness of therapeutic goods safety concerns as well as the larger need for regional therapeutic goods regulating mechanisms. It has aided in the creation of strong people-to-people ties, increased regional security, and produced a great deal of goodwill. In negotiations on the construction of a sub-regional pharmaceutical regulation framework, the TGA also served as an essential intermediary between Chief Pharmacists and the WHO.(16)

Because the pilot programme was a success, DFAT and the TGA reached an agreement for Phase Two of the programme, which began on July 1, 2021. PMTP Phase Two will last four years, through June 30, 2025, and will include participation from the twelve PICs participated in the pilot programme, as well as Timor-Leste. Phase Two of the PMTP will continue to focus on medications for noncommunicable illnesses, but will also involve testing of therapeutic items used in response to the COVID19 pandemic. On request, the TGA may also test therapeutic items that are considered to be substandard, or that have been related with an adverse event, issue or complaint.(16)

3.7 Australia-Canada-Singapore-Switzerland (ACESS) Consortium

Along with Swiss medic, the Swiss Agency for Therapeutic Products, and Health Canada, the TGA is a member of the ACESS Consortium. In order to encourage better regulatory coordination and the alignment of regulatory standards, "like-minded" regulatory authorities founded the medium-sized coalition known as the ACESS Consortium in 2007.(17) To ensure that customers have timely access to high-quality, secure, and effective pharmaceutical products, it aims to maximize international cooperation, decrease duplication, and strengthen each agency's competence. The ACESS Consortium explores opportunities for information and work-sharing initiatives in areas including, generic medicines registration, assessment reports for new prescription medicines, post-market medicine safety monitoring, and alignment of IT systems for information sharing, development of technical guidelines. The need for regulatory authorities to regularly communicate with one another has increased due to the trend towards the globalization of the therapeutic product sectors and the quick development of new technologies. This makes the most of current technical knowledge and guarantees a consistent, modern approach to evaluating the advantages and hazards of using medicinal items.(18)

3.8 International Coalition of Medicines Regulatory Authorities (ICMRA) (18)

Table 3. Membership of the interim ICMRA

Country	Regulatory authority
Australia	Therapeutic Goods Administration (TGA)
Brazil	National Health Surveillance Agency (ANVISA)
Canada	Health Products and Food Branch, Health Canada (HPFB-HC)
China	China Food and Drug Administration (CFDA)
Europe	European Commission - Directorate General for Health and Consumers (DG - SANCO) and European Medicines Agency (EMA)
France	French National Agency for Medicines and Health Products Safety (ANSM)
Germany	Paul-Ehrlich-Institut (PEI)
India	Central Drugs Standard Control Organization (CDSCO)
Ireland	Health Product Regulatory Authority (HPRA)
Italy	Italian Medicines Agency (AIFA)
Japan	Pharmaceuticals and Medical Devices Agency (PMDA), and the Ministry of Health, Labor and Welfare (MHLW)
Korea	Ministry of Food and Drug Safety (MFDS)
Mexico	Federal Commission for the Protection against Sanitary Risks (COFEPRIS)
Netherlands	Medicines Evaluation Board (MEB)

New Zealand	Medsafe, New Zealand Medicines and Medical Devices Safety
Nigeria	National Agency for Food Drug Administration and Control (NAFDAC)
Singapore	Health Sciences Authority Singapore (HSA)
South Africa	Medicines Control Council (MCC), Department of Health
Sweden	Sweden Medicinal Products Agency (MPA)
Switzerland	Swiss medic
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)
United States	Food and Drug Administration (FDA)

Source*:* International Coalition of Medicines Regulatory Authorities (ICMRA) FACT SHEET.

4. The global regulatory environment

The idea to establish an ICMRA is driven by the following trends in the global regulatory environment: The pharmaceuticals sold and consumed in home markets are becoming more and more commodities on the world market. The global integration, complexity, and potential ambiguity of the supply chains for manufacturing and distribution are all factors. A regulator must be aware of and confident in these supply chains, as well as exercise regulatory oversight at every level, in order to guarantee the safety, quality, and efficacy of a pharmaceutical product domestically; In order to manage the risks and benefits, pharmaceutical goods and their constituents are becoming more complicated, necessitating international cooperation among regulators to give access to shared resources and the best possible scientific and technological skills; and increased efficiency in managing international collaboration and the wealth of collective knowledge and resources involved in these projects is also required due to the range and diversity of current international initiatives, which are often performed at the technical/operational level.(18) Coordinating international cooperation among regulatory agencies for medicines will prevent duplication of effort and encourage informed risk-based resource allocation by enhancing communication, facilitating a wider exchange of accurate and comparable information, and encouraging greater leveraging of the resources and outputs of other regulatory agencies. These initiatives, together with others, would improve the quality, safety, and effectiveness of pharmaceuticals on a global scale. In this situation, regulators must work cooperatively on both the domestic and international levels. International talks, as well as those at the World Health Assembly and the International Conference of Drug Regulatory Authorities, have helped to build momentum for the establishment of the ICMRA. Currently, the ICMRA is in its interim stage (2014-2016).(18)

Pharmaceuticals, biologics, genetic treatments, radiopharmaceuticals, and "grey zone"/combination items will be the initial focus of the ICMRA. The ICMRA was established to allow the heads of medicine regulatory authorities to exert collective authority and concerted strategic leadership over existing and new international initiatives, as well as common regulatory issues and challenges, and to facilitate greater cooperation in order to better protect public health. By fostering more trust and closer cooperation among regulators, the ICMRA identifies opportunities for possible synergy between them and, where appropriate, facilitates international leveraging and resource conservation. Additionally, it synchronizes the objectives of recent and on-going activities with those of regulators' changing requirements.(19)

The ICMRA will eventually allow for a universal framework to encourage improved information sharing and communication, as well as to deal with regulatory science challenges. The following sectors will see the application of the ICMRA's strategic role: Regulatory convergence, alignment, and standards creation; regulatory collaboration and work sharing; technical assistance for capacity and competence building; criteria for comparing and evaluating regulatory systems; and regulatory science.(19)

The ICMRA will help to facilitate Improved integration and executive level championing of existing and new international regulatory initiatives; Prompt identification of and coordinated multi-country response to emerging issues, including global issues; Expanded exchange of reliable information through an efficient and strategic use or linking of existing networks, and establishing new networks, where necessary; Better informed risk-based allocation of regulatory authorities' resources to help address common work areas; Increasing coordination of regulatory technical cooperation and capacity/competence building for national and regional medicines regulatory authorities (MRAs) to help strengthen regulatory systems; and Awareness of the requirement for robust regulatory systems and functions at the national, sub-regional, and global levels.(20)

4.1 U. S. Food and Drug Administration (USFDA).

International Collaborations: The FDA encourages international cooperation with comparable foreign governmental institutions and non-governmental groups. Cooperation Arrangements (including Memorandums of Understanding and related instruments) and Confidentiality Commitments are two forms of international agreements the FDA uses to establish and document these partnerships. A Confidentiality Commitment (CC) is a compact that sets the legal basis for the transmission of particular categories of non-public information with FDA equivalents in other countries and international organisations as part of collaborative law enforcement or regulatory operations.(21) If a CC exists, FDA may communicate non-public information with its counterpart, but a CC never obligates FDA (or its counterpart) to divulge information. A cooperative arrangement is an agreement between the FDA and one or more foreign governments or international partners that specifies the FDA's preparedness and good faith intentions to engage in cooperative activities. Even if a Cooperation Agreement

is in existence, the FDA cannot divulge non-public material unless a Confidentiality Commitment is in place.(22)

4.2 Partnerships and Collaboration

The FDA collaborates with foreign governments, regulatory coalitions, development organizations, academic institutions, and other groups to carry out its mandate to oversee and guarantee the safety of the supply chain for food, feed, medical products, cosmetics, and tobacco products that enter the United States from other countries.(20)

International Collaboration of the FDA Regions of Concentration: To carry out its mandate of overseeing and ensuring the safety of the supply chain for food, feed, medical products, cosmetics, and tobacco products that enter the United States from other countries, the FDA collaborates with foreign governments, regulatory coalitions, development organisations, and academic institutions.(23)

Regulatory System Strengthening (RSS): A robust regulatory framework is required for any functional health system. The FDA is focusing on three interconnected areas to support RSS: igniting a global conversation about the importance of regulatory systems to public health; collaborating with others to identify practical means of system strengthening; and utilising resources for international health and development.(24)

Strengthening Safety Surveillance Systems Throughout the World: The FDA advocates for more comprehensive safety surveillance systems worldwide, including systems to assure the safety of pharmaceuticals and vaccines, as well as systems to detect defective and counterfeit items. Where required, the Office of Foreign Programs engages closely with relevant FDA Centre's to enhance research in these areas. The FDA seeks to improve global food safety rules, especially through international organisations. The Office of Foreign Programs works closely with key FDA Centres to promote FDA initiatives in these areas.(25)

4.3 Pan American Health Organization (PAHO)

The Pan American Network for Drug Regulatory Harmonization (PANDRH) is a joint initiative of the region's National Regulatory Authorities and the Pan American Health Organization that promotes regulatory convergence/harmonization processes in the Americas, taking into account national and sub-regional realities, needs, laws, and health policies.(26)

4.4 The PANDRH comprises

The Pan American Conference on Drug Regulation Harmonization, the Steering Committee, the Advisory Council, and the Technical Groups will work in as many areas as the Conference and the Secretariat deem important. Its mission is to promote regulatory convergence in the realm of health products, including aspects of quality, safety, effectiveness, and rational use of health products, as well as the strengthening of the capacities of the Americas region's National Regulatory Authorities (NRAs), based on the population's need for access to quality health products in accordance with scientific and technological progress within the context of national and sub-regional realignment. CBER engages with many Agency components.(26)

The Department of Communicable Diseases and Environmental Determinants of Health (CDE) promotes, coordinates, and implements technical cooperation activities for the surveillance, prevention, control, elimination, and/or reduction of communicable diseases and environmental threats to health that are technically sound and appropriate for the political and sociocultural context in which they are implemented. It strives to have a long-term influence on health by providing normative guidance, expanding the adoption of evidence-based treatments, developing alliances that enhance country capacity, improving the efficacy of international collaboration, and simplifying policy and decision-making procedures.(27)

Noncommunicable Diseases, Violence, and Injury Prevention Unit: The Noncommunicable Diseases Unit coordinates and implements the Regional Plan of Action for the Prevention and Control of Noncommunicable Diseases. Member countries receive technical assistance to strengthen their NCD capacities, with a focus on: fostering efficient public health policies, strategies, programmes, and evidence-based NCD management guidelines; facilitating an integrated approach to managing NCDs based on primary healthcare; monitoring and reporting on NCD burden; and fostering multi-stakeholder partnerships.(28)

The Health Systems and Services Section (HSS) develops technical cooperation initiatives to advance universal health coverage and access (universal health). Building and maintaining strong and resilient health systems, focusing on health governance and financing, health policies, strategies, and plans, as well as people-centered, integrated, quality health services, improving access to and wise use of safe, effective, and high-quality medicines, medical products, and health technologies, strengthening regulatory capacity, and an adequate supply of qualified health human resources, and a cultural shift are all important.(29)

4.5 The Impact of ICH on Industry

ICH is regarded as a fundamental endeavour in the field of regulatory harmonisation for medical devices. ICH's principal goal is to enhance public health. The goal is to contribute to the timely launch of innovative medications as well as the ongoing availability of current drugs to patients. For example, by reducing the use of animal testing and avoiding unnecessary duplication of clinical trials in humans while maintaining safety and effectiveness, as well as contributing to the efficient and cost-effective development, registration, and manufacturing of safe, effective, and high-quality medicines.

Furthermore, it attempts to achieve this goal by developing harmonised norms through a scientific consensus process including regulatory and industry experts. Additionally, the commitment of the ICH's

regulatory members to adopt its principles is critical to the organization's success. As a result, finalised ICH guidelines are implemented in the United States as FDA guidances via the standard Federal Register publishing procedure.(26)

The recommendations in this area have mostly reflected industry best practices.

- The EWGS in this area were able to identify what testing was necessary to study any one sort of toxicity, and therefore to develop a standard battery of tests, by carefully examining standard practice and the types of data that could be retrieved from studies.
- As a result, the standards include carcinogenicity testing, genotoxicity testing, reprotoxicity testing, and chronic toxicity testing in depth.
- There is also a guideline for biotechnology-derived medicines and a guideline for the scheduling of non-clinical safety investigations for the conduct of pharmaceutical human clinical trials (M3). This established the safety data that must be provided before the new medicine may be administered to human volunteers or patients.
- There is a standard set of tests recommended for most types of toxicity studies, a standard set of tests is advised. The scheduling, exact requirements (including dose), and necessity for toxicity studies for different indications or treatment durations have been specified.
- Only one long-term study (typically conducted in a rodent species) and one short- or mid-term trial are required for carcinogenicity research. Long-term research was made simple by the safe's recommendations.
- The particular case of biotechnological goods has also been addressed, with the results available by the end of 2000. All of these resulted in less redundant testing.
- As safety testing is a significant area of research effort, both in academia and industry, reducing the number of longstanding studies required, for example, should allow more resources to be diverted to other approaches to uncover potential risks like genotoxicity and carcinogenicity relevant to humans (along with reducing the use of animals).
- The continuous development of toxicity models is critical to the industry becoming more capable of evaluating the safety of new pharmaceuticals and delivering safe therapies to patients.
- ICH strives to keep recommendations current and under revision based on such research advancements.

Through its operations in the harmonisation of regulatory standards across the EU, Japan, and the US, ICH is assisting industry in shortening development periods by eliminating the duplication of research that was previously required to obtain market clearance for a new medicine in each of the three areas. Industry supports the International Conference on Harmonization (ICH) and its ongoing efforts to further harmonise the technical requirements for the registration of innovative drugs for three reasons: reduced development times and resources, including the elimination of duplicate clinical trials due to ethnic differences, easier simultaneous launch of a new drug in many countries (including across the three ICH regions), and ICH guidelines as a recognised standard, which will facilitate intra-company globalisation. Harmonization via ICH speeds up the supply of essential, life-saving medicines to patients.(30)

4.6 The International Program for Pharmaceutical Regulators (IPRP)

The International Pharmaceutical Regulators Programme (IPRP) was formally launched on January 1, 2018, after a resolution passed by the governing bodies of the International Generic Drug Regulators Programme (IGDRP) and the International Pharmaceutical Regulators Forum (IPRF) in November 2017. Both initiatives had similar aims and a generally overlapping membership of regulatory authorities and organisations, but they focused on different goods: IPRF focused on innovative pharmaceutical items and technology, whereas IGDRP focused on generic product problems of relevance. All parties agreed that by combining the two programmes, efficiencies and synergies might be realised. The IPRP strives to create an environment in which its members and observers can exchange information on issues of mutual interest and enable cooperation among regulatory authorities and organisations, maximising synergies and avoiding duplication of work, establishing a regulatory hub for medicines, and allowing for tighter collaboration with other projects, maximising synergies and minimising duplication of effort.(26)

IPRP meetings take place simultaneously with those of the International Council for Harmonisation for the benefit of efficiency (ICH). The ICH Secretariat offers IPRP with support services owing to funding from IPRP members such as the FDA. Former IPRF and IGDRP working groups continue to function. CBER scientists participate in the Working Groups on Gene Therapies, Cell Therapies, and Identification of Medicinal Product Standards (IDMP). The Center for Drug Evaluation and Research has joined the IPRP MC (CDER).(26)

4.7 International Affairs for non-regulated countries

The regulation of developing countries, such as ASEAN and India, have been studied. The major difference between regulatory developed and developing agencies is their regulatory capacity. Developing countries have very limited regulations as due to low-income countries cannot ensure the safety, efficacy, and quality of medicines in their markets due to a lack of expertise. The health and standard of living of people and communities in developing nations can significantly

improve with the strengthening of regulatory capability. It is anticipated that closer linkages between CDSCO and international regulatory authorities will improve the regulatory environment and boost Indian exports. Top drug regulators from around the world have agreed to collaborate with the CDSCO to look at regulatory options. Even India has actively contributed and provided support for the new SEARN. The PPWG in ASEAN member states has acknowledged that the activities need to be strengthened and expanded in order to facilitate coordination, execution, and monitoring on a systematic basis.(26)

5. Discussion

Developed countries, with established regulatory frameworks, have strived to align their regulations with international standards and promote a level playing field in the global marketplace. These efforts include streamlining regulatory procedures, enhancing transparency, and adopting international best practices. Developed nations also actively participate in international regulatory forums and engage in bilateral and multilateral agreements to promote harmonization.

On the other hand, developing countries face unique challenges in achieving regulatory harmonization due to diverse socio-economic conditions, resource limitations, and varying levels of institutional capacity. Nevertheless, these countries have demonstrated commendable commitment towards regulatory harmonization by implementing regulatory reforms, building regulatory institutions, and seeking technical assistance from international organizations. Developing nations are increasingly engaging in regional cooperation initiatives to harmonize regulations within their respective economic blocs.

International cooperation is required to analyze the state of regulations around the world and to support the NRAs of developing nations. The US-FDA for the United States, the TGA for Australia, the MHLW for Japan are the developed, and the CDSCO for India and the ASEAN nations are the developing regulatory agencies studied on a global basis. The major difference between developed and developing countries in the pharmaceutical sector resides in regulatory capacity. All developed countries have fully operational pharmaceutical regulations and systems to ensure the quality, efficacy, and safety of medicines, even if their systems and procedures slightly differ. However, developing countries have very limited or no regulation and systems. The reality is that many countries are not stand alone to ensure the safety, efficacy, and quality of medicines in their markets due to a lack of expertise, resources (i.e., staffing and financial), standards, systems, and training.

Global system must assist developing nations in overcoming the technical difficulties and capacity challenges they are facing, while minimizing any negative effects on the advanced technical exchange and cooperation between developed nations, given these significant differences in the levels of development between the various countries. The organization and structure must be able to accommodate the various needs that exist amongst the nations. This dual goal can be facilitated by the various levels of collaboration (i.e., bilateral, regional, and global). Separate initiatives may be launched as well, some including only wealthy nations, others involving all nations, and still others involving only developing nations, but they must all be incorporated into the larger global framework and plan. With the time developed countries started with various initiatives as per countries and global regulatory requirements need that are mentioned in this paper.

The health and standard of living of people and communities in developing nations can significantly improve with the strengthening of regulatory capability. Harmonization and collaboration are crucial to promoting public health in these developing nations (which collectively account for 4.8 billion people), and they should be taken into consideration when creating global harmonization. The coming together of the regions regulatory agencies marks a watershed moment that will ensure medical products produced and sold in the region do exactly what they are supposed to. For the Region's smaller countries SEARN will significantly expand the ability for national regulators to ensure medical products are safe and of adequate quality. SEARN will also provide economic benefits to INDIA being a major producer of medicinal products. The network will help strengthening of the National Regulatory Authorities (NRA) of member countries. Through this, NRAs in developing countries have the opportunity to exchange scientific information and expertise with regulators from well-resourced countries. Effective collaboration among member states and secretariat, leads to prevention and control of substandard and falsified (SF) medicinal products and associated activities. (31-36)

6. Conclusion

The harmonization efforts among regulatory bodies, namely CDSCO, MHLW, TGA, ASEAN countries, and the US, have emerged as a promising pathway to foster enhanced collaboration between developed and developing countries in the healthcare sector. This paper has highlighted the importance of building bridges and aligning regulatory frameworks to overcome challenges and unlock the potential benefits of harmonization. By establishing common standards, sharing knowledge and resources, and promoting mutual recognition agreements, these countries can streamline regulatory processes and ensure the quality, safety, and efficacy of pharmaceutical products. Furthermore, harmonization efforts facilitate the equitable access to affordable medicines, promote public health, and foster innovation and investment in the healthcare sector. The analysis of successful harmonization initiatives, such as information exchange platforms, regulatory convergence, and capacity-building programs, underscores the tangible progress that can be achieved through collaboration. These efforts have the potential to bridge the resource and technological gaps between developed and developing countries, leading to increased regulatory efficiency and effectiveness. The role of international organizations, including ICH, in facilitating harmonization efforts cannot be underestimated. Their

guidance, expertise, and support play a crucial role in ensuring that harmonization initiatives are robust, inclusive, and aligned with global best practices.

There was need to set national level organisation and the programs runs through them which have discussed in this work to effectuate several regional issues by their harmonisation. Overall alignment between global organisation and its regional governing programs not only enhance effective regulatory components of the health system but also strengthen the public health domain and contribute to safety outcomes.

In conclusion, the harmonization efforts among CDSCO, MHLW, TGA, ASEAN countries, and the US offer a promising framework for enhanced collaboration between developed and developing countries in the healthcare sector. By continuing to prioritize dialogue, knowledge sharing, and mutual trust, these countries can pave the way for a more integrated and equitable global healthcare ecosystem.

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Conflict of Interest

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