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# Global Pharmaceutical Quality Knowledge Management: Enhancing Regulatory Reliance and Agility

The protection of public health is core to the medicines regulatory mission, and this includes meeting patient needs by supporting the continued availability of critically important medicines.

ICMRA recognizes that pharmaceutical manufacturers seek agility to maintain robust supply chains and continually update manufacturing processes to incorporate changes and improvements as equipment ages, suppliers change, innovations are developed, and knowledge is gained. Companies manage these changes within their pharmaceutical quality systems and/or seek timely regulatory review when changes require prior approval. As the pharmaceutical industry is highly regulated, and the industry is globalized serving multiple markets, companies often must obtain these approvals from multiple national regulatory bodies with different timeframes, therefore potentially delaying implementation of changes.

ICMRA recognizes that regulatory authorities can gain efficiencies by developing common procedures, guidelines, requirements, and interoperable infrastructure that would facilitate the timely sharing of information among regulators on changes occurring within the supply chain. This may include reliance on the assessments of other regulators reviewing those changes. ICMRA considers that this could lead to more timely availability of medicinal products for patients by shortening approval timelines.

**A Coordinated Pharmaceutical Quality Knowledge Management Strategy**

ICMRA supports the prioritization of efforts to strategically work to further leverage the information, expertise and knowledge among ICMRA member authorities. This includes establishing a collective Pharmaceutical Quality Knowledge Management capability to ensure timely and complete information and assessments about the state of pharmaceutical quality management and risk management capabilities. The envisioned capability would provide for:

- Transitioning to harmonized structured and standardized electronic formats using unique facility identifiers for appropriate regulatory information to enable rapid analyses of quality information to support enhanced risk-based and targeted oversight of manufacturers.
- Secure sharing of information about pharmaceutical manufacturing facilities, which can be contributed to, and accessible by, multiple participating regulators.
- Developing a framework that might, in time, support full harmonization of data elements submitted in the quality modules of the common technical document. This could pave the way for sponsors to make simultaneous submissions within a marketing authorization application to all associated regulatory authorities and provide improved capabilities for both industry and regulators in management of post-approval changes (PAC).

- Enabling more extensive mutual reliance among regulators through work to harmonize specific data expectations for sponsors and standards for review among regulators, so that regulators can be assured of the comparability of the assessments and related determinations of other regulatory authorities on whom they intend to rely.

**Strategic Multi-Stakeholder Approach**

ICMRA is providing the global leadership and strategic vision to advance this work, which must be progressed through well-coordinated efforts undertaken by existing and highly experienced international regulatory harmonization, cooperation, and information-sharing bodies including the ICH, PIC/S, and IPRP.

In addition, given the global multi-faceted nature of this undertaking, ICMRA recommends that the work be informed by regular engagement with other key stakeholders in industry and other sectors, with expertise to help identify the best approaches and technology solutions to enable a more collective and coordinated approach to oversee continued quality improvement.

ICMRA therefore endorses a strategic multi-stakeholder approach to pursue this capability by:

- building on earlier work on technical standards and approaches for quality assessment and data sharing
- working with industry through ICH to harmonize key requirements for full harmonization of data elements submitted in the quality modules of the common technical document
- engaging regulators through IPRP to examine and align standards of quality assessment approaches and documentation for greater reliance
- engaging inspectorates through PIC/S to further harmonize inspection and assessment guides and templates for quality oversight and reliance
- harnessing new and already existing informatics and solutions using modern technology to protect commercial confidential information, personal data, and trade secret information
- seeking practical sustainable approaches in all dimensions including but not limited to legal, technical, financial, and operational considerations.

ICMRA recognizes that this work would be transformative and will require a sustained effort in the longer term to build this modern resilient capability. ICMRA seeks the collaboration of the other concerned international pharmaceutical organisations and calls on the international community of medicine regulators, legislators, and industry innovators to work transparently, collaboratively, and expeditiously to advance this work for the benefit of patients everywhere.

**About ICMRA**

ICMRA brings together the heads of 30 medicines regulatory authorities* from every region in the world, with the WHO as an observer. Medicines regulators recognise their role in facilitating access to safe and effective high-quality medicinal products essential to human health and well-being. This includes ensuring that benefits of vaccines outweigh their risks.

ICMRA is an international executive-level coalition of key regulators from every region in the world. It provides a global strategic focus for medicines regulators and gives strategic leadership on shared regulatory issues and challenges. Priorities include coordinated response to crisis situations.

**Members of ICMRA** include: Therapeutic Goods Administration (TGA), Australia; National Health Surveillance (ANVISA), Brazil; Health Products and Food Branch, Health Canada (HPFB-HC), Canada; China National Medical Products Administration (NMPA), China; European Medicines Agency (EMA) and European Commission - Directorate General for Health and Food Safety (DG - SANTE), European Union; French National Agency for Medicines and Health Products Safety (ANSM), France; Paul-Ehrlich-Institute (PEI), Germany; Health Product Regulatory Authority (HPRA), Ireland; Italian Medicines Agency (AIFA), Italy; Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), Japan; Ministry of Food and Drug Safety (MFDS), Korea; Federal Commission for the Protection against Sanitary Risks (COFEPRIS), Mexico; Medicines Evaluation Board (MEB), Netherlands; Medsafe, Clinical Leadership, Protection & Regulation, Ministry of Health, New Zealand; National Agency for Food Drug Administration and Control (NAFDAC), Nigeria; Health Sciences Authority (HSA) Singapore; Medicines Control Council (MCC), South Africa; Medical Products Agency, Sweden; Swissmedic, Switzerland; Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom; Food and Drug Administration (FDA), United States.

**Associate members** include: Argentina national Administration of Drugs, Foods and Medical Devices (ANMAT); Austrian Medicines and Medical Devices Agency (AGES), Colombia National Food and Drug Surveillance Institute (INVIMA); Cuba Center for State Control of Medicines, Equipment and Medical Devices (CECMED); Danish Medicines Agency (DKMA); Israel Ministry of Health (MOH); Poland Office of Registration of Medicinal Products and Biocidal Products (URPLWMiPB); Portugal National Authority of Medicines and Health Products (INFARMED); Russia Federal Service for Surveillance in Healthcare (Roszdravnadzor); Saudi Food and Drug Authority (SFDA); Spanish Agency of Medicines and Medical Devices (AEMPS).

The World Health Organization is an **Observer** to ICMRA.

For updates on ICMRA, including its role in the COVID-19 response, visit http://www.icmra.info