ICMRA Public Workshop on Strengthening Regulatory Convergence and Reliance Through Pharmaceutical Quality Knowledge Management

Summary Report

Date of Workshop: 19 September 2025

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Executive Summary

On 19 September 2025, the International Coalition of Medicines Regulatory Authorities (ICMRA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) hosted a virtual public workshop on strengthening regulatory convergence and reliance through Pharmaceutical Quality Knowledge Management (PQKM). This workshop served as a follow-up to the successful July 2023 workshop, providing an opportunity to update stakeholders on the significant progress made in the ICMRA PQKM project over the past two years.

The workshop highlighted the substantial achievements of the two pilot programs: the Collaborative Assessment Pilot and the Collaborative Hybrid Inspection Pilot (CHIP). Since the workshop held in July 2023, both pilots have been extended and expanded in scope, providing a valuable opportunity to gain further experience with these collaborative regulatory practices.

The ICMRA PQKM project aims to leverage collective resources and information sharing between regulatory agencies through alignment of data submissions, regulatory expectations, assessments, and inspections. The workshop demonstrated how these collaborative approaches significantly reduce the need for multiple separate submissions from sponsors, avoid duplicative assessments and inspections, and facilitate assessment and inspection reliance.

During the workshop, both industry and regulators shared comprehensive feedback on their experiences with the ongoing pilots, highlighting successes, challenges, and lessons learned. Participants explored practical solutions to identified barriers and discussed future directions for sustainable implementation of collaborative regulatory approaches.

Background and Progress Since 2023

ICMRA PQKM Project Evolution

HPRA opened the workshop by providing an overview of the project's evolution since its formal establishment in 2019. The project has been co-led by the US Food and Drug Administration (US FDA) and the Health Products Regulatory Authority (HPRA), and co-chaired by US FDA and HPRA, with the core objective of leveraging collective resources and information sharing between regulatory agencies. This collaboration is achieved through alignment of data submissions, expectations, assessments, and inspections in the post-approval setting.

Key developments relevant to the PQKM project since the 2023 workshop were highlighted, including:

- **Extended Pilot Programs:** Both the Collaborative Assessment Pilot and CHIP were extended beyond their initial phase and would run to the end of 2025, with expanded scope and increased participation.
- **ICH M4Q Revision Progress:** Significant milestones were reached in ongoing work of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) on the M4Q revision of the Common Technical Document (CTD) to harmonize data formats and standards to support regulatory submissions.
- **Identifiers Work:** A group within the ICMRA PQKM project undertook a review of existing standards and identifiers that allow regulators to confirm that it is the same product, entity or regulatory submission under evaluation. The group subsequently undertook a verification exercise, the findings of which were to be published in an updated progress report following the workshop.

Strategic Regulatory Partnership

The project continues to involve strategic collaboration with international expert regulatory bodies, including ICH, the Pharmaceutical Inspection Co-operation Scheme (PIC/S), and the International Pharmaceutical Regulators Programme (IPRP). These partnerships are essential for the development of the standards and infrastructures and shared understandings needed to enable collaborative global regulation.

Industry Perspective on PQKM Progress

IFPMA’s Continued Support

IFPMA representative emphasized industry's strong continued support for the ICMRA PQKM global strategy and pilots. They highlighted a number of the significant advantages observed from industry's perspective, including:

- **Benefits of the Collaborative Assessment Pilot:** Aligned sets of requests, responses, and outcomes; accelerated timelines for multi-region approval; greater clarity; and open engagement with regulators
- **Benefits of the CHIP:** Fewer inspections; aligned deficiency observations; and stronger trust overall in the inspectorates

- **Broader Impact:** The collaboration fuels and helps shape global regulatory reliance programs, establishing trust and aligned working methods that promote global patient access

Industry Engagement and Participation

A representative from Hoffman-LaRoche provided a comprehensive industry perspective, noting that the benefits of collaborative activities greatly outweigh the challenges. They outlined industry's hopes that the pilots become routine practice to improve patient access to important drugs. Key industry observations included:

- **Streamlined Processes:** The pilots provided increased efficiency, predictability, and a streamlined experience for industry, involving a single assessment or inspection with a harmonized outcome across multiple regulatory jurisdictions.
- **Continued and Expanded Participation:** The engagement and involvement of industry in the pilots is crucial to ensure the long-term success of these collaborative approaches to regulation. Industry also holds a strong desire to see participation of additional ICMRA member agencies.
- **Future Optimization:** Areas identified for potential consideration and improvement as part of future planning included development of clearly defined roles, responsibilities and procedures, an appropriate IT platform to enable collaborative regulatory assessments, and further refinement of the scope of eligible applications.

Collaborative Assessment Pilot

Through a collaborative review process, the Collaborative Assessment Pilot aims to align the scientific evaluation of Chemistry, Manufacturing, and Controls (CMC) Post-Approval Change Management Protocol (PACMP) submissions across multiple regulatory authorities and reach the same risk-based recommendations or conclusions.

Pilot Extension and Expansion

HPRA provided an overview of the pilot's significant achievements and an update on its status. The pilot was extended to the end of 2025 with an expanded scope, including:

- **High-impact changes** for medically important treatments
- **Innovative manufacturing technologies**
- Post-approval changes **impacting supply**
- **Generics and biosimilars**

Key Achievements

The first phase of the Collaborative Assessment Pilot demonstrated remarkable success across multiple metrics.

- **Common Assessment Timeline:** Development of a harmonized 120-day assessment timetable with almost simultaneous approvals across multiple regulatory regions (with same-day approval in several cases).
- **Harmonized Questions:** Up to 88% of all assessment questions or information requests were harmonized through intensive regulatory discussions. There was also a reduction of approximately 25% in the total number of information requests.
- **Successful Outcomes:** All five collaborative assessments were successfully completed and resulted in harmonized outcomes.
- **No Additional Regulatory Requirements:** There was no increase in regulatory expectations, with the assessment bar remaining unchanged.

A survey of regulators and industry who had participated in the pilot revealed that collaborative assessments required an increased resource investment, particularly for regulators. However, it was believed that this additional resource requirement would reduce over time as further experience was gained and defined procedures and systems developed.

Ongoing Activities and Future Cases

As of September 2025, the pilot continued to show momentum:

New Applications: At the time of the workshop, five additional applications had been submitted in 2025, with two accepted, one rejected, and two under evaluation.

Active Cases: The first pilot in the second phase was to begin in September 2025, involving a drug substance site transfer. The European Medicines Agency (EMA) would be acting as lead, US FDA, Swissmedic, and the Medicines and Healthcare products Regulatory Agency (MHRA) participating, and the National Medical Products Administration (NMPA), China acting as observer.

Process Improvements: Efficiencies identified during the first phase of the pilot would be introduced to enhance the experience for all participants.

Regulators' Perspectives

Extension Goals and Vision: The extension aims to maintain momentum and gain additional experience through more pilot cases, different product types (biosimilars, generics), and various submission types beyond PACMPs. The goal is to standardize and optimize the collaboration process while understanding requirements for sustainable models of international collaboration.

Regulatory Learning and Benefits: The pilots allowed regulators to gain a better appreciation of the complexity of regulatory processes across different authorities and improved understanding of how other regulators apply scientific standards and risk-based approaches. The pilot demonstrated that collaboration streamlines rather than multiplies questions to industry.

Value of the Observer Role: Observer participation provides a good starting point for understanding collaborative activities and helps agencies subsequently transition to lead or participating roles. The experience builds regulatory knowledge sharing that can support subsequent reliance activities.

Expanded Participation Benefits: Broader participation could serve to increase diversity in regulatory perspectives, improve consistency in application of guidelines, enhance alignment on science and risk-based approaches, and build trust among regulators while avoiding duplication of effort.

Industry Perspectives

Key Benefits for Industry Participants: The key advantage is a single regulatory strategy with a single data package, single set of health authority questions and responses, joint agency meetings if required, single timeline, and single approval. It's like dealing with one combined agency rather than multiple agencies in parallel.

Practical Experience: There were a number of anticipated challenges, including the need for completion of certain national procedures prior to submission, translation requirements, and coordination considerations. Conversely, the benefits included flexibility in terms of aforementioned national procedures, receiving a single set of technical questions, and no increase in regulatory expectations.

Simultaneous Global Approval: The pilot achieved the first-ever simultaneous approval from four health authorities (US FDA, EMA, Health Canada, and Japan's Pharmaceuticals and Medical Devices Agency (PMDA)) for one change, demonstrating the significant potential of collaborative approaches.

Generic and Biosimilar Applicability: While the initial scope of the pilots was limited to ensure maximal benefits for patient and public health, collaborative regulatory evaluation could be equally beneficial for generic and biosimilar manufacturers. Many manufacturers of generic and biosimilar medicines have global reach and face similar post-approval change needs. Delayed implementation can cause quality delays and even temporary manufacturing cessation, leading to market shortages.

Collaborative Hybrid Inspection Pilot

The CHIP involves simultaneous inspection of a facility by two or more authorities, with one authority taking the lead on-site and others participating remotely. The goal is to allow manufacturers undergo a single, hybrid inspection, the outcome of which is accepted by all participating authorities.

Key Achievements

A number of noteworthy outcomes and outputs of the first phase of the CHIP were highlighted, including:

- **Successful Inspections:** Three collaborative hybrid inspections completed with positive outcomes.
- **No Additional Regulatory Burden:** Survey results indicated CHIP did not add regulatory burden for industry.
- **Operational Success:** Good communication and interaction between authorities.
- **Tool Development:** Creation of model inspection schedules, document request templates, guidance for industry on what to expect from a hybrid inspection, and harmonized approaches for regulators.

Scope and Expansion

As with the Collaborative Assessment Pilot, the CHIP was extended to the end of 2025, with a slightly modified scope. The second phase of CHIP would focus on changes for medically important treatments, including generic drugs and biosimilar products, and support manufacturing innovations that could strengthen supply of medicinal products.

Regulatory Drivers and Goals

During the panel discussion, regulators were asked what the main drivers and motivators were for getting involved in the CHIP.

US FDA Perspective: The pilot leverages existing regulatory expertise in inspections while utilizing newer tools to enhance oversight capabilities, improve efficiencies, reduce regulatory burden, and improve timelines for risk-based decision making and public access to critical medicines.

EMA Perspective: Motivated by pandemic experiences that highlighted the need for hybrid inspection capabilities, the pilot supports regulatory collaboration, convergence, and reliance. It provides opportunities for real-world problem-solving and dialogue between authorities and industry.

Health Canada Perspective: Key drivers include global regulatory convergence, reducing inspection duplication, alleviating regulatory burden, and supporting faster approval and access to medically important drugs while leveraging digital technologies.

Swissmedic Perspective: The pilot represents executive-level commitment to greater global collaboration and reliance and provides tools for rapid response to future pandemic or emergency situations while leveraging involvement of local competent authorities who have direct facility access.

Industry Experience and Expectations

Pre-Application Considerations: The ICMRA website provides comprehensive guidance including a stakeholder expectations document, model inspection schedules, and document request templates. The PQKM project group were readily available to meet and address questions in advance of the inspection. The support of senior management is essential when considering applying to the pilots, and companies may benefit from evaluating potential risks and benefits.

Value of Collaboration: Internal alignment and understanding of resource requirements and outcomes are crucial. The pilot offers opportunities for harmonization in regulatory approaches, reduced duplication, improved efficiency, and enhanced trust and transparency between companies and regulators. For companies considering applying to the CHIP, the multiple significant benefits outweigh the risks.

Future Vision: The pilots are important steps toward a situation wherein we could have "one product, one regulatory program, one inspection and one assessment." Early engagement of observers leverages full potential toward reliance goals, requiring formal frameworks for broader scale execution.

Challenges and Solutions

Practical Challenges: Challenges included defining roles and responsibilities, managing time differences, addressing language barriers, handling IT infrastructure limitations, and accommodating different legal requirements and inspection timelines.

Process Development: Challenges were addressed through detailed implementation plans, dedicated coordinator roles, SharePoint platforms for secure information sharing, development of a stakeholder expectations document, preliminary meetings for IT setup and configuration, and model schedules for multi-time zone coordination.

Future Sustainability and Long-Term Vision for Both Pilots

Enablers for Long-Term Sustainability

Both pilots identified key enablers for transitioning from pilot to sustainable operations:

- **Voluntary Participation:** Maintaining voluntary participation with each regulatory authority maintaining full decision-making autonomy, while operating within existing regional legal and regulatory frameworks
- **Comparable Standards:** Ensuring comparable data protection, conflict of interest standards, and assessment standards, including implementation of applicable international guidelines
- **Administrative Support:** Establishing long-term administrative and secretarial support to sustain collaborative efforts
- **Technology Infrastructure:** Use of appropriate IT platforms to support secure access and sharing of documents, including assessment and inspection reports

Possible Future Scope and Considerations

Considerations for future collaborative activities include:

Impact on Supply: Post-approval changes impacting supply of medically important treatments by supporting increased manufacturing capacity

Innovative Technologies: Continuous manufacturing, technologies enabled by artificial intelligence, and advanced process control

Expanded Submission Types: Pre-submission scientific advice, post-approval supplements/variations, initial marketing applications, and pre-approval hybrid inspections

It was highlighted that the ICMRA Executive Committee was actively discussing how best to ensure a long-term, sustainable future for collaborative regulatory mechanisms.

Industry Recommendations and Future Engagement

Key Industry Recommendations

Industry participants provided several recommendations for enhancing and expanding the pilots:

- **Continued Pilot Programs:** Extension and expansion of both pilots with broader product scope
- **Enhanced IT Platforms:** Development of cloud-based platforms for more efficient data exchange

- **Additional Regulatory Authorities:** Inclusion of additional regulatory authorities as participants and observers
- **Broader Implementation:** Wider implementation of ICH Q12 lifecycle management tools
- **Global Regulatory Process:** Development of standardized collaborative tools for interagency and industry interactions

Call for Industry Participation

Both regulators and industry emphasized the critical need for continued industry participation to realize the full potential of these collaborative approaches. The pilots remain open for applications, with simplified two-page application forms and opportunities for informal discussions prior to submission.

Conclusions and Next Steps

The 2025 workshop demonstrated the significant maturation and success of the ICMRA PQKM collaborative pilots since the 2023 workshop. Both the Collaborative Assessment Pilot and CHIP have proven their value in:

- **Enhancing Regulatory Efficiency:** Reducing assessment timelines, harmonizing requirements, and eliminating duplicative processes
- **Building Trust and Collaboration:** Fostering strengthened cooperation between regulatory authorities and with industry
- **Supporting Global Patient Access:** Enabling faster implementation of critical manufacturing changes that support supply of medically important treatments to patients
- **Advancing Regulatory Science:** Promoting science and risk-based approaches while maintaining high standards

Key Take-Home Messages

- **Proven Benefits:** The pilots have demonstrated that collaborative approaches to regulation provide significant benefits that outweigh the challenges and resource investments required
- **Scalability Potential:** Both pilots show strong potential for scaling to routine operations, dependent on introduction of appropriate infrastructure and support
- **Industry Engagement Critical:** Continued and expanded industry participation is essential for realizing the full potential of collaborative regulatory approaches
- **Technology Infrastructure Needed:** A secure, efficient technology platform is viewed as a key enabler for future sustainable operations
- **Global Impact:** The pilots are already showing positive knock-on effects with other regulatory authorities leveraging the outcomes of collaborative assessments in their own evaluations as part of regulatory reliance initiatives

Future Outlook

The workshop concluded with a shared commitment to continue advancing efforts to develop a long-term, sustainable system for global collaborative regulatory practices. Such systems can help to enhance regulatory efficiency, reduce inspection burden on industry and regulators, and improve patient access to medically important treatments through a science- and risk-based approach.

Annex 1: Workshop Agenda and Participating Organizations

ICMRA-industry virtual workshop: Strengthening regulatory convergence and reliance through Pharmaceutical Quality Knowledge Management

Friday, September 19, 2025

7:00 – 9:00 ET | 13:00 – 15:00 CET

AGENDA

7:00 – 7:05	**ICMRA welcoming remarks** *Lorraine Nolan, Chief Executive, HPRA*
7:05 – 7:10	**Industry welcoming remarks** *Ginny Beakes-Read,* *Head, Global Regulatory Policy Group,* *Johnson & Johnson representing IFPMA*
7:10 – 7:20	**ICMRA presentation** *"ICMRA PQKM pilots: Experience to date and looking to the future"* *Sean Barry, Senior Pharmaceutical Assessor (Biologicals), HPRA*
7:20 – 7:30	**Industry presentation** *"ICMRA PQKMS Pilots – industry perspective"* *Markus Goese, Head EU CMC Regulatory Policy, F. Hoffmann-La Roche Ltd*
7:30 – 8:10	**Panel 1 - Experience and engagement on the Collaborative Assessment of Post-Approval Change Management Protocols Pilot** *Co-moderated by* *Janis Bernat, Director, Scientific & Regulatory Affairs, IFPMA* *William Lewallen, International Program Analyst, CDER, FDA*

Panellists: Regulators	***Panellists: Industry***
Larry Lee, *Deputy Director of Operations,* *Office of Pharmaceutical Quality, FDA*	*Mark Pellett,* *Executive Director and Section Head, CMC Regulatory Affairs, AstraZeneca*
Yasuhiro Kishioka, *PhD, Review Director,* *Office of Cellular and Tissue-based Products, PMDA*	*Wan-Li LIAO,* *GRA CMC Regulatory Intelligence Associate Director, Merck KGaA*
Evdokia Korakianiti, *Head of Quality and Safety,* *Human Medicines Div, EMA*	*Sarah Miksinski,* *Executive Director, CMC Regulatory Affairs,* *Gilead Sciences Inc.*
Sean Barry, *Senior Pharmaceutical Assessor (Biologicals),* *HPRA*	*Lisa Little-Tranter,* *Senior Director, CMC Biologics Global,* *Merck/MSD*

This workshop was jointly organised by ICMRA and IFPMA, and includes the participation of ICH, IPRP, PIC/S, ABPI, BIO, DCVMN, EFPIA, IGBA, JPMA, PhRMA, and Vaccines Europe

Evangelos Bakopanos,
Manager, Biotherapeutics Quality Division 2
BRDD, CORR, Health Canada

Markus Goese,
Head EU CMC Regulatory Policy,
F. Hoffmann-La Roche Ltd

Ramesh Potla,
Senior Technical Regulatory Advisor – Biologics
Global Regulatory Affairs CMC at Takeda

Nick Cappuccino
Chair, IGBA Science Committee

8:10 – 8:50 **Panel 2: Experience and Engagement on the Collaborative Hybrid Inspection Pilot (CHIP) Pilot**

Co-moderated by
Sérgio Cavalheiro Filho, Manager, Regulatory Affairs, IFPMA
Michael McDonald, Executive Assistant to the Chief Executive, HPRA

Panellists: Regulators	***Panellists: Industry***
Brendan Cuddy, *Scientific Senior Specialist, Quality and Safety of Medicines Department (H-QS), EMA*	*Stephen Mahoney,* *Executive Director,* *Head of Quality Policy & Advocacy, Gilead*
Magda Joseph, *Regional Manager of GMP Inspections, Regulatory Operations and Enforcement Branch, Health Canada*	*Andrea Kurz,* *Lead External Advocacy Europe,* *Quality Policy & Advocacy,* *F. Hoffmann-La Roche Ltd*
Christian Schaerer, *Head of Inspectorate,* *Swissmedic*	
Lane Christensen, *Branch Chief - Chemistry, Manufacturing & Controls,* *OPQ/CDER, FDA*	
Roberto Conocchia, *GMP Technical Lead, EMA*	

8:50 – 8:55 **Industry concluding remarks and key takeaways**
Ginny Beakes-Read,
Head, Global Regulatory Policy Group,
Johnson & Johnson representing IFPMA

8:55 – 9:00 **ICMRA concluding remarks and key takeaways**
Theresa Mullin,
Associate Director for Strategic Initiatives,
CDER, FDA

This workshop was jointly organised by ICMRA and IFPMA, and includes the participation of ICH, IPRP, PIC/S, ABPI, BIO, DCVMN, EFPIA, IGBA, JPMA, PhRMA, and Vaccines Europe

The workshop included comprehensive panel discussions with representatives from multiple regulatory authorities (US FDA, EMA, HPRA, Health Canada, PMDA, Swissmedic) and industry organizations (Roche, AstraZeneca, Merck, Gilead, Takeda, IFPMA, IGBA) who shared their direct experiences with the ICMRA PQKM pilots and provided insights for future development.

Glossary

CHIP	Collaborative Hybrid Inspection Pilot
CMC	Chemistry, Manufacturing, and Controls
CTD	Common Technical Document
EMA	European Medicines Agency
HPRA	Health Products Regulatory Authority
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IGBA	International Generic and Biosimilar Medicines Association
IPRP	International Pharmaceutical Regulators Programme
MHRA	Medicines and Healthcare products Regulatory Agency
NMPA	National Medical Products Administration
PACMP	Post-Approval Change Management Protocol
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PMDA	Pharmaceuticals and Medical Devices Agency
PQKM	Pharmaceutical Quality Knowledge Management
US FDA	US Food and Drug Administration

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