

# ICMRA collaborative assessment pilots: Outcomes and next steps

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# ICMRA Collaborative Assessment Pilot – Overview

## ➤ **Scope**

Multi-agency collaborative assessment of Post Approval Change Management Protocols (PACMPs)

Focused on medically important treatments, including chemical and biological products, but excluding vaccines

## ➤ **Application Process**

14 applications received

Prioritised based on impact to supply of critical medicines & potential for agreed regulatory approach

## ➤ **Pilot implementation**

5 proposals accepted

Identical submissions sent to all participating agencies

# Pilot cases

Application	Product	Indication	Proposed change	Lead Authority	Participating Authorities	Observer Authorities
Pilot Case 1	Monoclonal antibody	Follicular lymphoma	Additional active substance manufacturing site and additional QC testing site	EMA	FDA	PMDA
Pilot Case 2	Small molecule	Hyperkalaemia	Additional drug product manufacturing site	FDA	EMA	PMDA, Health Canada, HSA, ANVISA
Pilot Case 3	Small molecule	Non-small cell lung cancer	Additional active substance manufacturing site	PMDA	FDA, EMA, MHRA, <a href="#">Swissmedic</a>	HSA, Health Canada, TGA
Pilot Case 4	Antibody drug conjugate	Metastatic triple-negative breast cancer	Additional active substance intermediate manufacturing site and additional QC testing site	FDA	EMA, MHRA, <a href="#">Swissmedic</a>	Health Canada
Pilot Case 5	Monoclonal antibody	Multiple cancer indications	Improvements to the manufacturing process	EMA	FDA, PMDA, Health Canada	HSA, <a href="#">Swissmedic</a>

## Lead Authority

- Assess application
- Propose IRs
- Coordinate all activities
- Lead on project calls
- Consolidates IRs
- Applicants' main contact



## Participating Authorities

- Conduct independent assessment
- Participate in discussion meetings
- Propose IRs

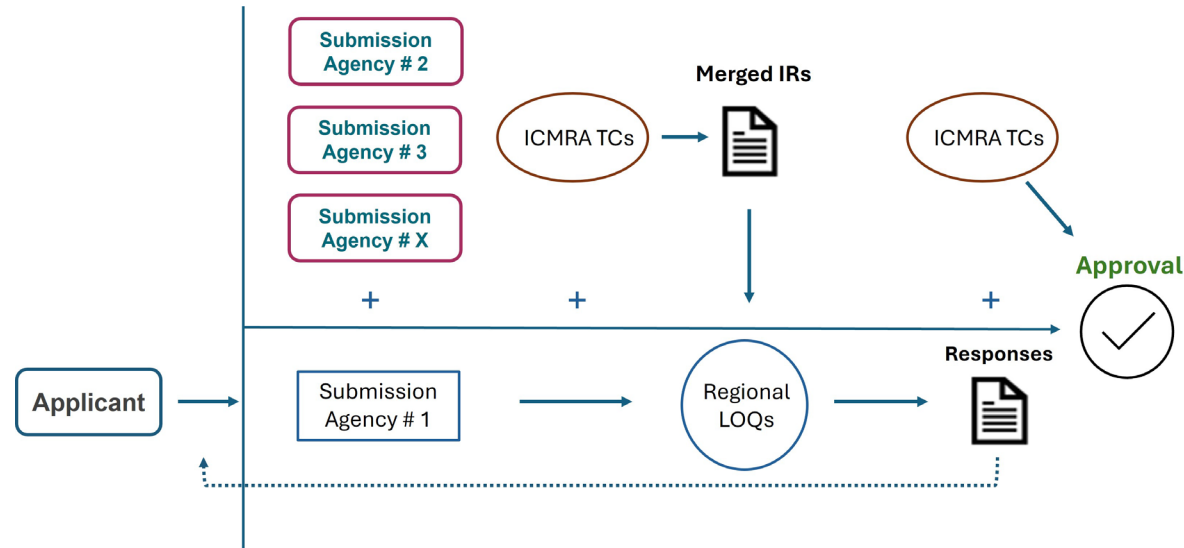


## Observer Authorities

- Participate in discussion meetings
- Cannot raise IRs



# Regional Procedures & ICMRA Pilot: How They Work Together



Once accepted into the ICMRA pilot, the procedure runs in parallel with standard regional procedures

Applicants submit formal applications through the usual regional channels (for participating agencies only — not observers)

Submissions are flagged for ICMRA pilot inclusion, alerting agency procedure managers to track them accordingly

A harmonised set of LOQs/IRs is prepared and sent to applicants by the ICMRA lead

In line with legal requirements, participating authorities may also send LOQs/IRs separately

However, a single harmonised response document can be shared with all participating agencies to streamline communication

# Key achievements



## Streamlined Timelines

- Agreed a common **120 day assessment timetable**
- **Near-simultaneous approvals** — a global first!

Overall duration (days)	Max difference in approval dates between participating authorities
115	0
118	0
105	0
122	2
119	12

## Efficiency & Harmonisation



- **88% of all assessment IRs** harmonized via intensive discussions
- Harmonisation achieved across all sections of Module 3
- **~25% reduction** in total IRs due to collaborative review meetings
- All 5 collaborative assessments completed successfully with **harmonised outcomes**
- No increase in standard expectations → the regulatory bar remained unchanged
- **Positive feedback** from industry and regulators (based on survey results)
- Increased resource requirements, especially for regulators

## Regional Specificities



- Some region-specific IRs (e.g. method transfer data, validation report requirements)
- A few region-specific administrative questions (e.g. applicant forms, GMP documentation)

# Key Benefits of Collaborative Assessment

## Benefits for industry

- ▶ Harmonized 120 day approval timeline across multiple jurisdictions
- ▶ Alignment on CMC data requirements across regions
- ▶ Increased predictability
- ▶ Faster implementation of global manufacturing changes
- ▶ Agile response to market shifts and capacity demands
- ▶ Reduced risk of divergence in global dossiers

## Benefits for regulators

- ▶ Enhanced knowledge sharing among global authorities
- ▶ Deeper insight into regulatory practices of other agencies
- ▶ Builds trust and confidence for future reliance and work-sharing
- ▶ Supports international harmonisation and convergence

## Benefits for Patients

- ▶ Increased availability of critical medicines through accelerated global approvals
- ▶ Assessment outputs support reliance in low- and middle-income countries

# Pilot extension

- ▶ Based on positive results, the pilots have been extended for 1 year and we are open to receiving applications
- ▶ Ongoing focus areas:
  - High-impact changes for medically important treatments
  - Innovative manufacturing technologies
  - Post approval changes (PACMPs) which impact supply
- ▶ Generics and biosimilars now included in the scope
- ▶ Applicants are encouraged to contact the PQKM Pilot Coordination Group to discuss potential applications
- ▶ **Informal discussions** are welcomed prior to application
- ▶ The application process is simple – just a 2 page form

[ICMRA website](#)



[Summary Report](#)



**Email contacts for queries**

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# How can ICMRA encourage new applications?

Possible concerns	How concerns are addressed
Lack of familiarity with the pilot	✓ A detailed report is now publicly available
Concern that CMC changes may be delayed	✓ Near simultaneous approval within 120 days
Fear of increased burden from IRs/assessment questions	✓ Fewer IRs overall compared to individual submissions
Perceived lack of benefit	✓ Multiple benefits identified for industry, regulators, and patients
Concerns about an increase in regulatory expectations	✓ No change to standard requirements
Limited use of PACMPs	✓ PACMPs enable early agreement on change plans with regulators
Other factors which ICMRA are unaware of	? Please raise during the panel discussion or informally with the PQKM Pilot Coordination Group

# Desirable factors for long term sustainability of the programme

## ➤ **Regulatory Alignment**

- Regulators apply comparable assessment standards, including implementation of ICH guidelines
- Comparable data protection and conflict of interest standards are upheld
- Regulators aim to align assessment outcomes within their legal frameworks, but are not bound by decisions of other authorities

## ➤ **Administrative support**

- Long-term secretarial and administrative support is available to sustain collaboration

## ➤ **IT support**

- Regulators can access and share relevant documents, such as assessment reports, securely
- Sponsors can authorize access to their regulatory submissions
- Sponsors can confirm identical submissions have been provided to all participating agencies

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## ► Administrative

- Long-term collaborative arrangements to be established to maintain

## ► IT support

- Regulators securely share data as assessment reports, and
- Sponsors can authorize access to their regulatory submissions
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**ICMRA Executive Committee  
currently considering how to  
ensure the long-term sustainable  
future of the collaborative  
assessment initiative**



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Thank you

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