ICMRA PACMP – Biologic DS Process Change – Experience and Learnings

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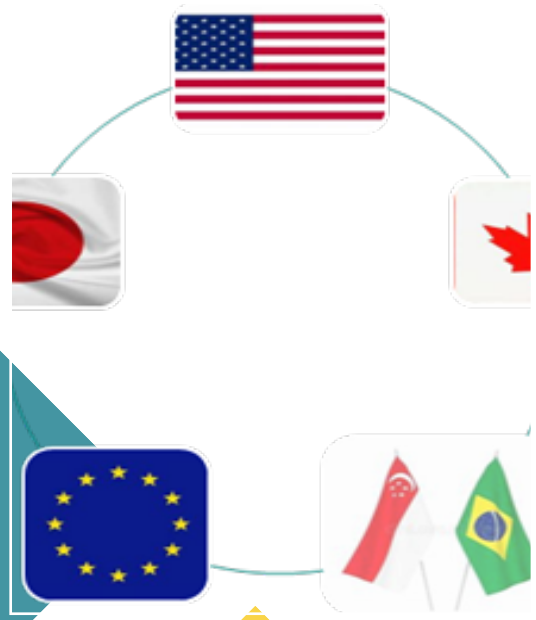
ICMRA Collaborative Assessment Pilot



ICMRA pilot (Keytruda)

2 Pilots accepted to Pilot

- Addition of a DP (manufacturing & testing) site
  - Withdrawn, project discontinued
- DS Process change, chemically defined media

- Objective: acceptance of a single PACMP across
- Participating Agencies: FDA, EMA, HC, PMDA,
- Observering Agencies: HSA, ANVISA, SwissMedic

PACMPs Key Messages

Pre-agreement on data requirements

- Reduces regulatory uncertainty

Applicable to multiple changes or products, provided CMC only

- Regulatory efficiency

Transparency of changes to regulators

- All changes made under a PACMP are still reported

Reduced reporting categories possible

- Faster implementation of changes

PACMPs facilitate the management of post-approval changes, including by Agencies

PACMPs have the potential to reduce and harmonise lead time to implement a change across markets

PACMPs contribute to strengthening the supply chain and availability of products to all patients globally.

Approval of PACMP for DS Process Change

- Reduced reporting category via adherence to PACMP defined acceptance criteria
  - US – PAS to CBE-30
  - EMA – Type II to Type IB
  - Canada – Level 1 to Level 2
  - PMDA – 2 step process, 40-day review for change submission
- DP, n=1 batch, release data
- 3-year transition to move to supply from new DS process
- May be applied to all registered DS sites

Numerous HAs have requested submission of PACMP and immediate submission of DS change

Experience

- Energizing
- Collaborative
- Agencies worked together and aligned on requirements
  - Previous Type C/D and SA meetings
    - Stability data
    - Criteria to downgrade reporting
    - 3-year transition plan information vetted
    - DP runs required to support DS process change
  - HC accepted and issued decision for PACMP
  - First experience with PACMP with PMDA
  - Great communication
    - informed of RtQ issuance to enable planning

PACMP Preparation Learnings - Opportunities

- ✓Unprecedent convergence opportunity: single submission, review and outcome
- ✓Drive observers' Agencies (ANVISA for biologics and HSA) introduction in their framework
- ✓Collaborate with ICMRA on lessons learnt and best practice for enhanced collaboration, and convergence framework
- ✓Identify and engage with other markets of interest to the business (incl. through Reliance)
- ✓Be ready when pilot is expanded and/or turned into normal practice

PACMP Preparation Learnings - Challenges

- ☞ Reduce/remove specific local requirements (complex with 7 markets)
- ☞ Align on timeline for the submission
- ☞ Site Accreditation Required for Japan site addition PACMP
- ☞ Updated AF4 provided with PACMP to PMDA
- ☞ Pre-Meetings required for several countries
- ☞ Alignment with EU submission calendar
- ☞ Progress and align across spread time zones and functions
- ☞ Differing Site Registration Status across 6 markets.
- ☞ Align on common language to be utilized across the participating Health Authorities.

Thank you

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