MRAs & their Role in Medicines Supply to Patients

An Industry Perspective

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How MRAs enable the delivery of safe and effective medicines to patients

Conformity Assessment

- Assessed by official GMP (Good Manufacturing Practices) Inspection services of each party
- Built on PIC/S* standards to confirm equivalence of GMP regulations and regulatory oversight

Opportunity for coordination of new agreements:
57 PIC/S Participating Authorities (members) from > 25 jurisdictions**
(PIC/S membership assesses equivalence of GMP standards and regulatory oversight)

Mutual Recognition Agreement

- MRAs between jurisdictions with comparable levels of regulatory maturity are established and effective
- For products in MRA scope:
  - Regulators mutually recognize each other's inspection and testing outcomes.
  - Products manufactured in a MRA partner territory are exempt from duplicate quality testing on import

Opportunities for existing agreements:
Full implementation of MRAs *(Pre-approval inspections)*
MRA scope extensions to more types of medicines *(vaccines, ATMPs)*
Agreements cover both inspections and batch testing

Patient Availability Globally

- Waived testing and inspection reliance prevent delays -> enable faster availability to patients incl. innovations
- Efficiency and sustainability gains: diversified supply, reduced costs and CO2 footprint and chemical waste

**Pharmaceutical Inspection Co-operation Scheme*
***EU counted as one*

Resources

- **European Medicines Agency (EMA):** Mutual Recognition Agreements and Joint Audit Programme
- **Swissmedic:** Mutual Recognition Agreements
- **UK:** Conformity assessment testing under mutual recognition or free trade agreements
- **Pharmaceutical Inspection Cooperation Scheme (PIC/S):** Assessment and Joint Resassessment Programme – Audit Checklist https://picscheme.org/docview/4647
- **WTO:** Trade Policy in a Pandemic: An integrated approach
- **Association of the British Pharmaceutical Industry (ABPI)**: facilitating-trade-in-health-products-through-international-manufacturing-recognition-and-harmonisation-policy-report and The case for agreeing medicine quality checks between the UK and EU
- **IFPMA** Position Papers:
  - Trade and Health Agenda: A Meaningful World Trade Organization Roadmap to Strengthen Global Health
  - Appropriate Control Strategies Eliminate the Need for Redundant Testing of Pharmaceutical Products
  - #AlwaysInnovating: Pharmaceutical Industry Facts & Figures
- **EFPIA:** Infographic inspection Landscape and Annual Regulatory GMP/GDP Inspection Survey

Doing now what patients need next