EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

International Coalition of Medicines Regulatory Authorities (ICMRA)

From Crisis Management to better Regulation

25th DGRA Annual Congress - May 4th and 5th, 2023 - Bonn

Presented by Riccardo Luigetti
International Affairs EMA

The ICMRA (1)

A global coalition of Medicines Regulatory Authorities, working together

- Strategic directions
- Information sharing
- Crisis response
- Regulatory science
- Enhanced communication

The ICMRA (2)

Global participation at HoAs level

- 40 participating authorities including WHO
- EMA chairs since 2017

Governance

- Chair: EMA
- Vice-Chairs: MHLW/PMDA; ANVISA
- Executive Committee
- Members, Associate Members, Observers

https://www.icmra.info/drupal/en/participatingRegulatoryAuthorities

ICMRA Strategic Framework and Related Activities

ICMRA Leaders will respond to current and emerging human medicine regulatory and safety challenges globally, strategically and in a transparent manner

STRATEGIC OBJECTIVES	Strategic Leadership Strategic leadership by identifying shared regulatory challenges and bring together initiatives/enablers to effectively respond	Enable and Facilitate Identify and support global collaboration needs and mechanisms , including the sharing of information and expertise to strengthen regulatory global initiatives	Inform/Engage Communicate to stakeholders ICMRA's goals and activities, and facilitate the leveraging of existing initiatives to address evolving regulatory challenges
WHAT WE DO	✓ identify shared regulatory challenges and exercise strategic leadership by taking a collective approach as a Coalition to avoid duplication of activities among regulatory authorities ✓ establish more effective channels of information sharing and communication ✓ create a framework for leadership, governance and action for shared regulatory concerns ✓ promote the leveraging of regulatory authorities' collective resources, including the sharing of knowledge, work products, expertise, experience and best practices ✓ prompt identification of and coordinated multilateral response to emerging global issues ✓ engage as a Coalition in strategic partnerships on issues of global impact/concern (e.g. WHO)	✓ enable regulatory systems which facilitate improved access to and availability of safe, efficacious and quality medicines ✓ enable innovation including novel regulatory approaches and the advancement of regulatory science ✓ foster the development of mechanisms and systems to facilitate regulatory collaboration and modernisation, including work and information sharing ✓ promote better informed risk-based allocation of regulatory resources ✓ facilitate the wider exchange of information ✓ promote convergence of regulatory frameworks, where appropriate ✓ promote the coordination of training initiatives and tools	✓ leverage and influence existing initiatives to advance common priorities (e.g. PIC/S, IPRF, IGDRP, ICH, APEC etc.) ✓ engage stakeholders (e.g., industry and non-governmental organizations) in addressing regulatory challenges ✓ promote the strengthening and alignment of regulatory systems across medicines regulatory authorities in developing countries by facilitating their involvement in regulatory initiatives

Why do we need an ICMRA

- Growing complexity of medicinal products and their ingredients
- Growing complexity and globalization of supply-chains
- Growing number of international regulatory initiatives, lack of integration and strategic oversight
- Need to control regulatory public expenditures
- Need for alignment of regulatory practice and activities

➢ **Global health crisis need global response**

No regulator can work alone in the 21st century

Historical background

May 2012

- High-level seminar hosted by Brazil before the 65th World Health Assembly in Geneva, highlighting importance of better coordinating international cooperation among MRAs

October 2012

- Meetings of MRA executives held in the margins of the WHO International Conference of Drug Regulatory Authorities

November 2012

- Seventh Heads of MRAs Summit in Manaus expressed support for creation of ICMRA

December 2013

- Eighth Heads of MRA Summit in Amsterdam establishes ICMRA

ICMRA way of working

Summit

- Strategic discussion at HoAs level
- Informal setting

Regulatory Forum

- Deep Dive on specific topics

Informal Networks

- Exchange of information
- Advice to network

Workshops

- Discussion among regulators or with stakeholders

Ad hoc activities

Summit November 2022 – Dublin - Looking into the future

Regulators as main source of information, fight misinformation, hesitancy

1) Challenging Our thinking on Ph.Vig.

2) Innovation and the Future Opportunities

3) Living with COVID-19

Equitable access to medicines

Innovation: enormous opportunities, challenges for regulators

ICMRA Regulatory Forum

Formerly COVID-19 Policy TC

Deep Dive on specific topics e.g.:

- Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP), from Critical Path Institute

ICMRA: Main Activity Areas

Communication

Innovation

Artificial Intelligence

Real Word Evidence

Public Health Emergencies Clinical Trials

COVID-19 Vaccine Pharmacovigilance

Anti Microbial Resistance

Pharmaceutical Quality Knowledge Management System

ICMRA has been extremely important during the pandemic, allowing global exchange of information and work sharing among regulators

With the pandemic easing, ICMRA is rationalising its processes and rethinking its priorities

From Pandemic Response to Future Preparedness

During the COVID-19 Pandemic the role of ICMRA became fundamental

Global coordinated regulatory actions were key in the fight against the virus

ICMRA allowed:

- Quick exchange of information
- Regulatory Cooperation
- Coordinated actions globally

➢ ICMRA is now working towards preparedness for future crises, lesson learnt and applying pandemic agilities and flexibilities to routine, post-pandemic activities

The Covid-19 Vaccines Pharmacovigilance Network

Information Sharing, advice to network during the pandemic

Huge network of regulators from all the world regions

- Real-time sharing of information and experiences
- Quicker identification of potential signals
- Collaboration on important safety signals
- Simulation exercise
- ICMRA/WHO Vaccines Confidence Statement

➢ Common approaches

➢ Reduced duplications

➢ Regulatory decisions supported by global data

The Public Health Emergency Clinical Trials Working Group

Preparing for the Future

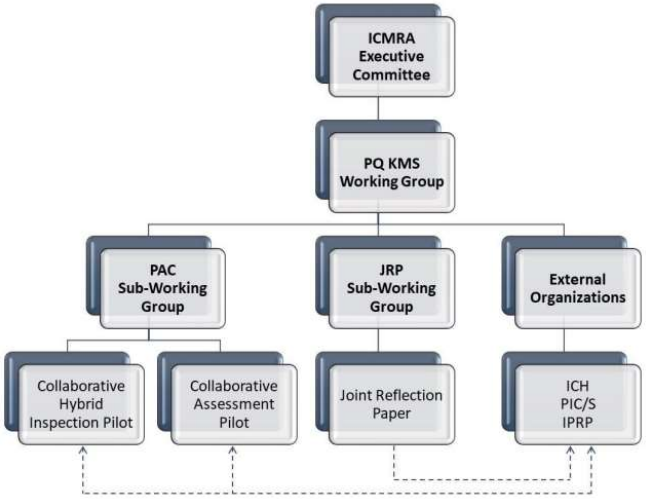
- Reflection Paper to enable implementation of multinational/multiregional platform clinical trials during Public Health Emergencies
- Key considerations for protocol elements that support initiation and conduct of platform clinical trials during Public Health Emergencies

➢ Facilitate use of core protocol elements for multinational/multiregional platform trials of vaccines and therapeutics in a cross-border public health emergency context, with COVID-19 as an initial model

➢ Shared understanding of these protocol elements to support global platform trials to be approved as well as implemented efficiently in more than one territory

The Pharmaceutical Quality Knowledge Management System (PQKMS) Working Group (1)

Leveraging lesson learnt during the pandemic to improve routine processes



The Pharmaceutical Quality Knowledge Management System (PQKMS) Working Group (2)

ICMRA providing strategic vision and coordination to work progressed at existing organisations (ICH, IPRP, PIC/S)

Objectives:

- Develop framework for collaborative PAC assessment and hybrid inspections
- Identify misalignments, differences, and areas for alignment across regions
- Pilot submission of the same CMC information to multiple regulators for the same product and manufacturing facility
- Increase confidence among regulatory authorities and among regulators and pharmaceutical industry

The Pharmaceutical Quality Knowledge Management System (PQKMS) Working Group (3)

- Joint Reflection Paper: ICMRA, ICH, IPRP, PIC/S
- Collaborative pilots:
  - Collaborative Post-Approval Changes Assessment Pilot
  - Collaborative Hybrid Inspections Pilot

Note the date!
PQKMS Workshop on
20-21 July

- Cross-organisational collaboration on Unique Identifiers for manufacturers
- ICH Workplan
  - CTD, new GL on Structure of Product Submission
- IPRP Workplan
  - Surveys (Quality Assessment Tool, ICH Q12), Analysis (PAC/Variations)
- PIC/S Workplan
  - Training (PQS assessment), promoting GMP reliance, Data format for inspection report

Key Messages

The pharmaceutical sector is globalised and extremely complex

Future Public Health emergencies are likely to be global

No regulator can fulfil its role on its own any more; need for cooperation, work-sharing, reliance

Global regulatory strategies are necessary

ICMRA role is strategic, not operational, it will leverage existing regulatory organisations/initiatives to operationalize its strategies

EUROPEAN MEDICINES AGENCY

Any questions?

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