

Regulatory collaboration

The International Coalition of Medicines Regulatory Authorities (ICMRA)

A new global collaboration brings together senior leaders to provide coordinated, consistent, and strategic leadership in an increasingly globalized and complex regulatory environment. The International Coalition of Medicines Regulatory Authorities (ICMRA) is a voluntary, executive level entity that provides direction for a range of areas that are common to many regulatory authorities' missions.

The global regulatory environment

Globalization directly affects the protection and promotion of public health everywhere. Medicinal products distributed and used in domestic markets are increasingly global commodities. The manufacturing and distribution supply chains are complex, multi-faceted, globally integrated and may at times be difficult to understand or unravel. The ability of a regulator to assure the safety, quality and efficacy of a medicinal product domestically requires knowledge of and confidence in these supply chains and regulatory oversight at all stages. There is also growing complexity in medicinal products and their

ingredients, and managing the risks and benefits requires regulators to consider international collaboration approaches to provide access to regulatory authorities' resources and the best available scientific and technical expertise. The resulting increase of global regulatory networks, usually conducted at the technical/operational level, also calls for increased efficiency in managing the expertise and resources invested in these initiatives. In short, Medicines Regulatory Authorities (MRA) regulate within an extremely complex domain – legally, technically, and scientifically – and recognize that the effectiveness of the plans and approaches used to address these challenges

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depends upon strategic-level leadership and new ways of working around the globe including information-sharing which gives room for potential synergies.

A collective, global understanding of these realities has fueled international discussions over the last few years including at the World Health Assembly, the World Health Organization's International Conference of Drug Regulatory Authorities (ICDRA), and the International Summit of Heads of Medicines Regulatory Agencies. Leaders of MRAs are harnessing this momentum to establish a new way of collaborating, the International Coalition of Medicines Regulatory Authorities (ICMRA).

What is the ICMRA?

The ICMRA is a venue for heads of national regulatory authorities around the world to enable a shared strategic leadership to address current and emerging global regulatory challenges and to better leverage resources in ways that expand global regulatory reach (1).

What sets the ICMRA apart from other existing regulatory initiatives is that it brings together senior leaders to provide strategic, high-level advocacy and leadership. ICMRA can provide direction for a range of areas and activities that are common to many MRAs' missions and goals, identify areas for potential

synergies to be made, and wherever possible, leverage existing efforts to maximize global impact. Four over-arching objectives help to guide the ICMRA:

- to protect human health throughout the life-cycle of medicinal products;
- to enable regulatory conditions which facilitate improved access to and availability of safe, efficacious and quality medicinal products. This also includes enabling innovation and advancing regulatory science as it related to medicine research and development;
- to promote coherent and strategic multilateral cooperation among regulatory authorities, in order to strengthen mutual reliance, trust, synergies and regulatory systems, and to achieve better use of collective resources/work products and sharing of best practices; and
- to promote the leveraging of regulatory authorities' resources, including knowledge and expertise.

ICMRA has a medicines focus at this stage, and participants are currently working on selected joint efforts to stimulate collaborative thinking and action, piloting new ways of working to build mutual reliance, and facilitating early and timely identification of emerging public health crises that intersect with medical regulatory authorities (Box 1).



Box 1. Current ICMRA Working Groups

- 1) Governance
- 2) Mapping
- 3) Communications/Outreach
- 4) GMP Inspections
- 5) Generic Medicines
- 6) Rapid Sharing of Information
- 7) Capacity Building

Indeed, much of ICMRA's true potential is in its ability to maintain a consistent and open dialogue among the heads of MRAs, enabling them to quickly connect on issues of mutual priority or concern. A good example of this coordinated response is the September 4, 2014 ICMRA Statement on Ebola (2).

The ICMRA is currently operating in an interim period (2013-2015) as it builds a strong foundation for governance and sustainable collaboration. It is supported by a Secretariat and guided by a Chair, two Vice-Chairs¹, and a Management Committee². Membership³, currently envisioned by a small number of current members emanating from earlier heads of medicines summits⁴, will be voluntary

and will include regulatory authorities for medicinal products⁵.

Envisioning a framework for action

Over time, ICMRA will enable a global architecture to support enhanced communication, information-sharing and crisis response. ICMRA will also focus on strengthening regulatory systems and capacity, and increasing awareness of and appreciation for the importance of strong regulatory systems and functions within national, sub-regional, and global contexts.

ICMRA benefits are multi-faceted and most importantly enable MRAs to coalesce around regulatory issues of mutual priority within a 21st century environment. ICMRA benefits will be stronger confidence and collaboration among regulators, less duplication of effort and more strategic use of human and financial resources. All heads of national regulatory authorities are encouraged to remain apprised of developments within ICMRA and engage with the ICMRA.

Potential for global synergies

As ICMRA begins to determine where it can best add value within an environment of various global regulatory efforts, it is clear that the potential for synergies are numerous. There are many well-established technical and scientific bodies already serving unique purposes with specific mandates, for example, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspection Convention and Pharmaceutical

¹ Health Canada's Health Products and Food Branch (HC-HPFB) is the interim ICMRA Chair and interim Secretariat, with Ireland's Health Product Regulatory Authority and Japan's Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency as Vice-Chairs.

² ICMRA Management Committee membership includes: Australia, Brazil, Canada, China, Europe, Ireland, Italy, Japan, the Netherlands, Singapore, South Africa, the United Kingdom, and the United States.

³ Current membership in the ICMRA includes the Heads of the regulatory authorities of: Australia (TGA), Brazil (ANVISA), Canada (HPFB-HC), China (CFDA), Europe (EMA and EC), France (ANSM), Germany (PEI), Ireland (HPRA), Italy (AIFA), Japan (PMDA and MHLW), Korea (MFDS), Mexico (COFEPRIS), the Netherlands (MEB), New Zealand (Medsafe), Nigeria (NAFDAC), Singapore (HSA), South Africa (MCC), Switzerland (Swissmedic), the United Kingdom (MHRA) and the United States (FDA), with the World Health Organization (WHO) as an observer.

⁴ The International Summit of Heads of Medicines Regulatory Agencies is an annual meeting that serves as an important forum for the exchange of information, views and regulatory strategies among the chief executives of major and like-minded medicines regulatory agencies.

⁵ Interested authorities should contact the ICMRA interim Chair, Health Canada's Health Products and Food Branch, ICMRA.SEC@HC-SC.GC.CA.

Inspection Co-operation Scheme (PIC/S). Dialogue between ICMRA and these organizations has already begun with the purpose of opening and maintaining ongoing communication on issues of common concern and interest. ICMRA will continue to connect with other initiatives, including those with a regional focus.

ICMRA continues to identify areas of potential synergy on discrete topics including: Good Manufacturing Practices (GMP), information-sharing and information-sharing platforms, Unique Facility Identifiers (UFI), generic drugs, and capacity building. Using ICMRA as a venue to convene MRAs on topics of mutual priority can yield significant benefits.

In sum, the ICMRA is a new governance and leadership model in the global

regulatory environment. By providing strategic and high-level oversight and guidance and early thinking, we, as the leaders of our respective regulatory authorities, hope to better leverage our resources, address issues of mutual concern, and increase shared thinking and action. We encourage all WHO Member States to increase their understanding of ICMRA and become engaged as we move to transform the global regulatory landscape. ●

References

- 1 [International Coalition of Medicines Regulatory Authorities \(ICMRA\). Fact Sheet. September 2014.](#)
- 2 [Statement on international regulatory cooperation regarding Ebola \[News release\]. Health Canada, 4 September 2014.](#)