



International Coalition of Medicines Regulatory Authorities (ICMRA)

FACT SHEET

The Global Regulatory Environment

The proposal to create an International Coalition of Medicines Regulatory Authorities (ICMRA) is driven by the following trends in the global regulatory environment:

1. The medicinal products that are 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 unclear. 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;
2. There is growing complexity in medicinal products and their ingredients, and managing the risks and benefits requires international collaboration among regulators to provide access to collective resources and the best available scientific and technical expertise; and
3. The range and diversity of existing international initiatives, usually conducted at the technical/operational level, also call for increased efficiency in managing international collaboration and the collective wealth of expertise and resources invested in these initiatives.

Coordinating international cooperation among medicines regulatory authorities in order to strengthen dialogue, facilitate the wider exchange of reliable and comparable information, and encourage greater leveraging of the resources and work products of other regulatory agencies, will avoid duplication of efforts and promote informed risk-based allocation of authorities' resources. These efforts and others would strengthen the quality, safety and efficacy of medicinal products globally.

In this context, regulators must act globally and domestically, and collaboratively.

Momentum to establish the ICMRA has been built over the last three years through international discussions as well as at the World Health Assembly and the International Conference of Drug Regulatory Authorities. The ICMRA is currently in its interim phase (2014-2016).

Scope

The initial scope of the ICMRA will be medicinal products for human use (pharmaceuticals, biologics, genetic therapies, radiopharmaceuticals and “grey zone”/combination products).

Objectives and Goals

The ICMRA is a voluntary, executive level, strategic coordinating, and leadership entity that provides direction for a range of areas that are common to many regulatory authorities' missions. The ICMRA identifies areas for potential synergies among regulators, and facilitates, where possible, international leveraging and resource savings by building confidence and deeper collaboration among regulators. It also aligns the agendas of existing and new initiatives and enablers with regulators' evolving needs.

Over time, the ICMRA will enable a global framework to support enhanced communication and information-sharing, and to address regulatory science issues.

The ICMRA's strategic role will be applied in the following areas:

- regulatory convergence, alignment and standards development;
- regulatory cooperation and work-sharing;
- capacity and competence building/technical assistance;
- regulatory systems comparability criteria and assessment criteria; and
- regulatory science.

Four over-arching objectives 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 relates to medicinal product 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' collective resources, including knowledge and expertise.

The ICMRA will help to facilitate:

- improved integration and executive level championing of existing and new international regulatory initiatives;
- prompt identification of and coordinated multi-country response to emerging issues, including global issues;
- expanded exchange of reliable information through an efficient and strategic use or linking of existing networks, and establishing new networks, where necessary;
- better informed risk-based allocation of regulatory authorities' resources to help address common work areas;
- increasing coordination of regulatory technical cooperation and capacity/competence building for national and regional medicines regulatory authorities (MRAs) to help strengthen regulatory systems; and
- awareness of the imperative of strong regulatory systems and functions within national, sub-regional, and global contexts.

There are currently seven ICMRA working groups covering: governance, mapping, communication, information sharing, GMP inspections, generic medicinal products, and capacity building.

Membership and Structure

Health Canada's Health Products and Food Branch (HPFB-HC) is the ICMRA interim Chair and interim secretariat with Ireland's Health Product Regulatory Authority and the Ministry of Health, Labour and Welfare, and the Pharmaceuticals and Medical Devices Agency of Japan¹ as interim Vice-Chairs. An interim Management Committee provides governance for the ICMRA: Australia (TGA), Brazil (ANVISA), Canada (HPFB-HC), China (CFDA), European Union² [European Medicines Agency (EMA) and European Commission (EC)], Ireland (HPRA), Italy (AIFA), Japan (PMDA and MHLW), the Netherlands (MEB), Singapore (HSA), South Africa (MCC), the United Kingdom (MHRA), and the United States (FDA).

Membership in the ICMRA is voluntary and is open to all regulatory authorities for medicinal products. During the interim period, membership in the ICMRA includes the Heads of the regulatory authorities of: Australia (TGA), Brazil (ANVISA), Canada (HPFB-HC), China (CFDA), European Union (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.

Note: The full name of each regulatory authority can be found in the Appendix.

Contact Information

The ICMRA interim secretariat can be contacted at: ICMRA.SEC@HC-SC.GC.CA.

¹ Competencies related to the activities of the ICMRA are shared for Japan between PMDA and MHLW.

² Competencies related to the activities of the ICMRA are shared for the European Union between the European Medicines Agency and the European Commission.

International Coalition of Medicines Regulatory Authorities

FREQUENTLY ASKED QUESTIONS

Q: What does ICMRA stand for?

A: ICMRA stands for **I**nternational **C**oalition of **M**edicines **R**egulatory **A**uthorities.

Q: What is the ICMRA?

A: The ICMRA is a voluntary, executive level, strategic coordinating, advocacy, and leadership entity of national and regional medicines regulatory authorities (MRAs) that work together to provide direction for a range of areas and activities common to many regulatory authorities' missions and goals; identify areas for potential synergies to be made; and, wherever possible, leverage existing efforts to maximize the global regulatory impact. The ICMRA is currently in its interim phase (2014-2016).

Q: Why is an ICMRA of this nature needed?

A: The medicinal products that are distributed and used in domestic markets are increasingly global commodities. The manufacturing and distribution supply chains are complex, multi-faceted, and globally integrated. 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. There is growing complexity in medicinal products and their ingredients, and managing the risks and benefits. These factors require regulators to collaborate in providing access to collective resources and the best available scientific and technical expertise.

Q: Who are the current members of the interim ICMRA?

A: Membership in the ICMRA includes the Heads of the regulatory authorities of: Australia (TGA), Brazil (ANVISA), Canada (HPFB-HC), China (CFDA), European Union (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.

Q: What are the benefits to becoming an ICMRA member?

A: The ICMRA's benefits are multi-faceted and most importantly enable MRAs (national and regional medicines regulatory authorities) to coalesce around regulatory issues of mutual priority within a 21st century environment. ICMRA benefits will be strengthened confidence and deeper collaboration among regulators, less duplication of effort and more strategic use of human and financial resources, including mutual reliance on scientific and regulatory expertise and work products.

The ICMRA's impact may be viewed within the following areas:

- patient safety;
- access to medicinal products;
- time to market/supporting innovation;
- agility in dealing with emerging issues;

- cooperation/collaboration/joint working/work sharing/output sharing;
- information exchange;
- surveillance/enforcement;
- efficiency/effectiveness/finances/value for money;
- facilitating trade/industry; and
- impact on national medicines regulatory authorities’ capacity and competence.

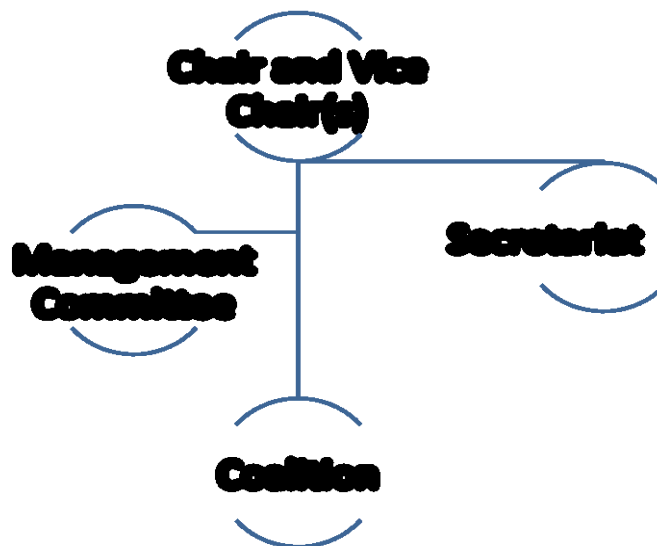
Q: If my organization is interested in becoming a member of the ICMRA, what should we do?

A: The ICMRA has voluntary membership and is open to all regulatory authorities for medicinal products from any jurisdiction. For 2014-2016, the ICMRA is undergoing its establishment phase, including developing a governance structure, a secretariat, criteria for membership, and the like. Interested authorities should contact the ICMRA interim Chair, Health Canada’s Health Products and Food Branch, via ICMRA.SEC@HC-SC.GC.CA.

Q: How is the interim ICMRA structured?

A: Since the ICMRA is a relatively new global organization, its organizational structure is under formation but regulatory authorities will be represented at the Heads of Agency level. A thirteen member interim Management Committee is essentially its current governing mechanism, responsible for the general oversight and guidance.

There is also an interim Chair (Health Canada’s Health Products and Food Branch) and two interim Vice-Chairs (Ireland and Japan) as well as an interim secretariat (staffed by the Chair). Here is a basic schematic.



The interim Chair and Vice-chair(s) facilitate the work of the Coalition and arrange reporting to the Coalition on a bi-annual basis. The interim Chair and Vice-Chair(s) are also responsible for chairing and coordinating meetings of the interim Management Committee and Coalition. The secretariat supports the activities of the interim Management Committee and the Coalition.

Q: How can my organization get a seat on the ICMRA interim Management Committee?

A: Since the ICMRA is a relatively new global organization, its organizational structure is still being finalized. The current Management Committee composition was established on an interim basis. How an organization can obtain a seat on the interim Management Committee will be clearer once the terms of reference are developed.

Q: What does the ICMRA do that isn't already being done by other groups of regulatory authorities?

A: The ICMRA recognizes the range and depth of regulatory contributions and leadership that exist, including for example, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the International Pharmaceutical Regulators Forum (IPRF), the International Medical Device Regulators Forum (IMDRF) and of course, the leadership of multilateral organizations such as the World Health Organization and its Regional Offices. The ICMRA works at the strategic level to leverage these initiatives and others in partnership, expanding our global regulatory reach in meaningful and sustainable ways and, over time, identifying additional opportunities for regulatory collaboration. To date, there has not been coordinated, consistent, and strategic global regulatory leadership and the ICMRA endeavors to fill that gap.

Q: Does the ICMRA have regular meetings?

A: The ICMRA has at least one in-person meeting annually which occurs within the context of the Summit of Heads of Medicines Regulatory Agencies. Face-to-face meetings of the ICMRA interim Management Committee also occur once or twice annually. The ICMRA interim Management Committee also communicates regularly via teleconferences and email exchanges.

Q: Where is the ICMRA located?

A: The ICMRA does not have permanent offices. The secretariat functions are performed “virtually” on an interim basis by the ICMRA Chair, currently Health Canada’s Health Products and Food Branch.

Q: Does the ICMRA have any work products?

A: Since the ICMRA is a relatively new global organization, its initial focus has been on establishing a governance mechanism, criteria for membership, initiating working groups and the like. It has already developed a number of working groups which are progressing projects in the following areas: governance, mapping, communication, information sharing, GMP inspections, generic medicinal products and capacity building.

Date: September 2014

APPENDIX: MEMBERSHIP OF THE INTERIM ICMRA

| Country and Regulatory Authority |
|---|
| Australia: Therapeutic Goods Administration (TGA) |
| Brazil: National Health Surveillance Agency (ANVISA) |
| Canada: Health Products and Food Branch, Health Canada (HPFB-HC) |
| Europe: European Commission - Directorate General for Health and Consumers (DG – SANCO) and European Medicines Agency (EMA) |
| France: French National Agency for Medicines and Health Products Safety (ANSM) |
| Germany: Paul-Ehrlich-Institute (PEI) |
| Ireland: Health Product Regulatory Authority (HPRA) |
| Italy: Italian Medicines Agency (AIFA) |
| Japan: Pharmaceuticals and Medical Devices Agency (PMDA), and the Ministry of Health, Labour and Welfare (MHLW) |
| Korea: Ministry of Food and Drug Safety (MFDS) |
| Mexico: Federal Commission for the Protection against Sanitary Risks (COFEPRIS) |
| Netherlands: Medicines Evaluation Board (MEB) |
| New Zealand: Medsafe, New Zealand Medicines and Medical Devices Safety |
| Nigeria: National Agency for Food Drug Administration and Control (NAFDAC) |
| China: China Food and Drug Administration (CFDA) |
| Singapore: Health Sciences Authority Singapore (HSA) |
| South Africa: Medicines Control Council (MCC), Department of Health |
| Switzerland: Swissmedic |
| United Kingdom: Medicines and Healthcare Products Regulatory Agency (MHRA) |
| United States: Food and Drug Administration (FDA) |

Note: The Head of the Medicines Regulatory Authority in the respective country is the Member with WHO as an observer.