Event:

Presentation: Introducing the ICMRA

Speaker:.....

Medicine Regulatory Authority: Country:

date:.....

ICMRA Introduces itself

- The ICMRA is a voluntary, high-level, strategic coordinating, advocacy and leadership entity of regulatory authorities that work together to
  - address current and emerging human medicine regulatory and safety challenges globally, strategically and in an on-going, transparent, authoritative and institutional manner
  - provide direction for areas and activities common to many regulatory authorities' missions
  - identify areas for potential synergies
  - wherever possible, leverage existing initiatives/enablers and resources
- ICMRA will provide a global architecture to support enhanced communication, information sharing, crisis response and address research gaps

A brief 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 some 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 ICMRA

December 2013

- Eighth Heads of MRA Summit in Amsterdam establishes interim ICMRA to explore its future role

Medicines Regulatory Authorities (MRA) Challenges

- Growing complexity in medicinal products and their ingredients (e.g. new chemical entities and innovative drugs)
- Growing complexity of globalised supply chains
- Ensuring the safety, quality and efficacy of medicinal products domestically requires knowledge of and confidence in these supply chains
- Growing number of international regulatory initiatives, lacking integration and strategic oversight
- Gaps/vulnerabilities in global regulatory oversight providing opportunities for the tampering and counterfeiting
- Pressures to control and reduce regulatory public expenditures
- Pressures to harmonise and align regulatory practices and activities

Medicines Regulatory Authorities Challenges (2) - Examples

Supply chains:

•Growing number of inspections to be performed (GLP, GMP, GCP, GVP, GDP)

•Large number of reviews - Quality, Safety, Efficacy for each medicinal product have to be evaluated

•Workload in implementing pharmacovigilance activities

•Policing of counterfeit medicinal products and API

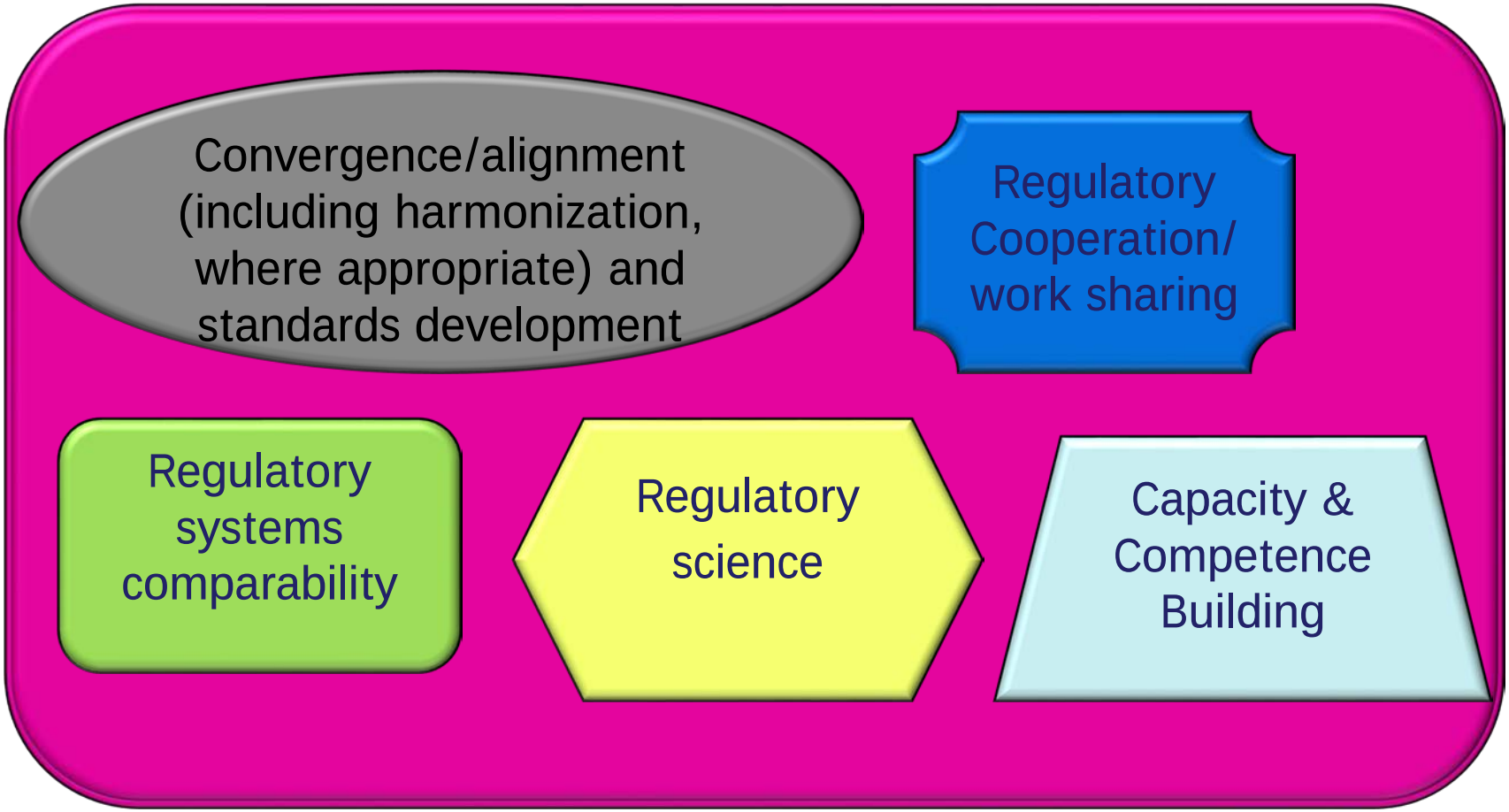
International leveraging and resource challenges:

•New chemical entities and innovative drugs - managing the risk and benefits requires international collaboration to provide access to collective resources and the best scientific and technical expertise

•Need to align the agendas of international initiatives/enablers with regulators' evolving needs (e.g., in areas such as standards development)

Acting Globally and Domestically

In the 21th century context regulators have to act (and to think) **globally, domestically** and **collaboratively** at the same time



ICMRA's Strategic Role will be applied in these Areas

ICMRA's Strategic Role

The ICMRA will endeavour to:

•Orient and leverage existing initiatives/enablers more strategically and efficiently

•Identify and implement opportunities for regulatory collaboration, including work-sharing and sharing of information, knowledge and best practices, and opportunities for novel regulatory approaches alongside scientific developments

•Promote and be an advocate for the equivalence and convergence of national/regional regulatory systems

•Promote regulatory system strengthening by facilitating and coordinating sustainable regulatory/technical assistance and capacity/competence building programs

Over-arching objectives

- To protect human health throughout the life-cycle of medicinal products
- To enable regulatory conditions which facilitate improved access to safe, efficacious and quality medicinal products, and advance regulatory science to address unmet needs
- To promote coherent and strategic multilateral cooperation; strengthen mutual reliance and synergies and achieve better use of collective resources/work products and sharing of best practices
- To promote the leveraging of regulatory authorities' collective resources, including their knowledge and expertise

ICMRA will help to facilitate

- Improved integration of existing and new international regulatory initiatives
- Prompt identification of and coordinated multilateral response to emerging issues, including global issues (e.g. integrity of the global supply chain)
- Expanded exchange of reliable and comparable information through an efficient and strategic use/linking of information technology and other networks
- Better informed risk-based allocation of regulatory authorities' resources to help maximize individual and collective results
- Coordination of regulatory technical assistance and capacity/competence building to ensure that MRAs' efforts are not duplicative.

Future Potential Global Governance

Global Strategic Direction from Regulatory Heads

Regulatory Information Sharing, Cooperation, and Convergence at Technical/Operational level

ICMRA

Identification of strategic issues/areas of shared need or opportunity, including work-sharing

IPRF

Range of activities depending on:

- Need/ Maturity of topic
- Issues raised by ICMRA
- Existing initiatives/organizations

**** The relationship between these bodies remains to be clarified and developed.***

Special role of WHO

ICH

Harmonization

Common Regulatory Standards/Tools

OECD

Common Regulatory Standards/Tools

APEC

Training/ Capacity Building

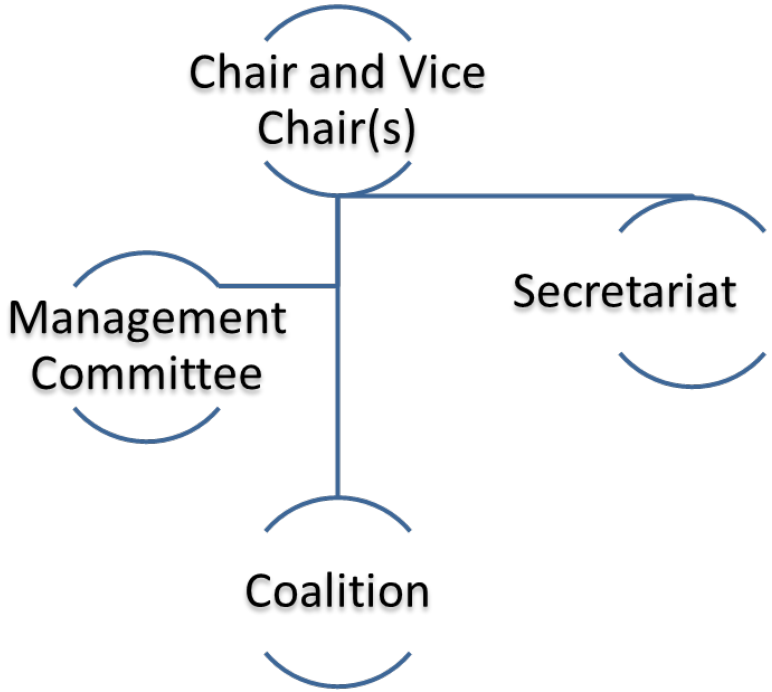
Promote Convergence and Best Practices

PIC/S

NRA Assessment
Training
Information-sharing

ETC….

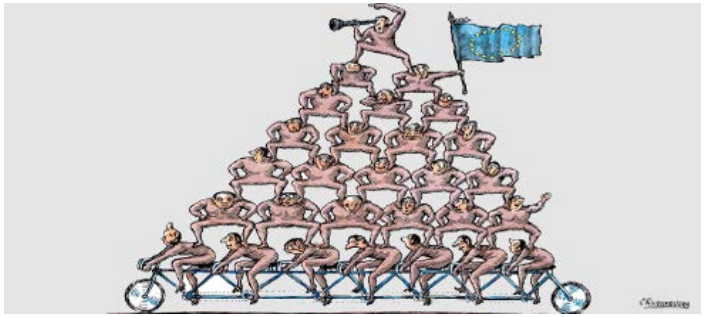
ICMRA Structure



ICMRA: A new Regulatory Coalition

Member States on Interim Management Committee are in Red

1. Australia (TGA)
2. Brazil (ANVISA)
3. Canada (HPFB-HC)
4. China (CFDA)
5. Europe (EMA and DG-SANCO)
6. France (ANSM)
7. Germany (PEI)
8. Ireland (IMB)
9. Italy (AIFA)
10. Japan (PMDA and MHLW)
11. Korea (MFDS)
12. Mexico (COFEPRIS)
13. Netherlands (MEB)
13. New Zealand (Medsafe)
14. Nigeria (NAFDAC)
15. Singapore (HSA)
16. South Africa (MCC)
17. Switzerland (Swissmedic)
18. United Kingdom (MHRA)
19. United States (FDA)
20. World Health Organization (WHO)



7 Working Groups set up by ICMRA

1. Governance
2. Mapping existing initiatives
3. Communication
4. GMP inspections
5. Generic medicines
6. Information sharing
7. Capacity Building

MEETINGS

- **ICMRA**:
  - At least one-in person annual meeting in the context of the Heads of Medicines Summit

- **Management Committee**:
  - Additional in-person meetings held in the margins of other conferences
  - Regular communication via teleconferences and email

Contact Information

- ICMRA does not have permanent offices
- The interim Secretariat functions are performed “virtually”
- Health Canada’s Health Products and Food Branch is the current Chair
- The interim Secretariat can be contacted through Health Canada’s Health Products and Food Branch at ICMRA.SEC@HC-SC.GC.CA