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

1 ICMRA is an international executive-level coalition of key regulators from every region in the world. It provides a global strategic focus for medicines regulators and gives strategic leadership on shared regulatory issues and challenges. Priorities include coordinated response to crisis situations. Members of the ICMRA include: Therapeutic Goods Administration (TGA), Australia; National Health Surveillance (ANVISA), Brazil; Health Products and Food Branch, Health Canada (HPFB-HC), Canada; China Food and Drug Administration (CFDA), China; European Medicines Agency (EMA) and European Commission - Directorate General for Health and Food Safety (DG - SANTE), European Union; French National Agency for Medicines and Health Products Safety (ANSM), France; Paul-Ehrlich-Institute (PEI), Germany; Ministry of Health and Family Welfare, India; Health Product Regulatory Authority (HPRA), Ireland; Italian Medicines Agency (AIFA), Italy; Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), Japan; Ministry of Food and Drug Safety (MFDS), Korea; Federal Commission for the Protection against Sanitary Risks (COFEPRIS), Mexico; Medicines Evaluation Board (MEB), Netherlands; Medsafe, Clinical Leadership, Protection & Regulation, Ministry of Health, New Zealand; National Agency for Food Drug Administration and Control (NAFDAC), Nigeria; Health Sciences Authority (HSA), Singapore; Medicines Control Council (MCC), South Africa; Medical Products Agency (MPA), Sweden; Swissmedic, Switzerland; Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom; Food and Drug Administration (FDA), United States.

HOW
Current and future mechanisms and activities

- ✓ Executive Committee Meetings
- ✓ Full ICMRA Membership Meetings
- ✓ Work Areas/Projects:
  - Good Manufacturing Practice (GMP)
  - Pharmacovigilance
  - Crisis management
  - Supply Chain Integrity
  - Capacity Building
  - Communications
- ✓ Establish an innovation project

- ✓ Governance structure:
  - ICMRA Mandate
  - ICMRA Terms of Reference
  - Executive Committee
  - Secretariat and virtual Secretariat
  - Roles of members, associate members and observers
  - Working Groups
  - International meetings and teleconferences
- ✓ Secure online IT platform for information sharing
- ✓ ICMRA Public Website
- ✓ GMP equivalency and data requirements for GMP
- ✓ Information sharing arrangement documents for generic medicines authorisation
- ✓ IT systems to facilitate information sharing

- ✓ Communication and engagement with PIC/S, ICH, IGDRP and IPRF
- ✓ Presentations on ICMRA to stakeholders
- ✓ PAHO and WHO journal articles
- ✓ ICMRA Fact Sheet
- ✓ Publications on ICMRA public web site
- ✓ Communication with key industry personnel
- ✓ Internal Engagement Plan
- ✓ Leveraging of other initiatives such as: PIC/S, IPRF, ICH, APEC-RHSC, WHO
- ✓ Communication with non-member regulators

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