# 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.

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

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.

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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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