

PMDA

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International Activities

ICMRA (International Coalition of Medicines Regulatory Authorities)



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1. About ICMRA

Introduction of ICMRA

The ICMRA is a voluntary, executive-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 Members

Therapeutic Goods Administration (TGA), Australia; National Health Surveillance (ANVISA), Brazil; Health Products and Food Branch, Health Canada (HPFB-HC), Canada; National Medical Products Administration (NMPA), 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; 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; South African Health Products Regulatory Authority (SAHPRA), South Africa; Medical Products Agency, Sweden; Swissmedic, Switzerland; Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom; Food and Drug Administration (FDA), United States, etc.




[ICMRA Public Website](#) ↗

2. Activities of ICMRA

ICMRA Statements, Reports and Reflection Papers

| Date | Title | Keywords |
|------------------|--|---------------------------------------|
| 14 January 2026 | ICMRA Statement on Regulators as communicators: strengthening regulatory communication for public health | Communication |
| 26 November 2024 | Reflection Paper on Facilitating Platform Clinical Trials During Global Public Health Emergencies | Clinical Trials, Emergency Use |
| 21 November 2024 | ICMRA statement on Antimicrobial Resistance | AMR |




| Date | Title | Keywords |
|-----------------|---|--|
| 26 June 2023 | ICMRA statement on the safety of COVID-19 vaccines | Vaccines, COVID-19, Safety |
| 21 October 2022 | International Coalition of Medicines Regulatory Authorities COVID-19 Working Group - Summary of Achievements [130.31KB]  | Global Collaboration, COVID-19 |
| 13 October 2022 | Framework for the Involvement of Health Regulatory Authorities in the Management of Global Health Crises [284.44KB]  | Global Collaboration, Pandemic |
| 19 August 2022 | A Regulatory Pharmaceutical Quality Knowledge Management System (PQ KMS) to Enhance the Availability of Quality Medicines ICMRA-ICH-PIC/S-IPRP Joint Reflection Paper | Quality Management |
| 22 July 2022 | ICMRA statement on international collaboration to enable real-world evidence (RWE) for regulatory decision-making [183.19KB]  | RWE, Global Collaboration |
| 17 May 2022 | Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness (Revised 17 May 2022) - Joint Statement from the International Coalition of Medicines Regulatory Authorities and World Health Organization | Vaccines, Health Care Professionals, Variants, Booster Doses, Children, Pregnancy, COVID-19 |






| Date | Title | Keywords |
|------------------|--|--|
| 10 December 2021 | Reflections on the regulatory experience of remote approaches to GCP and GMP regulatory oversight during the COVID-19 pandemic [281.18KB]  | Remote Inspections, COVID-19 |
| 10 December 2021 | ICMRA statement on need for continued focus on COVID-19 therapeutics | Therapeutics, COVID-19 |
| 10 December 2021 | Emergency Use Approval deep dive report on the review of provisions and procedures for emergency authorisation of medical products for COVID-19 among ICMRA members [1.02MB]  | Regulatory Flexibilities, Emergency Use, COVID-19 |
| 3 December 2021 | Report on regulatory flexibilities implemented by national regulatory authorities during the pandemic [455.59KB]  | Regulatory Flexibilities, COVID-19 |
| 11 June 2021 | Global Pharmaceutical Quality Knowledge Management: Enhancing Regulatory Reliance and Agility | Quality Management |
| 11 June 2021 | Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness (Revised 11 June 2021) - Joint Statement from the International Coalition of Medicines Regulatory Authorities and World Health Organization | Vaccines, Health Care Professionals, COVID-19 |
| 7 May 2021 | Joint Statement on transparency and data integrity - International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO) | Improving Transparency, COVID-19 |
| 19 January 2021 | ICMRA statement for healthcare professionals: How COVID-19 vaccines will be regulated for safety and effectiveness | Vaccines, Health Care |

| Date | Title | Keywords |
|------------------|---|--|
| | ctiveness | Professionals, COVID-19 |
| 27 November 2020 | Statement from Global Medicines Regulators on the Value of Regulatory Reliance | Reliance |
| 27 November 2020 | Statement on continuation of vaccine trials | Vaccines, COVID-19 |
| 6 November 2020 | WHO-ICMRA joint statement on the need for improved global regulatory alignment on COVID-19 medicines and vaccines | Vaccines, Therapeutics, COVID-19 |
| 24 June 2020 | ICMRA statement on clinical trials | Clinical Trials, COVID-19 |
| 17 June 2020 | ICMRA statement about confidence in vaccine safety and effectiveness (for healthcare professionals) | Vaccines, Health Care Professionals |
| 17 June 2020 | ICMRA statement about confidence in vaccines (for the general public) | Vaccines |
| 28 April 2020 | ICMRA statement on COVID-19 | Global Collaboration, COVID-19 |
| 31 July 2019 | Antimicrobial Resistance Statement | AMR |
| 9 February 2016 | Zika Virus Disease Press Release | Infectious Diseases |

| Date | Title | Keywords |
|-------------|--|---------------------|
| August 2014 | Consolidated Joint ICMRA statement Ebola | Infectious Diseases |

Workshops

| Date | Title | Deliverables | Keywords |
|-------------------|--|--|--|
| 19 September 2025 | ICMRA-Industry virtual workshop: Strengthening regulatory convergence and reliance through Pharmaceutical Quality Knowledge Management | Workshop report [494KB]  Agenda [158KB]  Presentation [1.89MB]  Recording ↗ | Manufacturing Capacity, Quality management, Collaborative assessment, Collaborative inspection |
| 3 December 2024 | Decentralised or Distributed Manufacturing including point of care (PoC) manufacturing | Workshop report ↗ | Innovation, Manufacturing technology |
| 2 October 2024 | Mpox workshop | Workshop report ↗ | Infectious Diseases, Vaccine |

| Date | Title | Deliverables | Keywords |
|-------------------------------|---|---|---|
| 16 to 17 September 2024 | Rare Disease Workshop | Workshop report [268KB]  | Rare Diseases |
| 20 to 21 July 2023 | ICMRA-industry virtual workshop on Development of a Pharmaceutical Quality Knowledge Management System | Workshop report [1.1MB]  Agenda [202KB]  Presentation [2.2MB]  Recording ↗ | Manufacturing Capacity, Quality management, Collaborative assessment, Collaborative inspection |
| 29 to 30 June 2022 | Real World Evidence Workshop | ICMRA statement on Real World Evidence [183KB]  | RWE |

For ICMRA workshops related to COVID-19: [3. Workshop related to COVID-19](#)

ICMRA Summit

Annual ICMRA Summit is an opportunity for Heads of Medicines Regulatory Authorities from around the world to come together and discuss current and emerging issues facing medicines regulators and common global strategies to address them.

[Past ICMRA Summit meetings](#) ↗

Working Group / Regulators Network

There are currently several ICMRA Working Group / Regulators Network (WG/RN) where ICMRA members collaborate on specific projects.

[List of WG/RN on ICMRA official website](#) ↗


3. COVID-19




[Statements related to COVID-19](#)

[Workshops related to COVID-19](#)

- [COVID-19 Vaccine Development](#)
- [COVID-19 Therapeutic Development](#)
- [COVID-19 Real-World Evidence and Observational Studies](#)
- [Vaccine Safety Collaboration](#)
- [Pregnancy and Lactation](#)
- [COVID-19 Virus Variants \(including Booster Doses\)](#)
- [Enabling Manufacturing Capacity](#)

Statements related to COVID-19

| Date | Title | Keywords |
|-----------------|---|--|
| 26 June 2023 | ICMRA statement on the safety of COVID-19 vaccines | Vaccines, Safety |
| 21 October 2022 | International Coalition of Medicines Regulatory Authorities COVID-19 Working Group - Summary of Achievements [130.31KB]  | Global Collaboration |
| 17 May 2022 | Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness (Revised 17 May 2022) - Joint Statement fro | Vaccines, Health Care Professionals, Variants, |

| Date | Title | Keywords |
|------------------|---|--|
| | m the International Coalition of Medicines Regulatory Authorities and World Health Organization | Booster Doses, Children, Pregnancy |
| 10 December 2021 | Reflections on the regulatory experience of remote approaches to GCP and GMP regulatory oversight during the COVID-19 pandemic [281.18KB]  | Remote Inspections |
| 10 December 2021 | ICMRA statement on need for continued focus on COVID-19 therapeutics | Therapeutics |
| 10 December 2021 | Emergency Use Approval deep dive report on the review of provisions and procedures for emergency authorisation of medical products for COVID-19 among ICMRA members [1.02MB]  | Regulatory Flexibilities, Emergency Use |
| 3 December 2021 | Report on regulatory flexibilities implemented by national regulatory authorities during the pandemic [455.59KB]  | Regulatory Flexibilities |
| 11 June 2021 | Statement for healthcare professionals: How COVID-19 vaccines are regulated for safety and effectiveness (Revised 11 June 2021) - Joint Statement from the International Coalition of Medicines Regulatory Authorities and World Health Organization | Vaccines, Health Care Professionals |
| 7 May 2021 | Joint Statement on transparency and data integrity - International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO) | Improving Transparency |

| Date | Title | Keywords |
|------------------|--|-------------------------------------|
| 19 January 2021 | ICMRA statement for healthcare professionals: How COVID-19 vaccines will be regulated for safety and effectiveness | Vaccines, Health Care Professionals |
| 27 November 2020 | Statement on continuation of vaccine trials | Vaccines |
| 6 November 2020 | WHO-ICMRA joint statement on the need for improved global regulatory alignment on COVID-19 medicines and vaccines | Vaccines, Therapeutics |
| 24 June 2020 | ICMRA statement on clinical trials | Clinical Trials |
| 28 April 2020 | ICMRA statement on COVID-19 | Global Collaboration |

Workshops related to COVID-19

Global Regulatory Workshop on COVID-19 Vaccine Development

| Date | Event | Keywords |
|---------------|--------------------|--|
| 22 June 2020 | #2 | Vaccine Development, Clinical Trials |
| 18 March 2020 | #1 | Vaccine Development, Pre-Clinical Data |

Global Regulatory Workshop on COVID-19 Therapeutic Development

| Date | Event | Keywords |
|--------------|--------------------|--|
| 20 July 2020 | #2 | Therapeutic Development, Clinical Trials |
| 2 April 2020 | #1 | Therapeutic Development, Clinical Trials |

Global Regulatory Workshop on COVID-19 Real-World Evidence and Observational Studies

| Date | Event | Keywords |
|-----------------|----------------------|----------------------------|
| 20 May 2022 | #7 ↗ | RWE, Observational Studies |
| 10 May 2021 | #6 ↗ | RWE, Observational Studies |
| 25 January 2021 | #5 ↗ | RWE, Observational Studies |
| 13 October 2020 | #4 | RWE, Observational Studies |
| 22 July 2020 | #3 | RWE, Observational Studies |
| 19 May 2020 | #2 | RWE, Observational Studies |
| 6 April 2020 | #1 | RWE, Observational Studies |

ICMRA Vaccine Safety Collaboration Workshop





| Date | Event | Keywords |
|-----------------|----------------------|--------------------------------|
| 13 January 2021 | #1 ↗ | Vaccines, Global Collaboration |

ICMRA Pregnancy and Lactation Workshop


| Date | Event | Keywords |
|-----------------|----------------------|----------------------|
| 9 February 2021 | #1 ↗ | Pregnancy, Lactation |

ICMRA COVID-19 Virus Variants Workshop

| Date | Event | Keywords |
|------------------------|----------------------|---|
| 26 to 27 February 2024 | #6 ↗ | Vaccine Development, Omicron Variant, Booster Doses, Variant-Adapted Vaccines |
| 8 May 2023 | #5 ↗ | Vaccine Development, Omicron Variant, Booster Doses, Variant-Adapted Vaccines |

| Date | Event | Keywords |
|------------------|--|--|
| 30 June 2022 | #4  | Vaccine Development, Omicron Variant, Booster Doses, Variant-Adapted Vaccines |
| 12 January 2022 | #3  | Vaccine Development, Omicron Variant, Booster Doses, Immunogenicity Bridging Studies |
| 24 June 2021 | #2  | Vaccine Development, Booster Doses, Immunogenicity Bridging Studies |
| 10 February 2021 | #1  | Vaccine Development, Virus Variants |

ICMRA Workshop on Enabling Manufacturing Capacity in the COVID-19 Pandemic

| Date | Event | Keywords |
|------------------|---|------------------------|
| 7 to 8 July 2021 | #1 [407.74KB]  | Manufacturing Capacity |

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