International Coalition of Medicines Regulatory Authorities COVID-19 Working Group

Summary of Achievements

Executive Summary

The International Coalition of Medicines Regulatory Authorities (ICMRA) COVID-19 Working Group was established in May 2020 to follow up on actions items from the ICMRA COVID-19 Policy meetings and to provide more in-depth work on certain priority topics. Furthermore, the working group rapidly progressed the practical matters on the development of common policy positions of ICMRA members on COVID-19 related issues and provided timely scientific/policy advice to COVID-19 related meetings organized under ICMRA.

Health Canada and UK Medicines and Healthcare products Regulatory Agency (MHRA) co-led the working group through 31 meetings to progress action items and share information on topics such as clinical trials results, communications strategies for COVID-19 vaccines and therapeutics, and COVID-19 vaccines and therapeutics pharmacovigilance signal checks. The group's coordinated efforts led to the publication of four ICMRA COVID-19 statements and other related significant documents, including three reports/reflection papers for ICMRA regulators. In addition, the group provided collective input to the WHO on COVID-19 documents/proposals. Many subgroups were established by the working group, such as the ICMRA COVID-19 Vaccine Pharmacovigilance Network.

The ICMRA COVID-19 Working Group has had many successes, including being a trusted leader in pronouncing on COVID-19 clinical trials and vaccine confidence through statements published on the ICMRA website. Working toward scientific alignment and collaboration brought stronger decision-making leading to expeditious access to COVID-19 vaccines and treatments and prompt follow up on emerging safety signals. Working group members, using insights gained from the ICMRA COVID-19 Working Group to identify various scientific and policy knowledge requirements requiring ICMRA regulator collaboration, went on to lead many of the ICMRA COVID-19 workshops that took place during the pandemic. Reports on the various workshops can be found in the ICMRA COVID-19 section online. The many achievements of the ICMRA COVID-19 Working Group and its subgroups are noted in the table below.

At the 23 March 2022 ICMRA Executive Committee meeting, it was agreed to disband the COVID-19 Working Group given this work is winding down. The remaining four subgroups (Crisis Management, Vaccine Pharmacovigilance Network, Clinical Trials, and Regulatory Agilities, Flexibilities and Sustainability) were decided to continue and report directly, as required, to the ICMRA COVID-19 Policy meeting, and/or to the Executive Committee or, in the case for the COVID-19 Vaccine Pharmacovigilance Network, to the ICMRA Observational Studies and Real World Evidence group.

Table of Achievements

Deliverable	Lead(s)	Description	Date
ICMRA statement on clinical trials	European Medicines Agency (EMA) and Danish	Statement on ICMRA's position and guiding principles for clinical trial coordination, patient enrolment in well-designed trials, and prioritization of compounds with the most potential.	24 June 2020

	Medicines Agency (DKMA)	The statement was published on the ICMRA website on 24 June 2020.	
List of COVID-19 master protocols	Health Canada	A list of all COVID-19 master protocols was developed and maintained to inform and support policy discussions.	26 June 2020
Query on acceptable clinical trial endpoints and outcomes for technical workshops on vaccines and treatments	Health Canada	Query of ICMRA members for the development of high-level principles on acceptable clinical trial endpoints and outcomes to ensure trial outcomes are actionable by regulators. Query results were utilized in technical workshops on COVID-19 vaccines and treatments.	20 July 2020
Letter addressed to organizations of medical journal editors on sharing of clinical trial results prior to publication	EMA	ICMRA letter sent to organizations of medical journal editors asking that journals consider sharing clinical study results with regulatory authorities prior to publication and encouraging peer-review of pre-prints. A reminder was sent September 2020.	4 August 2020
COVID-19 Vaccine Pharmacovigilance Network	Australia Therapeutic Goods Administration (TGA) and MHRA	The ICMRA COVID-19 vaccine pharmacovigilance network was established in August 2020 to share best practices and planning for COVID-19 vaccine pharmacovigilance. Key activities for the network include: ▪ **Pre-deployment** – systems for routine signal detection, plans and methodologies for proactive surveillance, priorities and definitions for outcomes of special interest, to be completed prior to Covid-19 vaccine rollout ▪ **Simulation exercises** – prior to adverse events of special interest being identified ▪ **Post-deployment surveillance** - early exchange of information on vaccine usage; emerging safety profile and signals; benefit-risk profile; communications planned.	From August 2020 to present
Clinical trials inventory of actionable trials	US Food and Drug Administration	COVID-19 clinical trial landscape analysis to share information about clinical trials ongoing in regions that may not have been available in known registries.	15 October 2020

ICMRA Vaccines Confidence Statement	TGA and MHRA	ICMRA and WHO joint statement to help healthcare professionals increase trust and confidence in COVID-19 vaccines and answer questions from patients about the development, regulatory review and safety monitoring of these vaccines. The statement was revised in June 2021 to address emerging adverse events of special interest and concerns about virus variants. Further updates to the statement made in May 2022 to include emerging information on paediatrics, boosters, variants, and pregnant and lactating persons. First version of the statement was published on the ICMRA website on 19 January 2021 and updated on 11 June 2021, then 17 May 2022.	19 January 2021 First revision: 11 June 2021 Second revision: 17 May 2022
Joint Statement on transparency and data integrity - ICMRA and the WHO	EMA	An ICMRA and WHO joint statement on transparency and integrity of communications, aimed at the pharmaceutical industry, on the importance of sharing data in relation to public health. The joint statement was published on the ICMRA and WHO websites on 7 May 2021.	7 May 2021
Report on the review of regulatory flexibilities/agilities as implemented by National Regulatory Authorities during Covid-19 pandemic	World Health Organization (WHO) and Italian Medicines Agency (AIFA)	A report featuring examples of regulatory flexibilities and extraordinary measures put in place by regulatory authorities to respond to the challenges faced during the COVID-19 pandemic. The report was published on the ICMRA and WHO websites on 3 December and 15 December 2021, respectively.	3 December 2021
Deep dive report on the review of provisions and procedures for emergency authorization of medical products for COVID-19 among ICMRA members	WHO and AIFA	A deep dive report by the ICMRA and WHO reviewing provisions and procedures for emergency authorisation of COVID-19 medicines used during the pandemic and summarizing the key findings, including similarities, unique features, enablers and limitations associated with emergency use procedures. The deep dive report was published on the ICMRA website on 10 December 2021.	10 December 2021
ICMRA Statement on Need for Continued Focus	Health Canada	Building on and updating the ICMRA statement on clinical trials that was issued in June 2020, a new statement on the need for continued focus on COVID-19 therapeutics was published on the ICMRA website on 10 December 2021.	10 December 2021

on COVID-19 Therapeutics			
Reflections on the regulatory experience of remote approaches to GCP and GMP regulatory oversight during the COVID-19 Pandemic	MHRA	The paper, Reflections on the regulatory experience of remote approaches to GCP and GMP regulatory oversight during the COVID-19 pandemic, covers challenges, successes and technologies of remote and hybrid inspections. The reflection paper was published on the ICMRA website on 10 December 2021.	10 December 2021
Framework for the Involvement of Health Regulatory Authorities in the Management of Global Health Crises	Anvisa and MHRA	The ICMRA Standard Operating Procedure for Crisis Management was updated to reflect the changing regulatory landscape, and ensuring that the framework and standard operating procedure remain current and fit for purpose in any future global health crisis. The updated version was published on the ICMRA website on 13 October 2022.	13 October 2022

Working group participants

1. Health Products and Food Branch, Health Canada (HPFB-HC), Canada
2. European Medicines Agency (EMA), European Union
3. Health Product Regulatory Authority (HPRA), Ireland
4. Italian Medicines Agency (AIFA), Italy
5. Ministry of Health, Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), Japan
6. Ministry of Food and Drug Safety (MFDS), Korea
7. Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom
8. Food and Drug Administration (FDA), United States
9. Danish Medicines Agency (DMKA), Denmark
10. World Health Organization (WHO)
11. Therapeutics Goods Administration (TGA), Australia
12. National Medical Products Administration (NMPA), China