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ICMRA provides a global architecture to support enhanced communication, information sharing, crisis response and address regulatory

ICMRA aims for international alignment on policy approaches and regulatory flexibility during COVID-19 pandemic

On 16 April, the International Coalition of Medicines Regulatory Authorities (ICMRA) convened a meeting of regulators from around the world to discuss alignment or regulatory requirements and approaches to respond to the COVID-19 pandemic. Delegates, representing more than 20 medicines regulatory authorities as well as experts from the World Health Organization (WHO) acknowledged the importance of regulatory convergence as well as regulatory flexibility to facilitate the development, evaluation and availability of medicines for treatment and prevention of COVID-19.

Regulators discussed high-level policy issues and regulatory challenges related to the rapid development of potential therapeutics and vaccines against COVID-19. In addition, continued availability of medicines, in particular those being used for patients with COVID-19 in intensive care units, was of critical concern to ICMRA members in light of the medical emergency presented by the pandemic. Participants shared various agile and accelerated

regulatory measures implemented in different countries to mitigate the negative impact of the ongoing COVID-19 outbreak. They agreed that regulatory rules should be applied with greater flexibility during the pandemic to facilitate development of potential COVID-19 treatments and secure continued supply of medicines.

Global regulators also recognised the need for prioritisation of large COVID-19 clinical trials and alignment on common study protocols. They stressed that large randomised controlled studies are the best way to collect robust evidence to determine which investigational agents or repurposed medicines are safe and effective for the treatment of COVID-19. They also highlighted that multiple underpowered studies that compete for essential resources should be discouraged.

Participants committed to continue exchanging information on COVID-19 policy issues and seek alignment in their approaches to enhance the efficiency and effectiveness of regulatory decision-making during the current pandemic.

ICMRA will organise bi-weekly meetings to facilitate information sharing and identify areas for potential synergies that will help regulators to expedite the development and evaluation of COVID-19 therapeutics and vaccines, and avoid shortages. These strategic discussions will build on the knowledge and experience gained from the series of ICMRA workshops on COVID-19 medicine development held in March and April 2020.

The discussion was moderated by Dr Janet Woodcock, Director of the Center for Drug Evaluation and Research at the US Food and Drug Administration (FDA). More details on the outcomes of the meeting will be published in due time.

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