EUROPEAN MEDICINES AGENCY
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Press release

Global regulators work towards alignment on policy approaches and regulatory flexibility during COVID-19 – update #4

The International Coalition of Medicines Regulatory Authorities (ICMRA) convened its regular virtual meeting of regulators from around the world on 12 June 2020 to discuss high-level policy issues and regulatory approaches to ensure a coordinated response to the ongoing COVID-19 pandemic.

Meeting participants discussed the progress made on the development of ICMRA guiding principles for COVID-19 clinical trials and prioritisation of compounds. They agreed that a clear distinction between exploratory clinical trials and confirmatory studies with investigational or repurposed medicines for the treatment of COVID-19 is critical for clinical trial prioritisation. Regulators also shared concerns about the discontinuation of clinical trials globally and the growing number of underpowered studies that might not generate the robust data required for regulatory decision-making. All ICMRA members stressed the need for continuation of COVID-19 clinical trials that might produce conclusive evidence on the effects of potential treatments and vaccines against COVID-19, provided that the safety of trial participants is ensured. They reiterated that the research community should pool resources into large, well-designed, randomised clinical trials to determine which investigational or repurposed medicines would be safe and effective for the treatment or prevention of COVID-19.

In addition, participants in the high-level meeting discussed the use of COVID-19 clinical trial master protocols around the world to accelerate the development and approval of potential treatments and vaccines against COVID-19. ICMRA members are currently working on a list of ongoing and planned COVID-19 clinical trials with master protocols in different countries and regions in order to compare the protocols and identify possible overlaps, for example regarding objectives and types of investigational agents studied. Regulators aim to update this list on a regular basis.

The ICMRA Working Group on COVID-19 also provided meeting participants with an update on its activities related to COVID-19 clinical trials, potential therapeutics and vaccines. Topics under discussion include ethical questions around human challenge trials and post-approval requirements for COVID-19 vaccines. ICMRA members agreed to analyse the regulatory flexibilities and extraordinary measures applied in different areas during the pandemic in order to identify practices that should be

maintained or stopped after the public health emergency. The ICMRA COVID-19 Working Group will keep updating all ICMRA members on the progress of these initiatives.

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). This was the fifth in a series of bi-weekly ICMRA meetings organised to allow medicine regulators worldwide to exchange information and build synergies for expediting COVID-19 medicine and vaccine development and approval and for preventing and mitigating medicine shortages. These strategic discussions build on the knowledge and experience gained from the series of ICMRA workshops on COVID-19 medicine development held in March and April 2020. EMA and FDA are taking turns to chair these meetings.

Notes

1. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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