9 April 2020
EMA/194459/2020
Media and Public Relations

Press release

Global regulators stress need for robust evidence on COVID-19 treatments

International regulators have published a report today highlighting their considerations on the development of potential COVID-19 therapeutics, clinical trials and compassionate use programmes. The report presents the outcomes of a workshop on COVID-19 therapeutic medicine development that was organised by EMA under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA).

At this point in time, no medicine has yet clearly demonstrated efficacy in treating COVID-19. Workshop participants stressed that the fastest way to serve patients was to collect robust evidence to determine which investigational agents or repurposed medicines would be safe and effective for the treatment of COVID-19. Regulators agreed that multi-centre randomised controlled studies are the best way to generate the data required to enable rapid development and approval of potential treatments for COVID-19. They also agreed on a harmonised approach to make best use of the available supply.

Participants committed to exchange information about the ongoing studies and results to support the global approach. ICMRA will convene another regulatory workshop to discuss the progress on COVID-19 medicine development in the coming months.

About the workshop

The regulatory workshop was held virtually on 2 April 2020 in the context of the ongoing COVID-19 pandemic. It brought together delegates from more than 25 different countries, representing 28 medicines regulatory authorities globally, as well as experts from the World Health Organization and the European Commission to discuss the available knowledge on possible treatments (drugs and biologics) for COVID-19. The meeting was co-chaired by Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and EMA.

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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