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Press release

Global regulators commit to cooperate on observational research in the context of COVID-19

Regulators from around the world have agreed three priority areas for cooperation on observational research during COVID-19. They will collaborate on pregnancy research, on medicines used in clinical practice and on vaccine safety and effectiveness monitoring.

High-quality observational research is an important complement to the evidence on the safety and effectiveness of vaccines and treatments for COVID-19 generated in randomised clinical trials. It is critical in understanding the safety and effectiveness of medicines when used in clinical practice for the prevention and treatment of COVID-19.

At a second workshop on observational studies of real-world data generated during clinical practice in the context of COVID-19, co-organised by the European Medicines Agency (EMA) and Health Canada under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA) on 19 May 2020, international regulators agreed to step up their cooperation in the following three areas:

- **Pregnancy research** to examine the impact of both coronavirus disease and medication use on pregnant women infected with SARS-CoV-2 and on their unborn babies in order to support COVID-19 medicine development, risk management, and planning for safety monitoring of vaccines and therapeutics;

- **Building international clinical cohorts of COVID-19 patients** to share expertise and increase study power and data quality in order to meet regulatory requirements and address existing knowledge gaps; and

- **Prepare strong infrastructure for monitoring the safety and effectiveness of vaccines** against COVID-19 in order to rapidly detect and minimise risks to patients.

Meeting participants agreed that global collaboration on observational studies of real-world data will help not only to contribute to the COVID-19 response but also to leave enduring legacy for future international observational research beyond the ongoing pandemic.

The meeting built upon the experience and knowledge gained from the first workshop on COVID-19 observational research held in April, which underlined the need and commitment by regulators to

cooperate and improve information-sharing globally in relation to the research and development of treatments and vaccines against COVID-19. It had participants from more than 25 countries, representing 28 medicines regulatory authorities and experts from the World Health Organization.

The discussion was moderated by Marc Mes, Director General of Marketed Health Products Directorate at Health Canada and Peter Arlett, Head of Data Analytics and Methods Task Force at EMA. More details on discussions and outcomes of the meeting will be shared in the coming days.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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