EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press release

EMA commissions independent research to prepare for real-world monitoring of COVID-19 vaccines

EMA is engaging early with researchers to ensure that a European infrastructure will be in place to effectively monitor COVID-19 vaccines in the real world, once these are authorised in the European Union. The Agency has signed a contract with Utrecht University as coordinator of the EU Pharmacoepidemiology and Pharmacovigilance Research Network, a public-academic partnership of 22 European research centres, to conduct preparatory research into data sources and methods that can be used to monitor the safety, effectiveness and coverage of COVID-19 vaccines in clinical practice. The ACCESS (vACcine Covid-19 monitoring readinESS) project will be led by the University Medical Center Utrecht (UMCU) and Utrecht University.

To authorise any COVID-19 vaccine, EMA will need to have strong evidence from clinical trials on the safety, efficacy and the quality of this vaccine. Once on the market, approved vaccines will be monitored closely, by the Agency and its Pharmacovigilance Risk Assessment Committee (PRAC), through planned and routine pharmacovigilance activities, including the spontaneous reporting of suspected side effects reported by patients and healthcare professionals through Eudravigilance, the European database of suspected adverse reactions to medicines. The infrastructure put in place by Utrecht University will provide additional information from clinical practice to complement data collected pre-authorisation through clinical trials and post-authorisation through spontaneous reporting.

The researchers will identify a Europe-wide network of data sources (including health insurance records, GP and hospital health records) and examine their utility in monitoring the coverage, safety and effectiveness of COVID-19 vaccines. The commissioned research will also identify possible adverse events of special interest that might need extra consideration in the monitoring of COVID-19 vaccines.

The research commissioned by EMA will be complemented by international collaboration on COVID-19 vaccine monitoring as agreed by the International Coalition of Medicines Regulatory Authorities (ICMRA) at its meeting on 19 May 2020. First deliverables of the commissioned research are planned for August 2020 with a final delivery by the end of the year.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on EMA's response to COVID-19 is provided on its website.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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