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## **EUROPEAN MEDICINES AGENCY**

## New guidance on safe use of medicines and the management of clinical trials during the Covid-19 pandemic

- The European Medicines Agency (EMA) is issuing advice on the safe use of medicines during the COVID-19 pandemic and is continuously reviewing all available clinical evidence. Advice is available on:
  - non-steroidal anti-inflammatory medicines (NSAIDs) such as ibuprofen,
  - angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs, or sartan medicines).
- The <u>Guidance on the management of clinical trials during the COVID-19</u>
  (<u>coronavirus</u>) <u>pandemic</u> has been updated covering safety reporting, the
  distribution of in-vitro diagnostics, medical devices and auditing;
  communicating with authorities, informed consent and the distribution of
  investigational medicines.
- The EMA has published <u>guidance on the actions that sponsors of ongoing clinical trials affected by the COVID-19 pandemic should take</u> to help ensure the integrity of their studies and the interpretation of study results while safeguarding the safety of trial participants as a first priority. This complements the <u>good clinical practice guidance on how sponsors should adjust the management of clinical trials</u> and participants during the pandemic. The draft is open for comments until 25 April 2020.
- The EMA and the <u>European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)</u> encouraged all researchers to register their pharmaco-epidemiological studies related to the COVID-19 pandemic in the <u>EU PAS Register</u>.
- The EMA started issuing <u>electronic certificates for medicines</u> in place of paper certificates. This applies to all ongoing and future requests for certificates during the COVID-19 pandemic.