EUROPEAN MEDICINES AGENCY
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Press release

EU actions to support availability of medicines during COVID-19 pandemic – update #4

The EU Executive Steering Group on Shortages of Medicines Caused by Major Events held a virtual meeting on 29 April 2020 to assess the implementation of the actions taken by EU authorities to ensure the continued availability of medicines in Europe during the ongoing COVID-19 pandemic. The heads of the national competent authorities (NCAs) of EU Member States also joined the meeting to discuss the various measures launched to safeguard the supply of medicines.

The steering group was updated on the progress of the i-SPOC (industry single point of contact) system. EMA's fast-track monitoring system has received the first notifications of possible or anticipated shortages affecting medicines for use in COVID-19 patients. The information received by the Agency so far concerns nationally authorised medicines, in particular antibiotics and anaesthetics. The cause of disruptions in the supply of these medicines is the unexpected surge in demand driven by the health emergency and the subsequent changes in prescribing behaviours. While the i-SPOC activity continues, EMA is working on a methodology to present aggregated data to the steering group.

The European Commission, EMA and the Heads of Medicines Agencies (HMA) are finalising a question-and-answer document for marketing authorisation holders (MAHs) of veterinary medicines to provide guidance on adaptations to the regulatory framework. These provisions aim to address some of the challenges posed to companies by the current pandemic and mirror the measures already implemented for MAHs of human medicines. The Q&A document on regulatory expectations for veterinary medicines will be published soon and additional information will be made available by EU authorities.

EU authorities are also working on an update of the Q&A for MAHs of human medicines. The European Commission, EMA and the Coordination group for Mutual-recognition and Decentralised Procedures – human (CMDh) will hold a virtual meeting with representatives of industry stakeholder organisations on 7 May 2020 to present and discuss these measures. Further information will follow in due course.

The steering group also noted the European Commission's publication of the updated guidance on the management of clinical trials that aims to minimise possible disruption of clinical research during the ongoing pandemic.

Lastly, the heads of the NCAs were updated on the efforts undertaken by several pharmaceutical industry associations to develop a forecasting model based on industry data that would help to predict and match demand and supply of medicines used in intensive care units in the EU. The steering group

members and the heads of the NCAs agreed to gather more in-depth information on this initiative and to further discuss it in future meetings.

Notes

1. For more information on EMA's contribution to the global response against COVID-19, see Coronavirus disease (COVID-19).
2. The EU Executive Steering Group on Shortages of Medicines Caused by Major Events is chaired by the European Commission. Its membership is made up of representatives from the European Commission, the Heads of Medicines Agencies (HMA), EMA, the chairs of the Coordination groups for Mutual-recognition and Decentralised Procedures for both human and veterinary medicines (CMDh and CMDv), as well as risk communication specialists.
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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