EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press release

EU actions to support availability of medicines during COVID-19 pandemic – update #3

The EU Executive Steering Group on Shortages of Medicines Caused by Major Events held a virtual meeting on 22 April 2020 to discuss the measures adopted to safeguard the supply of medicines during the ongoing COVID-19 pandemic for European patients.

EMA has provided an update on the i-SPOC (industry single point of contact) system, a fast-track monitoring system to help prevent and mitigate potential shortages of medicines launched on 17 April 2020. The i-SPOC allows each pharmaceutical company to report any issues related to the availability of both centrally and nationally authorised medicines for use in COVID-19 patients directly to EMA, in addition to national shortage reporting requirements. In this early phase the system is focusing on a subset of medicines being used in intensive care units (ICUs) across Europe and first reports have been received. Further updates on the i-SPOC activity will be provided as the implementation of the system progresses.

The European Commission, EMA and the Heads of Medicines Agencies (HMA) are currently working to consolidate the feedback received from stakeholders regarding the question-and-answer (Q&A) document that provides guidance on adaptations to the regulatory framework aimed at addressing challenges arising from the current pandemic. EU authorities are also considering a further update of the measures for marketing authorisation holders (MAHs) of human medicines, and further information will follow.

Additionally, a similar Q&A for MAHs of veterinary medicines is under development. The guidance will detail areas where regulatory flexibility is possible to address some of the constraints posed by the pandemic. It will comprise measures on marketing authorisation procedures, safety monitoring, inspections and good manufacturing practice (GMP) requirements for veterinary medicines. EU authorities will communicate further in due course.

Lastly, the steering group saw a presentation of a draft model developed by a number of pharmaceutical industry associations together with an external service provider that could potentially help to estimate and match supply with the demand for medicines used to treat COVID-19 patients, especially in ICUs across the EU. As this initiative is still in the development stage, further updates will be provided in future meetings of the steering group.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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

Contact our press officers

Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News