EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press release

EU actions to support availability of medicines during COVID-19 pandemic – update #2

The EU Executive Steering Group on Shortages of Medicines Caused by Major Events held a virtual meeting on 15 April to discuss the progress and implementation of the measures adopted to ensure the continued availability of medicines for European patients during the COVID-19 pandemic.

The Steering Group was informed that Member States and industry have welcomed the publication of the question-and-answer (Q&A) document that provides guidance to stakeholders on adaptations to the regulatory framework aimed at addressing challenges arising from the current pandemic. The European Commission (EC), EMA and the Heads of Medicines Agencies (HMA) are currently working on a first update of the Q&As that will comprise new provisions regarding good manufacturing practice (GMP) as well as safety monitoring. The measures deal with regulatory aspects such as the conduct of inspections, pharmacovigilance reporting as well as manufacture and import of medicines in the context of COVID-19. The update will be published soon. EU regulators are currently evaluating how these provisions would be applied to veterinary medicines.

EMA is fine-tuning the details of the i-SPOC (industry single point of contact) system that will allow each pharmaceutical company to report any issues related to the availability of certain medicines for use in COVID-19 patients directly to EMA. In the context of the i-SPOC, EMA will coordinate shortage notifications and, if necessary, after consultation with the Steering Group, discuss with the concerned industry contacts all relevant proposals to prevent or mitigate such shortages. The Agency organised a webinar with industry representatives to illustrate how the i-SPOC will work and to explain how potential shortages will need to be identified and notified to EMA in the new system. EMA also reiterated that, in parallel, companies must continue to report any potential issue in their supply chain to the competent national authorities concerned. Further information on the i-SPOC system will be published in due course.

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