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Press release

Update on EU actions to support availability of medicines during COVID-19 pandemic

The continued availability of medicines is one of the most important priorities for EU authorities that are adopting measures to mitigate possible disruptions to the supply of medicines caused by the ongoing COVID-19 pandemic. The EU Executive Steering Group on Shortages of Medicines Caused by Major Events met virtually on 8 April to discuss ongoing activities aimed at ensuring a coordinated response to the challenges posed by the COVID-19 pandemic.

The Steering Group is chaired by the European Commission (EC) and comprises representatives from the EC, 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.

EMA, together with pharmaceutical industry, is currently setting up the i-SPOC (industry single point of contact) system. Through the i-SPOC system pharmaceutical companies can report directly to the Agency any issues related to the availability of crucial medicines being used in the context of COVID-19, whilst also continuing to report to the Member States concerned. The testing of the system will start next week as soon as the composition of the i-SPOC is agreed with industry representatives.

The European medicines regulatory network is compiling a list of the medicines currently being employed across the EU to treat patients with COVID-19. The list will comprise active substances identified by the national competent authorities that are currently deemed crucial for the treatment of the infection, particularly in intensive care units (ICUs). A subset of the medicines used in ICUs which are at greater demand will be closely monitored for any possible disruption in the supply using the i-SPOC system.

In addition, the EU Executive Steering Group discussed the need to allow regulatory requirements pertaining to medicines to be applied more flexibly during the COVID-19 crisis. EU authorities are developing a Q&A document to provide guidance to stakeholders on areas where additional regulatory flexibility is possible. It will also detail the extraordinary procedures that can be applied to ensure the continued supply of these crucial medicines. More information on this guidance will be published shortly.

The Steering Group also discussed an update to the Guidance on the Management of Clinical Trials during the COVID-19 pandemic which will be published in due time.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. For the latest information from EMA on the COVID-19 pandemic see here.
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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