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Launch of enhanced monitoring system for availability of medicines used for treating COVID-19

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EMA, together with the pharmaceutical industry and the EU Member States, has launched its enhanced fast-track monitoring system to help prevent and mitigate supply issues with crucial medicines used for treating patients with COVID-19.

Under this system, each pharmaceutical company will appoint a single contact point (an industry single point of contact, or i-SPOC) who will report to EMA and <u>national competent authorities</u> all current and anticipated shortages of medicines

used in patients with COVID-19, both for centrally and nationally authorised medicines.

The new mechanism will allow better oversight of ongoing supply issues and a quicker flow of information between regulatory authorities in the EU and the pharmaceutical industry with the objective of mitigating and preventing shortages of medicines used during the COVID-19 health emergency.

The system has been set up by the EU Executive Steering Group on Shortages of Medicines Caused by Major Events, which provides strategic leadership for urgent and coordinated action on shortages within the EU in the context of the COVID-19 pandemic. EMA will coordinate information received from pharmaceutical companies on supply shortages and share it with the EU Executive Steering Group, which will decide on EU-level coordinated actions to address these supply shortages in the best way.

The mechanism is similar to the network of single points of contact in <u>national competent</u> <u>authorities</u> (EU SPOC network) that EMA, the <u>national competent authorities</u> in EU Member States and the European Commission have already been using to share information on shortages and availability issues of authorised medicines since April 2019.

Due to the large number of companies involved, the i-SPOC system is being launched in two phases:

- In the first phase, which started on Friday 17 April 2020, the scope of reporting by the
 pharmaceutical industry will focus on current or anticipated shortages of a subset of
 medicines, authorised and marketed in the EEA/EU, used in the treatment of COVID-19
 patients in hospital intensive care units (ICUs) such as anaesthetics, antibiotics,
 resuscitation drugs and muscle relaxants, which are currently in greatest demand;
- The second phase will focus on reporting of shortages for a broader range of medicines used in the treatment of COVID-19 patients.

Several hundred pharmaceutical companies have been contacted directly by EMA and provided with a template via which they can report current or anticipated shortages to EMA and propose mitigation measures.

A dedicated webinar took place on 16 April 2020 to explain to companies how to use the new system and to clarify additional reporting aspects.

Pharmaceutical companies are strongly reminded that in parallel they must continue to report shortages to the <u>national competent authorities</u> concerned in line with their applicable national legislation.

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CONTACT

European Medicines Agency Domenico Scarlattilaan 6 1083 HS Amsterdam The Netherlands

Tel: +31 (0)88 781 6000

For delivery address, see:

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