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Press release

EU authorities agree new measures to support availability of medicines used in the COVID-19 pandemic

The continued availability of medicines, in particular those used for patients with COVID-19, is of critical concern for EMA and its partners in the European medicines regulatory network in light of the medical emergency presented by the pandemic.

Some EU Member States have indicated that they are starting to see shortages of certain medicines used for patients with COVID-19 or are expecting such shortages to occur very soon. These include medicines used in intensive care units such as certain anaesthetics, antibiotics and muscle relaxants as well as medicines used off-label for COVID-19. EU authorities are therefore putting in place additional measures to mitigate the impact of the pandemic on the supply chain of medicines in a coordinated manner.

The number of shortages of medicines has increased in the past few years and the issue is aggravated in this pandemic by many different factors, e.g. lockdown in factories due to quarantine, logistical issues caused by border closures, export bans, lockdowns in third countries supplying medicines to the EU, increased demand due to the treatment of COVID-19 patients, stockpiling in certain hospitals, but also individual stockpiling by citizens as well as at Member State level. To avoid shortages due to stockpiling, some Member States have imposed restrictions on the number of packs that can be prescribed to patients or purchased by citizens.

To help mitigate supply disruptions, 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 this pandemic, is currently setting up, with the pharmaceutical industry, a system, the i-SPOC (industry single point of contact) system, to fast-track interaction on shortages between industry and the EU Executive Steering Group. With this system, each pharmaceutical company will report directly to EMA, both for centrally authorised and nationally authorised medicines, anticipated shortages or current shortages of critical medicines used in the context of COVID-19. It should be emphasised that, in parallel, these companies will continue reporting such shortages to the national competent authorities concerned.

The i-SPOC system, which is similar to the single point of contact (SPOC) network which was set up in 2019 between EMA and the national competent authorities to share information on medicine shortages,

is based on the appointment of an i-SPOC in each pharmaceutical company, who will feed information on current or anticipated shortages of COVID-19-related medicines to EMA. This new mechanism will allow better oversight of ongoing supply issues irrespective of the licensing route and a quicker flow of information with the pharmaceutical industry with the objective of mitigating and, if possible, preventing shortages in the context of COVID-19 medicines.

In the context of the pandemic, EMA and the EU network are considering mitigation measures such as regulatory actions to support increased manufacturing capacities, e.g. through speeding up the approval of a new manufacturing line or site. Discussions are also ongoing with the pharmaceutical industry to increase production capacity for all medicines used in the context of COVID-19, and in particular for medicines potentially at risk of supply shortages.

In addition, the EU Executive Steering Group is considering areas where regulatory rules could be applied with greater flexibility during the pandemic to secure supply of critical medicines. Further information will be given in a question-and-answer document, currently under development.

Although medicine shortages are dealt with at national level by national competent authorities, EMA has been asked to take on the role of a central coordinator to actively support Member States' prevention and management actions during this extraordinary health crisis. This is a new type of activity that cannot make use of existing mechanisms and means the Agency is having to put in place new ad hoc processes and prioritise resources to this activity. The Agency has been, for example, proactively gathering information from Member States to monitor or anticipate EU-level shortages in hospital settings. It has also liaised with Member States regarding how the export ban on 14 active substances (APIs) issued by the Indian authorities impacts the availability of certain medicines in Member States. Together with its partners in the regulatory network, EMA is monitoring the situation very closely.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. For more information on EMA's contribution to the global response against COVID-19 see here.
3. 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.
4. Information on ongoing medicine shortages in the EU is available in the relevant national shortages registers and EMA's shortages catalogue.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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