Addressing the potential impact of novel coronavirus disease (COVID-19) on medicines supply in the EU

EMA and its partners in the European medicines regulatory network are closely monitoring the potential impact of the outbreak of the novel coronavirus disease (COVID-19) on pharmaceutical supply chains into the European Union (EU). No reports of current shortages or supply disruptions of medicines marketed in the EU due to this outbreak have been received at this point. As the public health emergency develops, shortages or disruptions cannot be excluded.

The EU (EMA, the European Commission and national competent authorities in the Member States) have organised the first meeting of the EU Executive Steering Group on shortages of medicines caused by major events to discuss measures aimed at addressing the impact of the outbreak of COVID-19 on the supply of medicines in the EU.

The mandate of this group is to provide strategic leadership for urgent and coordinated action within the EU in case a crisis caused by major events, such as the COVID-19 outbreak, risks impacting the supply of medicinal products for human and veterinary use.

In the context of COVID-19, the group will identify and coordinate EU-wide actions to protect patients when medicines in the EU are at risk of supply shortage, e.g. due to a temporary lockdown of manufacturing sites in areas affected by COVID-19 or travel restrictions impacting shipment. The group will also ensure that patients and healthcare professionals across the EU are kept informed in a consistent and transparent manner about the risks and the remedial actions taken.

The steering group 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.

While the purpose of the group is to address disruptions of the supply of medicines in the EU through a coordinated approach, it is important to highlight that it is the responsibility of pharmaceutical companies to ensure the continuity of supply of their medicines. This includes for instance that manufacturers put in place appropriate resilience measures such as the increase of stocks or dual sourcing of products and materials.

**Actions already taken**
Medicines regulators are already taking measures to monitor the potential impact of the COVID-19 outbreak on medicines. The Agency and national medicines regulators are sharing information via the Single Point of Contact network on shortages.

The Agency requested EU pharmaceutical industry associations to raise awareness among their members of the potential impact of quarantine measures in China and elsewhere on the supply of medicines in the European Economic Area (EEA), both for human and veterinary use, and remind them of their obligation to report any possible shortages to the EU authorities.

EMA also asked the associations to assess the preparedness of their members to prevent possible shortages that may result from the outbreak and report back to the Agency and for specific products to the relevant competent authorities. Industry associations have indicated that no specific disruptions have yet been identified and that any impact in the short-term would be limited, given the current stocks in place. However, supply issues can be expected if lockdowns continue and/or other supply disruptions occur e.g. caused by logistical problems or export restrictions.

National medicines regulators are requesting information from marketing authorisation holders and or manufacturers in their Member States.

Industry associations at national and EU-level will be asked to provide further information on the resilience of companies’ supply chains to regulators, which will be monitored through the steering group.

The Agency has also started to review all manufacturing information for centrally authorised human and veterinary medicines to identify those most at risk of shortages and disruptions and prioritise them for discussions about remedial actions with the marketing authorisation holder. The CMDh and CMDv will be coordinating actions for nationally authorised medicines and EMA is working closely with them.

Notes
1. This press release, together with all related documents, is available on the Agency’s website.
2. More information about EMA’s response to COVID-19 is available here.
3. More information on actions taken to improve the availability of medicines in the EU is available here.
4. The epidemiological situation in relation to the outbreak is monitored by the ECDC who is providing regular risk assessments and situation updates. For more information, see ECDC: Novel coronavirus.
5. For more information on the EU’s response on coronavirus 2019-nCoV, see European Commission: Coronavirus response.