This update is brought to you by the European Alliance for Vision Research and Ophthalmology https://www.eueye.org





New EU measures to support availability of medicines used in the COVID-19 pandemic

Shortages are reported (or expected to occur soon) of certain medicines used for patients with COVID-19 including medicines used in intensive care units such as certain anaesthetics, antibiotics and muscle relaxants as well as medicines used off-label for COVID-19. Additional measures are therefore put in place to mitigate the impact of the pandemic on the supply chain of medicines.

- The <u>i-SPOC</u> (industry single point of contact) system is currently set with each pharmaceutical company reporting 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. This reporting is in parallel to the reporting of shortages to the national competent authorities concerned.
- The 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 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.
- 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.

Medicine shortages continue to be dealt with at national level by national competent authorities with the EMA centrally coordinating to actively support Member States by:

- proactively gathering information from Member States to monitor or anticipate EU-level shortages in hospital settings.
- liaising 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.