Briefing on medicine shortage in the EU

General note

The responsibility for the continuity of supply of medicines falls on the pharmaceutical companies which have to place appropriate resilience measures such as the increase of stocks or dual sourcing of products and materials. So far 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.

Actions at EU and national level

- The Coronavirus Response Team of the EU has eight Commissioners working on actions to mitigate the socio-economic impact of coronavirus 2019-nCoVin the European Union. see European Commission: Coronavirus response.

- The epidemiological situation in relation to the outbreak is monitored by the European Centre for Disease Prevention and Control who is providing regular risk assessments and situation updates. For more information, see ECDC: Novel coronavirus.

- An EU ***Executive Steering Group on shortages of medicines caused by major events*** has been set up to provide strategic leadership for urgent and coordinated action within the EU in case of a crisis caused by major events. The group is chaired by the European Commission and it is made up of representatives from the Heads of Medicines Agencies (HMA), European Medicines Agency (EMA), the chairs of the Coordination groups for Mutual-recognition and Decentralised Procedures for both human and veterinary medicines (CMDh and CMDv which coordinate actions for nationally authorised medicines), as well as risk communication specialists. The group has already discussed measures aimed at addressing the impact of the outbreak of COVID-19 on the supply of medicines in the EU and they will work on:
  - identifying and coordinating EU-wide actions to address disruptions of the supply of medicines, e.g. due to temporary lockdowns of manufacturing sites or travel restrictions.
  - ensuring 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 EMA and national medicines regulators are monitoring the potential impact of the COVID-19 outbreak on medicines and sharing information via the Single Point of Contact (SPOC) network on shortages. (*SPOCs are contact points at each human and veterinary medicines regulatory agency in the EU/EEA responsible for sharing information with other SPOCs and coordinating subsequent actions in relation to shortages and availability of authorised medicines. They have been nominated by the Task Force on Medicines Availability with the aim to facilitate better prevention, identification, management and communication of shortages and availability issues.)*

- The EMA has 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.

  - 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.

- The EMA has is reviewing manufacturing information for centrally authorised medicines to identify those most at risk of shortages and in need of attention by marketing authorisation holders.

- 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.