



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 March 2020
EMA/129860/2020

The ongoing epidemic of the COVID-19 infection, which started in Wuhan, China in December 2019, may have an impact on the supply of medicines to the European market. The disruption in supply may relate to the importation of active substances or finished products from the affected areas or the unavailability of starting materials, intermediates or excipients used in the manufacture of medicinal products. Other factors may also impact supply of medicines such as logistic issues (transportation) or shortages of medical devices required for the manufacture of medicines or required for administration of medicines. In addition, movement restrictions may also be another factor to consider.

The European Union Medicines Regulatory Network encourages European and National Industry Trade Associations to cooperate with EMA (for European Trade Associations) and their respective National Competent Authorities (for National Industry Trade Associations) by collecting information on the potential impact of the COVID-19 infection on the availability of human and veterinary medicines.

As well as ensuring National Competent Authorities are informed of potential risks and challenges arising in the supply chain of medicinal products authorised within the Union/EEA, your prompt and detailed responses will help inform regulators in taking the necessary steps to mitigate these risks or to meet some of the challenges, through providing adequate and relevant collaboration. In this context, it should be noted that National Competent Authorities and EMA are available to assist individual companies with regulatory advice should the need arise.

We would appreciate that you contact your members in order to collect information and report to EMA and National Competent Authorities on:

- Any anticipated shortages of medicinal products in general or of particular classes of products or therapeutic areas as a result of the current COVID-19 epidemic, either due to disruptions to the supply chain or logistic issues (e.g. transportation, shortage of ancillary supplies)
- Detailed reason for these anticipated shortages
- Markets impacted – particular MSs or all EU/EEA
- Timelines for any anticipated shortages, i.e. extent and duration of the shortage (start and possible duration)
- Shortage prevention plans developed in the context of the COVID-19 infection, including ability to mitigate the extent or duration of shortages and specific challenges they entail.
- We take the opportunity to thank you for your continued collaboration and for reminding your respective affiliated members that the above does not prevent and/or substitute their legal obligations to report any supply shortages and/or disruption within the 2 months legal deadline, *as per* EU Legislation.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact Telephone 5.1.2e



- We would appreciate receiving a first response by close of business on Tuesday 17 March 2020, and regular weekly updates, on Tuesdays, from Industry Trade Associations on the above.
- [for EMA letter – delete for NCA letters]:
- This information should be sent to EMA at 5.1.2e [@ema.europa.eu](mailto:5.1.2e@ema.europa.eu) and 5.1.2e [@ema.europa.eu](mailto:5.1.2e@ema.europa.eu)
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- [for NCA letter – delete for EMA letters]:
- This information should be sent to National Competent Authorities [NCAs to add specific details].
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