EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 March 2020
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Dear Colleagues,

Subject: Potential impact of the COVID-19 infection on the availability of human and veterinary medicinal products - Follow-up to my letter sent on 5 March 2020.

Reference is made to my letter sent to you on 5 March 2020. I can now provide you with an update on the potential impact of the COVID-19 infection on the supply of medicines taking into account all currently available information.

The information provided in this update was discussed at Wednesday's second meeting of the EU Executive Steering Group on shortages of medicines caused by major events. As indicated last week, I attach the updated Terms of Reference of the EU Executive Steering Group, for your information. The Steering Group on Wednesday discussed the current status on the potential impact of the COVID-19 infection on the availability of human and veterinary medicinal products, and the identification of the need for urgent action, including communication. The slide deck describing the current status covering the period from 4 to 11 March 2020 is attached. In addition, the following information is provided:

- **Analysis of EudraGMDP in relation to the EEA**

The attached Excel spreadsheet contains an overview of the APIs (part)-manufactured in the EEA and the manufacturers in the EEA. The data has been extracted from the EudraGMDP. Please note that this spreadsheet has not been manually cleaned. Duplication is mainly for the active substances, as different MSs have made different entries for what is, in many cases, the same substance. It should

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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also be emphasised that EMA does not have information if the particular site is active or dormant; neither does EMA have information on capacity and volumes.

The main actions agreed at Wednesday's second meeting of the EU Executive Steering Group, subject to approval by written procedure, are as follows:

- The Steering Group agreed on the **list of questions (LoQ)** to be sent by each Head of Agency to the Trade Associations at national level. The deadline for responses from Trade Associations is Tuesday, 17 March 2020, and regular updates should be provided (on a weekly basis, every Tuesday). EMA to circulate the LoQ (see attached letter). EMA will send the LoQ to the EU Trade Associations.
- EMA to provide any follow-up information shared within the EU SPOC Network.
- In addition to the information already sent out to the Network over the past weeks, EMA to circulate the **EUDRAGMDP data currently available,** i.e. mapping of active substance manufacturers in the EEA (see above). Once new pieces of information are available, EMA will circulate the new information to the Network.
- EMA to continue with the **data gathering exercise** for CAPs (e.g. mapping of manufacturing sites located in affected areas, identifying products at risk of supply, and whether they are considered critical). Similar exercise is currently being undertaken by NCAs for NAPs.
- The need was identified to go beyond data collection, and it was agreed to investigate the various possible scenarios on how to best manage the challenges of medicines supply. EMA was asked to propose a number of **scenarios** for discussion at the Steering Group - with the ultimate aim to provide technical input to support decision making at political level.
- The group also to reflect in the next meeting on the impact of the COVID-19 outbreak on the routine **regulatory work performed by the EU regulators** (e.g., inspections, assessments); and particularly, to discuss how essential regulatory activities shall be handled considering that crisis management tasks must be prioritised.

In addition to the information provided at Wednesday's second meeting of the EU Executive Steering Group, I also attach the following information:

- Letter from Medicines for Europe (MfE) on the Coordination with Industry on potential impact of COVID-19 on medicines manufacturing and supplies in Europe, dated 10 March 2020.
- Letter from AESGP on the potential impact of COVID-19 on the availability of medicines, dated 11 March 2020, which indicates a potential **supply disruption of paracetamol**, following India's restriction on exports of certain APIs.

As mentioned before, regular updates will continue to be provided to the EU Regulatory Network on the potential impact of the COVID-19 infection on the supply of medicines, as soon as further information emerges.

Yours sincerely,

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