



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 February 2020
EMA/77207/2020
Deputy Executive Director

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Dear colleagues,

Subject: Potential impact of the Coronavirus infection on the availability of human and veterinary medicinal products - Follow-up to my letter sent on 7 February 2020.

As indicated in my letter sent to you on 7 February 2020, please find below further information on actions taken. For completeness I also have included those actions that were already communicated to you last week Friday with any updates where relevant:

- On 6 February 2020 a letter was sent to EU Industry Associations for human and veterinary medicines, asking to report any temporary suspension of marketing or abnormal restriction of supply, as well as information on industry preparedness to prevent disruption on the supply of medicines in Europe.
Current status: No feedback has been received yet; a reminder will be sent.
- On 6 February 2020 a request was sent to the EU SPOC Network on the potential impact of the Coronavirus infection on the supply of medicines. Initial feedback was requested by 14 February 2020.
Current status: See further below.

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- On 6 February 2020 a teleconference of the Global Regulatory Shortage Network was held.
Current status: No change compared to the information provided on 6 February 2020, i.e. currently no impact on the supply of medicines has been reported by international partners.
- Lines to take were sent to the EU Regulatory Network on 10 February 2020 for the human medicines area and on 12 February 2020 for the veterinary medicines area.
- A coordination group at EU level (EU Executive Coronavirus Steering Group on the availability of medicines) is being setup, with rules of procedure being drafted. This Steering Group will be composed of EC, EMA and Member States representatives, representing both the human and veterinary medicines field. The Steering Group should provide a strategic steer in case of shortages of medicines that require urgent and coordinated action within the Network to manage and control the situation.
- This afternoon a joint IRN (for human medicines) and IRG (for veterinary medicines) teleconference took place to discuss currently available information and next steps. The main points presented and discussed during the teleconference related to:
 - Information received by EMA from the Chinese Authorities (NPMA) overnight that “except for the Hubei Province, the affected area, the production in other places in China has started successfully”. In addition, there have been some reassuring messages in the media, however also acknowledging that the shortages may only be felt later in Q2-Q3 if the current situation continues.
 - With respect to the direct import of active substances from China into EEA, data extracted from EudraGMDP for both CAPs and NAPs have indicated the following:
 - there are some 480 registered importers in the EEA importing active substances from China;
 - some 2,000-2,500 active substances are imported (please note that this figure contains duplicates that are currently being removed manually);
 - there are 778 active substance manufacturing sites located in China of which:
 - 55 manufacturing sites in Hubei Province (including Wuhan city), with 31,728 confirmed cases¹;
 - 20 manufacturing sites in Henan Province with 1,105 confirmed cases¹;
 - 222 manufacturing sites in Zhejiang Province with 1,117 confirmed cases¹;
 - 35 manufacturing sites in Guangdong Province with 1,177 confirmed cases¹.

These data may assist the Competent Authorities in identifying the concerned medicinal products.

 - In terms of feedback from the SPOC Network, 13 National Competent Authorities have responded so far (12 February 2020): Ireland H+V, Sweden H+V, Norway H+V, Portugal H, Belgium H+V, France H, Finland H+V, Estonia H+V, Greece H, Italy H+V, Latvia H, Hungary H, Germany H+V. No confirmed signals or supply disruptions related to the Coronavirus outbreak have been reported so far. EMA and National Competent Authorities continue to monitor the situation and are liaising with MAHs/relevant stakeholders to identify products at risk of supply.
 - As regards communication it was agreed that a statement should be issued by the EU Regulatory Network on the current situation. However, since a Council meeting (EPSCO) will take place on 13 February 2020, first the outcome of this meeting will be awaited including any communication that will result from the meeting. Subsequently, either communication will be drafted to complement communication stemming from the EPSCO meeting, or in the absence

¹ According to WHO: 11 February 2020 figures.

of such communication, a dedicated message from the EU Regulatory Network will be developed for publication either at the end of this week or the beginning of next week.

In conclusion, it needs to be acknowledged that there are still unknowns related to quantifying the future impact on the supplies of medicines to the EU market. Although there is no indication that the supply is currently impacted, the EU Regulatory Network, as stated in my previous letter, is nevertheless looking carefully into the issue and coordinating any necessary action to be undertaken.

Regular updates will continue to be provided to the EU Regulatory Network on the potential impact of the Coronavirus infection on the supply of medicines, as soon as further information emerges.



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Noël Wathion
Deputy Executive Director