EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Status Report from the EU Executive Steering Group on shortages of medicines caused by major events in relation to supply shortages caused by the COVID-19 infection

To the Commissioners 5.1.2e

Introduction

This status report provides the current status up to 26 March 2020 in relation to aspects identified by pharmaceutical industry with respect to supply shortages caused by the COVID-19 infection. It should be emphasised that this status report is based on non-product specific information provided by the EU Industry Associations; therefore, only general aspects are addressed.

In parallel, EMA and the National Competent Authorities of the Member States receive product specific information on supply shortages as reported by individual pharmaceutical companies, but these shortages are not discussed with the EU Industry Associations, only with the individual pharmaceutical companies. Therefore, this information is not included in this status report.

The information presented in this status report was discussed with the EU Executive Steering Group on shortages of medicines caused by major events (hereafter referred to as the Steering Group) at its meeting held on 26 March 2020. The agreed actions are reported in this status report.

Issues with the supply of medicines identified within the EU

All EU Industry associations:

- Highlighted hoarding/stockpiling by MSs as a big problem and call on EU authorities to limit the amount that can be purchased by patients as already done in Denmark, France and Belgium to allow rational use of resources. As such, they would like the Commission to issue guidance to MSs on stockpiling.
- Report lack of PPEs for their employees working on production and distribution in areas affected by confinement measures. They would like MSs to designate pharmaceutical companies among priority sectors entitled to receive PPEs and to continue to be able to access production sites in lockdown areas.

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- Report that workers put on quarantine are also affecting production levels, with effect likely to become visible in the coming weeks.
- Note problems for truck drivers crossing borders due to quarantine requirements. Additionally, report problems with air freight for medicines. Logistical issues are affecting their ability to move starting materials, APIs and finished products across EU Member States. Call on the EU to better enforce the Guidelines on Cross Border transports and border limit controls for essential services.
- Ask for regulatory flexibilities to speed up procedures in order to ensure fast approval of variations, to adapt current rules for GMP and GDP, in order to scale up production to meet the surge in demand.

Associations representing SMEs (EuropaBio, EUCOPE, Europharm) stress the latter may need financial support in the future since they have had to temporarily close facilities and stop some clinical trials due to confinement measures. They also reported that clinical trials have been either postponed or stopped.

Actions already taken, or agreed by the Steering Group at its 26 March 2020 meeting:

- The Steering Group agreed to the creation of an industry Single Point of Contact (SPOC) system to enable pharmaceutical companies to report directly to EMA (for CAPS and NAPs) on shortages of critical medicines that may be used in context of the COVID-19 infection, i.e. medicines used in the management of COVID-19 patients (symptomatic or anti-viral) and, used in primary care and hospital functioning during the outbreak.
- The Steering Group agreed to start developing a Q&A on regulatory issues due to COVID-19 to be updated regularly: possible flexibility in compliance with rules relating to GMP and GDP, fast track of variations being explored. The EU Industry Associations will be asked to further elaborate on the precise requests for regulatory flexibility.
- EMA has asked Member States to define a list of priority medicines used in their territory, based on the list of priority medicines developed by WHO. The medicines included in the consolidated list will be monitored for potential shortages. Follow-up actions could be finding therapeutic alternatives or scaling up of production during the outbreak. Results are due by Monday 30th March, after which EMA will prepare a combined EU list.
- The European Commission, EMA and Heads of Medicines Agencies (HMA) have published new recommendations for sponsors on how to manage the conduct of clinical trials in the context of the coronavirus disease (COVID-19) pandemic. An update will be published on 27 March in order to include recommendation that appropriate stocks of investigational medicinal products are maintained to ensure treatment in case of distribution failure.

Issues with the supply of medicines as a result of actions in 3rd countries

- EU Industry associations emphasised to the Steering Group problems with the supply of APIs and intermediates from India due to export restrictions in that country as announced by the Indian government and consequences stemming from the recent lock down imposed by the Indian government earlier this week. They would like the EU to start dialogue with the Indian

government to seek some exemptions to the bans. The EC informed industry that a TC between Commissioner 5.1.2e and the Indian health minister was held on 25 March.

- It should also be noted that additional export restrictions in other non-EU countries may be imposed in order to protect domestic demand in those countries, which will have an impact on the availability of those medicines in the EU.