25 March 2020

EU Executive Steering Group on shortages of medicines caused by major events

Industry Single Point of Contact (I-SPOC) system

1. Proposal

To establish, on a temporary basis and solely in the context of the COVID-19 infection, an Industry Single Point of Contact (I-SPOC) system to report on (current or anticipated) supply disruptions of medicinal products (for both CAPs and NAPs) used for the treatment of COVID-19 infection to EMA.

The EMA will channel information from the I-SPOC to the EU Executive Steering Group on shortages of medicines caused by major events (hereafter referred to as the "EU Executive Steering Group". EMA will subsequently provide such information to all Member States' Authorities.

2. Scope

The I-SPOC system shall be used temporarily to report information on (current or anticipated) shortages of medicinal products, either nationally or centrally authorised, used for the treatment of COVID-19 infection as per the list of medicines established by the EU Executive Steering Group.

The list (appended in Annex 1), which will be subject to regular revision, consists of medicines (for human use):

- Used in the management of COVID-19 patients (symptomatic or anti-viral), and,
- Used in primary care and hospital functioning during the outbreak.

This request to report to EMA on a temporary basis supply disruptions linked to the COVID-19 outbreak is **in addition** to existing requirements to report any potential supply disruptions under the current legislation, in order to facilitate the continuous availability at EU level of an as complete and up-to-date picture as possible. Normal reporting of shortages through the existing channels available at national/EU level should, however, continue.

3. Objective

The aim of the I-SPOC system in context of the COVID-19 outbreak, is:

- First, to gather additional information on medicinal product(s) used for the treatment of COVID-19 infection, which can be (potentially) at risk of supply disruptions. In the event shortages are anticipated the I-SPOC system should aim at preventing shortages from occurring;

- Second, to channel information on any identified supply shortages to the EU Executive Steering Group, which should decide on EU coordinated actions to address these supply shortages best (irrespective of their licensing route).

- Third, to support the regular status reports provided by the EU Executive Steering Group to the Commissioners in preparation for their weekly meeting with EU industry associations.

4. Process

Submission

Current/anticipated shortages affecting the list of identified medicines, will be reported via email, by using the template for reporting of shortages as detailed in the Annex I of Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (linked here).

Shortage notifications of **CAPs/ NAPs only/ mixed CAPs & NAPs**, should be sent:

- to EMA (via 5.1.2e @ema.europa.eu) as well as to the impacted national competent authorities (NCAs) via each identified NCA SPOC email address. The list of SPOC email addresses for each individual NCA is available in Annex 2.

When reporting, in their email subject, Industry SPOC persons shall use the following standard wording: *"COVID-19 – current/potential shortage - Product name(s) (INN) – CAP/NAP – CP/MRP/DCP/NP product number (e.g. EMEA/H/C/XXXX)".*

Roles and responsibilities

Industry SPOC (I-SPOC) persons:

- Shall be identified in the companies (at the level of MAHs) and must be linked to the list of medicines identified, to allow fast-track "company-regulator" interactions and prevent shortages from occurring;
- Share information in relation to (current or anticipated) supply disruptions of medicinal products used for the treatment of COVID-19 infection, using the pre-defined template, in accordance with the agreed list of medicines (see above);
- Provide additional information upon request by the EMA SPOC/NCA SPOC.

The I-SPOC system will be supported by the EMA. The EMA is also responsible for providing an overview of the reported market disruptions, including any follow-up undertaken. Such overview will in a first step be provided through an Excel table, updated on a weekly basis (or earlier if considered necessary) and circulated to the EU Executive Steering Group.

5. Annexes

Annex 1 – List of medicinal products used for the treatment of COVID-19 infection
Annex 2 - List of SPOC persons identified in the National Competent Authorities.