



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Impact of COVID-19 pandemic on the availability of human and veterinary medicinal products

Update from the EU SPOC Network and i-SPOC system

TC of EU Executive Steering group on shortages of medicines caused by major events, 4 November 2020



Presented by EMA,

5.1.2e

An agency of the European Union





Information received by the EMA through the **EU SPOC Network** on shortages of COVID-19 medicines

1. Shortages of human normal **immunoglobulins**

- Root cause: decrease in blood donations.
- Confirmed (ongoing or anticipated) critical shortages for Privigen (CAP) by **5** MSs.
 - EMA is liaising with the MAH (CSL Behring GmbH).
- Follow-up survey to PMF Holders launched on October 13th. EMA is also in contact with two Trade Associations (PPTA and IPFA).

2. Shortages of Pneumovax 23 (**pneumococcal vaccine**)

- Root cause: unexpected increase in demand.
- Confirmed (anticipated or current) supply disruptions in **8** MSs.



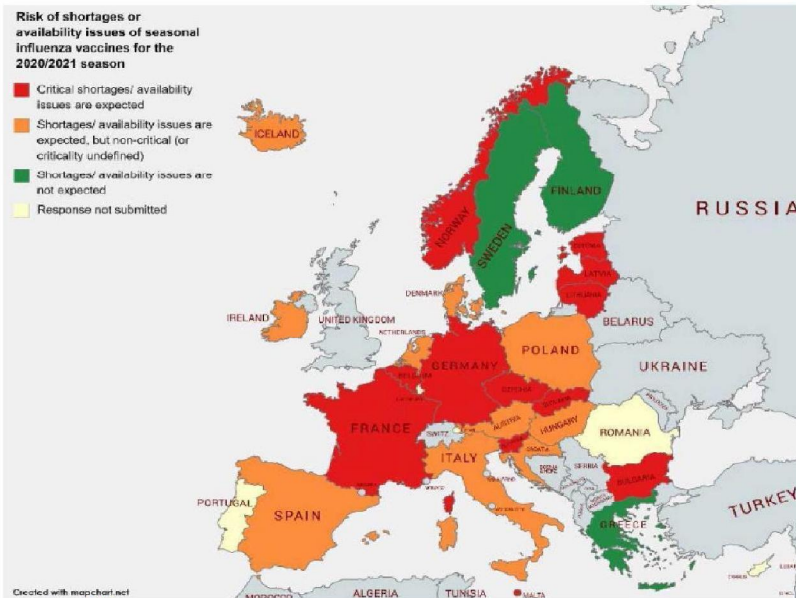
3. Risk of shortages of seasonal influenza vaccines

Background

- *June 2020*: EMA sent a request for information to the EU SPOC Network on anticipated shortages of flu vaccines.
 - Although some MSs indicated that shortages could occur, MSs did not identify issues in placing orders with manufacturers.
 - Industry also indicated (over the summer) that they were 'on track' to fulfil the orders received.
- *October 2020*: Several HoAs raised difficulties with the availability of flu vaccines within their countries (EU Executive SG meeting).
 - Therefore, EMA conducted a new survey (through the EU SPOC Network) to understand the risk of shortages (see **next slides**).



Survey results (as of 2 November 2020) (1/2)



- **Root cause: increased demand** due to COVID-19 pandemic (from “at-risk” and not “at-risk” groups).
- **Existing risk:** Most MSs **anticipate risk** of supply disruptions.
 - 22 NCAs (i.e. ~90%) confirmed expected shortages or availability issues.
- **Private versus Public sectors:** Supply issues being (already) **experienced** mostly in the **private** sector. Risk of shortages in the **public** sector (i.e. national vaccination programmes) is **not** ruled out.
 - 22 NCAs (in total) expect disruptions *at least* in the private sector (e.g. pharmacies, private surgeries). Of these 22 NCAs, 14 NCAs (i.e. ~65%) also expect disruptions in the public sector.
- **Criticality assessment:** Several MSs confirmed supply disruptions of flu vaccines are **critical**.
 - 12 NCAs (i.e. ~50%) anticipate the supply disruptions to be critical.



Survey results (as of 2 November 2020) (2/2)

▪ *Risk-mitigation measures undertaken/planned by MSs:*

Prioritisation of **at-risk** populations (e.g. aged >65-year-old, chronic diseases, pregnant women)

Continuous **dialogue** with MAHs and **monitoring** of vaccines distribution

Parallel **import** from other EU countries

Supply **redistribution** from the public to the private sector or vice-versa

Labelling **exemptions** for foreign language packages

Introduce parallel **export bans**



The vast majority of MSs (20 in total) initiated or will undertake actions to mitigate the impact of "anticipated" or "current" flu vaccine shortages for the oncoming season.



Information received by the EMA through the Industry-SPOC system (ICU medicines only)

As of 30 October 2020:

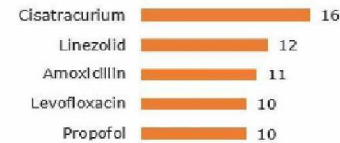
- A total of **~300** shortage notifications* reported are currently "active" (i.e. current or anticipated shortages)
 - Between October 20-30th, EMA received **32 "new"** notifications from MAHs.
- **No critical shortages** notified through the EU SPOC Network (i.e. therapeutic alternatives available at national level).
- EMA provides detailed report to the EMRN every two weeks.

***Shortage notification** = a single shortage instance reported for a medicinal product with a specific combination of strength/pharmaceutical form owned by one specific MAH affecting one specific Member State.

Breakdown by "shortage status" and its variation over time since the launch of i-SPOC Phase 1 (April 17th, 2020).



The 5 most reported active substance shortages in the **past 30 days** (only "anticipated" and "current" shortages)



Any questions?



Further information

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