



European Medicines Agency (EMA) and shortages reporting

factsheet

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Background

Shortages of medicines have been a serious concern in the EU for several years and have intensified during the COVID-19 pandemic due to sudden, unpredictably large demand surges. Shortages can compromise patient health and burden healthcare systems and healthcare professionals. They can lead to under-treatment and prolonged hospital stays. Shortages are

increasingly reported for products that have been on the market for many years and are widely used which may reflect the increasing consolidation of the generic medicine market. The root causes are multifactorial: economic causes, industrial factors, regulatory burden, a sudden surge in demand¹.

Current medicines shortages notification system

Marketing Authorisation Holders (MAHs) have the obligation to report potential shortages to National Competent Authorities (NCAs) via different portals. Due to a lack of harmonisation, companies submit different data depending on national requirements to multiple channels. The lack of a harmonised template for the data collection or use of master data makes it impossible to share information across National Competent Authorities and EMA. Consequently, the inconsistency of data and the different interpretations by national agencies make shortage reporting data irrelevant for crisis situations where multiple EU countries may be impacted.

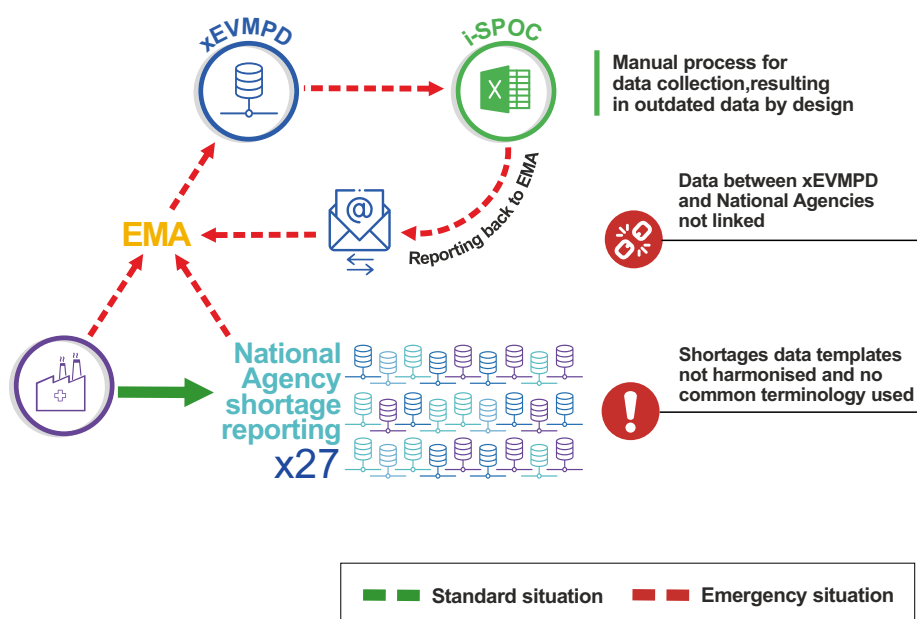
During COVID-19, the EMA attempted to solve this issue by creating the i-SPOC system as an additional reporting tool, resulting in a time-consuming manual process via Excel-based template and email exchange serving as the communication channel.

(1) [Infographic: medicines shortages: causes and recommendations explained](#)

- Multiple channels between EU and National Regulatory authorities:
 - not interconnected
 - not interoperable
 - not harmonized
 - non identifiable

- **27 different data sets and interpretations** based on the national requirements

- During Covid-19 an additional system (i-SPOC) has been created with excel-based manual process



Impossible for regulators to exchange data on products that are:

✗
not
harmonised

✗
not comparable or
identifiable across
countries

✗
in high risk of
error in data
population

Need to implement a robust harmonised digital shortage reporting system

By establishing the full implementation of the ongoing master data management (SPOR) by all stakeholders for all processes and all products and through the connection of existing data systems (e.g. SPOR and EMVO) national and EU agencies would have access to better data to evaluate the impact on of major events on the supply chain (e.g. suppliers from specific regions/countries), evaluate the availability of medicinal products within Europe (e.g. potentially tracking volume changes) and identify and signal shortages for critical products. This would require a patient-needs definition of a shortage at the national level and at the European level², to avoid the creation of artificial shortages (driven by hoarding or speculation in the market).

Indeed, COVID-19 underlined the critical importance of defining a shortage based on patient need as markets were quickly overrun with panic. This explains why most member states implemented strict oversight and control over pharmaceutical distribution (wholesalers, parallel traders, hospitals) during COVID-19. Based on a clear patient definition and by creating a more effective data collection system to efficiently assess risk and identify mitigation measures, many potential shortages could be prevented or mitigated.

(2) The current EMA definition does not integrate patient need: 'A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level.'

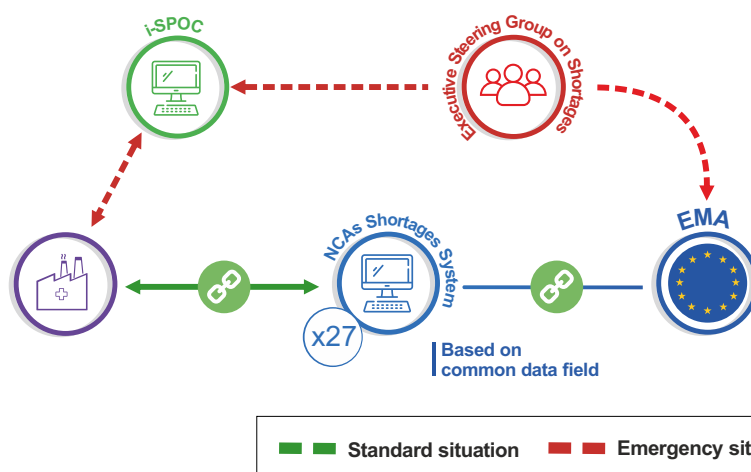
➤ The digital harmonised shortage reporting system would be implemented along with **existing digital infrastructure** and **ongoing digital projects**

➤ The shortage is notified by the Market authorisation holder (MAH) to all the relevant National Competent Authorities (NCAs) by **sharing data in harmonised digital format** to the interlinked NCA shortages reporting systems

➤ In case of large scale medicine shortage or pandemic, **the data can freely flow** between NCAs and EMA thanks to **interoperability of the digital systems**

➤ Opening **two-way communication** between EMA and MAHs to directly address the shortage and solve it

- The industry should be part of the Emergency Task Force
- "Supplementary information could be asked in case of crisis preparedness and major events via the iSPOC"



The ongoing digital infrastructure (telematics) should be based on:

- SPOR : master data management
- ISO IDMP : existing standard language for medicine product identification
- TOM: existing common approach to process medicinal data



This system would enable regulators to respond promptly and adequately to any emergent large-scale crisis

In case of a public health emergency and the escalation of the shortage to the EU Executive Steering Group on Shortages and Safety of Medicinal Products at EMA, the relevant data submitted by MAHs would be captured into SPOR. Via the integration of SPOR and EMVO data and harmonizing shortages reporting on the EU level, NCAs would have access to relevant information about the availability of certain products in markets where the situation is acute. The harmonised and unique entry point of data by MAH will prevent duplication and confusion, this will also allow the Executive Steering Group on Shortages and Safety of Medicinal Products at EMA to:

- Evaluate the impact on the supply chain across all EU countries (e.g. suppliers from specific countries/regions)
- Evaluate the availability of medicinal products with all EU countries
- Identify and signal shortages for critical products for specific countries (based on active substance, indication)
- Create an early warning system to efficiently assess and identify mitigation mechanisms avoiding patient impact and EU wide shortages.

As emerged during the COVID-19 outbreak, the industry is an essential actor for medicine shortages response. Therefore, single points of contact from industry (iSPOC) should support the work of this steering group in case of shortage event, by enabling to rapidly provide input to questions related to production capacities and bottlenecks. There should also be a clear framework for interaction between the Commission and industry to take appropriate legal and regulatory measures to mitigate a shortage. To avoid reporting duplications requirement on product data, the EMA would be already in possession of all necessary information already submitted by MAH towards NCA via the harmonized NCA shortages system.

Policy recommendations

- Definition of a shortage based on patient need instead of markets.
- Build on the existing digital regulatory infrastructure and ongoing projects on data management – a common repository for all medicinal products via SPOR data management supported by a Target Operating Model (TOM)
- NCA shortages reporting system should be based on common data fields at the national level – harmonized shortages reporting format and content provided by the Market authorisation holders to all Member States.
- A strong legal framework to ensure unified implementation of interoperable digital systems between all EU NCAs as well as the EMA to achieve an EU centralised mechanism through the interconnection of SPOR and EMVO–NMVOs.
- The Medicines Steering Group should be supported in its work by a working party comprised of single points of contact related to shortages from industry (iSPOC) and involving iSPOCs in the consultation phase to determine the list of critical products and the determination of solutions to the public health emergency. At the same time, the Steering Group should maintain two-way communication with the industry throughout the public health emergency.
- Medicines Steering Group to extract relevant information from the product and shortage related data as submitted by MAH towards NCA via SPOR/NMVO and not to lead to double reporting of similar data via iSPOC, only supplementary information would be requested by EMA to industry via iSPOC system.
- In crisis situations, a clear legal framework should be established by the Commission to provide appropriate competition law and regulatory law guidance on actions to mitigate a shortage.