Medicines for Europe Factsheet on the European Commission proposal for Regulation on reinforced role for the **European Medicines Agency (EMA)** in crisis preparedness and management for medicinal products and medical devices

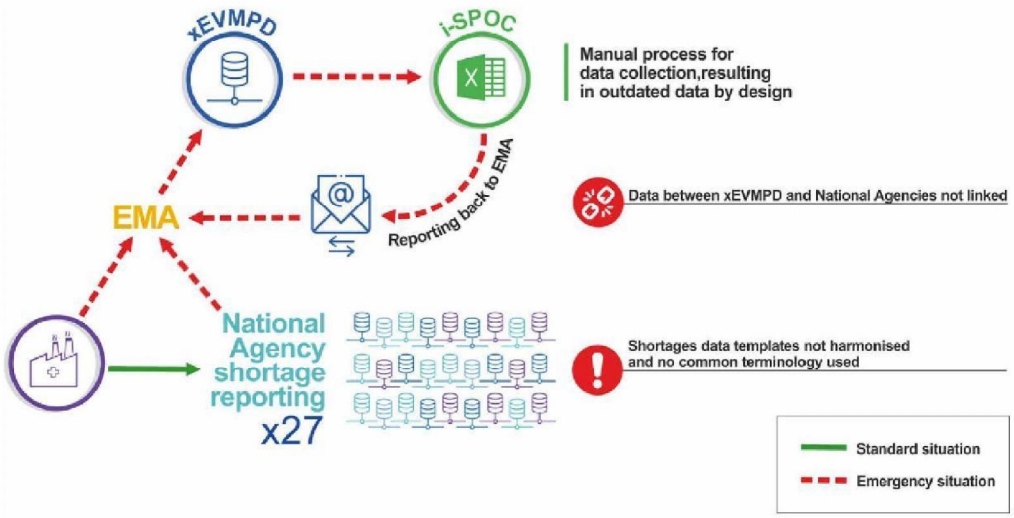
Background

Shortages of medicines have been a serious concern in the EU for several years and have increased during the COVID-19 pandemic. Shortages compromise patient health and severely burden healthcare systems and healthcare professionals. They can lead to under-treatment and prolonged hospital stays. Shortages are increasingly frequent for products that have been on the market for many years and are widely used. The root causes are multifactorial: economic causes, industrial factors, regulatory burden, a surge in demand[1].

Current medicines shortages notification system

Marketing Authorisation Holders (MAHs) have the obligation to report potential shortages to National Competent Authorities (NCAs) via different portals which are hosted by the National regulatory agencies. This is resulting in multiple channels to submit similar data, but with differences in specific information to be provided depending on the different national requirements. These inconsistencies are resulting in data quality issues and different interpretations by national agencies. The lack of harmonisation of a template for the data collection or use of master data leads to the impossibility of sharing information across National Competent Authorities and EMA.

During COVID-19 the i-SPOC system was created as an additional reporting tool, resulting in a time-consuming manual process via Excel-based template and email exchange serving as the communication channel.



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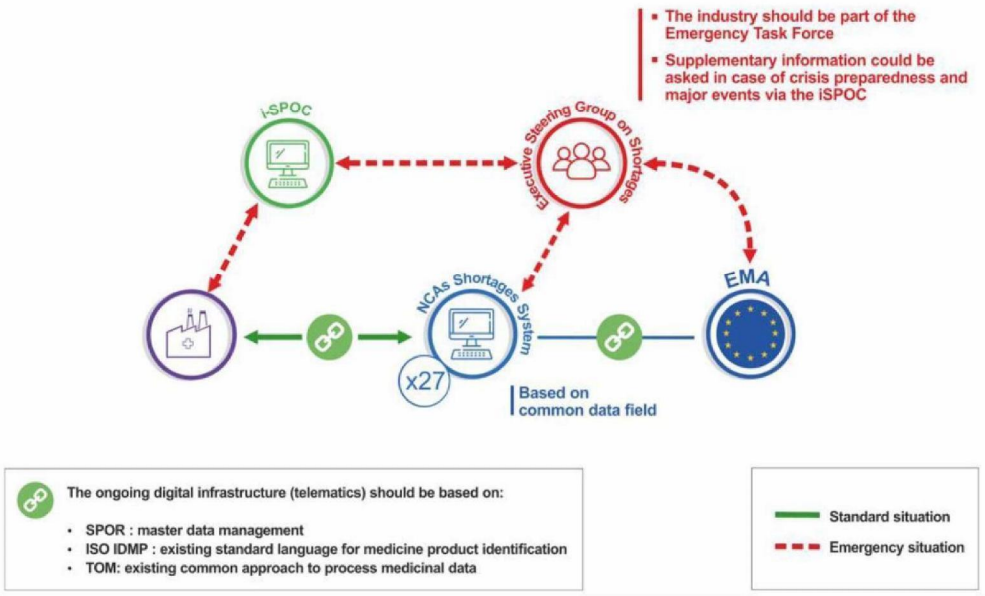
Need to implement a robust harmonised pan-European interoperable and digital shortage reporting system

By establishing the full implementation of the ongoing master data management (SPOR) by all stakeholders in all processes and all products and with the connection between existing systems (e.g. SPOR and EMVO) the national agencies would be in a position to better evaluate the impact 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 under the condition the definition of a shortage is amended toward the patient needs at the national level, to avoid the creation of artificial shortages. Indeed, during COVID-19 it was clear that a definition of a shortage should be centred on the patient need and not as per current EMA definition, which is too broad: *'A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level'*. The current definition can artificially create shortages by stakeholders in the supply chain, hence the ban on parallel import during COVID-19. Via the creation of an early alert system to efficiently assess risk and identify mitigation mechanisms the majority of the potential shortages could be prevented or mitigated.

In case of a public health emergency and escalation of the shortage by the NCA towards the Executive Steering Group on Shortages and Safety of Medicinal Products at EMA, all the relevant data as submitted by the MAHs are captured into SPOR and EMVO. Via the integration of SPOR and EMVO data and harmonizing shortages reporting on EU level, the EMA just like the NCAs could use the information about the availability of certain products into certain markets, even over several markets simultaneously as this would be a requirement for NCA to escalate the shortage towards the Executive Steering Group on Shortages and Safety of Medicinal Products. 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 (e.g. tracking volume changes)
- 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 to be involved in the 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 abling to rapidly provide input to questions related to production capacities and bottlenecks. In order 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.



Key Asks and Recommendations:

1. Definition of a shortage in relation to the patient need
2. Need to 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)
3. Need for a harmonised pan-European interoperable and digital NCA shortages reporting system based on common data fields - harmonized shortages reporting format and content provided by the Market authorisation holders to all Member States
4. 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 to monitor the entire value chain through the interconnection of SPOR and EMVO-NMVs.
5. The Medicines Steering Group shall 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 shall maintain two-way communication with the industry throughout the whole duration of the public health emergency.
6. Medicines Steering Group to extract relevant information from the product and shortage related data as submitted by MAH towards NCA via SPOR/EMVO 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.