

PCWP/HCPWP input to the HMA/EMA Concept Paper on Best Practices to Prevent Shortages

EMA PCWP/HCPWP joint meeting 2 June 2020

Methodology (1/3)

- 4 co-rapporteurs from PCWP/HCPWP
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- Input on **existing practices** and **policy recommendations** provided by 12 members of the WPs between 20 March and 17 April 2020



Methodology (2/3)

- Collected input divided into **two separate tables** and subsequently into **three different sheets** based on a type of proposed action

Inventory of Practices aiming at preventing medicines supply tensions or shortages

Existing Practices on prevention and notification of shortages

Action	Description	Publication date	by	Abbreviation	Working Title	Type of initiative
Reporting/early notification	In Ireland, pharmacists/wholesalers worked with the Health Products Regulatory Authority (HPRA) to produce a Medicine Shortages Framework and medicines shortages are notified by e-mail weekly and through the HPRA website	2019	Pharmaceutical Group of European Union	PGEU	Position Paper on Medicine Shortages	Existing practice
Reporting/early notification	Spanish Pharmacists' warning systems on medicines shortages (OSMED) is based on a communication infrastructure of pharmacies – provincial chambers – General Pharmaceutical Council of Spain. Automatic reporting – after categorisation and consolidation at national level, the shortages are publicly communicated on the General Council website. Real-time measurement of shortages by healthcare professionals with clustering at provincial and national level.	2017	Pharmaceutical Group of European Union	PGEU	Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages	Existing practice
Reporting/early notification	Detection and Assessment of Medicine Shortage. Submissions are usually made by pharmacies and each submission is checked by the respective MSA. 2. Information Source: The submission system is open to reports from manufacturers, wholesalers, pharmacists, other healthcare professionals and patients. 3. Level of Access: The Dutch system allows for public access to the information. 4. Content of Information System. The following content is contained in the system: product name; reason for shortage; expected date of availability, and possible solution for patients (substitution, compounding, importing, and possible alternatives). The information remains visible in the system for the duration of the shortage plus one additional month. 5. Governance: The system operating in the Netherlands ("Farmanco") is hosted and governed by KNMP – the Royal Dutch Pharmacists Association.	2017	Pharmaceutical Group of European Union	PGEU	Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages	Existing practice
Reporting/early notification	Detection and Assessment of Medicine Shortage. The system automatically registers the information on medicines not delivered to pharmacies by wholesalers. This automatic registry is done during the process of reception and verification of orders delivered to pharmacies. The information is used by CEPAR (centre for health research and evaluation) to produce a report every month. 1) Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages 2. Information Source: Shortages notifications by pharmacies to the National Association of Pharmacists (ANP) are on a voluntary basis although 85% of pharmacies participate in the system daily. 3. Level of Access: ANP keeps the history of shortages from the beginning of the system. The information is sent by CEPAR to the national agency (InFarme). 4. Content of Information System. The file created in the process by Sifarma (pharmacy stock management and dispensing software) is sent to ANP where the daily information is collected including name, strength, pharmaceutical form, package size and price, name of the market authorization holder, name of the supplier (wholesaler), number of units in shortage. 5. Governance: System is developed and supported by ANP. The pharmacy system is hosted at the IT department of ANP.	2017	Pharmaceutical Group of European Union	PGEU	Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages	Existing practice
	The OP-Fluaptes allows pharmacists in pharmacies and pharmacies for indoor use (PIU) to report supply shortages through their business software (only for pharmacists) or in web service mode (access to the					

Practices on prevention | practices on communication | Practices on management

Policy recommendations aiming at preventing medicines supply tensions or shortages

Policy recommendations on the prevention and early notifications of shortages

Action	Description	date	by	Abbreviation	Working Title	Type of initiative
Reporting/early notification	Develop catalogues of shortages All European countries should develop a national system for reporting medicines shortages based on a minimum set of data requirements. European regulatory authorities (Heads of Medicines Agency (HMA)/EMA) could 1) coordinate the development of a harmonised procedure for reporting of shortages, based on a shared definition, and 2) develop a platform/database to collate the reports from the national systems. All stakeholders, including patients and physicians, should have access to a user-friendly, web-based system to report shortages.	2017	European Society of Medical Oncology	ESMO	EU Cancer medicines shortages in Europe Policy recommendations to prevent and manage shortages	Policy
Reporting/early notification	Enhancement and enforcement of current obligations of pharmaceutical companies: clarification of Art 81 and 23a of the Community Code Directive and strengthening it by providing for sanctions.	4/4/2020	Standing Committee of European Doctors	CPME	CPME Policy on Medicine Shortages	Policy
Reporting/early notification	Introduce legislation for early notification requirements for medicines shortages National legislation for early notification from manufacturers should be implemented in all European countries, as stipulated in Directive 2001/83/EC. The legislation should include a requirement for manufacturers to provide information about the reasons for discontinuation of supply.	2017	European Society of Medical Oncology	ESMO	EU Cancer medicines shortages in Europe Policy recommendations to prevent and manage shortages	Policy
Contingency plans	Advocates for national contingency plans to ensure that the plasma-derived medicinal products developed on the basis of EU plasma remain in the EU after manufacturing in times of tensions		International Patient Organisation for Primary Immunodeficiencies	IPOPI		Other
Contingency plans	Establish strategic plans for medicines shortages Countries should establish a task force to develop a national strategic plan for medicines shortages, underpinned by national legislation and funding. This initiative could be proposed at a European level, with countries having an option to implement it on a national level.	2017	European Society of Medical Oncology	ESMO	EU Cancer medicines shortages in Europe Policy recommendations to prevent and manage shortages	Policy
Procurement	Establish procurement models designed to prevent medicines shortages Good procurement practices that address predictability and profitability for medicines manufacturers should be identified. These could include using tender criteria that include price as well as other factors, e.g. quality track record of manufacturers. Tender open harmonisation could be considered within and across countries. National procurement for medicines experiencing shortages could be considered.	2017	European Society of Medical Oncology	ESMO	EU Cancer medicines shortages in Europe Policy recommendations to prevent and manage shortages	Policy
Procurement	Prudent procurement practices as one of the best practices to prevent shortages. Procurement practices focusing solely on the price have resulted in manufacturers pulling out of national markets leading to market consolidation and consequently increasing the risk of medicines shortages. Allowing more than one winner for tenders of pharmaceutical products would lower the risk of single supplier dependence.		European Association of Hospital Pharmacists	EAHP	EAHP Position Paper on Procurement	Policy
Procurement – stockpiling – export bans – reducing dependency third countries	Increasing diversification of supply sources; reducing Europe's overreliance on external manufacturing; changing procurement practices to allow for more winners of tenders and apply other criteria than price; stockpiling of medicines at EU level. Avoiding national stockpiling beyond limited, justified stockpile of essential medicines for emergency use, allowing Member States to temporarily ban parallel export if justified, reasonable and proportionate.	4/4/2020	Standing Committee of European Doctors	CPME	CPME Policy on Medicine Shortages	Policy
	Develop essential medicines lists and assess the risk for shortages Countries should develop national essential medicines lists based on the WHO Model List of Essential				EU Cancer medicines shortages	

prevention | communication | management

Methodology (3/3)

- Existing practices and policy recommendations analysed according to the following **categories**:

Existing Practices on prevention and notification of shortages

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Reporting/early notification	Spanish Pharmacists' warning systems on medicines shortages CISMED is based on a communication infrastructure of pharmacies – provincial chambers – General Pharmaceutical Council of Spain Automatic reporting – after categorisation and consolidation at national level, the shortages are publicly communicated on the General Council website. Real-time measurement of shortages by healthcare professionals with clustering at provincial and national level.	2017	Pharmaceutical Group of European Union	PGEU	Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages

Type of initiative	Scope	Concerned MS	Impact	Notes	References
Existing practice	National	Ireland	Could help detecting and acting early	in Ireland, pharmacists/wholesalers worked with the Health Products Regulatory Authority (HPRA) to produce a Medicine Shortages Framework and medicines shortages are notified by e-mail weekly and through the HPRA website	https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/adv-g0020-medicines-shortages-framework-v2.pdf?sfvrsn=4 https://www.hpra.ie/homepage/medicines/medicines-information/medicines-shortages
Existing practice	National	Spain	Could help detecting and acting early		https://www.pgeu.eu/wp-content/uploads/2019/03/170201E-Supply-chain-Statement-on-Information-on-Med-Short.pdf

Existing Practices (1/2)

- 25 examples addressing prevention, detection, communication, reporting, prescribing, pricing and awareness raising...
- Examples:
 - COVID-19: **hospital preparations** of some products in risk of short supply due to increasing demand in clinical trials for COVID-19 and off-label use
 - 2008: mexiletine MAH announcement of withdrawal for commercial reasons. Patient group **requests** hospital pharmacies **to continue manufacturing** (2010) and **co-funds a phase III clinical trial** to extend the authorisation to non-dystrophic myotonia
 - **Complaint to antitrust authorities** about the shortage of three cancer drugs due to their price increase (abuse of dominant position)

Existing Practices (2/2)

- Examples:
 - Early, automatic **reporting** and real-time **measurement** of shortages by healthcare professionals
 - Creation of „**medicine shortages coordination groups**” that can e.g. locate and acquire raw material that can be used to produce drugs for which shortages are anticipated (compounding)
 - Essential medicines: Creation of a **national registry** for immunoglobulins uses, for which there are no alternatives and of an alliance of patient organisations advocating for good prescription practices / calculation of dose needed

Policy recommendations

- 17 measures related to reporting mechanism, current legislative framework, contingency plans and procurement practices, among others.
- Examples:
 - Development of harmonised **national systems for reporting** medicine shortages and a user-friendly **database** accessible by all stakeholders
 - Enhancement and enforcement of current **obligations of pharma companies**
 - Amendment of **procurement practices** to focus on more criteria than price and allowing more than one winner for tenders of pharmaceutical products
 - Creation of an **EU Joint Action** to further support the exchange of best practices among Member States and to help develop common prevention measures.

Next steps

- PCWP/HCPWP will work with TWG2 and TWG3 on the draft concept paper – the WPs' members are still invited to provide their input to the presented documents
- The WPs can contribute to the EU institutions' ongoing and forthcoming initiatives on medicine shortages
- The WPs are revising their 2013 Common Position on Supply Shortages of Medicines
- Should the WPs organise a follow-up call or a workshop dedicated to medicine shortages in 2021?

Revision of the WPs' 2013 Common Position

- The position will include examples of the **impact** of medicine shortages on patients and healthcare professionals and proposed **management** measures
- Potential **areas to cover** – for discussion:
 - Bringing back manufacturing of medicines and APIs to Europe
 - Stockpiling of ('essential') medicines at EU level
 - Competence shifts at EU level for the prevention and/or management of medicine shortages including an expanded role of the European Medicines Agency
 - Creation of one or more non-profit European pharmaceutical undertakings for the production of certain medicines of strategic importance
 - Closer cooperation and 'solidarity' between Member States
 - Regulatory flexibility to facilitate movement of medicines across borders
 - ...

Political initiatives on shortages at EU level

- European Parliament's **report on the shortages of medicines** - how to address an emerging problem 2020/2071(INI)
- European Commission's **study on root causes** of medicine shortages
- European Commission's new **pharmaceutical strategy**
- European MedicinesRegulatory Network Strategy to 2025
- COST action CA15105
- The STAMP's* discussions on shortages

*Commission Expert Group on Safe and Timely Access to Medicines for Patients

Thank you for your attention

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on behalf of PCWP/HCPWP co-rapporteurs