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
 - Francois Houyez (EURORDIS), Charlotte Roffiaen (EPHA), Jan De Belie (PGEU) and Christiaan Keijzer (CPME)
- Input on existing practices and policy recommendations provided by 12 members of the WPs between 20 March and 17 April 2020



















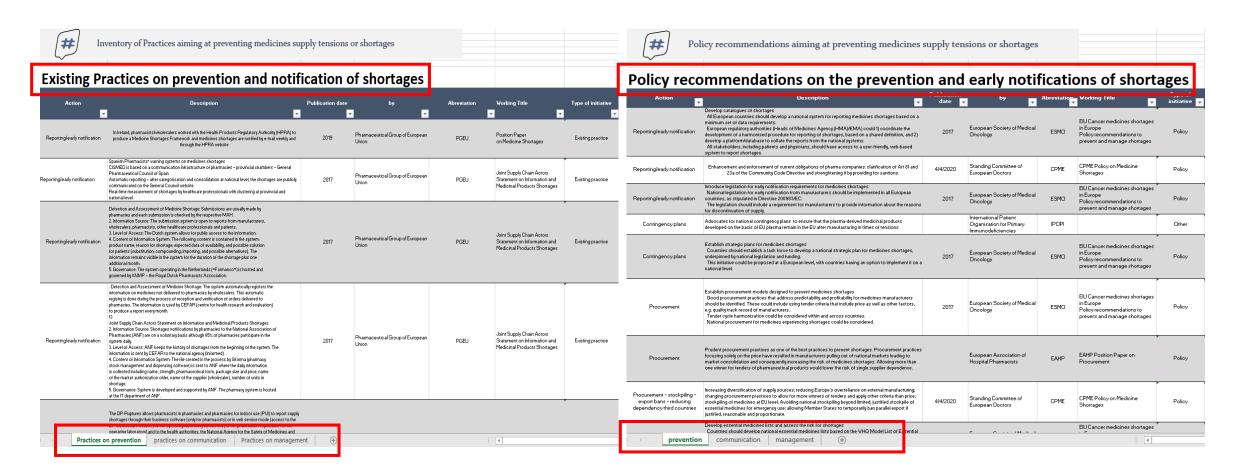






Methodology (2/3)

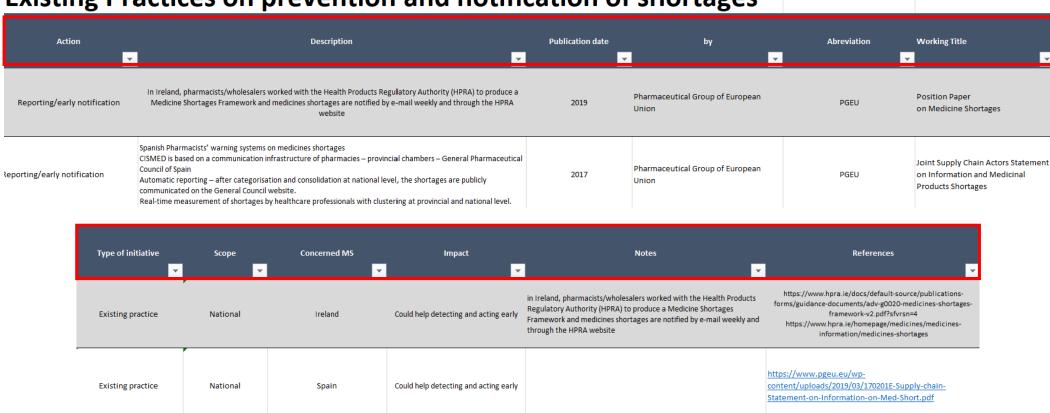
 Collected input divided into two separate tables and subsequently into three different sheets based on a type of proposed action



Methodology (3/3)

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

Existing Practices on prevention and notification of shortages



Existing Practices (1/2)

• 25 examples addressing <u>prevention</u>, 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

Thank you for your attention

Piotr Kolczyński (CPME)

on behalf of PCWP/HCPWP co-rapporteurs