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Non-paper
– Improving the security of medicines supply in Europe –
(BE, AT, NL, LU, HU, CZ, ES, FR, DE, EE, SI, RO, LV, LT, EL, MT, PL, IT)

Introduction

The EU has been confronted with severe medicines shortages over the past few months. Essential medicines such as antibiotics, thrombolytics and insulin were particularly difficult to obtain, while antipyretics and painkillers were also in short supply. These problems are not new: medicine shortages have increased over the past few years. According to the OECD, shortage notifications increased by 60% between 2017 and 2019.[i] Annual surveys of EU pharmacists show that since the start of reporting in 2019, all EU countries have experienced shortages on a yearly basis. In 2022, 75% of surveyed countries reported that shortages had worsened compared to the previous year.[ii]

The reasons for shortages are complex, and range from unexpected increases in demand to manufacturing and quality issues, factory closures or relocations, bottlenecks in the supply chains, and regulation and reimbursement policies.[iii] In several member states, parallel exports, combined with a lack of transparency on supply, cause serious disruptions that have detrimental effects for patients.

In addition to these problems, the EU is becoming increasingly dependent on imports from a few manufacturers and regions for its medicines supply, adding a security dimension to the question. In 2019, globally more than 40% of APIs were sourced from China. Furthermore, almost all API producers depend on China for intermediate inputs, even if they are located in another country.[iv] Next to the geographic concentration, there is also a concentration of manufacturing sites: for more than 50% of APIs globally, less than 5 CEP[1] manufacturers exist.[v] As a result, Europe (and the world) depend on a few manufacturers for a large bulk of their medicines supply.

To prevent the escalation of medicines shortages in the EU, the Executive Steering Group on Shortages of Medicines Caused by Major Events (MSSG) was set up, bringing together experts from EMA, the Commission and the EU member states. Valuable work was done in the area of antibiotics, such as identification of the root causes of certain shortages, monitoring of supply, setting up a single point of contact with the industry (iSPOC), and contacting new international suppliers. For other shortages, such as thrombolytics and medicines for diabetes, EMA assisted member states with finding alternative sources of supply. In addition, the new pharmaceutical legislation will provide strengthened measures for managing shortages, such as an increased timeframe for the notifications of market withdrawals and expected shortages, as well as the obligation for Market Authorisation Holders (MAHs) to maintain shortage management plans.

However, considering the complexity of the problems and the risks associated with them, we believe that the EU must take more drastic steps to improve the security of medicines supply.

[1] 'Certificate of Suitability of Monographs of the European Pharmacopoeia' (CEP)

To this end, we propose the following points of action:

(i) installing a voluntary solidarity mechanism within the MSSG to, as a last resort, temporarily alleviate acute shortages in member states

(ii) establishing a European list of critical medicines whose supply, production and value chains must be monitored

(iii) Exploring a Critical Medicines Act to reduce dependencies for critical medicines and ingredients, particularly for products where there are only a few supplying manufacturers or countries

These three proposals are targeted at the **short**, **medium** and **long term**, and should be seen as complementary to the initiatives already taken (work by EMA and the MSSG) or announced (pharmaceutical legislation). Together, they should prevent the worst case scenarios of patients not being properly treated due to empty stocks, and provide a more structural response to the root causes of our problems.

I. An EU solidarity mechanism

Next to tailored actions on EU antibiotics shortages, EMA has helped individual member states alleviate critical shortages by proposing medical alternatives and identifying alternative suppliers inside or outside the EU. While this an important and even preferred course of action, it has in some cases proven insufficient to remedy acute problems. In cases where there are already significant market pressures, it can prove difficult for countries to find new suppliers. Moreover, not all medicines are replaceable, and often the alternatives are also in short supply.

In extreme cases where no alternative suppliers or medicines can be found and a member state risks falling completely without a certain important medicine, EU countries should be able to call for help from other member states. **While all member states face shortages, shortages are not the same in all member states**: some countries might face acute problems for antibiotics, while others might run out of epileptics or thrombolytics, for example. By helping each other out in acute situations, we can prevent patients from facing serious consequences in Europe.

To this end, a voluntary solidarity mechanism should be set up within the MSSG. Member states must agree beforehand when this mechanism can be used, avoiding the creation of additional data structures. The European 'bazaars' that were established to organise solidarity for the COVID-19 and Mpox vaccines could serve as an inspiration. Member states where stocks of important medicines are critically low and where all other available options have been exhausted, can send out a **notification** through this mechanism, to which other member states may respond to provide some **temporary relief**. In addition, the mechanism should invite manufacturers and wholesalers to participate.

II. A European list of critical medicines

In order to better prepare for next autumn, it is pivotal that the MSSG accelerates its work on a European list of critical medicines. This list should be a practical, concise and living document, taking into account the work that was already done in this regard in previous studies and stakeholder consultations, as well as by HERA and the WHO among others. For these medicines, the supply must be monitored, the global value chains must be mapped and (potential) suppliers and vulnerabilities identified – to begin with **those medicines for which there have been repeated shortages in the past.** HERA is already mapping the value chains of some medicines in the framework of preparedness. This work could be further built upon and expanded to avoid double work, thereby making optimal use of digital solutions to avoid creating excessive administrative burden for companies.

This should trigger a timely reaction by the MSSG and the Commission when the European security of medicines supply is severely threatened, for instance by entering into dialogue with suppliers along the value chain, organising matchmaking events to solve bottlenecks, using diplomatic channels to reduce trade irritants, etc. This would repeat some of the successful recipes developed by the Task Force for Industrial Scale-up of COVID-19 Vaccines during the pandemic.

III. A Critical Medicines Act

As a first step to a more structural, long-term approach, we want to follow the example of the European Chips Act and the Critical Raw Materials Act, which aim to increase the European market share of semiconductors and (the processing of) key raw materials. A Critical Medicines Act for supporting the European green, digital manufacturing of key medicines, APIs and intermediate ingredients for which the EU is entirely dependent on one country or a limited number of manufacturers, should be explored. The Act should be seen as a **toolbox of different instruments** and must be viewed as complementary to the European review of pharmaceutical legislation.

The Critical Medicines Act can build on the Critical Raw Materials Act, which will work, among other things, on the supply of certain ingredients important for the health industries. It should take lessons learned from the Chips Act and Critical Raw Materials Act into account, such as the need for appropriate financing mechanisms. Moreover, it could take into consideration the lessons of the 'Structured Dialogue on Medicines Security',[vi] as well as the outcome of a number of issues that are have been analysed recently, such as the impact of different public procurement systems on the security of supply.[vii] Relevant activities of HERA and the Joint Action on Shortages in this area should be taken into account to complement the work and avoid duplications.

[i] Chapman, S., G. Dedet and R. Lopert (2022), "Shortages of medicines in OECD countries", OECD Health Working Papers, No. 137, OECD Publishing, https://doi.org/10.1787/b5d9e15d-en.
[ii] Pharmaceutical Group of the European Union (2022), "Medicine Shortages: PGEU Survey 2022 Results", https://www.pgeu.eu/wp-content/uploads/2023/01/Medicine-Shortages-PGEU-Survey-2022-Results-1.pdf.
[iii] Jongh, T., D. Becker, M. Boulestreau et al., "Future-proofing pharmaceutical legislation : study on medicine shortages : final report (revised)", European Commission, Publications Office of the European Union, 2021, https://data.europa.eu/doi/10.2875/211485

[iv] Raza, W., J. Grumiller, H. Grohs et al. (2021) "Post Covid-19 value chains: options for reshoring production back to Europe in a globalised economy", European Parliament, Policy Department for External Relations, https://www.europarl.europa.eu/RegData/etudes/STUD/2021/653626/EXPO_STU(2021)653626_EN.pdf.
[v] MundiCare (2020) "Where do our active pharmaceutical ingredients come from? - A world map of API production", https://progenerika.de/app/uploads/2020/11/API-Study_long-version_EN.pdf.
[vi] Commission Staff Working Document (2022), "Vulnerabilities of the global supply chains of medicines – Structured Dialogue on the security of medicines supply", European Commission, Directorate-General for Health and Food Safety, https://health.ec.europa.eu/latest-updates/staff-working-document-vulnerabilities-global-supply-chains-medicines-structured-dialogue-security-2022-10-17_en.
[vii] Vogler, S., M. Salcher-Konrad, K. Habimana (2022), "Study on best practices in the public procurement of medicines : final report", European Commission, Publications Office of the European Union, https://data.europa.eu/doi/10.2925/044781.