Position Paper

on

Preventing and Managing Medicine Shortages

European Social Insurance Platform (ESIP)

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About the European Social Insurance Platform (ESIP)

The ***European Social Insurance Platform*** **(ESIP)** represents over **50 national statutory social insurance organisations** in **17 EU Member States, the United Kingdom and Switzerland**, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

Statement regarding positions submitted by ESIP: ESIP members support this position in so far as the subject matter lies within their field of competence

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Position Paper
Preventing and Managing Medicine Shortages

Continuous supply of high quality, effective and safe medicines is key to ensure access to and safe delivery of healthcare in Europe. Therefore, the European Social Insurance Platform (ESIP) welcomes the current discussion on securing the supply of medicines in the European Union (EU). As input to the discussion, ESIP proposes the following actions:

- A profound, evidence-based evaluation of supply bottlenecks in the EU and its Member States;
- Discussion towards a unified definition at EU level on what should be viewed as strategically important or essential medicines and active pharmaceutical ingredients (API) in Europe;
- Strict application of Directive 2001/83/EC and the introduction of mandatory sanctions, including financial, for market authorisation holders and wholesalers that fail to comply with their obligations under Articles 81 and 23a of the Directive to ensure supplies and inform about eventual shortages;
- A balanced approach between measures for greater diversification of production and reshoring production back to Europe;
- Common global social standards covering occupational health and safety rights of workers at production sites;
- An open multi-stakeholder discussion on the possibilities for public production in Europe;
- Mandatory participation to a common reporting system at EU level to enhance transparency regarding availability / non-availability of medicinal products;
- Further development and simplification of the existing framework for joint procurement to prevent bottlenecks and manage potential shortages;
- Real-time information to enable effective management of shortages across the supply chain (healthcare professionals, hospitals, competent authorities, payer organisations, wholesalers);
- A European stockpiling system for essential medicines.

General remarks

Medical treatments in Europe's healthcare systems rely on a global production and supply chain for medic(in)al products. The ongoing COVID-19 pandemic has highlighted existing structural problems in this supply chain impacting the availability of medicines as well as medical devices and personal protective equipment in the EU and elsewhere. In this paper we will focus on the supply of medicinal products in the EU.

In recent years, Europe's national healthcare systems have experienced an increasing number of medicine shortages.[1] The temporary or permanent unavailability of medicines poses serious problems for the delivery of healthcare in European countries.

According to Article 168 (TFEU), "the Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care". ESIP emphasises that national healthcare systems have their specific characteristics in handling medicine shortages that need to be respected. Nonetheless, joint efforts to increase transparency across supply and production chains will lead to more resilient healthcare systems across the EU.

While not every medicine shortage is critical or impairs treatment since equivalent or suitable alternative products are often available, reduced or hampered access to medicines may lead to treatment disruptions. Change, delay or postponement of treatments may have adverse physical and/or psychological effects on patients with financial consequences for health systems as well as national economies. In addition, healthcare professionals may face challenges associated with a higher workload due to the unavailability of specific products.

As a first step to finding potential solutions to medicine shortages, **ESIP considers that a profound, evidence-based evaluation of the situation throughout Europe and within the Member States is paramount**. This analysis should take into account the reasons for and the real extent of shortages and their concrete impact on patients' health and safety, on healthcare professionals as well as on healthcare systems' efficiency and financial sustainability. It should guide the development of instruments best suited to ensure the supply of medicines in the EU without threatening Member States' healthcare budgets.

When talking about medicine shortages, it is necessary to clarify which API and medicines are addressed in the discussion. Within the European discussion, the terms essential or strategic medicines are often used incoherently. While the World Health Organisation has specified its understanding of essential medicines,[2] deviating interpretations exist within the EU Member States. **A common understanding based on a unified definition is needed at EU level on what should be viewed as strategically important or essential medicines and API in Europe**.

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[1] "A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level", EMA/674304/2018

2 "Essential medicines are those that satisfy the priority health care needs of the population". https://www.who.int/medicines/services/essmedicines_def/en/

Prevention and management of medicine shortages

The causes of medicine shortages are multifactorial. Every national healthcare system has its individual strategies to manage medicine shortages and its effects on the delivery of care, taking into account the respective national system and functioning.

Pharmaceutical supply shortages are a global challenge and require action at international, European, national and sometimes regional level. In order to secure access to medicines, a holistic approach is needed that addresses **the regulatory framework** and the causes of shortages related to **production**, **supply** and **demand**.

1. Regulation

The legal provisions under Article 81 of Directive 2001/83/EC oblige market authorisation holders and wholesale distributors to ensure appropriate and continued supplies to cover the needs of patients in the individual Member States. This obligation was reiterated by the Pharmaceutical Committee on medicine shortages in its statement of 25 May 2018.[3] In this context, specific precautionary measures should be applied to products for which the manufacturing process is dependent on single production sites or in markets where no or limited alternatives are available.

Currently, the legislation does not specifically mention mandatory sanctions for non-compliance. Such sanctions could have a positive impact on the effective fulfilment of delivery obligations including the prevention of bottlenecks through appropriate capacity and storage provision. Sanctions could also be introduced in the case of non-compliance with the obligation under Article 23a of the Directive to provide complete and timely information on expected shortages.

Therefore, ESIP calls for the **strict application of Directive 2001/83/EC and the introduction of mandatory sanctions, including financial, for market authorisation holders and wholesalers that fail to comply with their obligations under Articles 81 and 23a of the Directive**.

2. Production

Business decisions aimed at maximising profit have led to a market concentration for specific medicinal products in parts of the market leading to dependence on a small number or even single production sites for some APIs and medicines. This can create critical bottlenecks in access to API, excipients or medicines and increase the impact of quality issues, including contamination, and subsequent recalls on the supply.

[3] "Obligation of continuous supply to tackle the problem of shortages of medicines", EU-COM (2018)

In case of a strong market concentration, failures in the production process, such as quality issues, have a greater impact on the availability of medicines. Hence, diversification is needed to spread the risk between different production facilities around the globe.

Diversification alone, however, may not solve the issues of availability of medicines in the EU since, currently, the large majority of production sites are situated in third countries. This can lead to disruptions in supply chains. One possible solution to tackle this problem being discussed among Member States, the European Commission and the European Parliament, is reshoring production back to Europe. Relocation of production to the EU could also be an appropriate measure to ensure strategic independence of supply. Therefore, **ESIP calls for a balanced approach between measures of greater diversification of production and reshoring production back to Europe based on a sound analysis of the options**.

With a view to reshoring production to Europe, it has been argued that this needs to be supported by measures to ensure a level playing field in global production by introducing common global standards with respect to quality and environmental aspects. ESIP argues in this case that these **global standards should** also **include social standards covering occupational health and safety rights of workers at production sites**.

The European Parliament is currently debating the creation of European public, non-profit production capacities, for the production of certain medicines that are a priority for healthcare systems and/or of strategic importance. This discussion is also developing among the Member States. The European Commission should assess the conditions under which public production can be considered for specific products and to develop a set of guidelines. **ESIP supports an open multi-stakeholder discussion on the possibilities for public production in Europe**.

3. Supply

Business decisions can lead to the withdrawal from the market or ceasing production of low-priced products or products that are no longer considered profitable enough. Some of these products may still have an important role to play in clinical practice. Parallel export can also cause shortages in some countries.

Article 23a of the Directive 2001/83/EC states the obligation for manufacturers to notify competent authorities of the volume and duration of anticipated shortages in supply. Better implementation of the existing legislation is needed to ensure access to the necessary information to better manage shortages.

A joint platform establishing an information sharing and reporting system, coordinated by the European Commission, would benefit Member States, competent authorities, payer organisations and healthcare professionals. ESIP

supports enhanced cooperation between national competent authorities to anticipate emerging and existing medicine shortages. This would help to prevent or alleviate the effects of shortages at an early stage. We therefore support the establishment of a single point of contact network at European level as envisaged by the Task Force on the Availability of Authorised Medicines for Human and Veterinary use of the Heads of Medicines Agencies and the European Medicines Agency.[4] While notification systems may already exist at national or regional level, **a coordinated reporting system shared between national competent authorities would enhance transparency regarding current and future stocks and shortages**.

National competent authorities still record data on the scope, causes and duration of shortages in a heterogeneous way. This needs to be harmonised. **Tackling medicine shortages at EU level requires**, above all, **a common understanding of and common criteria for the detection and reporting of shortages**.

Responsibility for EU-wide monitoring of supply and shortages should lie with the European Commission, in cooperation with EMA, Member States and relevant healthcare stakeholders. Regular, comprehensive reports should include an overview of shortages within Member States, along with an analysis of the causes and effectiveness of counter measures in place. A common European approach on this matter could effectively complement the measures already taken at Member State level.

An effective monitoring system, as envisaged above, could provide a comprehensive overview of current and expected supplies and shortages in Europe. This would provide a good starting point to assess opportunities for targeted public procurement of medicines. In this context, the **European Commission should carry out an assessment to further develop and simplify the existing framework for joint procurement, ensuring the involvement of Member States** in the decision process.

4. Demand

Medicine shortages may occur due to sudden and unforeseen increases in demand for certain products as exemplified by the COVID-19 pandemic. Even changes in prescription behaviour, treatment guidelines or clinical practices at national or regional level may account for an increased demand that can affect the global availability of specific medicinal products.

To allow all downstream stakeholders to react promptly when medicine shortages occur, greater transparency along the supply chain is essential. **Real-time information is needed by healthcare professionals, hospitals, competent**

[4] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines#eu-level-coordination-on-medicines-availability-section

authorities, payer organisations and wholesalers in order to better manage shortages.

In general, production and supply chains provide for a certain level of stock that can balance some volatility in demand. However, to avoid longer periods of shortages, stocks of essential medicines should be encouraged. **A decentralised, digitally enabled European stockpiling system for essential medicines would** enhance transparency, increase the economic viability and **facilitate access to these medicines across the EU**. Such a system should serve to complement and not replace Member States' national supplies, in compliance with TFEU Article 168.