Capsulas

Reflections on medicine shortages in the light of recent policy proposals

Opinion of the European Committee of the Regions and the European Commission Programme

If there is a shared objective among all actors involved in the lifecycle of a medicinal product, it is to avoid shortage. If we agree that the patient should be at the centre, it is essential they have access to the medicinal product they need, when they need them.

This reality became clear during the Covid-19 pandemic, when the European Union (EU) had to contend with a sudden surge in demand for medicinal products, particularly vaccines. Now it is crucial to apply the lessons learned and adapt them to regular production and distribution of medicinal products.

Pharmaceutical companies are used to monitoring their stock levels and demand in real time. The latest digital tools are undoubtedly a major boost in terms of quality and reliable data. However, challenges such as energy price variations, geopolitical conflicts or dependence on non-EU suppliers still lead to bottlenecks in the delivery and supply of medicinal products.

This brings up the ongoing question of when and how the public sector should intervene to support and complement the efforts of the private sector.
In this context, on 17 September, the European Committee of the Regions issued an opinion addressing medicine shortages. It provides recommendations to national governments, the European Commission and other key actors, aiming to strengthen the EU's autonomy in the pharmaceutical sector. Some of the more ambitious measures proposed include:

1. Increased local production in the EU and diversification of supply partners to reduce external dependence. This can be encouraged through fiscal and financial support measures, as well as foster an attractive environment for research and development.

2. Create a European Voluntary Solidarity Mechanism for Medicines, where countries can help others in critical situations. This idea, highlighted during the Belgian Council Presidency, should be seen as a last resort, as overuse use can lead to collapse due to the administrative burden.

3. While the mandate of the European Medicines Agency (EMA) was extended by Regulation (EU) 2022/123, the opinion emphasises that the EMA must continue to actively monitor and communicate critical information to patients and healthcare professionals regarding the duration of shortages and available alternatives.

4. Increased digitalization and data tracking must be integrated as essential tools to anticipate and manage supply disruptions.

These measures should be emphasised in rural and remote areas, where scarcity has a serious impact, as well as difficulty in accessing health services.

It is not insignificant that the Committee calls the Commission to investigate how the data collected within the European Medicines Verification System (EMVS) could feed automatically into the European Shortages Monitoring Platform.

This is a long-standing debate. The EMVS was created in the framework of the Falsified Medicines Directive to prevent falsified medicinal products from entering the market, through end-to-end verification. The industry advocates using EMVS data to monitor shortages as it is an already available tool; while healthcare professionals' representatives argue it was not designed as a monitoring and tracking system, but merely provides batch data at specific points in time.

The opinion seems to propose a middle ground, where EMVS data would be integrated or complemented with other sources to provide an unbiased, real-time view of supply levels.

The quo vadis of the possible new EU health commissioner

On the same day, curiously, Von der Leyen's mission letter to Olivér Várhelyi, her nominee to succeed Stella Kyriakides as the new health commissioner, was made public. In the letter, she mandates him to propose a regulation on critical medicinal medicines to address shortage and reduce dependencies relating to critical medicines

As mentioned earlier shortages are complex and multi-causal, closely related to other aspects of health policy. For example, most antibiotics are on the list of critical medicines that will be subject to reinforced measures. On the other hand, in the fight against antimicrobial resistance, policies are being adopted to create incentives that make the development of new antimicrobials more attractive. This is why it is crucial to understand pharmaceutical legislation reform as a whole.

Returning to Olivér Várhelyi's nomination, the European Parliament must now approve his appointment. Beforehand, the Parliament has the opportunity to question the candidate on the key aspects of his agenda. In his written answers, the Hungarian confirmed that he accepts the challenge of proposing a regulation on critical medicines, while also aiming to promote preventive health. This is because it is clear that the issue of shortages can be mitigated through greater preventive healthcare, which would result in reduced demand for medicines. Turning back to the issue of shortages, he announces "additional non-legislative measures," though without providing further details for now.

From policy to practice

1. A harmonised definition of shortage as "a situation in which the supply of a medicinal product authorised and marketed in a Member State does not meet the demand for that medicinal product in that Member State, irrespective of the cause" is introduced. This last clause was not included in the text originally proposed by the Commission.

2. The requirement for marketing authorisation holders (MAHs) to have shortage prevention plans for the products they market is generalised. The EMA will publish guidance on how to draft these plans, but we can anticipate that they will need to include information such as marketed alternatives or a detailed supply chain analysis that identifies potential vulnerabilities.

3. The Parliament updates the notification requirements for MAHs in cases of suspension or cessation of marketing. MAHs will have to "state their reasons" to the competent authority in the Member State where the medicine is marketed. In addition, it is important to remember that they must notify any temporary suspension or abnormal supply disruption as soon as possible, and at least six months in advance if the situation is foreseeable.

These notifications often generate controversy in practice, because supply issues are not always

foreseeable six months in advance. The regulation includes indeterminate concepts, such as what is considered foreseeable, which could lead to increased discrepancies between companies and national agencies.

4. The Parliament strengthens the reporting obligations for distributors and wholesalers. Thus, if a MAH reports a supply issue, the distributor or wholesaler will be required to provide data on stock levels and movements related to the cause of the disruption.

5. The recitals of the proposed regulation call for reflection on the importance of improving public procurement procedures. It recognises that tenders "based solely on price and where there is only one bidder increase the risk of shortages of medicinal products and reduce the number of suppliers in the market".

The European Union and its actors do not need labels; instead, they should emphasize the value of the work they do within their areas of control. Healthcare stakeholders recognize that the causes of shortages are diverse, interconnected, and multifaceted. This is a challenge in designing and implementing solutions, as it involves multi-causal dynamics with global implications. Ensuring equitable and sustainable access for patients makes this effort truly worthwhile.

°°°°°