

PGEU Response to the European Commission's Roadmap for the EU Pharmaceutical Strategy

PGEU, the European organisation representing community pharmacists, welcomes the Roadmap on a Pharmaceutical Strategy for Europe. Please find below PGEU's views on the main objectives highlighted in the Roadmap.

1. Ensure greater access and availability of pharmaceuticals to patients

PGEU welcomes the European Commission's efforts to address the critical issue of medicine shortages, which has a tremendous negative impact on patients and pharmacy practice. Overall, when developing laws, policies and business strategies that can affect the timely and adequate supply of medicines, it must be ensured that patients' needs are put first.

In order to create a stronger and more structured cooperation on medicine shortages between Member States at EU level, we support an expanded role of the European Medicines Agency (EMA) in the coordination of Member States activities on the prevention and management of shortages, building on the lessons learnt during the COVID-19 crisis and notwithstanding national competence which remains the most relevant to solve problems on the field, according to local needs and specificities. EMA's expanded role should be achieved by increasing resources and by clarifying and updating its legal activities by amending Regulation (EC) No 726/2004. One of the main EMA activities should be the central information collection and monitoring of (anticipated) medicine shortages at EU level in close collaboration with HMA, complementing existing national systems, through further development of the EU SPOC and i-SPOC system. This should go hand in hand with increased transparency and effective communication to affected stakeholders. Timely and complete information on (anticipated) shortages will reduce the negative impact on patients and will allow community pharmacists to better manage patient care and ensure continuity of treatment. However, across European countries, strong differences exist in terms of legal solutions community pharmacists can offer in case of a shortage¹. It is therefore crucial for the scope of pharmacy practice to be extended when medicines are in short supply. Community pharmacists already provide an increasing number of public health services in addition to its main dispensing service. This contributes to the resilience of health systems in Europe, by playing a key role in increasing accessibility, affordability, and quality of healthcare, as well as by reducing the pressure on overburdened secondary care systems.²

¹ Please refer to the PGEU Position Paper on Medicine Shortages which includes the results of the PGEU Medicine Shortages Survey 2019: <https://www.pgeu.eu/wp-content/uploads/2019/03/2019-PGEU-Position-Paper-on-Medicine-Shortages-1.pdf>

² <https://www.pgeu.eu/sustainability-of-health-systems/>



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Furthermore, as a measure to resolve certain medicine shortages it must be ensured that medicines available on the European market can effectively be redistributed to those patients who need them most regardless the EU country where they live, especially in times of health crises. We therefore welcome further regulatory and administrative simplification to help achieving this goal as well as needed clarity on liability for parties involved. It will however be crucial to ensure that patients continue to have access to objective and neutral product information on pharmaceuticals in their own language. Given that 80% of marketing authorizations are national ones, it could also be explored to have a pan-European database of patient information leaflets / summaries of product characteristics translated into national languages. The paper patient leaflet ('PL') or primary packaging could consequently include a statement directing to the electronic product information available in other EU languages and refer to the most up-to-date version of the PL available.

At the same time, as a response to occurring medicine shortages it is also vital that the flow of medicines and medical devices across borders within the EU is better planned and coordinated to prevent that the supply for a given country is unwillingly compromised as a consequence of the EU Single Market rules. It should be a key requirement that the flow of medicines meets patients demands and is not based on pure commercial interests. This will require the establishment of further EU guidance to Member States on the import and export of medicines across borders, as well as addressing certain regulatory challenges.

Equally, effective compliance with EU and national laws related to the public service obligations of supply chain actors needs to be assured and further clarified during the possible revision of the pharmaceutical legislation.

Lastly, PGEU considers that the European Medicines Verification system is not an appropriate tool to monitor shortages. The system has not been designed as a track and trace system therefore the level of authentication doesn't necessarily reflect stock level data and it is not a timely and reliable indicator of the national demand, especially for products is short in supply. Moreover not 100% of packs are authenticated. Lastly, multi-market packs are uploaded in all potential destination markets and counted multiple times without being available in these markets.

2. Ensure affordability of medicines for patients and health systems financial and fiscal sustainability

PGEU welcomes³ efforts to ensure the affordability of medicines for patients and health systems financial and fiscal sustainability. In addition to the areas mentioned, PGEU believes that expanding and rewarding the role of community pharmacy and strengthening primary care systems are key policy levers to lead the

³ <https://www.pgeu.eu/sustainability-of-health-systems/>



way towards a more sustainable, inclusive, and healthier future in Europe. An additional measure at national level to improve access to innovative and/or specialty (biosimilars and biological) medicines can be increasing the supply of these products via community pharmacies with appropriate patient follow-up. This is a unique opportunity to combine the dispensing service with the support of their safe and effective use by patients in the pharmacy. Generics uptake and rational use of medicines by community pharmacy should also be incentivised to make medicines more affordable while rewarding community pharmacists for this important economically sustainable service.

3. Enable innovation including for unmet medical needs in a way that harnesses the benefits of digital

PGEU acknowledges⁴ the value of innovative technologies such as Artificial Intelligence (AI) as well as the access and analysis of Big Data and consider these technologies to be a useful tool to support health professionals and EU health systems. In routine practice at national level, these tools shall always be accompanied by pharmacists' expert and professional advice to improve workflow efficiency, while promoting patient safety, therapy effectiveness and offering the highest standard of pharmacy services to patients. In the era of digitalization and multiple information sources, community pharmacy remains a trusted source of reliable and independent health information for patients. The potential use of real-world evidence including evidence generation in community pharmacies to evaluate effectiveness and therapeutic added value of innovative medicines in practise should therefore also be rewarded.

4. Support EU influence and competitiveness on the global level, reduce direct dependence on manufacturing in non-EU countries, seek a level playing field for EU operators.

PGEU welcomes the proposed solutions to reduce the dependence on third countries for the manufacturing of certain vulnerable and critical medicines and chemicals. However, bringing back to Europe manufacturing of certain medicines, active pharmaceutical ingredients (APIs) and other critical excipients will bring its own challenges and risks for continued supply, such as price increases for some medicines, which would only be acceptable if these are considered proportionate to the provided guarantees for security of supply. It would also be essential to ensure compliance with EU environmental norms while monitoring the impact on the environment of increased manufacturing of pharmaceuticals in Europe.

At the same time, it will be critical for the EU to maintain and further develop trade relationships with third countries on medicines and chemicals in order to prevent the breakdown of supply chains and limit

⁴ <https://www.pgeu.eu/big-data-artificial-intelligence/>



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or address the use of protectionist measures, such as import and/or export restrictions during health crises or unfair subsidies which may distort the EU market.

To resolve existing vulnerabilities of the medicines supply chain, we also recommend developing additional strategies to achieve a stronger diversification of supply within the medicines supply chain. This could include setting requirements for manufacturers to rely on more than one API/excipient provider.

PGEU also welcomes⁵ references made to address the environmental implications of production, use and disposal of medicines as well as promoting the rational use of medicines. Community pharmacists across Europe are ideally placed to advise patients on the appropriate handling and disposal of pharmaceuticals, including on antimicrobials. In addition to several State or government-led disposal and collection schemes for medicines, most of the European population can return expired or unused medicines to their community pharmacy, although the organisation and financing of these schemes varies. Since community pharmacies are easily accessible and frequently visited by the public, Member States should ensure that, where implemented, pharmacy-led disposal and collection schemes are appropriately funded in order to make the best use of these resources. At the same time, it is also key that for certain risk medicines the quantity of medicines dispensed matches the duration of treatment as much as possible in order to reduce the amount of leftover medicines, for example by optimising the package size of certain risk medicines.

The European Commission could foster best-practice exchanges between Member States on measures addressing the growing presence and negative impact of pharmaceuticals in the environment and fund more research to fill current existing knowledge gaps on the potential negative impact of pharmaceuticals on the environment as well as the links between the presence of antimicrobials in the environment and the development and spread of antimicrobial resistance. To conclude, it should at all-time be ensured that actions to address the risk of pharmaceuticals in the environment do not jeopardise sufficient room for independent clinical decision-making by healthcare professionals on public health grounds.

⁵ <https://www.pgeu.eu/wp-content/uploads/2019/04/191114E-PGEU-Position-Paper-on-Pharmaceuticals-in-the-Environment.pdf>