PGEU GPUE

Pharmaceutical Group of European Union

DRAFT position paper on the European Commission roadmap/inception impact assessment on the Evaluation and revision of the general pharmaceutical legislation

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

Rue du Luxembourg 19, 1000 Brussels, Belgium | Phone: +32 2 238 08 18 | AISBL BE 0468 971 838

pharmacy@pgeu.eu | www.pgeu.eu

PGEU GPUE
Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

Executive Summary

PGEU welcomes the opportunity to provide input in the context of the European Commission roadmap/inception impact assessment on the Evaluation and revision of the general pharmaceutical legislation. Our contribution addresses the issues that have a direct impact on community pharmacy, namely security of supply of medicines including shortages, medicines accessibility, and environmental sustainability.

In particular, we believe the revision of the general EU pharmaceutical legislation should aim at:

- Developing a fair framework for pharmaceuticals which puts guarantees for security and timeliness of medicines supply for patients at its core;
- Expanding the role and resources of the European Medicines Agency (EMA) in the coordination of Member States activities on the prevention and management of shortages in close collaboration with the Heads of Medicines Agencies (HMA). At national level, national pharmacy organisations should be closely involved in strategies related to the monitoring, prevention and management of shortages;
- Ensuring increased transparency and timely communication to affected stakeholders such as community pharmacists to prevent and minimize the impact of shortages;
- Developing fair and effective redistribution mechanisms for medicines available on the European market, to those patients who need them the most, regardless the EU country where they live, especially in times of health crises and other additional extraordinary circumstances, such as Brexit, which can have a strong impact on medicine supply in some countries;
- Establishing further EU guidance to Member States on the import and export of medicines across borders to ensure that as a response to occurring medicine shortages the flow of medicines and medical devices across borders within the EU is better planned and coordinated;
- Assuring effective compliance with EU and national laws related to the public service obligations of supply chain actors through further clarification of these obligations;
- Confirming the complementary nature of electronic product information to the paper package leaflet as outlined in the joint EMA-HMA-EC Key Principles on Electronic product information for human medicines in the EU;
- Reducing pharmaceutical waste caused by leftover medicines by ensuring that systems are in place to encourage the dispensing of quantities of certain risk medicines

matching the duration of treatment as much as possible - for example by optimising the package sizes – and to collect leftover or expired medicines;

- Develop and ensure compliance with environmental quality standards for pharmaceuticals as a measure to promote greener manufacturing.

PGEU GPUE
Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

Introduction

PGEU welcomes the opportunity to provide input in the context of the European Commission roadmap/inception impact assessment on the Evaluation and revision of the general pharmaceutical legislation. Our contribution addresses the issues that have a direct impact on community pharmacy, namely security of supply of medicines including shortages, medicines accessibility, and environmental sustainability.

1. Enhance the security of supply of medicines and address shortages

PGEU supports the European Commission objective to "*enhance security of supply through stronger obligations for supply and transparency, earlier notification of shortages and withdrawals of medicines, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages*" *and to "improve the transparency and oversight of the supply chain".*

The 2020 results[1] of the PGEU annual medicines shortages survey show the continued high incidence of medicine shortages in Europe and their daily and burdensome impact on patients and pharmacy practice.

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

[1] https://www.pgeu.eu/wp-content/uploads/2019/03/2020-PGEU-Medicine-Shortages-Survey-Results-v2.pdf

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 shortage. While we understand this is outside the competences of the EU and of the scope of the revision of the EU pharmaceutical legislation, we would like to stress that it is crucial for the scope of pharmacy practice to be extended when medicines are in short supply. This includes substituting with the most appropriate alternative as part of a shared decision-making process with prescribers and patients, or in accordance with national protocols, where appropriate, and preparing compounded formulations when no alternatives are available anymore. Shared electronic communication tools between pharmacists and prescribers (e.g. shared electronic health records) can enable this process effectively and safely, contributing to increasing interprofessional collaboration.

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 and other additional extraordinary circumstances, such as Brexit, which can have a strong impact on medicine supply in dependent EU Member States such as Malta, Ireland and Cyprus and in the outmost peripheric regions of the EU (e.g. Azores). 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 and their carers continue to have access to updated, 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 user-friendly 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 link 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 revision of the general pharmaceutical legislation.

With regards to the reporting and monitoring of shortages we suggest making use of pharmacy-based reporting systems already in place in many countries, thus guaranteeing harmonization of criteria and comparability of data. These should take into account differences in the definition of a medicine shortage across borders.

2. Ensure access to affordable medicines for patients

PGEU welcomes the European Commission efforts to ensure the affordability of medicines for patients. While we understand this would fall outside the scope of the revision of the EU legislation, we would like to stress that expanding and rewarding the role of community pharmacy and strengthening primary care systems are key policy levers to lead the way towards more sustainable health care systems.

The promotion of the rational and responsible use of medicines should be at the core of any policy aiming to enhance the affordability of medicines for health systems. This can be implemented by appropriately remunerating cost-effective healthcare services which show to improve therapy outcomes and adherence and minimise the risks related to using medicines. This includes an adequate, fair and sustainable remuneration of medicines dispensing and other services such as adherence-focused new medicines services [2], medicines use reviews [3], implementation of validated clinical rules [4], common ailment [5] and chronic disease management [6,7] services.

Together with the promotion of the rational and responsible use of medicines, more investments in prevention and in strengthening primary care systems should be strongly encouraged.

---

[2] Elliott, et al. (2016). Supporting adherence for people starting a new medication for a long-term condition through community pharmacies: a pragmatic randomised controlled trial of the New Medicine Service. Pharmacoeconomics. 2017 Aug 3. doi: 10.1007/s40273-017-0554-9

[3] Jódar-Sánchez, F. et al. Cost-Utility Analysis of A Medication Review With Follow-Up for Older People With Polypharmacy in Community Pharmacies in Spain: Consigue Program. Value in Health, Volume 17, Issue 7, A511 - A512

[4] https://www.knmp.nl/actueel/nieuws/nieuws-2020/mfb2019s-helpen-bij-terugdringen-onnodig-geneesmiddelgebruik

[5] Watson M, Holland R, Ferguson J, Porteous T, Sach T, Cleland J. Community Pharmacy Management of Minor Illness (the MINA Study) London: Pharmacy Research UK; 2014.

[6] Marra C et al. Cost-effectiveness of pharmacist care for managing hypertension in Canada. Can Pharm J (Ott). 2017 Mar 21;150(3):184-197 doi: 10.1177/1715163517701109

[7] Hughes, Jeffery David et al. "The role of the pharmacist in the management of type 2 diabetes: current insights and future directions." Integrated pharmacy research & practice vol. 6 15-27. 16 Jan. 2017, doi:10.2147/IPRP.S103783

Moreover, generics uptake by community pharmacy should be incentivised to make medicines more affordable while rewarding community pharmacists for this important economically sustainable service.

We also believe that strengthening EU cooperation on health technology assessment (HTA) by broadening regional initiatives such as Beneluxa or the Valletta Declaration Group should also be encouraged.

Lastly, it is important to increase patients access to specialty medicines. In many countries innovative medicines and high price medicines are available only through hospitals which leads to inequalities in patients access. The dispensing of this medicines through community pharmacies increases equity of access, reduces costs to patients and can improve monitoring and adherence.

3. Enhance environmental sustainability of the production, use and disposal of medicines

PGEU supports the European Commission objective to address the environmental implications of production, use and disposal of medicines as well as promoting the rational and responsible use of medicines. Community pharmacists across Europe are ideally placed to advise patients on the appropriate handling and disposal of pharmaceuticals, including on antimicrobials[8]. 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. 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. It should however 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.

[8] PGEU Best Practice Paper on Green and Sustainable pharmacy

It would also be useful to foster EU research and innovation on "greener" production of medicines, and making information on greener products available so that, when possible, pharmacists can advise patients on this issue.

Lastly, there should also be a focus on combatting illegal online sales of antimicrobials by encouraging the use of "bricks and mortar" pharmacies and better promoting the EU common logo for legal online pharmacies.