PGEU
European Community Pharmacists

PGEU position paper on the reform of the EU Pharmaceutical Legislation

About Us

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.

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Executive Summary

European community pharmacists welcome the European Commission's proposal for the reform of the EU pharmaceutical legislation. The Pharmaceutical Group of the European Union (PGEU) believes the proposal includes important provisions to improve the supply of medicines to meet patients' needs, regardless of where they live in the Union.

Medicine shortages

The proposal introduces important and useful tools to address medicine shortages, including the earlier notification of anticipated supply disruptions, marketing cessations and withdrawals. PGEU welcomes the intention of the European Commission to strengthen Member States' coordination in monitoring and mitigating shortages, with a stronger involvement of the European Medicines Agency (EMA) and a key role for the Executive Steering Group on Shortages and Safety of Medicinal Products, also known as Medicine Shortages Steering Group (MSSG). PGEU also welcomes the European Commission's proposal to expand the use of the European Shortages Monitoring Platform (ESMP) to facilitate the collection of information on shortages, supply and demand for medicinal products, including information on marketing status and marketing cessations.

PGEU supports the provisions that foresee the possibility for supply chain actors to report medicine shortages to competent authorities, as currently the first signals of supply issues are frequently detected at pharmacy level. While the reporting of anticipated shortages is strengthened by the proposal, community pharmacists would like to see clearer provisions regarding transparent and timely communication to the impacted stakeholders, in a rational and phased manner.

Community pharmacists are supportive of the measures being introduced in the legislation that require manufacturers to have a better oversight of their supply chain by requiring them to have in place shortages prevention and mitigation plans. It is essential that these plans are transparent and accessible to the medicines regulators and that they are efficiently implemented once a shortage is anticipated or confirmed. Furthermore, PGEU welcomes the much-needed clarification of the responsibilities of marketing authorization holders and wholesale distributors to ensure the appropriate and continued supply as this will help Member States define the appropriate obligations for each actor and result in a smoother supply chain to the benefit of patients.

PGEU calls for:

The expanded role of the European Medicines Agency (EMA) in the monitoring and management of shortages via the European Shortages Monitoring Platform (ESMP) to be accompanied by an increase in the Agency's resources.

Ensuring the increased transparency and timely communication on medicine shortages to affected stakeholders.

Allow for supply chain actors other than MAHs to report information regarding medicine shortages.

Electronic product information

Community pharmacists are concerned with the proposal regarding the implementation of the electronic product information leaflet, which would allow Member States to implement legislation removing package leaflets entirely. PGEU is especially concerned with the absence of any consideration regarding the practicalities involved in providing patients with an up-to-date free printed version of the electronic product information (ePI) and the lack of references to the appropriate implementation and monitoring of the key principles for the use of electronic product information for EU medicines as adopted by the EMA, the Heads of Medicines Agencies (HMA) of EU Member States and the European Commission. In addition, we view with concern the ability of the European Commission to implement legal acts defining the mandatory and exclusive character of the ePI in all Member States. Finally, community pharmacists would like to see more legal certainty with respect to the hosting and access management of the electronic version of the paper leaflet by competent authorities, namely through a neutral, objective, and non-commercial source.

PGEU calls for:

Using the electronic Product Information (ePI) as a tool to complement but not replace the current paper versions of the package leaflets.

Including stronger provisions to safeguard patient privacy and to allow the access to the ePI preferably via the national regulatory authorities or the Agency.

Antimicrobial Resistance

PGEU believes the proposed measures to address medicines shortages will have a positive impact on the continuous availability of antimicrobials and in particular antibiotics in Europe. Furthermore, we highlight the provisions regarding the Environmental Risk Assessment, which will contribute to limiting the impact of these medicines in the environment and the rise of resistance due to the manufacturing of antimicrobials. PGEU welcomes the idea of including an "awareness card" as a support material for patients which pharmacists can use when informing patients on the prudent and correct use of antimicrobials, as well as their effective disposal. However, we raise concerns on the modalities used to grant access to this information for patients in a way that is consistent and aligned with the availability of the product information.

While we welcome the principle that antimicrobials should only be made available to patients upon consultation with a healthcare professional, we are concerned that the current definition of antimicrobials paired with the requirement for a prescription for all antimicrobials will impact in practice patient access to common antimicrobials that have been safely dispensed in pharmacies, supported by pharmaceutical advice, to address common and uncomplicated infectious ailments.

Regarding the new incentive proposed by the Commission to encourage the development of novel antimicrobials, the complexity of the issue and scarcity of solutions requires thorough discussion to address the potential uncertainty generated by this measure. This is especially relevant when considering the ability to commercialize the transferable exclusivity voucher, a model previously rejected in other world regions. Albeit regulated in terms of quantity, the transferable exclusivity vouchers have the potential to create unforeseen costs for already strained pharmaceutical budgets in unrelated therapeutic areas. In this regard, we believe that discussions and proposals being put forward by the Health Emergency Preparedness and Response Authority (HERA), especially in pull incentives, can be further explored, and included in the context of the current revision.

PGEU calls for:

Finding workable solutions that would allow community pharmacists to continue to advise and safely dispense common antimicrobials to patients to treat uncomplicated infections.

Maximizing the contribution community pharmacists can make to tackling AMR and encouraging the prudent use of antimicrobials, including with the use of the "awareness card" as a support material for patients.

Supporting the development of innovative incentives and business models for new antimicrobials whilst guaranteeing continued access to existing antimicrobial therapies.

Scope

The current proposal broadens the scope of the medicines covered by the Directive by bringing within scope medicinal products which have not been industrially produced (previously exempt from scope). We advocate to maintain the scope as it currently stands so as not to inadvertently bring within scope compounding by community pharmacists, which has notably been an important tool for ensuring continued access to treatment, of particular importance in the case of shortages or unavailability of medicinal products. At minimum, where the scope is changed, appropriate derogations are necessary to permit compounding by community pharmacists in line with Member States' competence to organise their health systems according to national requirements – for example, while the proposal foresees a new derogation allowing hospitals to manufacture in bulk for 7 days' needs based on estimated prescriptions, we fail to understand why no similar derogation is envisioned for community pharmacy compounding.

PGEU calls for:

Stimulating and encouraging pharmaceutical compounding, recognising this as an important tool to mitigate medicine shortages.

Falsified medicines

At the time the European Commission is preparing the evaluation of the implementation of the Falsified Medicines Directive (2011/62/EU) (FMD) and Delegated Regulation (2016/161/EU), the legislative proposal does not modify the existing provisions instated by the FMD. Indeed, the European Commission states under the recitals that is not its intention to amend these in the current revision. We are therefore, concerned about the inclusion of an additional use for the national repositories envisioned by the Commission to inform the Member States of the marketing status of medicinal product to the purpose of attribution of an extension of regulatory data exclusivity.

PGEU calls for:

Maintaining the provisions referring to the establishment and use of the repository systems, dedicated to preventing falsified medicines from entering the legal supply-chain.

Pharmacovigilance

Community pharmacists call for the maintenance of the concept of 'medicines under additional monitoring', the recognisable black inverted triangle symbol (▼) accompanied by a note explaining the concept in a simple and comprehensive manner in the package leaflet to allow for better identification of possible side effects of medicines approved through accelerated pathways with limited information on its safety profile and to ensure efficient implementation of risk mitigation measures as necessary.

PGEU calls for:

Maintaining the concept of 'medicines under additional monitoring', the recognisable black inverted triangle symbol (▼) and respective package leaflet explanatory note of the concept.

Timelines and broader legislative context

European community pharmacists have called for urgent action to address medicine shortages. While this proposal contains important provisions to address and mitigate the issue, the timeframe for the discussion and implementation leaves European patients waiting too long for decisive and effective action to address the issue immediately. In that regard, PGEU welcomes the non-paper on security of supply of medicines in Europe co-signed by 22 countries and dated 2 May 2023 and the European Commission communication of 24 October 2023 titled 'Addressing medicine shortages in the EU'.

Ensuring greater access, availability and affordability of medicines to patients

PGEU believes that the proposals presented by the European Commission on 26 April 2023 take important steps to address several issues identified by community pharmacists in Europe with regard to the availability and the accessibility of medicines.

Improving shortages prevention and monitoring at European level to ensure patient access at national level

PGEU supports the proposals from the European Commission to address medicine shortages by enhancing prevention, monitoring, and cooperation at European level. As such, we welcome the **expanded role of the European Medicines Agency (EMA) in the monitoring and management of shortages via the European Shortages Monitoring Platform (ESMP).** We believe that this continued central information collection and monitoring of (anticipated) shortages for medicines at EU level, done in close collaboration with the Heads of Medicines Agencies (HMA) via the strengthened role of the Medicine Shortages Steering Group (MSSG), will greatly enhance European coordination in the response to medicine shortages.

The ESMP should build on existing national systems to report medicine shortages and to make these systems interoperable at EU level, allowing for centralised monitoring by the EMA, Member States and the European Commission. To facilitate the reliable exchange of information in a robust and consistent manner, it should be ensured that there are harmonised reporting protocols and criteria for marketing authorisation holders (MAHs) and national competent authorities (NCAs) via single points of contact (SPOC). **EMA's expanded role should be accompanied by an increase in the Agency's resources** to reflect the higher expectations of its role in monitoring and coordinating action on medicine shortages.

PGEU also welcomes the European Commission proposal to **allow for supply chain actors other than MAHs to report information regarding medicine shortages**. Where pharmacy-reporting systems are available at national level, community pharmacies contribute to the collection of relevant information for NCAs on shortages. These systems[1] provide a valuable complementary tool to the mandated notifications from MAHs, detecting early signals and providing warnings on anticipated shortages allowing for a more complete picture of the incidence of medicine shortages at pharmacy level. Regarding the reporting of medicine shortages by community pharmacists, the type of data requested should be proportionate, justified by **building-in flexibility for Member States to adapt the type of data requested** to their national contexts.

PGEU calls for clearer provisions ensuring increased transparency and timely communication on medicine shortages to affected stakeholders, in a rational and phased manner[2]. Only timely and transparent communication on both anticipated and confirmed medicine shortages will allow community pharmacists to better manage patient care and ensure continuity of treatment to reduce the negative impact of shortages on patients. In this regard, we refute argumentation that providing this information to community pharmacists would exacerbate the issue by triggering hoarding by pharmacies, on the contrary, this can be avoided by clear and transparent communication and advice from the competent authorities, rather than leaving healthcare professionals to act upon unofficial information.

Furthermore, PGEU recalls that the European Medicines Verification System (EMVS), which has been created to implement the Falsified Medicines Directive (2011/62/EU) and Delegated Regulation (2016/161/EU), does not provide accurate stock or demand data in the European Union and the various Member States, primarily due to the system being an end-to-end system and containing multi-country medicines packs that are uploaded multiple times in the systems but are only available in one market[3]. As such, **the EMVS is not a workable nor appropriate system to monitor medicine shortages**.

PGEU welcomes the **clarification of the responsibilities of marketing authorization holders and wholesale distributors regarding the continuous supply of medicines** to the national markets, particularly to pharmacies. We believe that these clarifications will allow better compliance and regulatory oversight of the various supply chain stakeholders and will empower Member States to clarify and define the appropriate public service obligations for each actor and result in a better functioning supply chain to the benefit of patients.

[1] Examples include the Royal Dutch Pharmacists Association Farmanco Platform, the French Chamber of Pharmacists Dossier Pharmaceutique Ruptures, the Spanish General Pharmaceutical Council CISMED platform, the Portuguese National Pharmacy Association medicine shortages database and the Belgian medicines authority PharmaStatus – more information on the PGEU Position Paper on Medicine Shortages

[2] E.g. Communication of shortages of Hydrea® (22 May 2023 – 24 August 2023) and Ozempic ® (1 January 2023 – 31 December 2023 [Expected]) via FarmaStatus

[3] PGEU statement on the potential use of the data contained in the EMVS to monitor shortages

Prevent and mitigate medicine shortages by leveraging pharmacists' competencies and European solidarity

The Single Market adds a layer of complexity to addressing the root causes of medicine shortages. The opacity regarding the supply chain flows and medicines allocation to the different Member States can make difficult the identification and mitigation of medicine shortages. It is therefore vital that the flow of medicines within the Single Market is better planned and coordinated. It should be a key requirement that the flow of medicines addresses patient demand and is not based on commercial interests. This will require the establishment of **EU guidance to Member States on the movement of medicines across borders**, offering the necessary predictability and legal certainty for supply chain operators and ensuring compatibility with the different national healthcare contexts.

PGEU believes that should Member States or the EU have the need to create buffer stocks in the medicines' supply chain, they should be proportionate and should not exert unnecessary pressure on the general supply of medicines within the country or in other EU Member States. This could be achieved by requiring such stocks to be gradually built over time and managed according to stock management best practices to avoid waste.

When it comes to localized medicine shortages (i.e., shortages that happen in one or few countries), we believe it must be ensured **that medicines available on the European market can effectively be redistributed to those patients who need them the most**. This aspect of European solidarity takes an even more relevant role in times of health crisis (e.g., COVID-19) or in extraordinary circumstances that disrupt the normal flow of medicines in Europe (e.g., Brexit).

Safeguard the ability of pharmacists to compound and substitute medicinal products as a mean of tackling medicine shortages

Community pharmacists play an active role in finding solutions to mitigate medicine shortages and should be empowered to make full use of their professional competence to ensure patients can receive treatment in a timely manner. Member States should **allow pharmacists to substitute the medicine in short supply 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. Similarly, Member States can **stimulate and encourage pharmaceutical compounding** to help mitigate shortages of medicinal products for which there are no suitable alternatives available on the market. In this regard, we welcome the clarity offered by the European Commission's proposal, maintaining the existing **exclusion for medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient or in accordance with a pharmacopoeia** from the scope of the Pharmaceutical Directive.

However, we have reservations regarding the broadened scope of this Directive which will include medicinal products which have not been industrially prepared, which may constrain the pharmacists' ability to compound. It is vital that the new Directive must **not restrict Member States' existing competence to organise their health systems, including the supply and preparation of medicines by community pharmacies,** which is an important tool for addressing shortages. Therefore, we advocate for the current scope of the Directive to be maintained. Otherwise, at minimum there must be appropriate provisions to continue to allow compounding by pharmacists – for example, the new derogation for hospital pharmacies to prepare in advance the equivalent of 7 days needs seems a welcome approach in duly justified cases not only for hospital pharmacies but also for community pharmacies – for instance as a response to an anticipated or confirmed medicine shortage, which has become a relatively common practice in some European countries.

Improve patient access while ensuring affordability

PGEU welcomes the European Commission proposals to ensure the affordability of medicines for patients and health systems[4]. We had previously noted that launch prices of new medicines have increased in some therapeutic categories, sometimes without commensurate health benefits.[5] As a result, EU Member States adopted pure cost-containment policies which negatively affected availability of medicines[6] and shifted the financial burden of the costs of medicines on patients.

Community pharmacists are convinced that the European Commission's proposals **incentivizing companies to market newly authorized medicines in all European Member States** will contribute to improving patient access in the medium to long-term and is in line with the pharmaceutical industry's own commitment to file for pricing and reimbursement (P&R) across Europe and thus market in all Member States[7].

To promote affordability and sustainability of health systems, **generic uptake by community pharmacy should be incentivized** at national level while appropriately rewarding community pharmacists for this service.

Simultaneously, it is important to increase patients' access to specialty medicines in community pharmacies, counteracting the trend of these medicines being only available through hospitals and care centres, frequently distant from patients' residence or place of work. **Empowering community pharmacists to provide the full range of medicines in pharmacies, including innovative and specialty medicines** (e.g., biological medicines, including biosimilars) can increase equity of access to patients, reducing patient's direct and indirect costs and potentially improving monitoring and adherence to these typically costly treatments. This is a unique opportunity to combine the dispensing service with the support of their safe and effective use by patients in the pharmacy (e.g., by guiding patients on how to use an injection device). Ensuring that a wide range of medicines are available locally, close to the patient's home or place of work minimizes the environmental impact associated with patients' travel[8,9].

While we recognize that pricing and reimbursement are out of the scope of this revision and exclusive competence of the Member States, PGEU stresses the need to **encourage better cooperation among EU countries on tools evaluating the cost-effectiveness and added therapeutic value of new therapies.** In this respect, we welcome the European Commission's efforts to implement the Health Technology Assessment regulation and the various cross-country collaborations established in different areas, including on pricing and reimbursement and on the joint procurement of medicines. PGEU believes coordination among **EU Member States will ensure that pricing decisions taken by one EU country do not lead to negative impacts on patient access in another country.**

[4] PGEU Position on Affordability of Medicines and Health Systems Sustainability
[5] OECD Pharmaceutical innovation and access to medicines
[6] OECD Pharmaceutical pricing policies in a global market
[7] EFPIA Addressing Patient Access Inequalities in Europe: The Industry commitment to file pricing and reimbursement applications across Europe and the European Access Portal
[8] PGEU Best Practice Paper on Green and Sustainable Pharmacy in-Europe
[9] Consejo General de Colegios Oficiales de Farmacéuticos de España - Study and assessment of experiences of collaborative dispensing of medicines for Hospital Diagnostics and Dispensing (DHDH) during COVID-19 (Spanish only)

Lastly, **the promotion of the rational 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 minimize the risks related to using medicines. Examples of such health interventions are adherence-focused services, such as the new medicine service[10], medicines use review (pharmacotherapy follow-up)[11], implementation of validated clinical rules, common ailment[12], chronic disease management[13,14], and prescription renewal services.[15]

[10] 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
[11] 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
[12] 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.
[13] 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
[14] 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
[15] Pharmacy Services in Europe: Evaluating Trends and Value. Executive Summary. Lisbon: Institute for Evidence-Based Health (ISBE); 2020.

Supporting EU competitiveness and reducing dependence of non-EU countries

Community pharmacists are positive regarding the revision proposals to improve pharmaceutical supply chains oversight by **requiring manufacturers to develop and implement shortages prevention and mitigation plans**. PGEU believes that these plans should be **fully transparent and accessible to the medicines regulators** to ensure that once a shortage is anticipated or confirmed they are readily and efficiently implemented to prevent and mitigate medicine shortages.

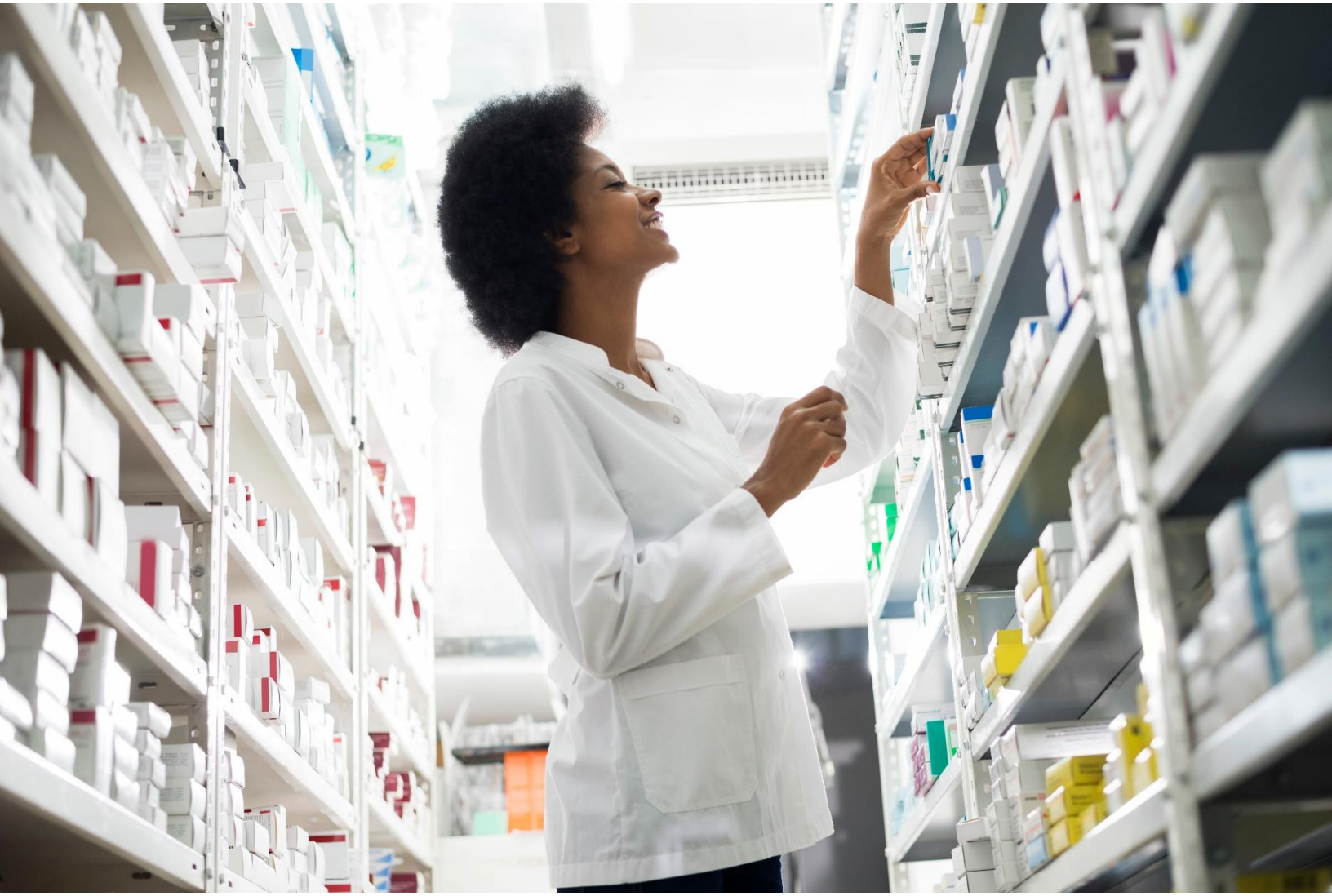
In addition, we welcome the steps taken by the revision to facilitate the **diversification of supply within the medicines' supply chain**. **Reducing the dependence on third countries for the manufacturing of vulnerable and critical medicines and chemicals is an essential step to tackle medicine shortages.**

With the objective of strengthening the European medicines supply, the **EU should seek to maintain good trade relations with third countries on medicines and chemicals used to produce medicines**, guaranteeing that the global supply chain of medicines is not disrupted during crisis by trade restrictions, such was the case during the COVID-19 pandemic. To ensure that the European medicines manufacturing base remains competitive, the EU should also try to establish a level-playing field for manufacturers operating in the Union and those outside. This can be achieved, for example by remaining vigilant for unfair foreign subsidies that would distort the EU market and by **ensuring full compliance with EU environmental standards included in the proposals**, regardless of the geographic location of the manufacturing.

The proposal to create a European list of critical medicines is a welcome step to increase the security of supply. In this respect, we would welcome increased clarity and consistency with the terminology already included in the Regulation 2022/123/EU to allow for a common understanding of the composition and role of the various medicines' lists being created and maintained by the Agency and Member States.

Finally, PGEU welcomes the initiative of the Member States in the Non-paper on Improving the security of medicines supply in Europe[16]. While we are convinced that reshoring production of medicines and active pharmaceutical ingredients is not the end-solution for supply issues and is only applicable to a very restricted set of critical medicines, a common European approach such as the one suggested in the paper will certainly render better results than individual country measures.

[16] 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, PT)



Addressing patient needs with a patient-centred digitalized regulatory framework

One of the main challenges of the EU regulatory framework for medicines is the reliance on paper-based procedures and information exchange. While this has proven to be a reliable way to guarantee patient safety and the quality of medicines supplied in Europe for the past two decades, the pandemic and the increased role of regulatory agencies in managing shortages and supply chain oversight, require the use of efficient digitalized tools.

Encourage the use of digital technologies while ensuring patients safety, privacy and needs are put first

PGEU welcomes the European Commission proposal to digitalize the European regulatory framework by requiring document submissions to be made in digital format. Similarly, community pharmacists **support the use of electronic Product Information (ePI) as a tool to complement but not replace the current paper versions of the package leaflets**[17]**.** In this sense, we are particularly concerned with the provisions proposed by the European Commission that allow individual Member States to eliminate paper versions of the leaflets in favour of the exclusive use of the ePI. Furthermore, the European Commission gives itself powers to create legal acts that will remove the paper leaflet from all the European Member States five years after the entry into force of the new legislation.

While PGEU welcomes in principle the regulation of the ePI in the current proposal, we believe that in its current writing it does not sufficiently safeguard appropriate time for the implementation of the EMA-HMA-EC key principles for electronic product information for human medicines in the EU. Similarly, we are greatly concerned by the lack of thought given to the practicalities, such as those necessary that patients can have access to updated free of charge printed versions of the leaflet. **Community pharmacists do not believe that printing the leaflet on-demand at the pharmacy is a practical, workable, economical, or environmentally sound solution**. In this respect, we are also cautious regarding the lack of mention to the economic burden of printing a paper version of the leaflet and we stress that this cost cannot be borne by community pharmacies.

Furthermore, PGEU considers the provisions protecting patient privacy to be insufficient to safeguard patient data to be stored and used by third parties facilitating or granting the access to the electronic product information. We call on the co-legislators to **include stronger provisions to safeguard patient privacy and to allow the access to the ePI preferably via the national regulatory authorities or the Agency**.

Lastly, PGEU believes the reform could have been a good opportunity to **amend the current legislation regarding the content, structure and design of the paper package leaflet**, in line with the Commission's own report recommendations[18]. We trust the Commission and the Member States will continue with their ambition to improve the printed leaflet in close cooperation with patients and healthcare professionals, continuing to share good practices from key stakeholders such as community pharmacists at national level to improve the information sharing on medicines.

[17] PGEU Position Paper on electronic product information leaflet

[18] COM/2017/0135 - Report from the Commission to the European Parliament and the Council in accordance with Article 59(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

Explore the pharmacists' potential to generate valuable real-world data and evidence

Real-world evidence can be generated based on real-world data gathered in community pharmacies and is an important tool to inform safety and effectiveness assessments of medicines in the real world.[19]

Additionally, real-world evidence aims to cover not only the safety and effectiveness profile of medicines used under the conditions for which its marketing authorization was granted, but also to **characterize their off-label use.** This leads to a more comprehensive knowledge about the safety and effectiveness profile of medicines, but also about the (heterogeneous) population using those medications, which should be considered in the risk-benefit analysis and in any potential repurposing procedure of a medicine.

We are highly supportive of **more coordination among key actors for integrated medicines development and post-authorization monitoring.** Within this process, we believe that pharmacy organizations, should be included considering that pharmacies are key sources of real-world data which contribute to evidence-based regulatory decision-making, especially in post-marketing authorization, and public health policy.

The potential use of real-world evidence, including evidence generation in community pharmacies to evaluate effectiveness and therapeutic added value of innovative medicines in practice, should therefore also be rewarded.

To avoid unnecessary additional burden and uncertainty, both regarding the collection and use or real-world data and evidence, full compatibility of the medicinal regulatory framework with the future European Health Data Space and the General Data Protection Regulation must be achieved.

Community pharmacists support the proposal to include **incentives to stimulate the repurposing of off-patent medicines**, targeting new indications in areas where **important public health benefits** are likely to be achieved. These incentives **must not impact the access to the off-patent medicines being repurposed for patients undergoing treatment for the previously authorized indications**, being it due to an increase in price or supply issues arising from the increased demand.

[19] PGEU Position Paper on Digital Health

Ensure a strong pharmacovigilance system

With the new regulation proposing regulatory sandboxes and accelerated approval schemes, it is likely that the volume of medicines approved with a conditional marketing authorization will greatly increase, in line with recent trends. The existing legal framework requires these medicines to be under 'additional monitoring' allowing for better identification and notification of possible side effects and to apply risk mitigation measures more efficiently.

Community pharmacists believe that the European Commission proposal to eliminate the inverted black triangle (▾) will negatively impact the ability of pharmacists to inform patients about these medicines and compromise the concept of 'additional monitoring' and the thorough reporting of suspected adverse events.

PGEU calls for the revised legislation to **maintain the concept of 'medicines under additional monitoring', the recognisable black inverted triangle symbol (▾) and respective package leaflet explanatory note of the concept**. This will increase patients and pharmacists' awareness on the need to report suspected side effects, contributing to better establishing the safety profile of medicines approved under accelerated pathways, early access schemes, and medicines approved with limited evidence that require specific post-marketing safety monitoring. To improve patients and health care professionals' understanding of the meaning of the inverted black triangle, dedicated awareness campaigns should be organized at national level.

Combating antimicrobial resistance

Community pharmacists have an important role in providing patients with high quality and reliable information on the prudent and correct use of antimicrobials[20]. As such, **PGEU welcomes the proposal to include the "awareness card" as a support material for patients that pharmacists can refer to when advising patients about antimicrobials**. However, we have some concerns on the modalities used to grant access to this information for patients and we believed it should be made in such a way that is consistent and aligned with the available product information.

While PGEU welcomes the principle that antimicrobials should only be made available to patients upon consultation with a healthcare professional, we are concerned that the current definition of antimicrobials paired with the requirement for a prescription for all antimicrobials will impact, in practice, patient access to common antimicrobials that have been safely dispensed in pharmacies, supported by pharmaceutical advice, to address common and uncomplicated infectious ailments (e.g., topical antivirals for the treatment of cold sores, antibiotic creams for superficial skin infections, or antifungals for vaginal candidiasis or athlete's foot). We call on the European Commission and the Member States to **find workable solutions that would allow community pharmacists to continue to advise and safely dispense common antimicrobials to patients to treat uncomplicated infections**, promoting early access to treatment. This could be achieved, for example, through limiting the need for prescription on antibiotics or encouraging Member States to implement protocol-based dispensing. This would allow patients to continue to receive timely access to treatment and advice from community pharmacists, while avoiding an unnecessary burden on primary healthcare systems, patients and general practitioners.

At national level, health authorities should **maximize the contribution community pharmacists can make to tackling AMR and encouraging the prudent use of antimicrobials**. They should closely involve community pharmacists in AMR action plans and make greater use of pharmacists to raise awareness on vaccination and where appropriate, greater use of pharmacists to administer vaccines. In some European countries, pharmacists can play a key role in minimizing the use of antibiotics by performing point-of-care testing to screen for early signs of infectious diseases and differentiate between viral and bacterial infections, ensuring antibiotics are only used for the treatment of conditions for which they are really needed. Additional measures could include providing indications on prescriptions for antimicrobial medicines and making greater use of shared medication records as means to enhance multi-professional collaboration and communication on AMR. 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.

[20] PGEU Position Paper on Antimicrobial Resistance

Community pharmacists **support the development of innovative incentives and business models for new antimicrobials** which could stimulate the development of new antibiotics whilst guaranteeing **continued access to existing antimicrobial therapies**. PGEU understands the complexity of this issue and the scarcity of proven effective solutions available. The transferable exclusivity voucher incentive proposed by the European Commission to encourage the development of novel antimicrobials is likely to create uncertainty and add pressure to already strained public budgets. We believe that this incentive requires thorough discussion in the context of the current revision to address potential uncertainty it can generate. In addition, the proposals being put forward by the Health Emergency Preparedness and Response Authority (HERA), especially regarding pull incentives, can be further explored. .

Reducing the negative impact of pharmaceuticals in the environment

PGEU welcomes the provisions to **address the environmental implications of production, use and disposal of medicines**, including the Environmental Risk Assessment studies and their public register. We recall that community pharmacists across Europe are ideally placed to advise patients on the appropriate handling and disposal of pharmaceuticals, including antimicrobials. While we recognise that the disposal of medicinal products is primarily managed at country or regional level, we call on the European Commission and Member States to **continue to highlight the importance of appropriately disposal of medicinal products to limit their environmental impact**. In most European countries, citizens can return expired or unused medicines to their community pharmacy, although the organization and financing of these collection schemes varies. Considering that community pharmacies are easily accessible and frequently visited by the public, Member States should ensure that, where implemented, pharmacy-led collection and disposal schemes are

appropriately funded in order to make the best use of these resources. At the same time, it is also key to ensure that systems are in place that encourage the prescription and dispensing of quantities of certain medicines that can have a harmful impact in the environment, such as antibiotics, in package sizes matching the duration of treatment as much as possible[21].

We also support **setting adequate environmental quality standards** for pharmaceuticals posing a risk at national level and to **encourage action in third countries** where pharmaceutical emissions from manufacturing and other sources are suspected of contributing to the global spread of antimicrobial resistance as well as harming the environment and ecosystems.

In addition, 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 jeopardize sufficient room for independent clinical decision-making by healthcare professionals on public health grounds.

[21] PGEU Best Practice Paper on Green and Sustainable Pharmacy in-Europe

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