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

PGEU Position Paper on the Pharmaceutical Strategy for Europe

Executive Summary

European community pharmacists welcome the ambitions set forward in the Roadmap on the Pharmaceutical Strategy for Europe to help ensure Europe's supply of safe and affordable medicines to meet patients' needs and to support the financial sustainability of health systems.

Today's ongoing COVID-19 pandemic and the unacceptable, increasingly negative impact medicine shortages have on patients access to medicines require bold, ambitious and coordinated actions at all policy levels.

The European Union has the powers within its areas of competence to play a more prominent role in creating and coordinating policies that bring meaningful solutions to patients and healthcare professionals across Europe.

We therefore believe that the Pharmaceutical Strategy for Europe should aim to achieve the following objectives:

- **Ensure greater access and availability of pharmaceuticals to patients by:**
- Developing a fair framework for pharmaceuticals which puts guarantees for security and timeliness of medicines supply for patients at the core of medicines regulation and incentives in the EU;
- 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 on shortages to affected stakeholders;
- Developing fair and effective redistribution mechanisms for medicines available on the European market 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;
- 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, if deemed necessary through further clarification of these obligations during the revision of the pharmaceutical legislation;
- Extend the scope of pharmacy practice to manage medicines shortages at national level;

- Empowering community pharmacists to provide the full range of medicines in pharmacies, to deliver medicines to care homes and patients' homes and to offer a wider range of medical devices in community pharmacies;

❖ **Ensure affordability of medicines for patients and health systems financial and fiscal sustainability by:**

- Promoting the rational use of medicines through the remuneration of cost-effective pharmaceutical care services at national level which show to improve therapy outcomes and adherence and minimise the risks related to using medicines;
- Increasing the share of resources within healthcare budgets allocated for investments in prevention and strengthening primary care systems.

❖ **Enable innovation in a way that harnesses the benefits of digital technologies by:**

- Supporting the active development and uptake of the EU Health Data Space to leverage the potential of Big Data and AI for healthcare across Europe and as a result support healthcare professionals, including community pharmacists, to provide more personalized services and treatment to patients and robust, evidence-based information on issues related to therapies while promoting safe and rational medicines use.
- Rewarding the use of real-world evidence including evidence generation in community pharmacies at national level to evaluate effectiveness and therapeutic added value of innovative medicines in practise.
- Facilitating the production of Big Data in healthcare, via linking electronic health records with e-Prescribing systems, allowing health professionals involved in patient care to access the necessary patient's information, subject to the patient's consent.
- Promoting interoperability of information systems in Europe to foster exchange of data across community pharmacies.
- Using the potential of big data to use it to promote more collaboration across many different health professionals serving the same patients as well as to promote integration of primary care systems.

❖ **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 by:**

- Incentivising the return of production to Europe of medicines, active pharmaceutical ingredients (APIs) and other excipients which are identified to be particularly critical and vulnerable in terms of supply;
- 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.

❖ **Reduce the negative impact of pharmaceuticals on the environment and combat antimicrobial resistance by:**

- Maximising the contribution community pharmacists can make to tackling antimicrobial resistance (AMR) and encouraging the prudent use of medicines including antimicrobials at national level by closely involving community pharmacists in national action plans to tackle AMR and improving vaccination coverage;
- Ensuring appropriate funding of pharmacy-led disposal and collection schemes for medicines at national/regional level, where implemented, as an easily accessible channel for the public to correctly dispose of their leftover or expired medicines;

- Reducing pharmaceutical waste caused by leftover medicines by ensuring that systems are in place that encourage the dispensing of quantities of certain risk medicines matching the duration of treatment as much as possible;
- Fund more research to fill knowledge gaps on the potential negative impact of pharmaceuticals on the environment and the links between the presence of antimicrobials in the environment and the development and spread of antimicrobial resistance;
- Develop and ensure compliance with environmental quality standards for pharmaceuticals as a measure to promote greener manufacturing.

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 shortage[I]. It is therefore 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.

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.[II]

[I] 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

[II] https://www.pgeu.eu/sustainability-of-health-systems/

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. 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 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 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.

An additional measure at national level to ensure greater access and availability of pharmaceuticals for patients is make sure that patients can access their full treatment close to their home or place of work. This should be done by empowering community pharmacists to provide the full range of medicines in pharmacies, including increasing the supply of innovative and/or specialty (biosimilars and biological) medicines via community pharmacies where this is not yet the case. This is a unique opportunity to combine the dispensing service with the support of their safe and effective use by patients in the pharmacy. In addition, community pharmacists should also be empowered to deliver medicines to care homes and patients' homes, to assist patients with the management of complex treatment regimens and to offer a wider range of medical devices in community pharmacies;

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. Lastly, multi-market packs are uploaded in all potential destination markets and counted multiple times without being available in these markets. Alternatively, we suggest to make use of pharmacy-based reporting systems already in place in many countries guaranteeing harmonization of criteria and comparability of data, which should take into account differences in definition of a medicine shortage across borders.

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

PGEU welcomes[III] the European Commission 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 way towards a more sustainable, inclusive, and healthier future in Europe.

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 minimise the risks related to using medicines. Examples of such services are adherence-focused new medicines services[IV], medicines use reviews[V], implementation of validated clinical rules[VI], common ailment[VII] and chronic disease management [VIII,IX] services.

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

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

Lastly, we believe that strengthening EU cooperation on health technology assessment (HTA) by broadening regional initiatives such as Beneluxa should also be encouraged.

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

PGEU acknowledges[X] 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

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[III] https://www.pgeu.eu/sustainability-of-health-systems/

[IV] 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

[V] 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

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

[VII] 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.

[VIII] 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

[IX] 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

[X] https://www.pgeu.eu/big-data-artificial-intelligence/

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.

In order to harness the benefits of digital for enabling meaningful innovation and enhancing patient care, a key requirement is to develop trust by all stakeholders involved through guaranteeing a high level of data protection. Patient data must be processed under a high level of data protection standards within trustworthy infrastructures that enable the access to secure data services. It also has to be ensured that data access and analysis are amenable to European rules for privacy and data protection.

Furthermore, PGEU supports a European approach to excellence and trust on Artificial Intelligence, as outlined in the White Paper on Artificial Intelligence[XI] published by the European Commission, with the twin objective of promoting the uptake of AI while addressing the risks associated with certain uses of this new technology in some sectors, including healthcare

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 continue 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 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.

5. **Reduce the negative impact of pharmaceuticals on the environment and combat antimicrobial resistance**

PGEU also welcomes[XII] 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

[XI] https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf
[XII] https://www.pgeu.eu/wp-content/uploads/2019/04/191114E-PGEU-Position-Paper-on-Pharmaceuticals-in-the-Environment.pdf

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. 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.

At national level, health authorities are also strongly encouraged to maximise the contribution community pharmacists can make to tackling AMR and encouraging the prudent use of antimicrobials[XIII]. They should closely involve community pharmacists in AMR action plans and make greater use of pharmacists to raise awareness for vaccination and where appropriate, greater use of pharmacists to administer vaccinations. Additional measures could be to provide 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.

[XIII] PGEU Best Practice Paper on AMR, available from: https://www.pgeu.eu/wp-content/uploads/2019/03/170629E-PGEU-Best-Practice-Paper-on-AMR.pdf