

PGEU Position Paper on the revision of the general pharmaceutical legislation

Executive Summary

European community pharmacists welcome a revision of the EU general pharmaceutical legislation as a tool to help ensuring Europe's supply of safe and affordable medicines to meet patients' needs and to support the financial sustainability and the resilience of health systems.

Both the 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, whilst respecting the differences in the organisation of healthcare systems across the EU. In this regard, PGEU supports that the revision¹ would confirm the nature of the legislation in the form of a Directive to safeguard the flexibility inherent to the transposition process, and the adaptation to the social, cultural, demographical and geographical needs of each Member State.

We believe that the revision of the general pharmaceutical legislation should aim to achieve the following objectives:

Ensure greater access and availability of pharmaceuticals to patients by:

- 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) by increasing resources and by clarifying and updating its legal activities through amending Regulation (EC) No 726/2004;
- Creating an EU monitoring system for (anticipated) shortages of all medicines in the EU, allowing for a centralised monitoring by the EMA, Member States and European Commission and the coordination of Member States activities on the 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 EU Member States such as Malta, Ireland and Cyprus, whose supply chains are typically interconnected with the UK;
- Assuring effective compliance with EU and national laws related to the public service obligations of supply chain actors through further clarification of these obligations;
- Requiring pharmaceutical companies seeking an EU marketing authorization to place the medicine on the market of all Member States.

¹ In particular, the Revision of Directive 2001/83/EC

- Stimulating pharmaceutical compounding by community and hospital pharmacists as a solution for unmet medical needs of small populations, where appropriate, as well as shortages of medicinal products for which there are no suitable alternatives available on the markets.

Create an adequate regulatory framework which puts the needs of patients at the centre and harnesses the benefits of digital opportunities

- Implementing electronic Product Information (ePI) as a tool **to complement but not to replace** to current printed leaflets, whilst providing an adequate framework to guarantee appropriate implementation and monitoring of the EMA-HMA-EC key principles of electronic product information for human medicines in the EU.
- Exploiting the potential of real-world data for regulatory decision making and Health Technology Assessment (HTA) through adequately including and rewarding evidence generation in community pharmacies at national level which can help to evaluate effectiveness, safety, off-label use and therapeutic added value of medicines in practice.
- Promoting more coordination among key actors for integrated medicines development and post-authorisation, which involves pharmacy organisations.
- Supporting initiatives to stimulate the repurposing of off-patent medicines targeting an indication in an area where important public health benefits are likely to be achieved whilst ensuring that it does not lead to accessibility issues for patients using these medicines for the currently authorised indications.

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

- Promoting better coordination among EU countries on tools evaluating cost-effectiveness and added therapeutic value of new therapies, including HTA, and to ensure that pricing decisions taken by one EU country do not lead to negative impacts on patient access in another country
- Promoting the rational use of medicines through the adequate 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.

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), other excipients and basic chemical compounds 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:

- Developing innovative incentive/business models for new antimicrobials which could stimulate the development of new antibiotics whilst guaranteeing continued access to existing antimicrobial therapies.
- Developing 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 strongly supports the opportunity to address medicine shortages in the revision of the pharmaceutical legislation, since this critical issue 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.

A. EU level monitoring of (anticipated) medicine shortages

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 **continued central information collection and monitoring of (anticipated) shortages for medicines at EU level in close collaboration with HMA**, complementing existing national systems. We recommend building on existing national systems to report medicine shortages and to make these systems interoperable at EU level, allowing for a centralised monitoring by the EMA, Member States and European Commission. To facilitate the reliable exchange of medicinal product 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) in place, building on the single points of contact (SPOC) reporting systems developed during the COVID-19 pandemic. In this regard, we believe that the revision should specify the formal establishment and responsibilities of the single point of contact in marketing authorisation holders and national competent authorities for shortages reporting.

Community pharmacies could, where pharmacy-reporting systems are available or would become available in the future at national level, contribute to the collection of relevant information by NCAs on shortages in their country by reporting relevant signals on potential shortages such as unmet demands to national competent authorities. Several existing pharmacy-reporting systems across Europe², have demonstrated to be highly successful as a complementary tool to notifications from marketing authorisation holders (MAHs) to detect early warnings on anticipated shortages in real time and obtain a more complete picture of the incidence of medicine shortages at patient access level. Moreover, any information requested from pharmacies

can only be collected and managed by the NCAs and should not be shared with MAHs due to the commercially sensitive nature of this information. For pharmacies, data protection is a core element in the relationship based on trust and confidence with the patients.

² [PGEU Position Paper on Medicine Shortages](#) – examples include the Royal Dutch Pharmacists Association [Farmanco Platform](#), the French Chamber of Pharmacists [Dossier Pharmaceutique Ruptures](#), the Spanish General Pharmaceutical Council [CISMED platform](#), and the Portuguese National Pharmacy Association drug shortages database. To facilitate the development of such an EU-wide system, lessons could be learnt from pan-European projects on early detection of medicines supply problems such as the DHE Twinning, funded by the Union through Horizon Europe. This project, which involved pharmaceutical associations from France, Italy, Portugal and Spain demonstrates that this type of tool generates valuable information for authorities, with enormous potential to advance the early detection of supply problems. It also facilitates effective pan- European cooperation to mitigate the impact of supply problems.

We strongly believe that all types of medicines that become unavailable can be critical for patients who need them, and the serious impact of shortages on patients and healthcare professionals on a daily basis requires both a central EU monitoring of shortages and the coordination of Member States activities on the prevention and management of shortages.

At the same time, we urge to foresee **sufficient flexibility to Member States** and to ensure that the type of data requested from supply chain actors, including community pharmacies, is proportionate, justified and necessary. In this regard, we believe that the collection of stock level data for all marketed medicinal products from community pharmacies would only have a limited use for regulators to map the available supply of a given product in the market. Moreover, it is a system that can potentially become very complex. In PGEU's view, it is important to ensure that the effort to obtain a very comprehensive registration does not make the overall system unmanageable and thus unusable.

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 in short 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 making 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. More generally, **PGEU considers that both from a technical and from a governance point of view, the EMVS is not suitable for any secondary use.**

B. Improving communication and mitigation at national level to reduce the impact of shortages

The EU monitoring system 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 shortage³. 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.

³ Please refer to the PGEU Position Paper on Medicine Shortages which includes the results of the [PGEU Medicine Shortages Survey 2019](#)

C. Addressing the dynamics of the EU Single Market on medicine shortages

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 EU Member States such as Malta, Ireland and Cyprus, whose supply chains are typically interconnected with the UK.

Where requirements for creating additional buffer stocks in the supply chain are considered necessary and proportionate, for instance during health crises, it should be ensured that these will not be of such an extent that the general supply of medicines will be jeopardized within the country and/or affect the general supply of medicines in other countries.

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 additional challenges such as the necessary predictability and legal certainty for operators and stakeholders.

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 pharmaceutical legislation.

PGEU is also **supportive of introducing obligations to companies applying for an EU marketing authorization to place the medicine on the market of all Member States.**

An additional measure at national level to ensure greater access and availability of pharmaceuticals for patients is to 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. By ensuring that a wide range of medicines are available locally, close to the patient's home or place of work, the environmental footprint can also be reduced.⁴⁴ This has been demonstrated in a pilot study in Portugal, which evaluated the dispensing of hospital only medicines in the community setting and revealed that patients noted a highly reduced average travel time to the community pharmacy than to the hospital pharmacy. This study also showed that most patients stated that they walked to the community pharmacy, whilst a similar percentage of them reported that they drove their own car if they had to visit the hospital pharmacy.⁵

⁴ [PGEU Best Practice Paper on Green and Sustainable Pharmacy in-Europe](#)

⁵ [Outpatient Hospital only Medicines Dispensing: the Impact of the Community Pharmacies' Intervention](#)

Lastly, we believe that **pharmaceutical compounding** by community and hospital pharmacists should be further promoted at national level as a solution for unmet medical needs of small populations, where appropriate, as well as shortages of medicinal products for which there are no suitable alternatives available on the markets. In this regard, we believe that the **revision should confirm that the general pharmaceutical legislation does not apply to any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient** (commonly known as the magistral formula).⁶

2. Create an adequate regulatory framework which puts the needs of patients at the centre and harnesses the benefits of digital

A. Electronic product information

PGEU **supports the use of electronic Product Information (ePI) as a tool to complement but not to replace current printed leaflets.**⁷ Maintaining printed material bound up to the box addresses the paramount need for immediate and equal access to information crucial to minimise risks, regardless of the equipment and ease with technology.

Today, the package leaflet is widely used to complement information received from healthcare professionals for a very diverse group of citizens, including parts of the population with limited access to digital tools such as certain elderly citizens and people with limited financial resources. Due to its importance, it is crucial to ensure that at all times, product information is made universally and instantly accessible, both for prescription and non-prescription medicines. Indeed, in line with the ongoing work at EMA on risk minimisation measures, access to essential information (contra- indications, dosage, adverse effects, etc.) should not be weakened in any way.

The public consultation lists “Introduce rules on electronic product information to replace the paper package leaflet” as one of the surveyed measures to improve patient access to medicines across the EU. **PGEU strongly opposes any reference to the replacement of the paper leaflet by digital versions** as we believe that in primary care product information should always accompany each pack and be easily accessible to all patients and carers – also those with limited digital skills and limited access to digital tools and internet such as elderly patients and people with limited financial resources – at any point in time without the need for digital technology.

Here we would like to stress that within the **current regulatory framework – article 63 (3) of Directive 2001/83/EC**– Member States are, in case there are severe problems in respect of the availability of the medicinal product, **already able to grant a full or partial exemption** to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market.

PGEU does not consider that the replacement of paper leaflets within packages of medicinal products might eventually lead to a significant reduced impact on the environment. European community pharmacists anticipate that a significant percentage of patients would still need and/or prefer to access a paper package leaflet with their dispensed medication, including parts of the population which have limited digital skills and no guaranteed access to internet and/or digital devices to access ePI. In order to give access to paper product information for those patients who cannot access ePI, it is suggested by industry stakeholders that pharmacists and pharmacy teams could print the product information from

⁶ [ECJ C-276/15](#) - Hecht-Pharma GmbH v Hohenzollern Apotheke, Winfried Ertelt

⁷ [PGEU Position Paper on electronic product information leaflet](#)

pharmacies. In that scenario, it could be envisaged that over 400,000 community pharmacies in Europe would be requested to print a significant amount of paper package leaflets every day, with every paper package leaflet consisting of multiple pages of paper in A4 format with higher paper weight, noting that many patients are on multiple medications. In addition to causing serious workflow disruptions and delays in the delivery of medicines to patients, it would also place an unsustainable financial burden on pharmacies and a responsibility that is today a key regulatory obligation for pharmaceutical companies. Moreover, these leaflets would need to be printed in pharmacies via non-industrial printing techniques resulting in increased paper use per package leaflet to be printed as explained above.

European community pharmacists acknowledge that comprehension of the current patient information leaflet and its readability today can still be improved. We therefore call on the European Commission to **revise the current provisions⁸ on the content, structure and design of the paper package leaflet in Directive 2001/83/EC in close dialogue with key stakeholders such as patients and healthcare professionals**. Special attention should be drawn to the lessons learned from the European Commission PIL-S Study⁹ and the ongoing good practices from key stakeholders such as community pharmacists at national level to improve the information sharing on medicines.¹⁰

With regards to the implementation of ePI at EU level, we would like to reiterate that ePI is intended for the delivery of regulator-approved medicine product information only, and it should not be used by any means to **deliver promotional information**. It will be crucial that citizens, using the various technologies and applications to access ePI as an intermediate, will **be directed to independent sources** such as the official websites of EMA and/or national competent authorities.

Moreover, it needs to be ensured that **third-party applications do not store any personal information** linked to the request of accessing ePI for a specific medicine and that the appropriate **application of European and national data protection legislation**, should be guaranteed and closely monitored in these third-party applications or websites at all times. In this regard, any patient consent request must be explicit, clear, understandable and fully informed. Any form of patient tracing and profiling should be strictly prohibited.

B. Real-world evidence for regulatory decision-making

Real-world evidence (RWE), including based on real-world data generated in community pharmacies, could be of utmost importance to inform safety and effectiveness assessments of medicines in clinical practice since it may provide a more generalizable picture of treatment effects in the real world.¹¹

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-authorisation**. Within this process, we believe that pharmacy organisations should be included since pharmacists are key sources of, at the moment underused, real-world data which contribute to evidence-based regulatory decision-making, especially in post-marketing authorization, and public health policy.

⁸ Article 59 of Directive 2001/83/EC in combination with the EC Guideline on the readability of the labelling and package leaflet of medicinal products for human use (2009)

⁹ [European Commission report on package leaflets](#)

¹⁰ [PGEU Position Paper on electronic product information leaflet](#)

¹¹ [PGEU Position Paper on Digital Health](#)

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.

Lastly, we are also **supportive of initiatives to stimulate the repurposing of off-patent** medicines, targeting an indication in an area where **important public health benefits** are likely to be achieved. However, at all times **it needs to be guaranteed that repurposing of off-patent medicines does not lead to accessibility issues for patients using these medicines for the currently authorised indications** due to for example price increases or due to not adequately responding to the expected increase in demand.

C. Healthcare professional involvement in the EMA Management Board

In relation to amending Regulation (EC) No 726/2004, **we believe that Article 65 (1) addressing the composition of the EMA Management Board should be adjusted**. Today this specifies that “the Management Board shall consist of one representative of each Member State, two representatives of the Commission and two representatives of the European Parliament. In addition, two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations (...)”. We strongly believe that **“doctors' organisations” should be rephrased to “healthcare professionals' organisations”** to encompass also non-doctor organisations such as pharmacists' organisations.

Pharmacists' organisations are, thanks to their expert knowledge on medicines and their use among patients in daily practice, in an ideal position to contribute meaningfully to the objectives and tasks of the EMA Management Board, whilst continuing to ensure a good balance of expertise among representatives. Moreover, expanding the wording to “healthcare professionals' organisations would be in line with the wording of recital 18 of Regulation (EC) No 726/2004 where it is specified that the various bodies of the Agency should establish and develop appropriate contacts with the parties concerned, in particular representatives of patients and health-care professionals. In this regard, pharmacists' organisations have already contributed actively and meaningfully as a member or alternate of EMA scientific committees, including the Pharmacovigilance Risk Assessment Committee (PRAC).

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

PGEU welcomes¹² 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.

PGEU notes that launch prices of new medicines increased in some therapeutic categories, sometimes without commensurate health benefits.¹³ As a result, EU Member States adopted pure cost- containment policies which negatively affected availability of medicines¹⁴ and shifted the financial burden of the costs of medicines on patients. PGEU believes that **promoting better coordination among EU countries to ensure that pricing decisions taken by one EU country do not lead to negative impacts on patient access in another country** is an appropriate way the EU can help improve affordability of medicines for health systems.

¹² [Sustainability of health systems](#)

¹³ [OECD Pharmaceutical innovation and access to medicines](#)

¹⁴ [OECD Pharmaceutical pricing policies in a global market](#)

In order to design appropriate incentives for innovation, **EU cooperation should also be encouraged on tools evaluating cost-effectiveness and added therapeutic value of new therapies.** This includes Health Technology Assessment and cross-country efforts to define transparent criteria for pricing policies or to optimize the use of managed entry agreements. We also recognize that in recent years, a number of voluntary cross-country collaborations have been established on different areas, including on pricing and reimbursement and on the joint procurement of medicines. We believe these collaborations to be useful and successful experiences should be further promoted. Furthermore, PGEU considers that **the regulation of medicines prices should be operated through a mix of policy instruments and not only leveraging on a single pricing policy tool.** It is also desirable for Member States to carry out periodic review of pricing and reimbursement policies, conducting adequate policy evaluation, and taking into account any changing conditions in the pharmaceutical market and in the population.

Moreover, **generics uptake by community pharmacy should be incentivised** at national level to make medicines more affordable while rewarding community pharmacists for this important economically sustainable service. It is also important to increase patients access to specialty medicines at national level. 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, where possible, increases equity of access, reduces costs to patients and can improve monitoring and adherence.

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 minimise the risks related to using medicines. Examples of such services are adherence-focused new medicines services¹⁵, medicines use reviews¹⁶, implementation of validated clinical rules, common ailment¹⁷ and chronic disease management ^{18,19} services.

¹⁵ 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

¹⁶ 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

¹⁷ 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.

¹⁸ 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

¹⁹ 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

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 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 welcomes²⁰ 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 to ensure that systems are in place that encourage the prescription and dispensing of quantities of certain risk medicines in package sizes matching the duration of treatment as much as possible.

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

²⁰ [PGEU Best Practice Paper on Green and Sustainable Pharmacy in Europe](#)

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.

In order to help combatting antimicrobial resistance, we **support the development of innovative incentive/business models for new antimicrobials** which could stimulate the development of new antibiotics whilst guaranteeing **continued access to existing antimicrobial therapies**.

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**²¹. 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.

²¹ [PGEU Best Practice Paper on AMR](#)