



**PGEU GPUE**

*Pharmaceutical Group of European Union  
Groupement Pharmaceutique de l'Union Européenne*

## **Position Paper on Medicine Shortages**

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*The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 31 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.*

*PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.*

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## Executive Summary

The unavailability of medicines is on the rise in Europe and it has a tremendous impact on patients. Medicine shortages occur across all healthcare settings and involve both essential life-saving medicines and very commonly used drugs.

Community pharmacists are very concerned about this phenomenon, which can compromise patients' health. Moreover, pharmacies and pharmacists invest a lot of resources dealing with shortages which constitutes not only a financial burden but also a loss of opportunity to spend time with other patient-centred tasks and to improve the quality of care.

Today, community pharmacists still manage to ensure continuity of care and minimise the impact on their patients' health status in most cases. However, several barriers should be removed to further support community pharmacists in this key role, considering that the impact on practice is increasing every day.

PGEU calls for a number of coordinated actions that should be taken at different policy levels to reduce the burden of medicine shortages on the public, healthcare professionals and supply chain actors:

1. **Ensure availability:** All stakeholders and governments must *put patients' needs first* when developing business policies, national laws and strategies that can affect the timely and adequate supply of medicines. Equally, effective compliance with EU & national laws related to the public service obligations of supply chain actors needs to be assured.
2. **Widen professional competence:** The scope of pharmacy practice should be extended when medicines are in short supply, so pharmacists can use their skills and knowledge to better manage patient care and ensure continuity of treatment. Shared electronic communication tools offer opportunities for an effective and close collaboration with prescribers in order to ensure continuity of care and patient safety.
3. **Improve communication:** Effective communication frameworks between all medicine supply chain actors and national competent authorities should be set up to ensure that community pharmacists have timely information on a (foreseen) medicine shortage.
4. **Compensate financial impact:** The negative financial impact of medicine shortages on patients should be compensated through appropriate reimbursement and remuneration provisions. The resource investment by pharmacists and pharmacies should equally be recognized and valued.
5. **Develop effective governance systems:** A close collaboration between EU Member States and the European Medicines Agency (EMA) is needed especially to improve reporting, monitoring and communication on medicine shortages. At national level, more structural, timely and transparent collaboration models between supply chain stakeholders and national competent authorities must be developed in order to increase the efficiency and effectiveness of joint notification and assessment practices, and to empower pharmacists in reducing the impact on their patients.



# 1. Introduction

Medicines shortages are today one of the biggest barriers towards patients' access to medicines in Europe. Over the past years, the situation has worsened significantly<sup>1,2,3,4</sup>, leading to a high impact on patients.

Across countries and institutions, medicine shortages are defined through a range of diverging definitions<sup>5</sup>. Most of these definitions do not capture the full impact of the unavailability of medicines on patients, including the frequently occurring short-term unavailability of medicines, or are due to their specific purpose (such as harmonising reporting criteria for marketing authorisation holders) not applicable for both supply and demand side.

For the purposes of this paper, the term “medicine shortage” covers *every (temporally) inability for a community or hospital pharmacy to supply patients with the medicinal product requested as a result of factors beyond their control, requiring the dispensing of an alternative agent or even discontinuation of an ongoing medical therapy*. It should also be noted that equally for medical devices, shortages occur and can strongly impact patient care.

PGEU has conducted an annual survey for a number of consecutive years to evaluate the progression of medicine shortages in Europe and to understand their impact on the community pharmacy practice. The 2019 survey results showed that **all responding countries experienced medicine shortages** in community pharmacies in the past 12 months, and in the vast majority (87%) of countries respondents indicated that the **situation got worse** compared to 2018. For instance, in Portugal, the National Association of Pharmacies (ANF) reported in 2018 a 32.8% increase of medicines short in supply when compared to 2017.

These shortages occur across all healthcare settings and involve both essential life-saving medicines and very commonly used medicines such as ibuprofen<sup>6</sup>. The European Association of Hospital Pharmacists' 2018 Medicine Shortages Survey has highlighted that in the hospital setting, medicine shortages have become more problematic in recent years and offer a high burden on patients and pharmacy practice<sup>4</sup>. Ultimately, patients and consumers are the ones affected by medicine shortages. The unavailability of a medicine causes inconvenience and distress to the patient, but worse, may negatively affect health outcomes.

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<sup>1</sup> <https://nos.nl/artikel/2267384-weer-meer-medicijnen-niet-leverbaar.html>

<sup>2</sup> [https://www.rtf.be/info/societe/detail\\_les-pharmaciens-tirent-la-sonnette-d-alarme-une-grosse-penurie-de-medicaments?id=10062023](https://www.rtf.be/info/societe/detail_les-pharmaciens-tirent-la-sonnette-d-alarme-une-grosse-penurie-de-medicaments?id=10062023)

<sup>3</sup> <https://www.bbc.com/news/health>

<sup>4</sup> EAHP's 2018 Survey on Medicines Shortages to improve patient outcomes, available from: [http://www.eahp.eu/sites/default/files/report\\_medicines\\_shortages2018.pdf](http://www.eahp.eu/sites/default/files/report_medicines_shortages2018.pdf)

<sup>5</sup> De Weerd, Elfi et al. “Toward a European definition for a drug shortage: a qualitative study.” *Frontiers in pharmacology* vol. 6 253. 30 Oct. 2015, available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4626567/>

<sup>6</sup> <https://www.apotheke-adhoc.de/nachrichten/detail/markt/ibuprofen-jetzt-wird-kontingiert/?platform=hootsuite>



Results of a survey<sup>7</sup> run by the French patient organisation France Assos Santé showed that 25% of respondents had already been denied supply to a medicine because of a shortage. 45% of these impacted respondents had to delay, change or stop treatment, which 21% found distressing. Consequences included aggravation of symptoms (14%), errors when taking an alternative medicine (4%) and even hospitalisation (4%).

If a prescribed medicine is not available, the patient may be given an alternative, which in some cases is not adequate and may be more expensive. Where there are no alternatives available, and the patient does not receive his/her treatment, the outcome may be fatal. Ultimately, patients may lose confidence in the health system. The root causes of the problem are diverse and complex, but **medicine shortages generally are the result of different economic, manufacturing or regulatory causes**<sup>8</sup>, such as:

- The increasingly globalised nature of pharmaceutical manufacturing, including Active Pharmaceutical Ingredients (API), with production concentrated in fewer sites distributed around the world;
- Shifts in demand, resulting from longer term factors such as demographic change, but also short-term factors such as tendering of medicines leading to difficulties in providing sufficient quantities of medicines for some markets;
- Pricing strategies, both low and high, and regulatory changes that in some cases may have an impact on supply;
- The imposition of fixed quotas of medicines by the pharmaceutical industry, often not sufficient in relation to patients' actual needs;
- The removal of the traditional role of the full line wholesalers as a result of Direct to Pharmacy (DTP) schemes in some markets;
- The abolition and ineffectiveness of public service obligation/minimum national stock keeping requirements in some countries;
- The lack of priority given to smaller markets;
- The effects of the European internal market dynamics (e.g. exports).

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<sup>7</sup> <http://www.france-assos-sante.org/sites/default/files/Penuries-medicaments-Resultats-BVA-dec2018.pdf>

<sup>8</sup> Addressing medicine shortages in Europe, a report by The Economist Intelligence Unit. Available from : <http://graphics.eiu.com/upload/topic-pages/medicine-shortages/Addressing-medicine-shortages-in-Europe-EIU.pdf>



## 2. Impact on community pharmacy practice

In 2018, pharmacy organisations in several European countries have raised attention to the problem of unavailability of medicines. For instance, its increasing occurrence in Belgium<sup>2</sup>, France<sup>9</sup>, the Netherlands<sup>1</sup>, Portugal<sup>10</sup> and the United Kingdom<sup>3</sup> has been covered extensively in national media in 2018 and has triggered a public debate.

Our 2019 Survey on Medicine Shortages highlighted that **pharmacists in Europe spend on average 6.6 hours/week on mitigating shortages**. This time is invested by pharmacists to ensure patients can continue treatments where possible and such a task is done without receiving any type of financial compensation. Time solving problems caused by shortages is time that pharmacists could better spend advising and caring for patients.

Pharmacists try to reduce the inconvenience for patients and the impact on their care to the absolute minimum. Especially, for essential and life-saving medicines, community pharmacists often ensure a minimum stock of a number of highly expensive medicines for an individual patient, taking the risk of not being able to dispense them anymore when unforeseen therapy switches occur.

Additionally, in some countries **medicine shortages are even resulting in a direct loss to pharmacists** caused by increased sourcing prices as a reaction to low availability of a certain medicine<sup>3,11</sup>.

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<sup>9</sup> <https://www.bfmtv.com/sante/penurie-de-medicaments-les-ruptures-de-stock-s-aggravent-1554956.html>

<sup>10</sup> According to data of the National Association of Pharmacies (ANF), in 2018 64.1 million cases of packs on shortage were reported, 32.8% more than in the same period in 2017.

<sup>11</sup> <https://psnc.org.uk/funding-and-statistics/funding-distribution/dispensing-at-a-loss/>



### 3. Solutions offered by community pharmacy

As highlighted above, searching for solutions to ensure continuity of treatment due to medicine shortages has become a daily activity of community pharmacists in Europe. However, the type of solutions community pharmacists can offer to patients differ between European countries as a result of national legislation and regulation.

For the purposes of this paper, we adopt the following definitions related to the scope of pharmacy practice:

- Generic substitution: *The practice of exchanging at pharmacy level one medicine instead of another with the same active substance, strength and pharmaceutical from another manufacturer, without consulting the prescriber.*

In the context of medicine shortages, this covers both the substitution from a branded drug to a generic drug, substitution from one generic drug to another generic drug, and the substitution from a generic drug to a branded drug in exceptional circumstances (e.g. branded drug is the only available alternative).

- Therapeutic substitution: *The practice of exchanging at pharmacy level one medicine instead of another with a different active substance and with the same therapeutic intent, in consultation with the prescriber and patient or in accordance with national/local protocols.*

Currently<sup>12</sup>, in most EU countries where therapeutic substitution is allowed in case of medicine shortages, it is done in consultation with the prescriber and patient. In early 2019, in the UK changes to legislation were started to permit the Government to use Serious Shortage Protocols (SSPs) in the event of a serious shortage of a medicine. These protocols would allow UK pharmacists to perform therapeutic substitution, amongst other options, as a solution to manage the medicine shortage<sup>13</sup>. Each protocol would set out precisely what action pharmacists can take, under what circumstances and for which patients.

- Therapeutic switching: *The decision by the prescriber to exchange one medicine for another with the same therapeutic intent.*

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<sup>12</sup> May 2019

<sup>13</sup> <https://psnc.org.uk/contract-it/brexit-and-community-pharmacy/serious-shortage-protocols-ssps/>



Depending on national rules, the most common solutions offered by community pharmacists are the following:

- Sourcing the same medicine from alternative authorised sources (e.g. other pharmacies where legally allowed or sourcing directly from manufacturers in case of contingency plans);
- Changing to the same medicine with a different strength when still available, and adjusting therapy posology accordingly;
- Generic substitution;
- Therapeutic substitution;
- Preparing a compounded formulation;
- Importing the medicine from a country where it is available and legally allowed.<sup>14</sup>

According to recent data<sup>15</sup> of the Royal Dutch Pharmacists Association (KNMP) Farmanco<sup>16</sup> platform, **community pharmacists in the Netherlands were able to ensure continuity of treatment for their patients in 99% of medicine shortages cases:**

- 62%: solution possible with medicine containing the same active substance (through sourcing from other pharmacies, substituting brand, pack size and/or dosage);
- 25%: therapeutic substitution in consultation with the treating physician;
- 10%: import from another country;
- 2%: preparing a compounded medicine.

**In several European countries, generic and/or therapeutic substitution by community pharmacists is still not legally allowed** to assist the patients in need, even if they have the appropriate professional skills and knowledge. In case of prohibition of generic substitution, pharmacists must contact the prescriber or even have to send patients back to their doctor asking for a new prescription in order to dispense alternative medicines. Due to the high frequency of these requests, this offers an additional high burden on pharmacists and patients, and results in practical frustrations when, for instance, a prescriber cannot be reached immediately. In countries where generic and/or therapeutic substitution is allowed, **it is crucial that pharmacists have access to sufficient information** (e.g. through shared electronic patient/medication records) to make well-informed decisions in case of medicine shortages. Vice versa, it is **equally important that pharmacists share any information on a therapeutic substitution/switch with the prescriber** so that **continuity of care** is ensured as part of a shared decision-making process. Systems should also be in place so that prescribers are better informed on existing medicine shortages and, consequently, can immediately prescribe an alternative medicine for their patients.

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<sup>14</sup> the authorisation to import a foreign medicinal product with the same composition than the affected medicinal product in exceptional circumstances. This can include the approval of the exemption to certain labelling and package leaflet obligations.

<sup>15</sup> <https://farmanco.knmp.nl/tekorten-in-cijfers>

<sup>16</sup> <https://farmanco.knmp.nl/>



## 4. Communication within the Supply Chain

An additional source of frustration among community pharmacists is the **lack of communication about the shortage, its severity, potential alternatives and how long it will take to be resolved**. This information, if provided in a timely and efficient manner, would allow pharmacists to serve their patients better and plan their practice and stock accordingly.

Together with the European associations representing manufacturers of medicinal products, parallel distributors, pharmaceutical wholesalers, industrial pharmacists and hospital pharmacists, PGEU has addressed the issue of communication in the **2017 Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages**<sup>17</sup>. The recommendations call for greater transparency and availability of medicine shortage data, early detection and assessment of potential shortages, consistency of reporting, increased access to the information available across all parts of the supply chain, improved data infrastructure, and collaborative governance processes.

At the same time, pharmacists often experience or foresee supply difficulties before the industry or wholesalers are aware that there is, or will be, a problem. **Reporting systems should therefore be open to reports from all medicine supply chain stakeholders (including community pharmacists)**, with reference to the origin of reports of suspected shortages. 'Signals' of medicine shortages can then be periodically assessed by the national competent authority (NCA) to see if signals anticipate potential shortages or reflect actual shortages.

For example, in Ireland, the key stakeholders mentioned above have worked with the Health Products Regulatory Authority (HPRA) to produce a Medicine Shortages Framework<sup>18</sup> and medicines shortages are notified to all stakeholders by e-mail weekly and through the HPRA website<sup>19</sup>.

In France, supply chain actors (manufacturers, wholesalers, community and hospital pharmacists) can notify shortages experienced at their respective level, both top-down and bottom-up through the electronic 'DP-Ruptures' system<sup>20</sup>. This automated system, developed by the French Chamber of Pharmacists, also connects the French Medicines Agency ANSM allowing for efficient exchange of information with supply chain stakeholders.

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<sup>17</sup> 2017 Joint Supply Chain Actors Statement on Information and Medicinal Products Shortages available from: <https://pgeu.eu/en/component/attachments/attachments.html?task=attachment&id=4468>

<sup>18</sup> HPRA Medicinal Product Shortages: a framework for a multi-stakeholder approach to handling shortages of human medicinal products. Available from: <https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/adv-g0020-medicines-shortages-framework-v2.pdf?sfvrsn=4>

<sup>19</sup> <https://www.hpra.ie/homepage/medicines/medicines-information/medicines-shortages>

<sup>20</sup> <http://www.ordre.pharmacien.fr/Le-Dossier-Pharmaceutique/Ruptures-d-appvisionnement-et-DP-Ruptures>





## 5. Role of public authorities

The European dimension to the issue of medicine shortages has been acknowledged by both national authorities and EU institutions. In 2016, the European Medicines Agency (EMA) and the Head of Medicines Agencies (HMA) created an **HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use** to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability. In August 2018, the new EMA/HMA Taskforce published its new work programme aiming to tackling the problem from three critical angles: marketing authorisation, supply chain disruptions and communication.

PGEU welcomes a **close collaboration between EU Member States and the EMA** and sees particularly opportunities in **improving reporting, monitoring and communication on medicine shortages**. A comprehensive EU communication strategy on shortages could ensure that information to healthcare professionals and the public on medicine shortages is universally accessible across Europe.

Today, across EU member states there are still too many differences in information provision on medicine shortages to key stakeholders such as pharmacists<sup>21</sup>. Results of a 2018 European Commission survey<sup>22,23</sup> have highlighted the **heterogeneous transposition by EU Member States of Article 23a of EU Directive 2001/83/EC<sup>24</sup>**, which states that in case of foreseen disruption of a medicinal product's supply (temporarily or permanently), the marketing authorisation holder shall notify the competent authority of the respective Member State no less than two months prior to the supply interruption.

Additionally, the survey responses<sup>20</sup> have shown **varying practices in regards to sharing this obligatory notification information to pharmacists**, with some countries making this information accessible to pharmacies, others requiring MAH to communicate directly to pharmacies, and finally highlighting countries that have no clear communication strategy to pharmacists at all.

In response to this issue, in several European countries, pharmacy associations have pro-actively developed tools for pharmacists that provide timely and effective information to support them in mitigating shortages for their patients, often in close collaboration with their national competent authorities.

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<sup>21</sup> Bochenek, Tomasz et al. "Systemic Measures and Legislative and Organizational Frameworks Aimed at Preventing or Mitigating Drug Shortages in 28 European and Western Asian Countries." *Frontiers in pharmacology* vol. 8 942. 18 Jan. 2018, doi:10.3389/fphar.2017.00942.

Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5779072/>

<sup>22</sup> [https://ec.europa.eu/health/sites/health/files/files/committee/ev\\_20180525\\_summary\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_summary_en.pdf)

<sup>23</sup> [https://ec.europa.eu/health/sites/health/files/files/committee/ev\\_20180525\\_rd03\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_rd03_en.pdf)

<sup>24</sup> [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir\\_2001\\_83\\_consol\\_2012/dir\\_2001\\_83\\_cons\\_2012\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf)



Examples are the Royal Dutch Pharmacists Association (KNMP) Farmanco Platform<sup>16</sup>, the French Chamber of Pharmacists (Ordre national des pharmaciens) Dossier Pharmaceutique Ruptures<sup>20</sup>, the Slovakian Chamber of Pharmacists (Slovenská Lekárnická Komora) drug shortages database<sup>21</sup>, the Spanish General Pharmaceutical Council (Consejo General) CISMED platform<sup>17</sup>, and the Portuguese National Pharmacy Association (ANF) drug shortages database<sup>17</sup>.

National competent authorities and the European Medicines Agency should use these best practices as examples for developing **structural, timely and transparent collaboration models with supply chain actors** in order to increase the efficiency and effectiveness of joint notification and assessment practices, and to empower pharmacists in reducing the impact on European patients.

Member States also have a strong responsibility in taking appropriate measures in relation to the **obligation of continuous supply by marketing authorisations holders and wholesaler distributors** as laid down in article 81<sup>25</sup> of EU Directive 2001/83/EC. Depending on the national situation and public service obligations laid down in national legislation, Member States have several policy levers to ensure compliance by supply chain actors, taking into account the dynamics of the EU internal market<sup>26</sup>.

Finally, as recommended by the European Parliament in its resolution on EU options for improving access to medicines<sup>27</sup>, Member States must also assess the **impact of parallel trade and supply quotas** and address the **withdrawal of effective medicines** from the market for **economic reasons**.

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<sup>25</sup> This article states that the holder of a marketing authorisation for a medicinal product and distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered

<sup>26</sup> Paper on the obligation of continuous supply to tackle the problem of shortages of medicines Agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018. Available from: [https://ec.europa.eu/health/sites/health/files/files/committee/ev\\_20180525\\_rd01\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_rd01_en.pdf)

<sup>27</sup> European Parliament resolution of 2 March 2017 on EU options for improving access to medicines. Available from : <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P8-TA-2017-0061&language=EN&ring=A8-2017-0040>



## 6. Recommendations

To effectively address the growing issue of medicine shortages in Europe, PGEU calls on the EU Institutions, Member States and supply chain actors to:

- 1. Ensure availability:** In developing business policies and national laws and strategies all stakeholders and governments must *put patients' needs first*. These strategies should first and foremost aim to ensure timely and adequate supply of medicines to patients. The full impact of policies aimed at reducing medicine prices on the supply and availability of medicines needs therefore to be taken into account by policy makers. Equally, appropriate measures need to be taken to ensure compliance with EU & national law related to the public service obligations by marketing authorisation holders and wholesaler distributors, taking into account the dynamics of the EU internal market.
- 2. Widen professional competence:** The scope of pharmacy practice should be extended when medicines are in short supply, so pharmacists can use their skills and knowledge to better manage patient care and ensure continuity of treatment. When a medicine is not available, pharmacists should be allowed to substitute 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. Shared electronic communication tools between pharmacists and prescribers (e.g. shared electronic health records) can enable this process effectively and safely.
- 3. Improve communication:** The following principles should be adopted by national and European competent authorities, when developing policies and communication strategies on shortages:
  - a. Ensure greater transparency and availability of medicine shortages data;
  - b. Encourage early detection and central assessment of potential shortages by connecting all medicine supply chain actors and NCAs at national level in consistent reporting systems;
  - c. Increase access to the information available across all parts of the supply chain.
- 4. Compensate financial impact:** The negative financial impact of medicine shortages on patients should be compensated through appropriate reimbursement and remuneration provisions. The resource investment by pharmacists and pharmacies should equally be recognized and valued.
- 5. Develop effective governance systems:** A close collaboration between EU Member States and the European Medicines Agency (EMA) is needed especially to improve reporting, monitoring and communication on medicine shortages. At national level, more structural, timely and transparent collaboration models between supply chain stakeholders and national competent authorities must be developed in order to increase the efficiency and effectiveness of joint notification and assessment practices, and to empower pharmacists in reducing the impact on European patients.