



PGEU Medicine Shortages Report 2023

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- » Each year PGEU conducts a survey among its members to map the impact of medicine shortages across Europe from the community pharmacists' perspective.
- » The 2023 Survey was open to [all PGEU member organisations](#) and has been conducted between 4 December 2023 and 17 January 2024.
- » A total of 26 PGEU members responded to the survey (1 response per country):

Countries that participated in the survey

	Austria		Ireland
	Belgium		Italy
	Bulgaria		Luxembourg
	Croatia		Netherlands
	Cyprus		Poland
	Czech Republic		Portugal
	Denmark		Romania
	Estonia		Slovakia
	Finland		Slovenia
	France		Spain
	Germany		Sweden
	Greece		North Macedonia
	Hungary		Norway

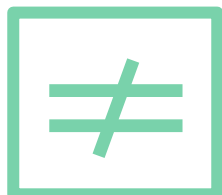
For the purpose of this report, the term “medicine shortage” covers every (temporary) inability for a community pharmacy to supply patients with the medicinal product requested as a result of factors beyond their control, requiring the dispensing of an alternative agent or even discontinuation of an ongoing medical therapy. Shortages of drug-device combinations were counted towards shortages of “medicines”. In terms of reporting/notification of medicine shortages, respondents were asked to apply their national definition, if available.



Key Findings



- » In 2023, medicine shortages continued to affect all European countries, and grew worse compared to 2022 in most countries.



- » Shortages of medical devices available in pharmacy continue to exist across all categories in various European countries, with significant differences across countries.



- » Pharmacists across the EU spend nearly three times as much time addressing shortages as they did a decade ago, amounting to almost 10 hours per week on average.



- » The burden of medicine shortages on patients and pharmacies across Europe has increased when compared to previous years, negatively impacting patients' trust in the pharmaceutical supply chain.



- » Despite community pharmacists' continued efforts, there are gaps in information, tools, and legal solutions available in many European countries, preventing them from effectively helping patients in case of a shortage.

Policy Recommendations

Community pharmacists are, in most cases, successful in minimising the negative impact of shortages on patients' health and ensuring continuity of care. However, to effectively address the growing problem of medicine shortages in Europe, **PGEU calls on policy makers** to adopt urgent, bold, and ambitious measures, namely:

- » **Ensure availability:** Governments and stakeholders must put patients' needs first when developing national laws and business strategies, respectively. These should first and foremost aim to ensure a timely and adequate supply of medicines to patients. These principles should apply also to the ongoing reform of the European pharmaceutical legislation, where patients' interests should prevail over commercial ones. It is also necessary to ensure effective compliance with EU and national laws related to the public service obligations of supply chain actors. Policy makers also need to consider the impact of pricing policies on medicines availability and on the security of the supply chain.
- » **Widen professional competence:** The scope of pharmacy practice should be extended when medicines are in short supply, so pharmacists can use their skills, knowledge, and experience to better manage patient care and ensure continuity of treatment. When medicines are 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 and/or in accordance with national protocols. Shared electronic communication tools between pharmacists and prescribers (e.g., shared electronic health records) can facilitate this process effectively and safely.
- » **Develop effective governance systems:** A close collaboration between EU Member States and the European Medicines Agency (EMA) is needed 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 to increase the efficiency and effectiveness of joint notification and assessment practices, and to empower pharmacists in reducing the impact on European patients.
- » **Improve communication:** It is vital to ensure greater transparency and availability of medicine shortages data. Effective communication, early detection and central assessment of potential shortages can be achieved by connecting all medicine supply chain actors and NCAs at national level in consistent reporting systems. This will ensure that community pharmacists have timely information on current and foreseen medicine shortages. It is also necessary to increase access to the information available across the supply chain.
- » **Compensate financial impact:** The resource investment by pharmacists and pharmacies to manage shortages must be recognized and valued.

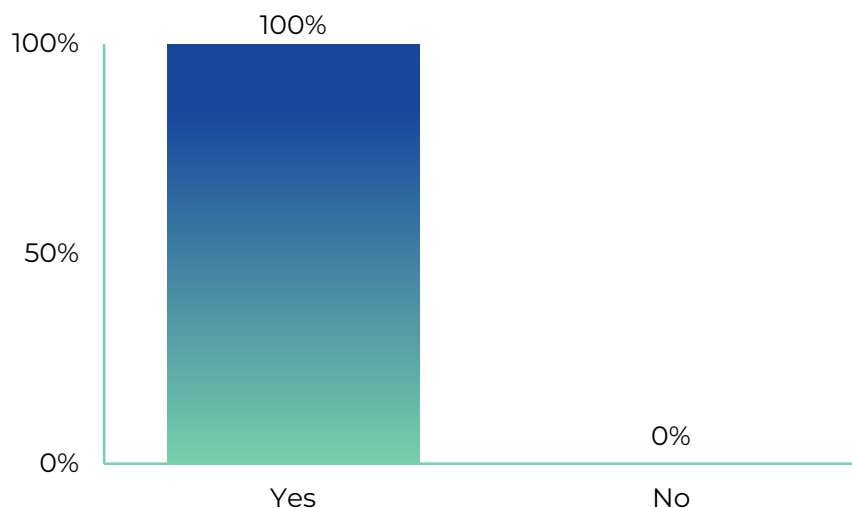
For more information please read the [PGEU Position Paper on Medicine Shortages](#).

Survey Results



Question 1. In the last 12 months, have you experienced shortages of medicines in community pharmacy in your country?

(% of responding countries)



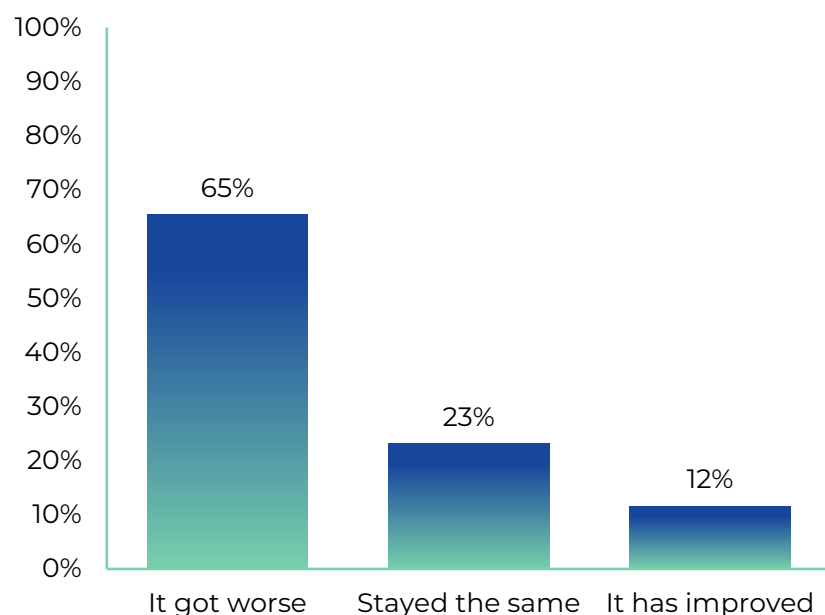
100% of responding countries (26) experienced medicine shortages in the last 12 months.



Since 2019, all surveyed countries have experienced shortages.

Question 2. If you have experienced shortages, how would you compare to the situation in the previous 12 months:

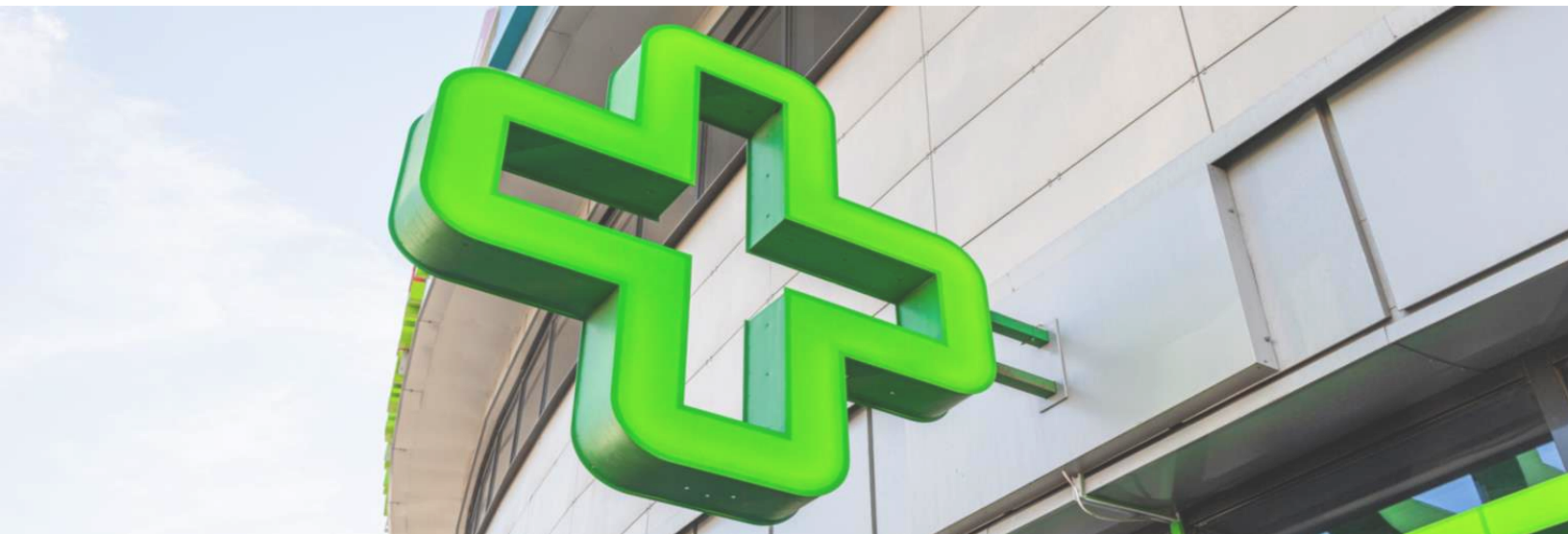
(% of responding countries)



Compared to the previous 12 months, in 2023, in 17 of the 26 responding countries the situation grew worse (65%) and stayed the same in 6 countries (23%). Only 3 countries, namely Cyprus, Greece and North Macedonia registered improvements when compared to the year before.



In 2022, 76% of the responding countries said the situation had gotten worse or stayed the same in 24% of the cases.



» Comments received:



Spain

Based on the Medicines Supply Information Centre (CISMED), there was an increase in 36% of medicine shortages compared to the previous year.



Ireland

According to the Irish Pharmacy Union shortages have significantly increased in the last year and pharmacists in Ireland do not receive sufficient advance warnings of shortages.



North Macedonia

In 2023 there was better forecasting and supply of medicines compared to 2022. The main reasons are a better organisation and improved management along the supply chain.



Portugal

The number of medicines in short supply communicated by pharmaceutical companies has increased in the last months. The number of medicines reported by pharmacies as being unavailable has increased by 47% compared with the same period of the last year, with 36,8% of these being generic medicines.



Sweden

Just in September 2023, 2.457 packages were reported to be in shortage to the Swedish Medical Products Agency, contrasting with 1.615 packages related to 2022. This increase is partially explained by the worsening of the situation but also due to an increased reporting from pharmaceutical companies.



Greece

The situation has improved from last year due to new regulations imposed by the government and an increase in local production for national distribution.



Netherlands

The number of medicine shortages in the Netherlands over 2023 was higher than other years – the KNMP information system Farmanco has registered 2.292 medicine shortages in 2023 (in comparison 2022 registered 1.514 medicine shortages). An impact analysis shows that 5 out of 13 million medicine users in the Netherlands have been affected by shortages.

Question 3. If you have experienced shortages in the last 12 months in your country, which medicine classes have been in short supply in community pharmacy?
(ATC Level 1, multiple answers per country, % of responding countries)

Medicines	Responding countries (%)
Anti-infectives for systemic use (antibiotics)	100%
Respiratory system	96%
Cardiovascular system	92%
Alimentary tract and metabolism	77%
Antineoplastic and immunomodulating agents	77%
Nervous system	77%
Musculo-skeletal system	69%
Vaccines	69%
Blood and blood forming organs	65%
Systemic hormonal preparations, (excl. sex hormones/insulins)	65%
Dermatologicals	62%
Genito-urinary system and sex hormones	62%
Sensory organs	62%
Various	58%
Antiparasitic products, insecticides and repellents	46%

Top 3

From those, the three classes of medicines most frequently in short supply were:



Anti-infectives for systemic use,
such as antibiotics
(84%)

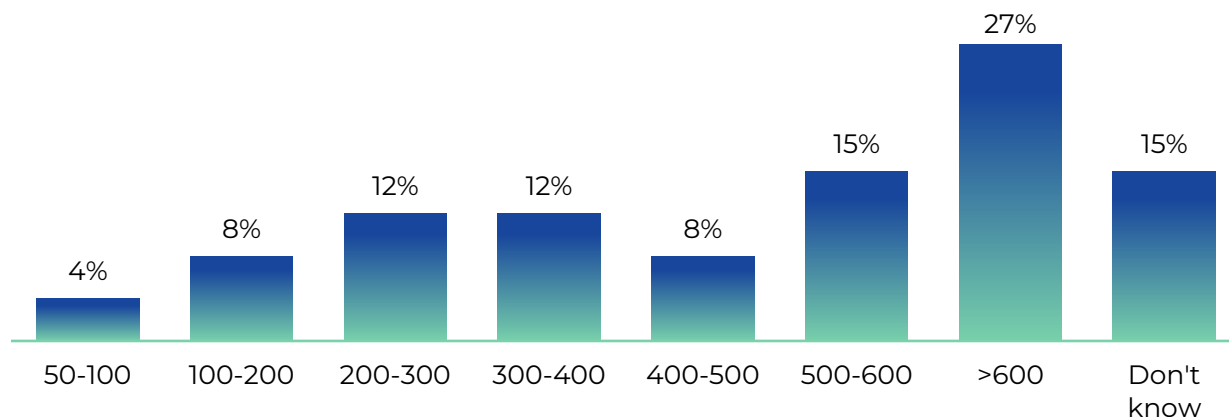


Nervous system (60%)

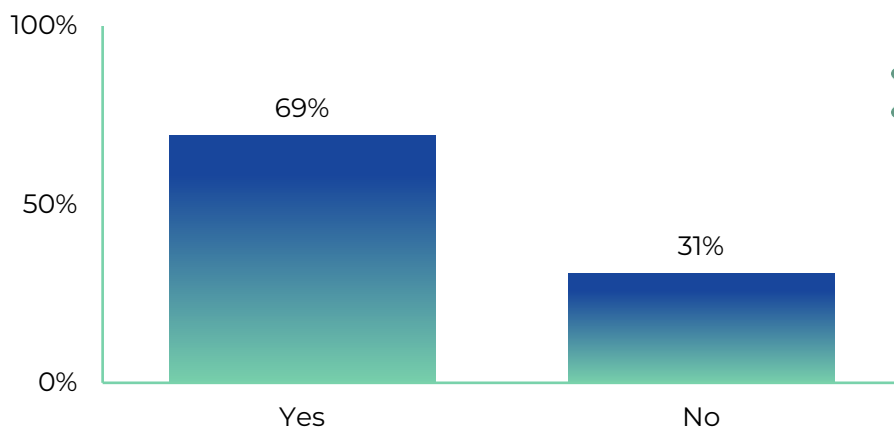


Cardiovascular system (56%)

Question 4. How many medicines are short in supply at the time of completing this survey? (according to your national definition of a medicine shortage if applicable)?
(% of responding countries)



Question 5. In the last 12 months, have you experienced shortages of medical devices in community pharmacy in your country?
(% of responding countries)



» 69% of responding countries experienced shortages of medical devices in community pharmacy in the last 12 months, which shows a slight increase from last year's situation (66%).

Question 6. If you have experienced shortages of medical devices in your country in the last 12 months, which types of medical devices have been in short supply in community pharmacy?
(EU Medical Devices Regulation classification, multiple answers per country)
(% of responding countries)

Medicines	Responding countries (%)
Class I (low risk - e.g. bandages, thermometers, surgical face masks)	27%
Class IIa (medium risk - e.g. lancets, needles, short-term contact lenses)	23%
Class IIb (medium to high risk- e.g. oxygen concentrator)	12%
Class III (highest risk - e.g. Contraceptive intrauterine devices)	12%
In-vitro diagnostics (e.g. self-tests)	15%
Other	23%

» Countries have experienced shortages across **all classes of medical devices**.

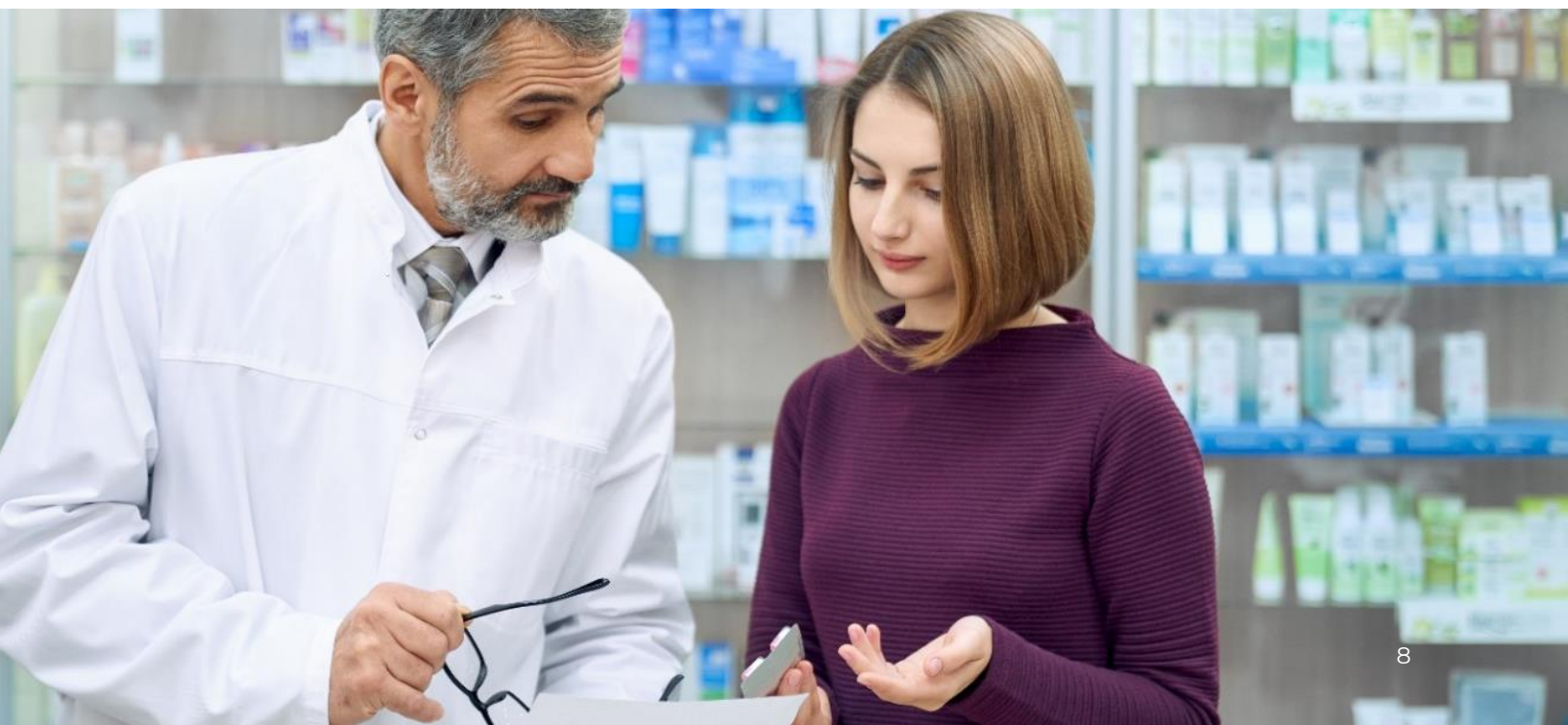
Only **two** countries mention that there is a **medical device shortage monitoring system** providing information to pharmacists.

» **Comments received:**



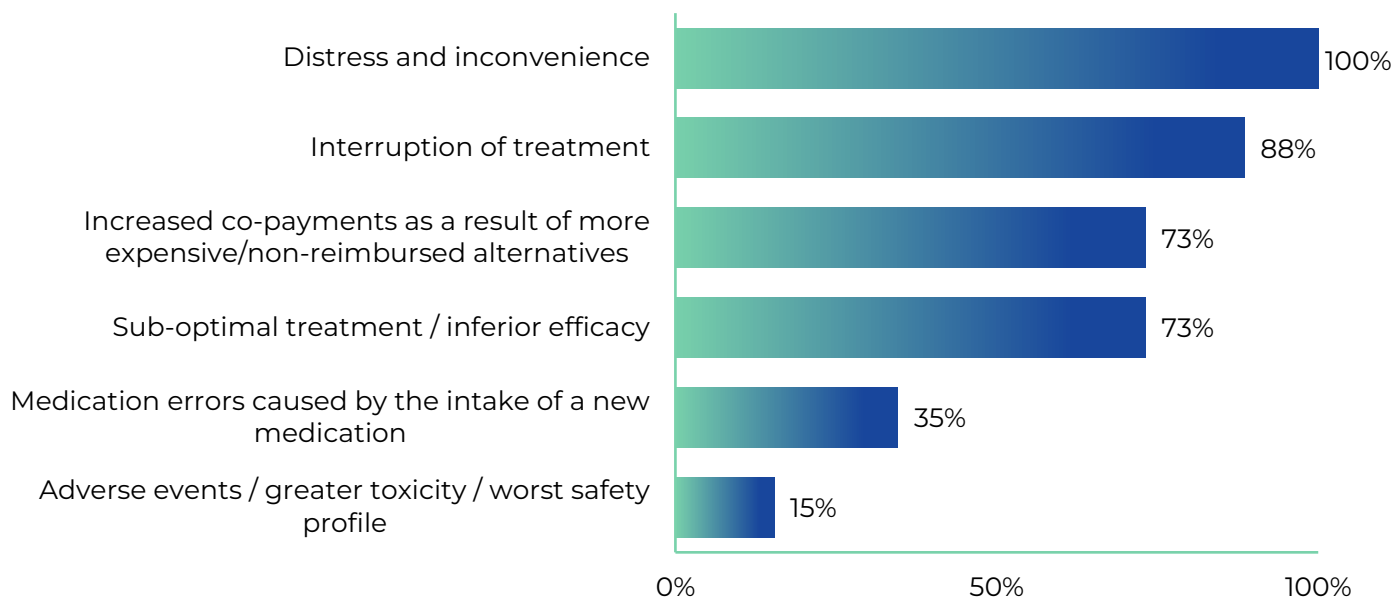
France

Shortages have impacted patients' quality of life. For example, due to shortages of glucose sensors for continuous monitoring, some patients had to revert to prick a finger several times a day to check their blood glucose levels.



Question 7. In your experience, how have medicine shortages adversely affected patients in your country?

(multiple answers per country, % of responding countries)

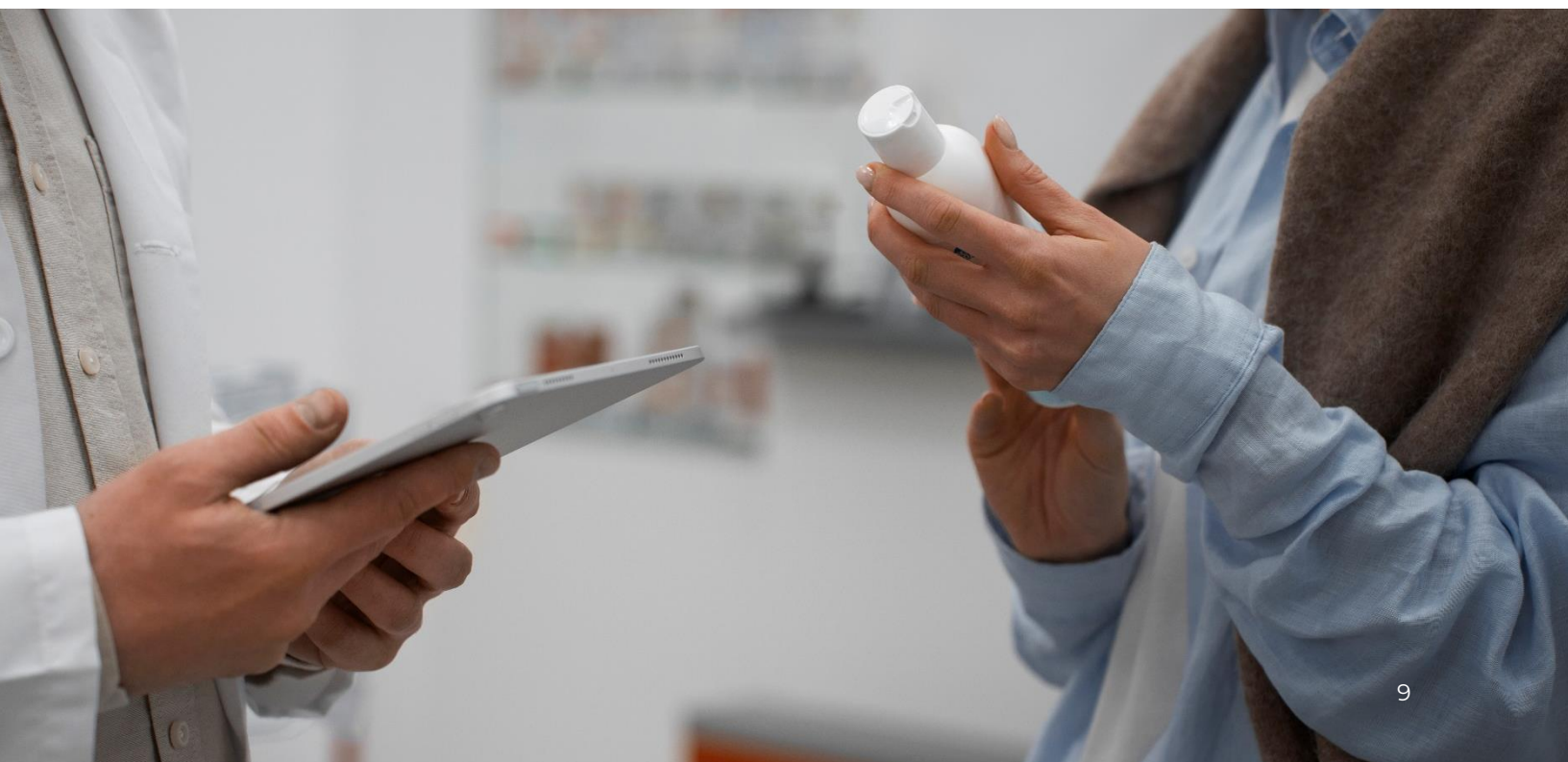


» Comments received:



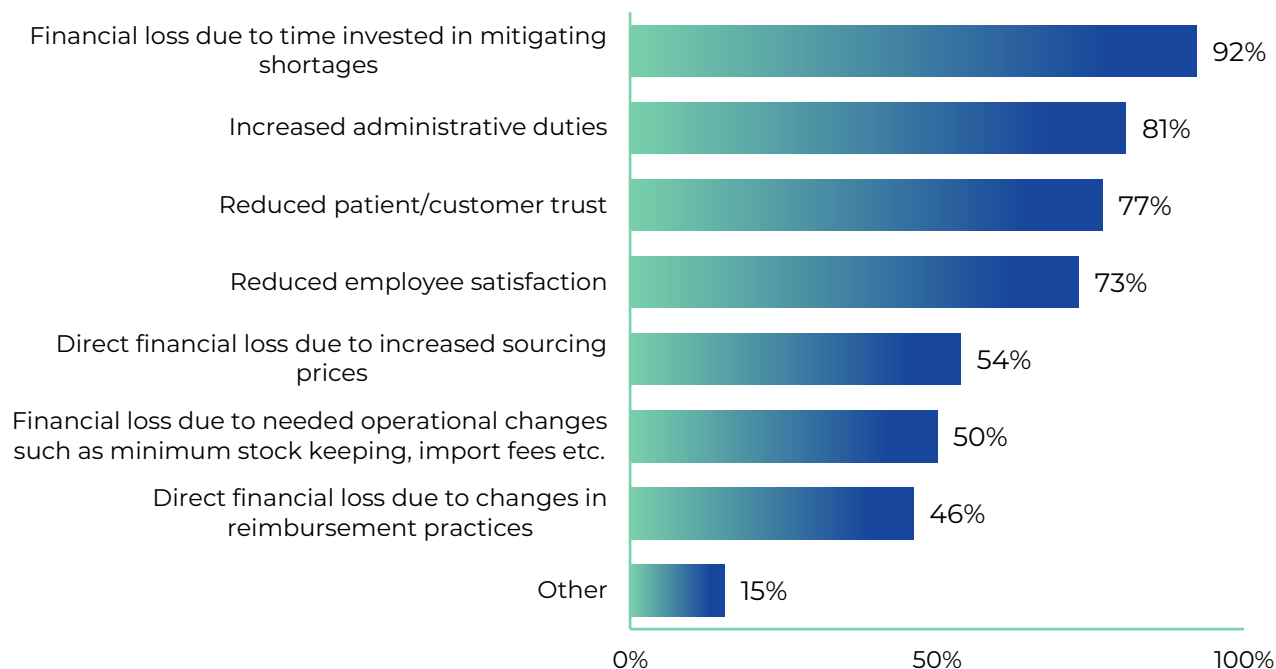
Slovenia

Patients have demonstrated progressively lower trust in medicines and in the supply system, due to the constant unavailability.



Question 8. In your experience, how have medicine shortages affected community pharmacies in your country?

(multiple answers per country, % of responding countries)



» Comments received:



France

In several cases pharmacists have experienced hostility and assaults from patients who do not understand why the medicine cannot be supplied immediately.

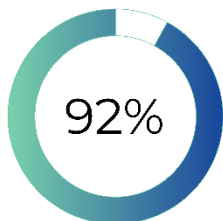


Ireland

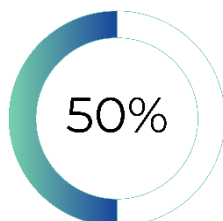
The workload in management of shortages and associated phone calls from patients is rising year after year, leading to increased stress in pharmacy staff and mental health issues.



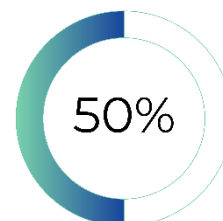
Question 9. Which solutions can legally be offered by pharmacists in case of a shortage?
(multiple answers per country, % of responding countries)



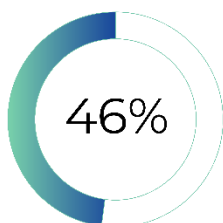
Generic substitution



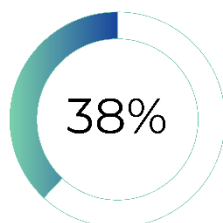
Preparing compounded
formulations



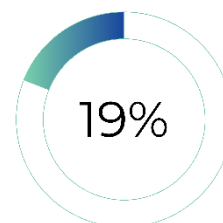
Therapy and posology
adjustment
(medicine available in different
strength)



Importing from EU/EEA
(when available in other countries)



Alternative sources
(other pharmacies, manufacturers)



Therapeutic substitution

» Comments received:



Bulgaria

Pharmacists can only do therapeutic and posology adjustments when the same medicine is available in a different strength. Any other solution is not permitted by law yet.



Spain

During the antibiotic shortages crisis in the beginning of the year 2023, pharmacists were granted regulatory flexibilities to compound paediatric formulations.



Denmark

Pharmacists have been strongly advocating for introducing increased substitution possibilities through shortages protocols like the ones introduced in the UK.



Netherlands

Pharmacists can only source a medicine directly from manufacturers, as sourcing it from other pharmacies is not permitted.

**Ireland**

There is an ongoing legislative process for a medicine shortage protocol that allows for therapeutic substitution by a pharmacist in limited circumstances where a medicine is in short supply. Normally a pharmacist liaises with the prescriber for an alternative medicine to be supplied, still requiring a new prescription.

**Belgium**

Sourcing medicines from other pharmacies is only permitted in exceptional circumstances when the continuity of treatment is at stake.

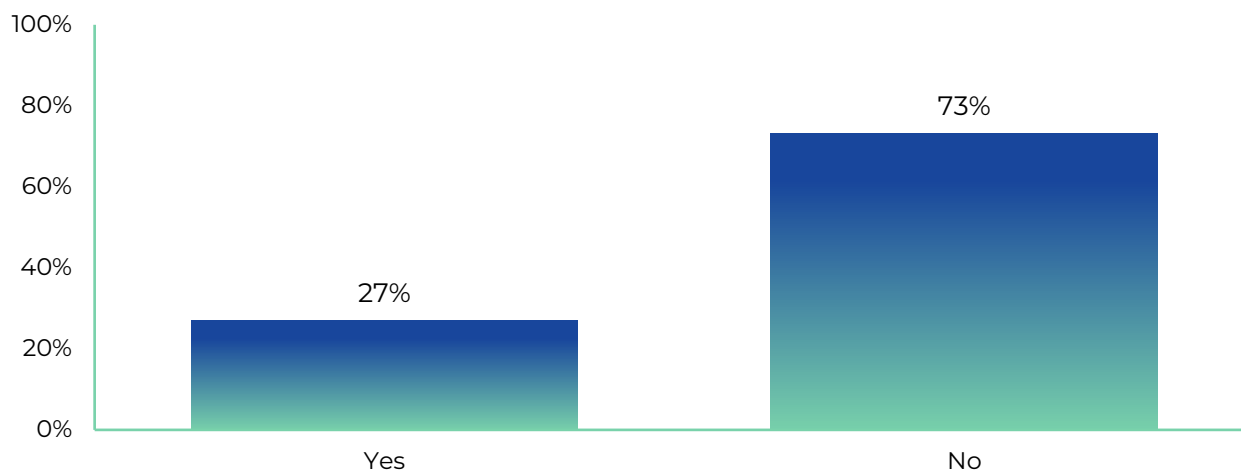
**France**

The Social Insurance 2024 Budget Law foresees a new formula called “special officinal formula” that can be produced by some community pharmacies specifically authorised to that effect, upon medical prescription, according to a monography published by the National Medicines Agency (pharmaceutical raw materials need to be supplied by a hospital pharmacy authorised for that activity).

**Norway**

After contacting the prescriber, pharmacists can provide a medicine with different strength and proceed with a therapeutic substitution. Pharmacists can dispense imported medicines when the Medicines Agency has approved these in special circumstances.

Question 10. Have you seen an expansion of the legal scope of pharmacy practice to manage shortages in your country over the last 12 months (including regulatory flexibilities, permanent or temporary)? (% of responding countries)



» Comments received:



Greece

A new regulation guarantees that a temporarily suspension of exports is imposed when a critical medicine is in short supply.



Portugal

The possibility for pharmacists to dispense medicines with a different dose, pack size and equivalent pharmaceutical form was recently introduced in the legislation.



Germany

Pharmacists have now a new legal basis to deviate from the medical prescription without consulting the prescribing doctor upon certain conditions defined by law in case of a shortage (e.g. package number and size, pack partial dispensing, strength).

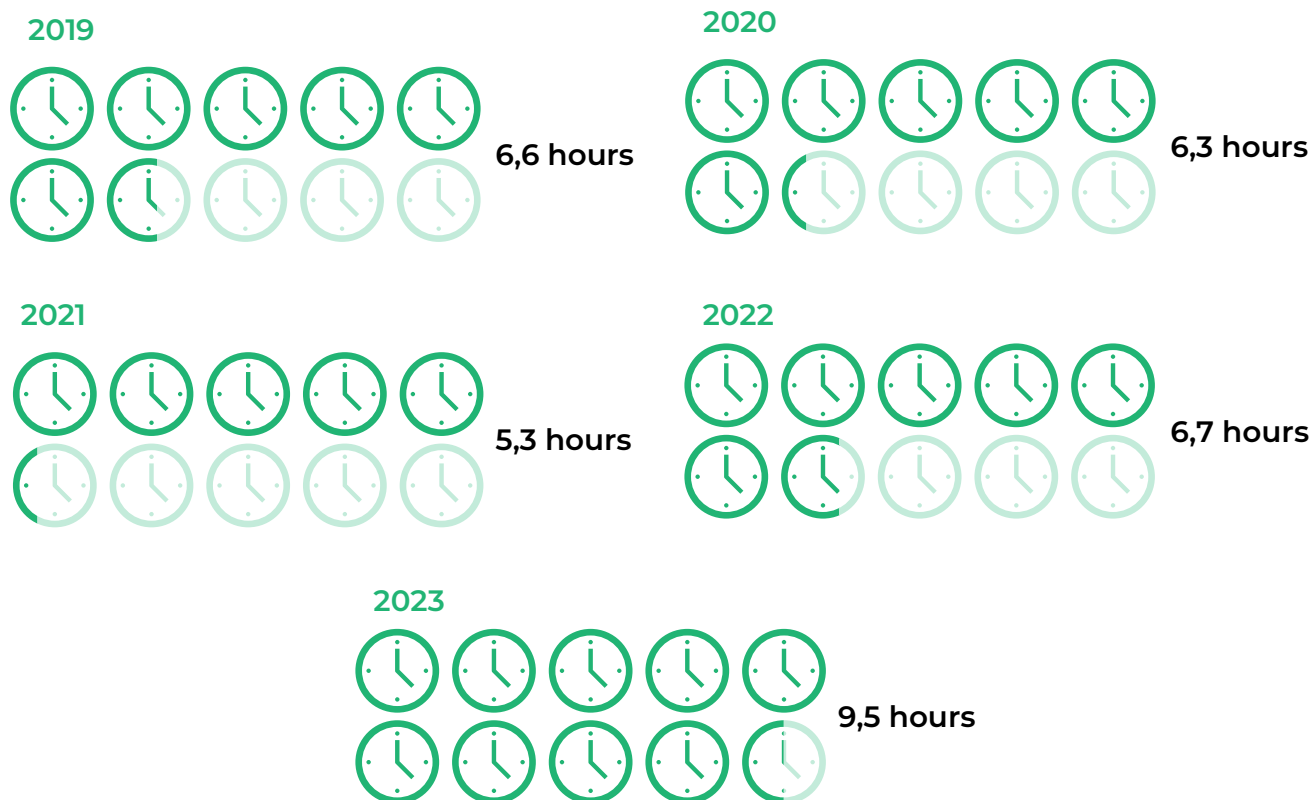


Spain

During the crisis of antibiotic shortages at the beginning of 2023, in order to supply paediatric amoxicillin oral suspensions pharmacists were allowed to dispense tablets, adjusting the dose to the child's needs, and provide information on how to take the medication. This was a temporary and exceptional expansion of the legal scope for substitution in community pharmacy authorized by the Spanish Medicines Agency last winter.

Question 11. On average, per week, how much time does pharmacy staff spend dealing with medicine shortages?

(time expressed in hours)



» Comments received:

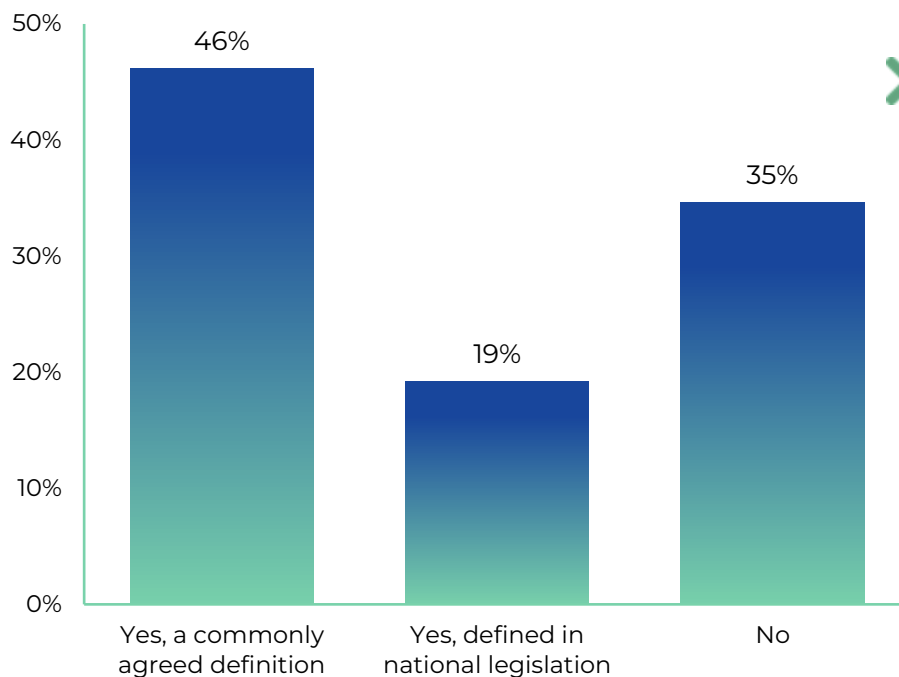


Netherlands

According to KNMP's survey among community pharmacies in the Netherlands, every pharmacy needs an equivalent of 1 Full Time Equivalent employee (FTE) just to manage medicine shortages, which includes time spent in finding alternatives to provide patients with appropriate medication.

Question 12. Is there a definition of medicine shortages in your country?

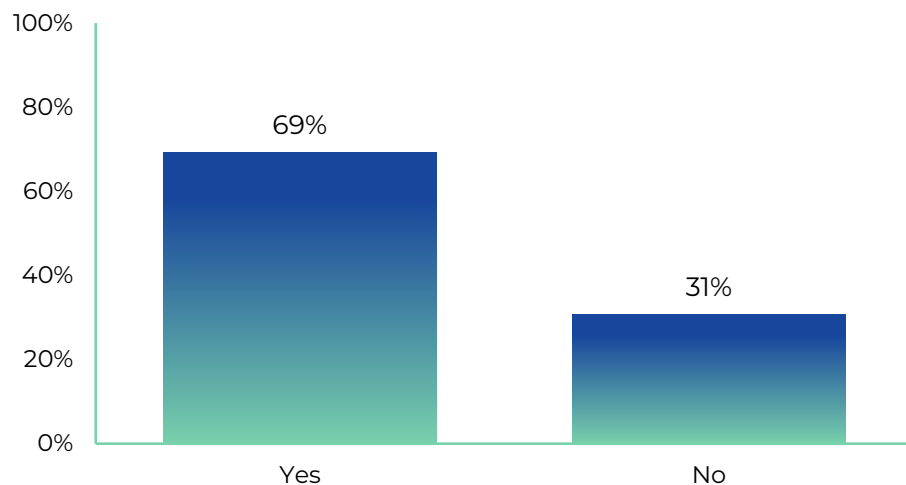
(% of responding countries)



» In 12 out of the 26 responding countries (46%) there is a commonly agreed definition of medicine shortages at national level, and in 5 countries (19%) the definition of medicine shortages is enshrined in the national legislation.

Question 13. Does your country have (a) reporting system(s) for shortages in place which can be used by community pharmacists?

(% of responding countries)

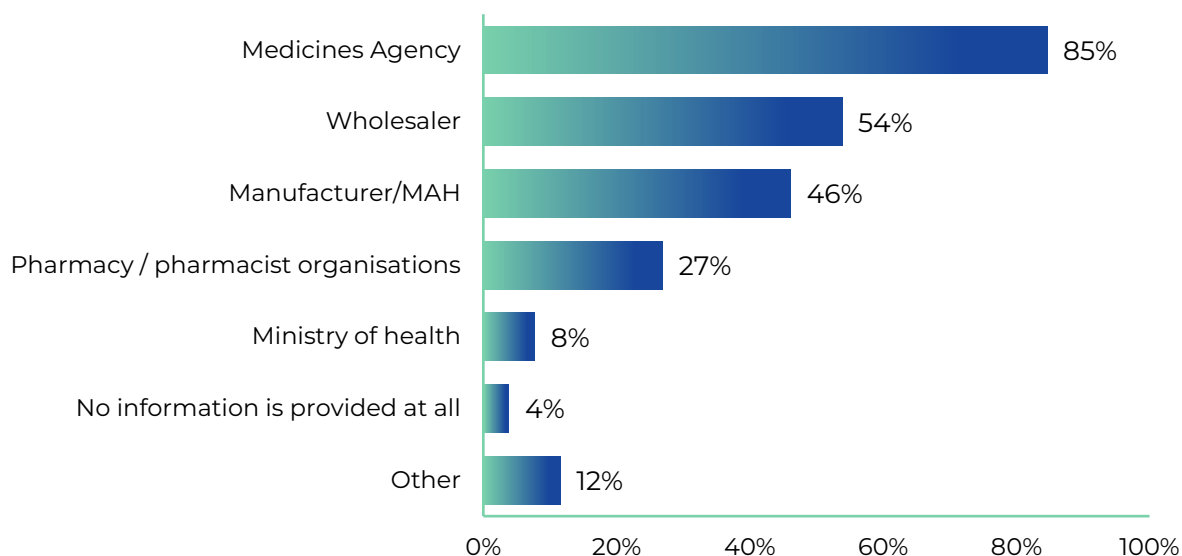


» In 18 out of the 26 countries surveyed (69%), there are reporting systems for shortages in place that can be used by community pharmacists.

Question 14. Who provides information on medicine shortages to pharmacists in your country?

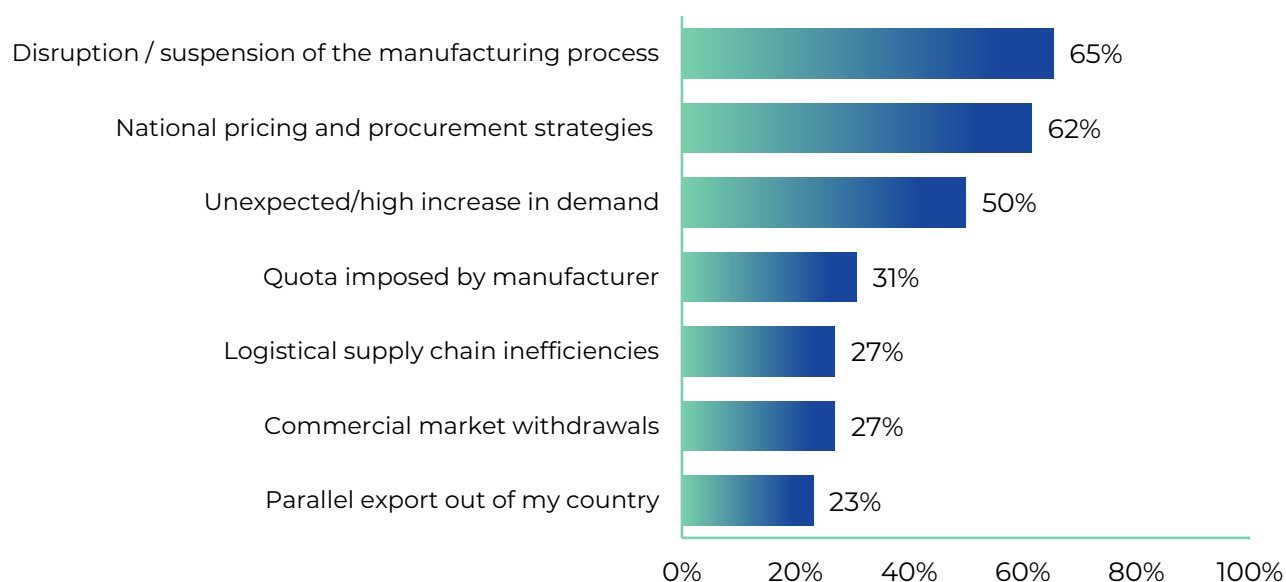
E.g. - How long medicines will be unavailable for? / Reasons for shortages

(multiple answers per country, % of responding countries)



Question 15. From your experience and daily practice, what have been the 3 most common causes of shortages in your country?

(multiple answers per country, % of responding countries)



Conclusion



In the last 12 months, **all countries that responded to the PGEU survey experienced medicine shortages in community pharmacies**. Similar to the previous year, a majority of these countries (65%) noted a deterioration in the situation compared to the preceding 12 months. In a few instances, the situation remained unchanged (23%), while a smaller percentage of countries reported positive improvements (12%).



Medicine shortages in community pharmacies have an **impact on every medicine class** across the countries surveyed - shortages of anti-infectives for systemic use (such as antibiotics) were experienced in all countries. Furthermore, **96% of the countries** registered shortages of medicines for the **respiratory** and **cardiovascular systems (92%)**. The most frequent medicines in shortage were anti-infectives for systemic use, medicines for the cardiovascular system, and medicines for the nervous system.



In a significant number of countries that participated in the survey (27%), the **list of medicines facing shortages exceeded 600** at the time of survey completion. When compared to data from the previous year, both evidence and feedback from pharmacists indicate a **worsening of the situation**, with an increasing number of countries reporting a larger number of medicines in short supply over the course of the year.



A total of **69% of the countries** that contributed to this year's study reported encountering **shortages of medical devices in community pharmacies**, reflecting a slight increase from the previous year's figure of 66%. These shortages span across all categories of medical devices. However, in **only 2 countries there are systems to monitor shortages of medical devices**, making it difficult to have a clear picture of the situation across Europe.



All responding countries indicated that they believe medicine shortages **cause distress and inconvenience to patients**. The most perceived consequences include **treatment interruptions** (reported by 88% of countries), **increased co-payments** due to more expensive or non-reimbursed alternatives (73%), and **suboptimal treatment with reduced efficacy** (73%). Notably, these percentages have shown an increase compared to the previous years.



In most of the countries (92%), community pharmacies are adversely affected by medicine shortages, leading to financial losses due to time invested in addressing shortages and **increased administrative responsibilities** (81%). Pharmacists also note negative effects such as **diminished patient trust** (77%) and **reduced employee satisfaction** (73%). Importantly, almost all of these percentages have shown an increase compared to the previous year.



On average pharmacies across the EU dedicated last year almost **10 hours per week to address medicine shortages**, a notable increase compared to previous years. This marks the highest recorded time in PGEU Medicine Shortages Surveys since their inception in 2013.



Available solutions to community pharmacists in the event of shortages vary significantly across European countries. **Generic substitution** (92% of countries), **preparing compounding formulations** (50%), and **adjusting therapy and posology when the same medicine** is available in a different strength (50%) are commonly permitted solutions in many European countries. However, it is worth noting that **some of these solutions may be subject to restrictions** (e.g. requiring a new prescription). Additionally, the implementation of these solutions can be cumbersome and time-consuming for both the patient and the pharmacist.



In 69% of the countries there are reporting systems for shortages in place that can be used by community pharmacists. In 31% of the countries, there is still no established reporting system for shortages that can be used by community pharmacists.

The main root causes for shortages pointed out by pharmacists are disruption/suspension of the manufacturing process (65%), national pricing and procurement strategies (e.g. tendering policies) (62%), and unexpected/high increase in demand of medicines (50%), such as in the case of paediatric formulations of antibiotics.



Only 46% of the surveyed countries have a commonly accepted definition of medicine shortages at the national level, with an additional 19% incorporating this definition into their national legislation. In 35% of the countries, there is no standardized definition for shortages. There have been positive developments in this area compared to last year's data, where 52% of responding countries reported a lack of a commonly agreed definition for medicine shortages in their respective countries.

About Us

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 33 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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