

Medicine Shortages

PGEU Survey 2022 Results



PGEU Medicine Shortages Survey 2022

- Each year PGEU conducts a survey among its membership to map the impact of medicine shortages across Europe from the community pharmacists' perspective.
- The 2022 Survey was open to [all PGEU member organisations](#) and has been conducted between 14th November – 31st December 2022.
- 29 PGEU members (1 response per country) responded to the survey:

Countries that participated in the survey

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



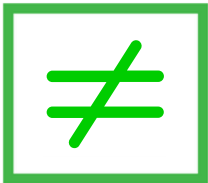
For the purpose of this survey, the term “medicine shortage” was defined as every (temporary) inability for a community or hospital pharmacy to supply patients with the medicinal product requested as a result of factors beyond their control, requiring the dispensing of an alternative agent or even discontinuation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



» Among the **key findings** of the survey are:



The continued high incidence of medicine shortages in most European countries, which worsened substantially compared to the last year in the majority of the countries.



The confirmation of occurring shortages of medical devices across all categories available in pharmacies, with stronger differences among countries.



The average time spent by pharmacists to deal with shortages has increased and reached a maximum compared with the last 3 years.



The daily and burdensome impact of medicine shortages on patients and pharmacy practice across Europe, which has deteriorated when compared to previous years.



The existing gap in needed information, tools and legal solutions available to community pharmacists in many European countries for providing solutions to patients in case of a shortage.

Policy Recommendations

To effectively address the growing problem of medicine shortages in Europe, **PGEU calls on policy makers** to adopt urgent, bold and ambitious measures, namely:

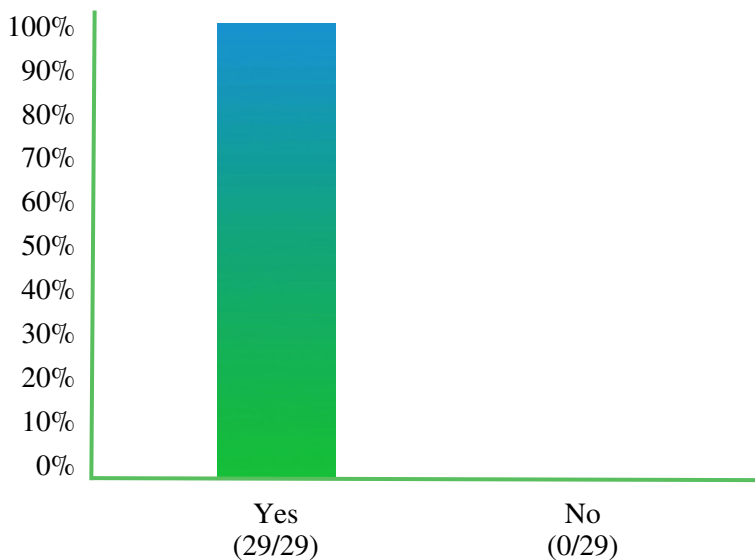
- **Ensure availability:** All stakeholders and governments must put patients' needs first when developing business policies, national laws and strategies that can affect the timely and adequate supply of medicines. Effective compliance with EU and national laws related to the public service obligations of supply chain actors needs to be assured.
- **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 guarantee continuity of treatment. Shared electronic communication tools offer opportunities for an effective and close collaboration with prescribers to ensure continuity of care and patient safety.
- **Improve transparency, reporting, monitoring and communication on medicine shortages**



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

Survey Results

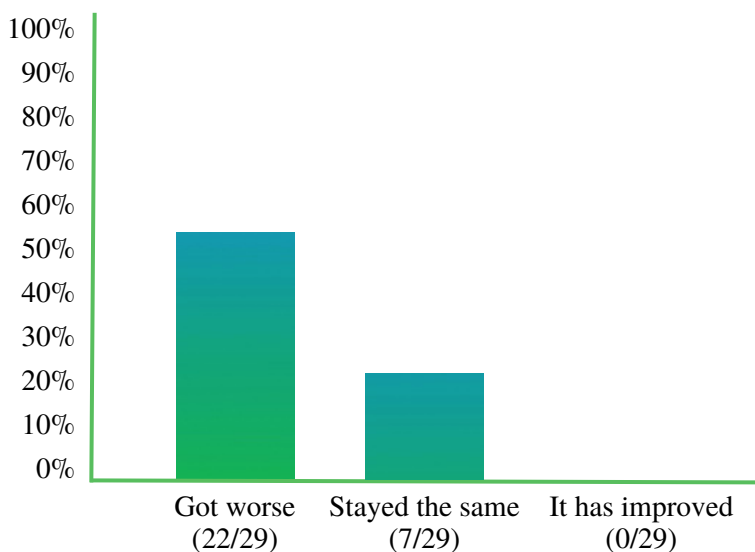
» **Question 1. In the last 12 months, have you experienced shortages of medicines in community pharmacy in your country?**
(% of responding countries)



» 100% of responding countries experienced medicine shortages in the last 12 months.

» In 2019, 2020, and 2021 medicine shortages were also experienced in all responding countries.

» **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 2022, in 22 of the 29 responding countries the situation has gotten worse (75,86%) and stayed the same in 7 countries (24,14%).

» In 2021, in 7 of 27 responding countries the situation has gotten worse (25,93%) and stayed the same in 14 countries (51,85%), and it eventually improved in 6 country (22,22%).

Survey Results



Comments received:



Belgium

The number of unavailable medicines is stable but there are more shortages of very commonly used medicines. The latter gives, especially at patient level, the feeling that the problem grows day by day.



Portugal

The number of medicines on shortage communicated by the marketing authorization holders has increased in the last few months. Also, the number of medicines reported by pharmacies as unavailable has increased by about 30% compared with the same period (September 2021 vs September 2022).



Ireland

The Irish Pharmacy Union keeps a medicines shortages list. Whilst in November 2021 there were 245 medicines shortages, in November 2022 there were 348 medicines shortages.



Spain

CISMED, the information system that allows community pharmacies to report medicine supply incidents, identified 140% more shortages than in the previous year 2021.

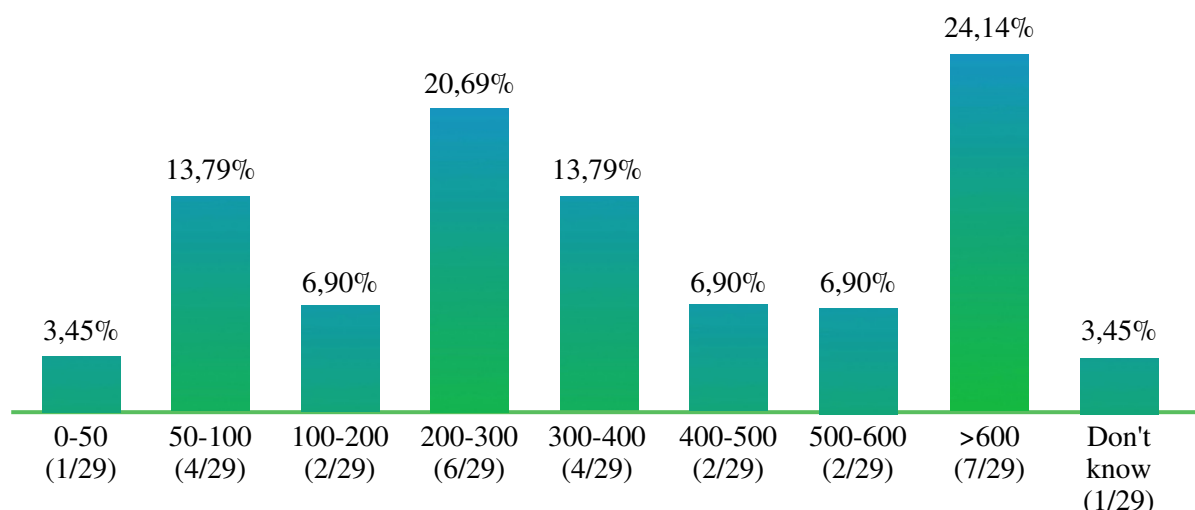


Survey Results

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

Medicines	Responding countries (%)
Cardiovascular medications	82.76%
Nervous system	79.31%
Anti-infectives for systemic use (e.g. antibiotics)	79.31%
Respiratory system	75.86%
Antineoplastic and immunomodulating agents	68.97%
Musculo-skeletal system	65.52%
Systemic hormonal preparations	65.52%
Dermatologicals	65.52%
Blood and blood forming organs	65.52%
Gastrointestinal medications	65.52%
Various	62.09%
Genito-urinary system and sex hormones	62.09%
Vaccines	55.17%
Sensory organs	55.17%
Antiparasitic products, insecticides and repellents	48.28%

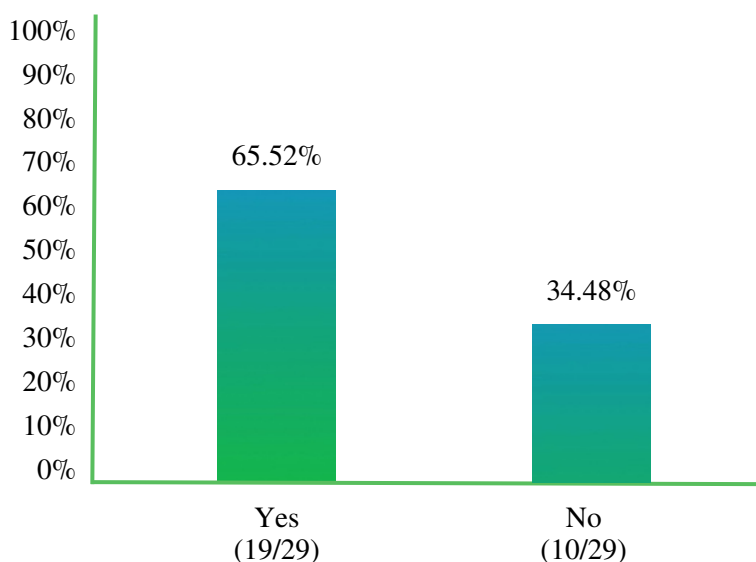
➤ **Question 4.** How many medicines are short in supply at the time of completing this survey? (according to your national definition of a medicine shortage if applicable)?^[1] (% of responding countries)



[1] The quantification takes into account the national definition of a medicine shortages in each responding country, which can show differences between them. The comparison of these numbers should therefore be interpreted as an indication rather than exact comparison.

Survey Results

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



- 65,52% of responding countries experienced shortages of medical devices in community pharmacy in the last 12 months.

- **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)

Medical devices	Responding countries (%)
N/A. There have been no medical devices shortages in my country in the last 12 months	13.79%
Class I (low-risk - e.g. bandages, thermometers, surgical face masks)	20.69%
Class IIa (medium-risk - e.g. lancets, needles, short-term contact lenses)	20.69%
Class IIb (medium to high-risk - e.g. oxygen concentrator)	13.79%
Class III (highest risk - e.g. contraceptive intrauterine devices)	6.90%
<i>In-vitro</i> diagnostics (e.g. self-tests)	17.24%
There is no medical devices shortage monitoring system	48.28%

Survey Results

» **Question 7. In your experience, how have medicine shortages adversely affected patients in your country?**
(multiple answers per country, % of responding countries)

93.10%

Distress and inconvenience
(27/29)

89.66%

Interruption of treatments
(26/29)

72.41%

Increased co-payments
(21/29)

58.62%

Sub-optimal treatment
(17/29)

34.48%

Medication errors
(10/29)

21.14%

Adverse events
(7/29)

13.79%

Death
(4/29)

» Comments received:



Denmark

In most cases the pharmacy is able to substitute to another medicine yielding equal effect. In severe cases the doctor's authorization is required to change the prescription which can cause inconvenience for the patient.



France

Cases have been recorded about patients taking duplicate doses of their medicine due to unavailability of their usual generic medicine and further dispensing of another equivalent generic medicine, which doesn't look the same, thus causing confusion and medication errors.



Finland

A case has been recorded of one patient who committed suicide due to not getting their psychiatric medication because of medicines shortage.

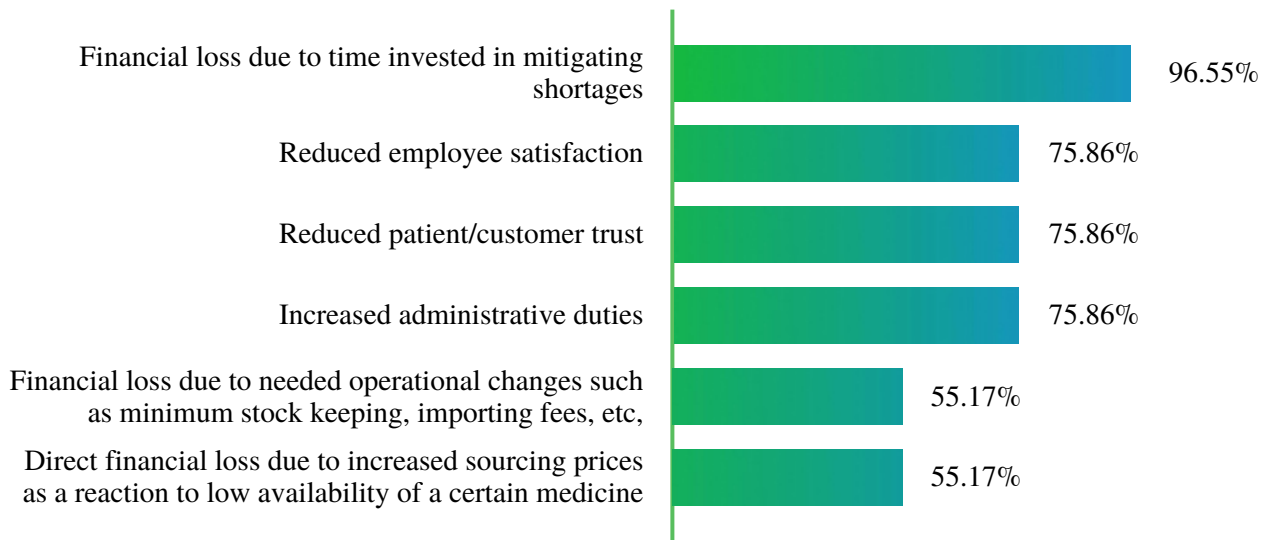


Spain

Problems have been observed with some medicines, namely those which cannot be substituted, inhalers for COPD or medicines for digestive and metabolic disorders. In addition, there have been unexpected supply disruptions of amoxicillin oral suspensions for paediatric use in the last weeks that have been turning into official supply problems.

Survey Results

» **Question 8. In your opinion, how have medicine shortages affected community pharmacies in your country?**
(multiple answers per country, % of responding countries)



» **Question 9. Which solutions can legally be offered by pharmacists in case of a shortage?**^[2]
(multiple answers per country, % of responding countries)

93.10%

Generic substitution
(27/29)

62.07%

Sourcing the same medicine from alternative authorised sources
(18/29)

62.07%

Preparing a compounded formulation
(18/29)

55.17%

Changing to the same medicine with a different strength
(16/29)

44.83%

Importing the medicine from another country
(13/29)

20.69%

Therapeutic substitution
(6/29)

[2] Importing the medicine from another country: 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 exemption to labelling and package leaflet obligations.

Survey Results



Comments received:



Austria

Generic substitution, preparing a compounded formulation, changing to the same medicine with a different strength when still available - adjusting therapy posology accordingly - and therapeutic substitution can only be offered after consultation with the prescribing doctor.



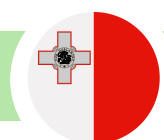
Germany

Most of the above-mentioned solutions can only be offered in coordination with the prescriber and potential changes to the prescription.



France

Sourcing directly from manufacturers is authorised, sourcing from other pharmacies is not. Changing to a different strength and posology is possible but only after agreement from the prescriber. Therapeutic substitution is possible according to guidelines issued by the Medicines Agency in case of shortage of critical medicines. Otherwise, the patient needs to come back to the pharmacy with a new prescription for the new treatment. Preparing a compounded formulation is possible in the form of a magistral formula with a prescription for a given patient. The compounded formulation is reimbursed only if the medicine is officially registered as unavailable (not just in short supply) on the website of the National Medicines Agency.



Malta

In some case the implementation of the above-mentioned solutions such as therapeutic substitution requires the agreement of the prescriber.



Sweden

Preparing a compounded formulation can only be done after a new prescription from the prescriber. Compound formulation is carried out by one major "ex tempore-pharmacy" delivering to all pharmacies. Importing from another country requires a special application to the Medical Product Agency and a new prescription.

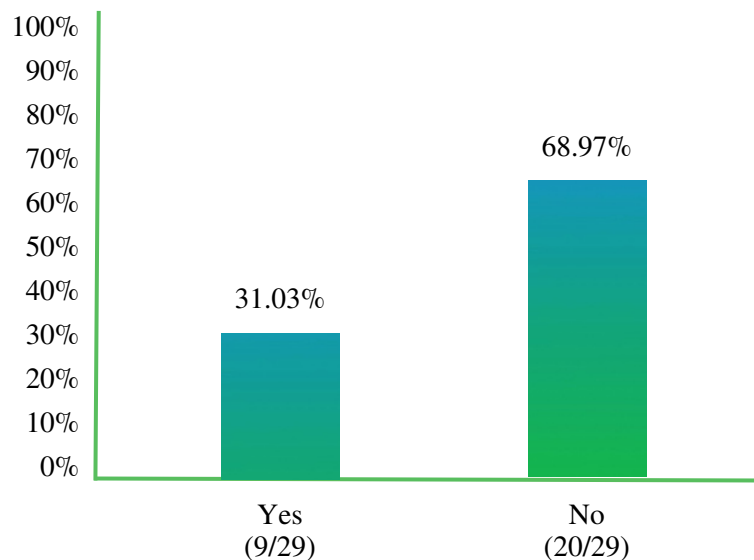


Spain

Following supply problems with paediatric amoxicillin suspensions during the last quarter of 2022, the Spanish Agency for Medicines and Medical Devices (AEMPS) has temporarily enabled pharmacists to substitute different dosage forms of amoxicillin (e.g. suspensions for tablets). This highlights the feasibility of this type of substitution and makes the pharmacist a key player in providing solutions to supply problems, informing patients about existing alternatives and how to correctly prepare and administer the substitution medicine to the child.

Survey Results

» **Question 10.** Have you seen an expansion of the legal scope of pharmacy practice to manage shortages in your country since the start of the COVID-19 pandemic (March 2020)?
(% of responding countries)



» Comments received:



New legislation has been introduced since COVID-19. It includes specific substitution rights for pharmacists, transparency rules of stock levels for marketing authorization holders and wholesalers, export bans in case of shortages.



Pharmacists have been given more options to deviate from the packaging size, number of packages or strength, in case the prescribed medicine is unavailable and to substitute it with a pharmacologically and therapeutically comparable medicine in order to reduce repeated patients' visits to the pharmacy and/or to the doctor's office.



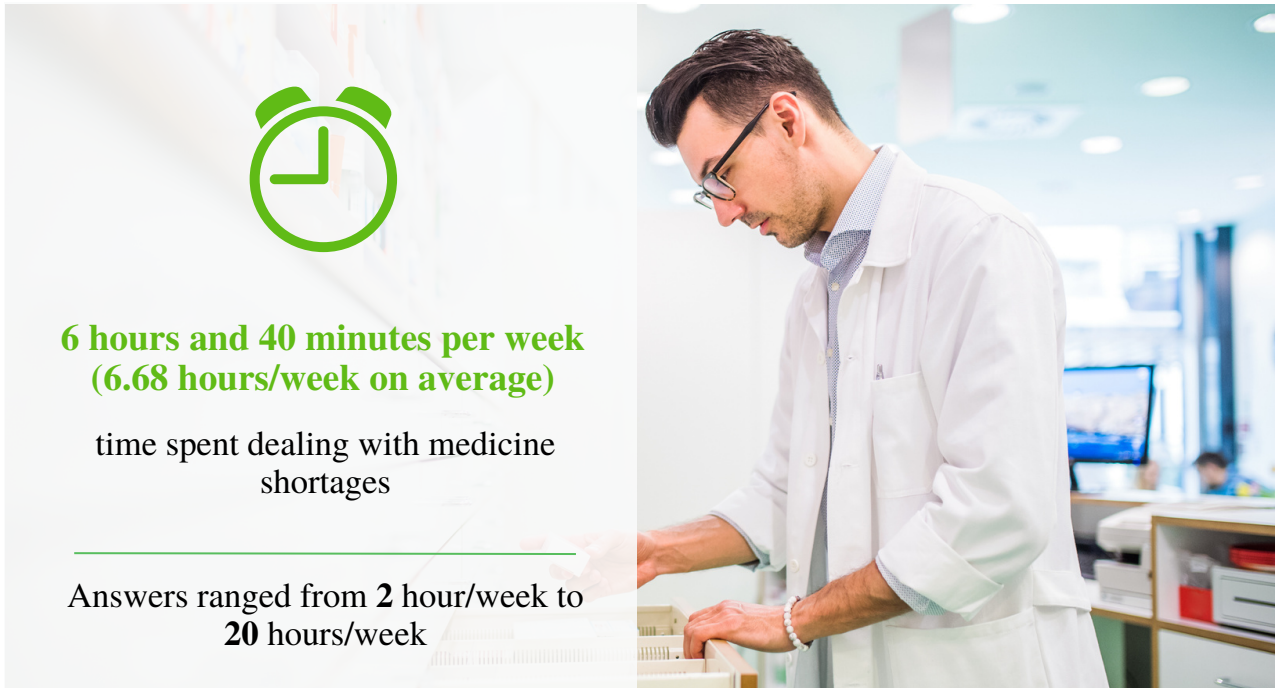
Pharmacies have been required to report stock status of all critical medicines every day. In addition, the Danish Medicines Agency has been given the right to redistribute medicines if deemed necessary.



In the case of substitution by pharmacists of paediatric amoxicillin suspensions by other dosage forms (tablets) or adaptations in electronic prescription systems for the correct implementation of such substitutions.

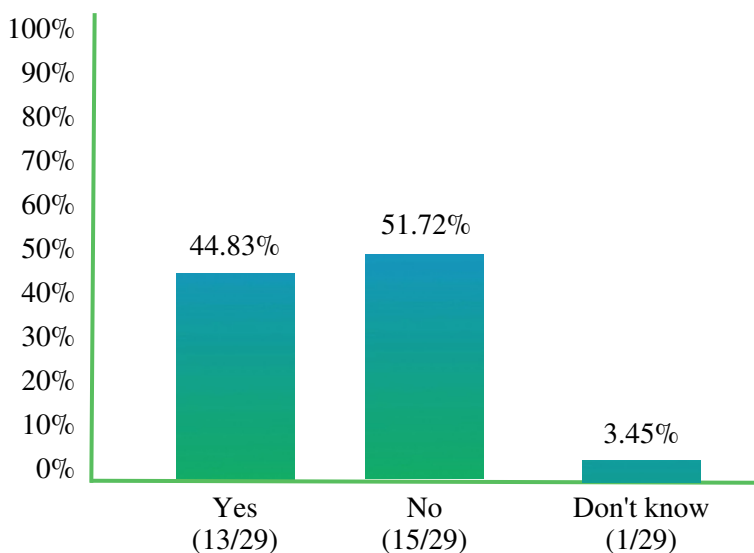
Survey Results

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



In 2020, pharmacy staff spent 6,3 hours/week on average. In 2021, pharmacy staff spent 5,3 hours/week on average.

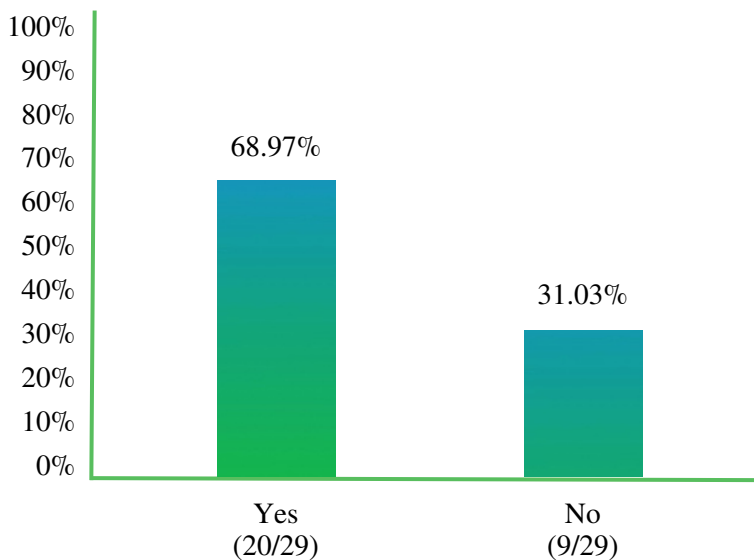
» **Question 12.** Is there a commonly agreed definition of medicine shortages in your country, and/or is there a definition of medicine shortages at national legislation?
(% of responding countries)



» In 13 out of the 29 responding countries there is a commonly agreed definition and/or this definition of medicine shortages is enshrined at the national legislation.

Survey Results

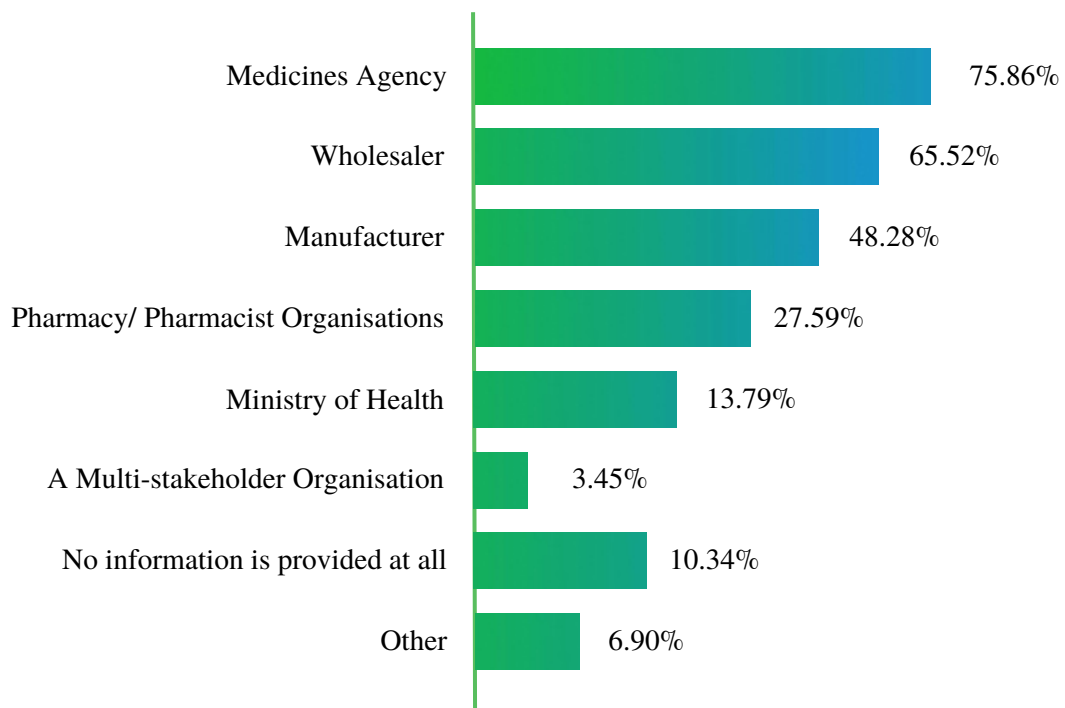
» **Question 13. Does your country have (a) reporting system(s) for shortages in place which can be used by community pharmacists?**
(% of responding countries)



» In 20 out of the 29 countries surveyed (68,97%), there are reporting systems for shortages in place that can be used by community pharmacists.

» In 2019 (18 countries), 2020 (20 countries) and 2021 (17 countries) had a reporting system for shortages in place which can be used by community pharmacists.

» **Question 14. Who provides data / information on medicine shortages to pharmacists in your country? E.g. - How long they will be unavailable for? / When you should expect them to be available**
(multiple answers per country, % of responding countries)



Survey Results

» **Question 15. In your opinion, what have been the 3 most common causes of shortages in your country?**
 (multiple answers per country, % of responding countries)

65.52

Disruption / suspension
of the manufacturing
process
(19/29)

55.17%

Quota imposed by
manufacturer
(16/29)

48.28%

Unexpected /
high increase in
demand
(14/29)

41.38%

National pricing and
procurement strategies
(16/29)

34.48%

Commercial
market
withdrawals
(13/29)

31.03%

Parallel export
out of my
country
(6/29)

20.69%

Logistical supply chain
inefficiencies
(16/29)

10.34%

Delays in
marketing
authorisation
(13/29)

10.34%

Product recalls
(6/29)

Main Findings



All responding countries experienced medicine shortages in community pharmacies in the past 12 months. Contrary to the positive tendency from the last year, the majority of the countries reported that the situation got worse compared to the previous 12 months (75,86%), or stayed the same (24,14%). There were no countries which registered improvements.



All classes of medicines are affected by medicine shortages in community pharmacies across the different responding European countries. **Cardiovascular medicines** have been short in supply in the highest percentage of countries (82,76%), followed by both medicines for the nervous systems and antiinfectives for systemic use - antibiotics (79,31%), and medicines for the respiratory system (75,86%).



In the majority of responding countries (24,14%), **over 600 medicines were listed as in short supply** at the time of completing this survey. Compared to the previous year (median over 200-300 medicines in short supply), the evidence suggests that year to date analysis in the countries shows worsening of the situation.



65,52% of responding countries indicated that they had experienced shortages of medical devices in community pharmacies. These shortages have been experienced among almost all classes of medical devices (I, IIa, IIb), including **in-vitro diagnostics**. However, countries reply that in most cases there is not a medical device shortage monitoring system that helps to clarify the real situation.



Almost all responding countries indicated that they believe medicine shortages cause **distress and inconvenience** to patients (93,10%). **Interruption of treatments** (89,66% of countries), **increased co-payments** as a result of more expensive/non-reimbursed alternatives (72,41%) and **suboptimal treatment/inferior efficacy** (58,62%) are also perceived as common negative consequences of medicine shortages on patients. Compared to the previous year, these percentages have increased.

Main Findings



Medicine shortages affect community pharmacy businesses in most countries by **financial loss** due to time invested in mitigating shortages (96,55% of countries), and equally **reduced patient trust; reduced employee satisfaction; and increased administrative duties** (75,86%).



Across European countries, **strong differences** exist in terms of **legal solutions** community pharmacists can offer in case of a shortages. **Generic substitution** (93,10% of countries), **sourcing the same medicine from alternative authorised sources** and preparing a compounding formulation (both 62,07%) are the solutions which can be provided in most countries. However, some of these solutions are subject to restrictions (e.g. new prescription is needed) and can be cumbersome and time-consuming for the patient and the pharmacist.



The time pharmacy staff has to spend on dealing with medicine shortages is **6,68 hours per week on average**, which is substantially higher than the time reported in 2021 (5,3 hours), 2020 (6,3 hours per week) and 2019 (6,6 hours per week). Pharmacists spend on average 6 hours and 40 minutes per week actively managing shortages.



51,72% of respondents indicated that **there is not a commonly agreed definition of medicine shortages in their country**, and **31,03%** indicated that there is still **not yet a reporting system** for shortages in place which can be used by community pharmacists.



The main causes for shortages have been pointed out as disruption/suspension of the manufacturing process (65,52%), quota imposed by the manufacturer (55,17%), and unexpected/high increase in demand of medicines (48,28%), such as in the case of paediatric formulations of antibiotics.

Policy Recommendations

In most cases community pharmacists are still managing to ensure continuity of care and minimise the impact of shortages on their patients' health. However, the situation is worsening and **PGEU calls for a number of coordinated actions** that should be taken at different policy levels to reduce the burden of medicine shortages:

- » **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. Moreover, appropriate measures need to be taken to ensure compliance with EU and national laws related to the public service obligations for marketing authorisation holders and wholesaler distributors, taking into account the dynamics of the EU internal market.
- » **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 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.
- » **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 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.
- » **Improve communication:** It is vital to ensure greater transparency and availability of medicine shortages data and 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. It is also necessary to increase access to the information available across all parts of the supply chain.
- » **Compensate financial impact:** The resource investment by pharmacists and pharmacies to manage shortages be recognized and valued.

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