












PGEU Medicine Shortages Survey 2021 Results



PGEU Medicine Shortages Survey 2021

- Each year PGEU conducts a survey among their membership to map the impact of medicine shortages across Europe from the community pharmacists' perspective.
- The 2021 Survey was open to [all PGEU member organisations](#) and has been conducted between 22 November 2021 – 14 January 2022.
- 27 PGEU members (1 response per country) provided their responses to the survey coming from the following countries:

Countries that participated in the survey

 Austria	 Italy
 Belgium	 Kosovo
 Bulgaria	 Latvia
 Croatia	 Luxembourg
 Cyprus	 Netherlands
 Czech Republic	 Norway
 Denmark	 Portugal
 Estonia	 Serbia
 Finland	 Slovakia
 France	 Slovenia
 Germany	 Spain
 Greece	 Sweden
 Hungary	 United Kingdom
 Ireland	



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.

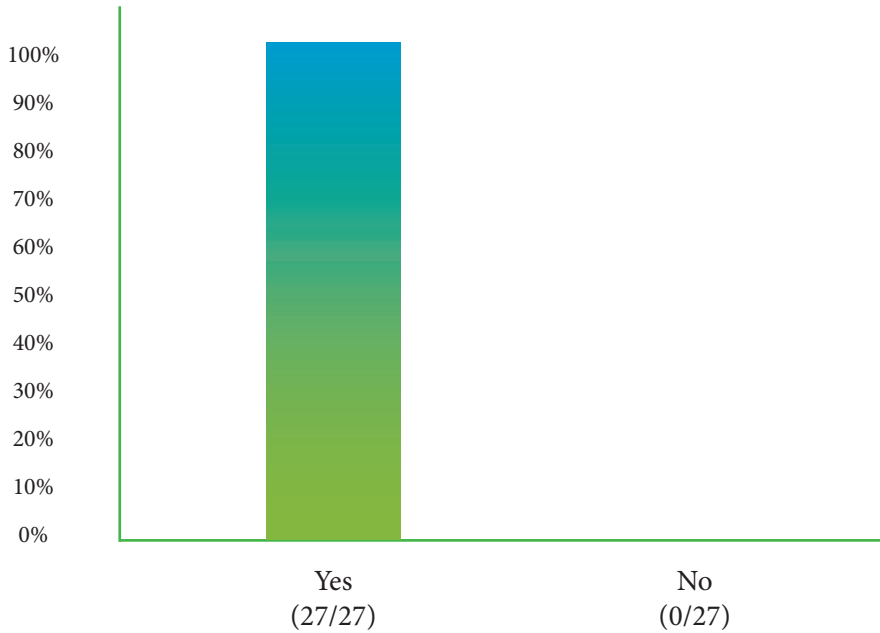


Among the **key findings** of the survey are:

- The continued high incidence of medicine shortages in most European countries, although the majority of countries reported for the first time in years that the situation did not get worse compared with the previous year.
- The confirmation of occurring shortages of medical devices in pharmacies in the majority of European countries.
- Slight improvement in terms of the average time spent by pharmacists to deal with shortages.
- The daily and burdensome impact medicine shortages have on patients and pharmacy practice across Europe.
- 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.

Survey Results

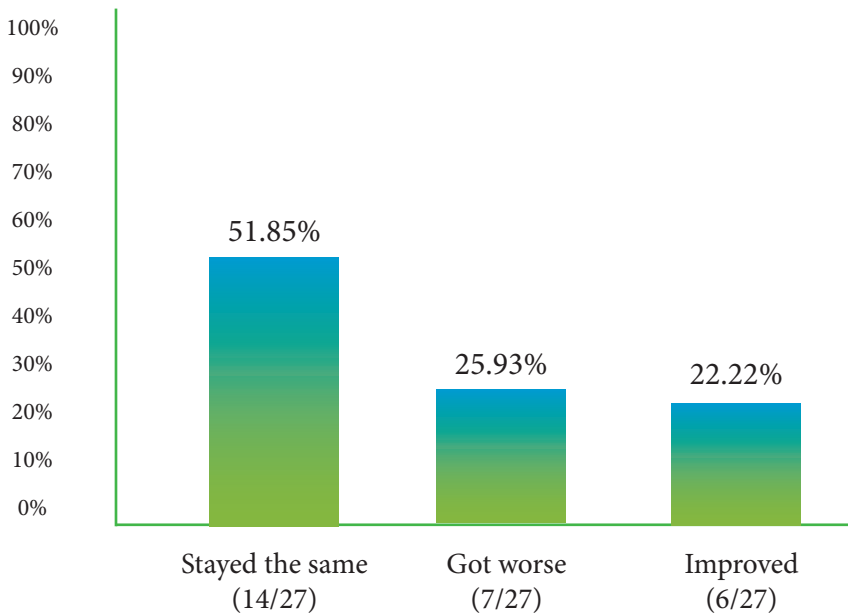
» **Question 1.** In the last 12 months, have you experienced medicine shortages in your country?
(% of responding countries)



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

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

» **Question 2.** If yes, compared to the previous 12 months, the situation has:
(% of responding countries)



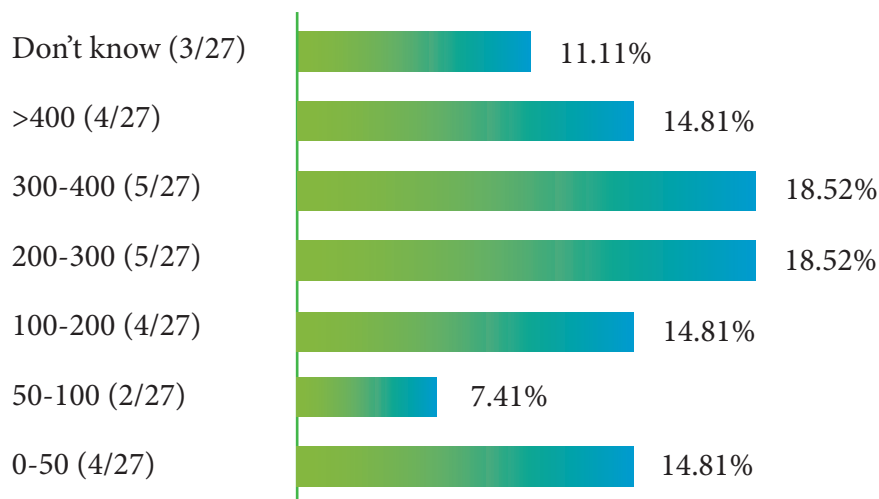
» Compared to the previous 12 months, in 7 of 27 responding countries the situation has gotten worse and stayed the same in 14 countries.

» In 2019, the situation got worse in 22 countries and stayed the same in 3 countries. In 2020, in 17 of 26 responding countries the situation has gotten worse and stayed the same in 8 countries.

➤ **Question 3.** If yes, which medicines have been in short supply? Tick all that apply.
(% of responding countries)

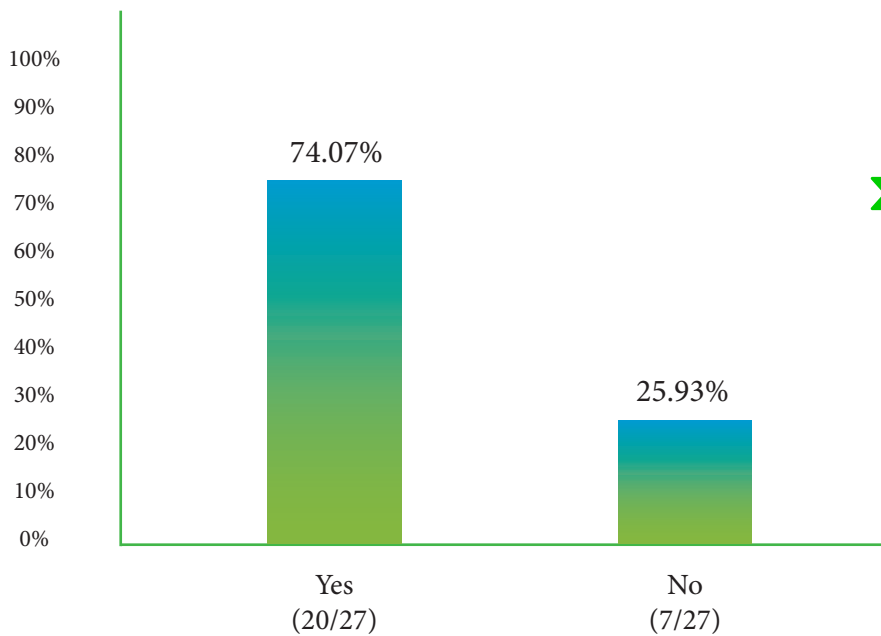
Medicines	Responding countries (%)
Cardiovascular medications	85.19%
Nervous system	77.78%
Respiratory system	74.07%
Antiinfectives for systematic use (e.g. antibiotics)	70.37%
Musculo-skeletal system	70.37%
Genito-urinary system and sex hormones	66.67%
Antineoplastic and immunomodulating agents	66.67%
Systemic hormonal preparations	62.96%
Gastro-intestinal medications	62.96%
Dermatologicals	62.96%
Blood and blood forming organs	59.26%
Sensory organs	55.56%
Various	48.15%
Antiparasitic products, insecticides and repellents	48.15%
Vaccines	44.44%

➤ **Question 4.** How many medicines are short in supply at the time of completing this survey?¹
(% of responding countries)



¹The quantification takes into account the national definition of a medicine shortage 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.

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

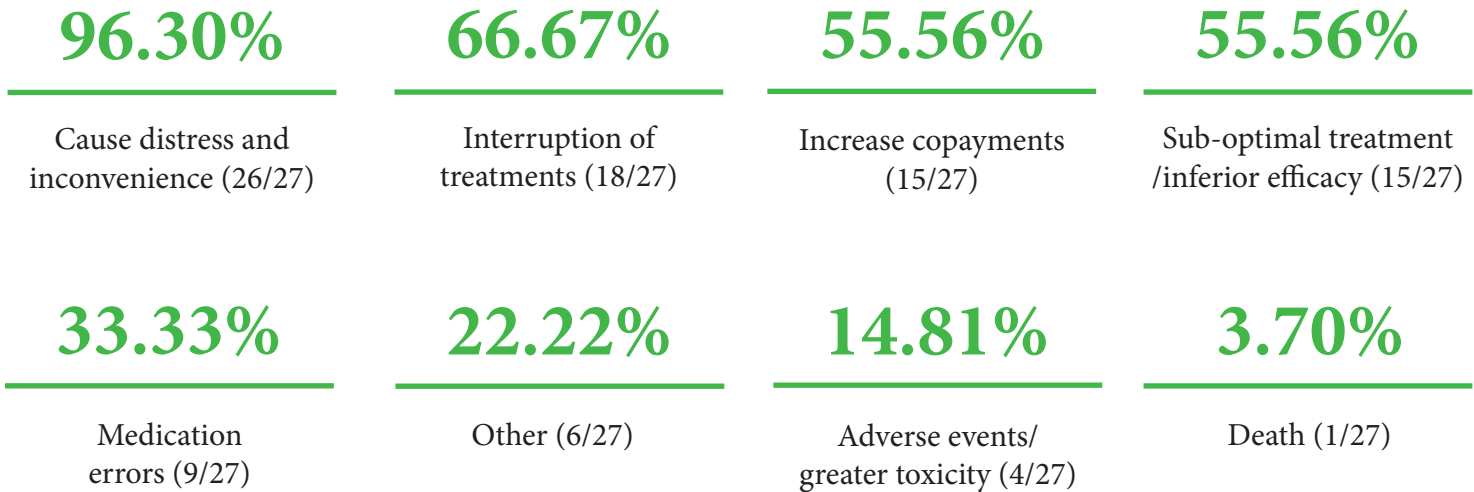


» 74.07% of responding countries experienced shortages of medical devices in community pharmacy in the last 12 months.

» **Question 6.** If yes, which types of medical devices have been in short supply in community pharmacy? Tick all that apply. (% of responding countries)

Medical devices	Responding countries (%)
In-vitro diagnostics (e.g. self-tests)	33.33%
Class I (low risk - e.g. bandages, thermometers, surgical face masks)	33.33%
Class IIa (medium risk - e.g. lancets, needles, short-term contact lenses)	25.93%
N/A. There have been no medical devices shortages in my country in the last 12 months.	18.52%
Other	14.81%
Class II b (medium to high risk - e.g. oxygen concentrator)	7.41%
Class III (highest risk - e.g. contraceptive intrauterine devices)	0.00%

» **Question 7. In your opinion, how have medicine shortages adversely affected patients in your country?**
Tick all that apply. (% of responding countries)



» Comments received:



Denmark

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



Spain

The General Pharmaceutical Council of Spain has been able to identify specific problems with some non-substitutable medicines for patients with rheumatic and musculoskeletal diseases, e.g. presentations containing chondroitin sulphate as API.



Portugal

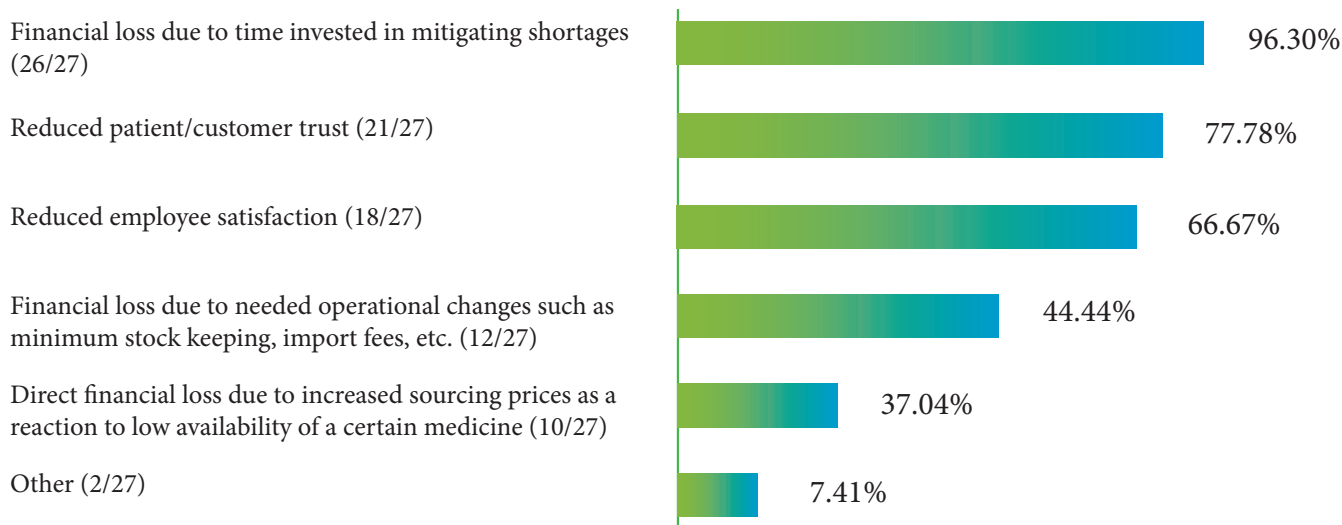
There is an additional indirect economic impact it has on patients if they have to return to doctor to get a new prescription or to go to different pharmacies to find the medicines they need.



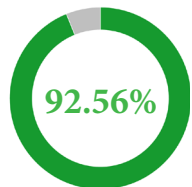
The United Kingdom

An inordinate amount of time has been spent sourcing these products, time that could have been spent with patients.

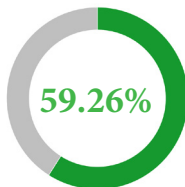
» **Question 8. In your opinion, how have medicines shortages affected community pharmacies in your country?**
 Tick all that apply. (% of responding countries)



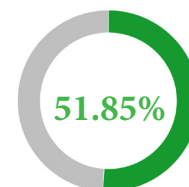
» **Question 9. Which solutions can legally be offered by pharmacists in case of a shortage?²**
 Tick all that apply (% of responding countries)



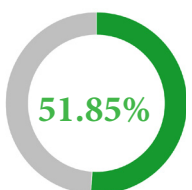
Generic substitution (25/27)



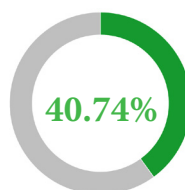
Sourcing the same medicine from alternative authorised sources (16/27)



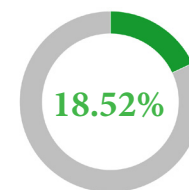
Importing the medicine from another country (14/27)



Preparing a compounded formulation (14/27)



Changing to the same medicine with a different strength (11/27)



Therapeutic substitution (5/27)

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 the exemption to certain labelling and package leaflet obligations.

» Comments received:



Austria

Generic substitution is not allowed in Austria.



Bulgaria

Very rarely the preparation of compounded formulation is the solution. Generic substitution is not allowed. The other possible solutions neither.



Estonia

Therapeutic substitution is possible only for OTC medicinal products.



France

Alternative sources: sourcing directly from manufacturers is authorised, sourcing from other pharmacies is not.

Changing to a different strength and posology: yes, but only after agreement from the prescriber.

Therapeutic substitution: 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: yes, for magistral formula (with a prescription for a given patient).



Belgium

Sourcing medicines from other pharmacies is only permitted in exceptional circumstances (such as shortages when the continuity of treatment is at stake). Generic substitution is in theory subject to the prescriber's permission, but - in emergency situations, and in the interest of the patient, often the pharmacist takes his responsibility and dispenses a substituted medicine.



Germany

Most of the above-mentioned solutions can only be offered in correspondence to the prescriber and potential amendments to the prescription.



Kosovo

If for a certain medicines that is in shortage there is no generic substitution possible, it is allowed by legislation that it could be imported from other EU countries. In some cases, this helped to minimize shortages (not in all cases the medicine could be imported).



Sweden

Generic substitution can be carried out without contacting the prescriber. For importing medicine and compounded formulation the doctor has to write a new prescription, but the pharmacy often helps finding the right alternative. For importing medicines, the pharmacy has to apply for a special license for that medicine. Changing to the same medicine with different strength can be done after contacting the prescriber.



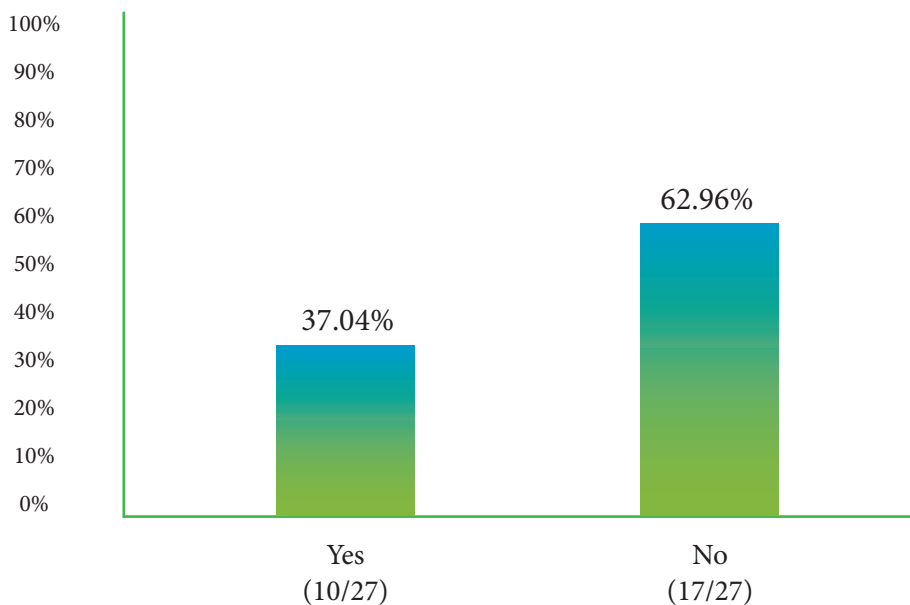
Spain

The General Pharmaceutical Council of Spain has developed FarmaHelp. More than 3,000 patients from all over Spain have found their medicine in 2021 thanks to Farmahelp, which has enabled community pharmacists to contact pharmacies in their area when a patient needs a medicine due to urgency or unavailability reasons. It is currently ongoing in more than 2,500 pharmacies in Spain and helps to avoid medication discontinuation with the consequent health risks and associated costs.

In Spain, almost all the Regions allow authorised centres to dispense medicines imported from European countries when it is not possible for the pharmacist/prescriber to substitute or switch them. The AEMPS is in charge of importing and following-up the foreign medicine or, for instance, putting in place exceptional marketing rules to ensure that the patient can continue with the treatment. Moreover, in some Regions such as Navarre, procedures have already been implemented in collaboration with pharmacists for the final and safe dispensing of these imported medicines via community pharmacies.



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:



Belgium

Various temporary measures have been taken to limit the shortage of medicines needed to fight the pandemic: limitation of the export of certain essential medicines or limitation of the sale of certain medicines.



Bulgaria

A specialized electronic system for tracking and analysis of medicinal products has been launched.



Denmark

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. However, this right has not been applied.



Finland

Pharmacies must stock medicines corresponding for an amount of 2 weeks demand.



France

Temporary rules: For a few months in 2020, community pharmacists were allowed to substitute medical devices in case of a shortage. Another temporary measure is still in place for now: dispensing clonazepam off label in case of a shortage of midazolam.



Kosovo

For medicines that were in the protocol for treating COVID-19 symptoms or problems (antivirals, antimicrobial medicines) there were special imports allowed.



Germany

During the SARS-CoV-2-Pandemic, where a possible worsening of drug supply was anticipated, pharmacists were given more options to deviate e.g. from the package size, the number of packages or the strength, in case the prescribed drug is unavailable - including “aut-simile”-substitution of a pharmacologically and therapeutically comparable medicinal product (in correspondence to the prescriber) to reduce repetitious patient visits of the doctor or the pharmacy.



Netherlands

e.g. temporarily allowed to exchange stock between pharmacies. Veterinarian propofol for human use.



Portugal

During the pandemic therapeutic substitution in case of shortages, based on protocols and communication between doctors and pharmacists, was foreseen in the temporary regulatory changes but it was never implemented.



Slovakia

Possibility to prepare and dispense hand disinfection in community pharmacies.



Spain

The adoption of the Pharmaceutical Strategy for Europe is expected to provide the basis for triggering actions at national level.



The United Kingdom

Serious Shortage Protocol.

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



5,1 hours/week on average

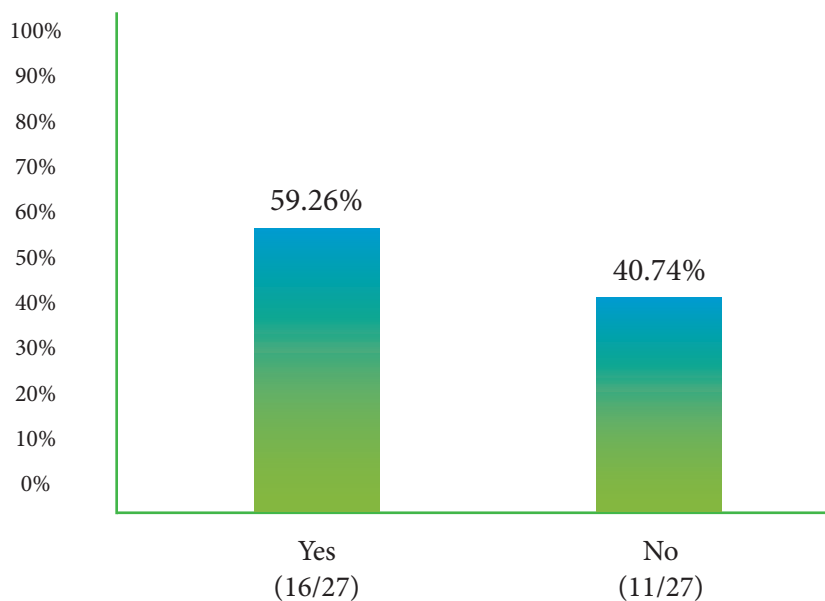
pharmacy staff spend dealing with medicine shortages

Answers ranged from 1 hour/week to 18 hours/week



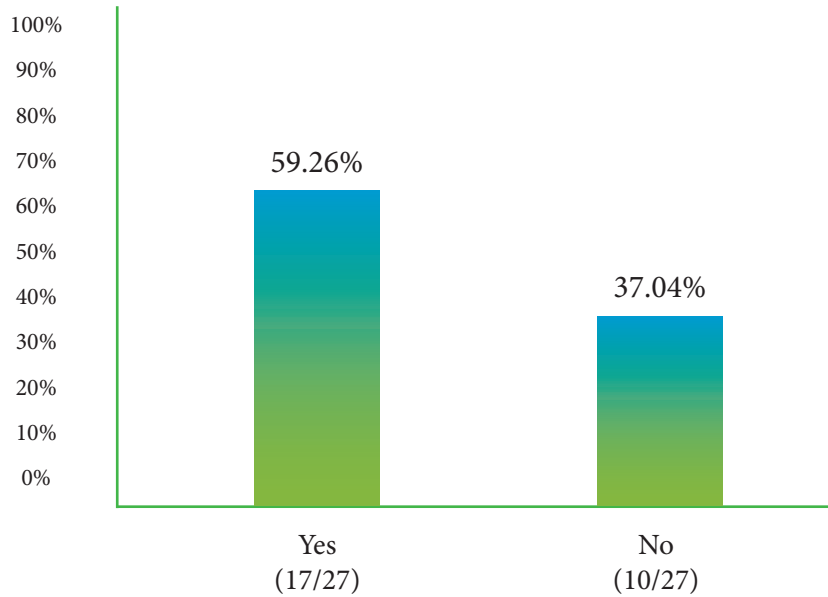
In 2019, pharmacy staff spent 6,6 hours/week on average and in 2020, 6,3 hours/week on average dealing with medicine shortages.

» Question 12. Do you have a national definition of a medicine shortage?
(% of countries)



» 16 of 27 responding countries have a national definition of a medicine shortage.

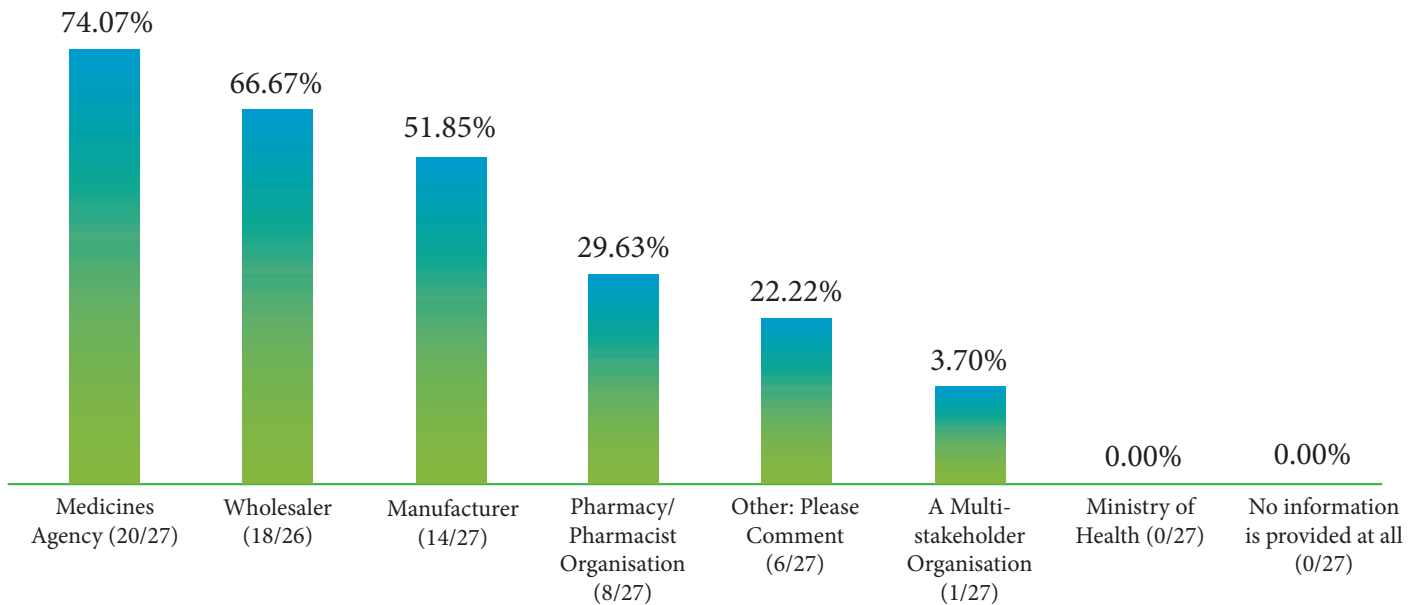
Question 13. Does your country have a reporting system for shortages in place which can be used by community pharmacists?
(% of countries)



17 of 26 responding countries have a reporting system for shortages in place which can be used by community pharmacists.

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

Question 14. Who provides data / information on medicines shortages to pharmacists in your country?
Tick all that apply (% of countries)



Main Findings



All responding countries experienced medicine shortages in community pharmacies in the past 12 months. However, for the first time in years, the majority of countries reported that the situation did not get worse compared to the previous 12 months (52% stayed the same, 22% improved).



All classes of medicines are affected by medicine shortages in community pharmacies across the different responding European countries. **Cardiovascular medications** have been short in supply in community pharmacies in the highest percentage of countries (85%), followed by medicines for nervous systems (78%) and respiratory systems (74%).



In the majority of responding countries (52%), **over 200 medicines were listed as in short supply** at the time of completing this survey, with 2 countries indicating that there were even more than 400 medicines short in supply.



74% of responding countries indicated that they had experienced shortages of medical devices in community pharmacies. Among the most common types of medical devices reported in shortage were **Class I medical devices** and **in-vitro diagnostics** (both 33% of countries).



Almost all responding countries indicated that they believe medicine shortages cause **distress and inconvenience** to patients (96%). **Interruption of treatments** (67% of countries), **increased co-payments** as a result of more expensive/non-reimbursed alternatives (56%) and **suboptimal treatment/inferior efficacy** (56%) are also perceived as common negative consequences of medicine shortages on patients.

Main Findings



Medicine shortages are believed to affect community pharmacy businesses in most countries by **financial loss** due to time invested in mitigating shortages (96% of countries), **reduced patient trust** (78%) and **reduced employee satisfaction** (67%).



Across European countries, **strong differences** exist in terms of **legal solutions** community pharmacists can offer in case of a shortages. **Generic substitution** (93% of countries), **sourcing the same medicine from alternative authorised sources** (such as other pharmacies) (59%) and **importing the medicine** from a country where it is available (52%) are the solutions which can be provided in most of the European 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 **5,1 hours per week on average**, which is lower than the time reported in 2020 (6,3 hours per week) and 2019 (6,6 hours per week).



41% of responding countries indicated that there is **no national definition of a medicine shortage**, and 37% indicated that there is still **no reporting system for shortages** in place which can be used by community pharmacists in their country, despite pharmacists often experiencing or foreseeing supply difficulties before the industry or wholesalers are aware that there is, or will be, a problem.

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