

PGEU SURVEY ON MEDICINE SHORTAGES 2019

Pharmaceutical Group of the European Union [PGEU]





PGEU Medicine Shortages Survey 2019 Results

Each year PGEU conducts a survey among their membership to map the impact of medicine shortages across Europe from the community pharmacists' perspective.

The 2019 Survey was open to all [PGEU member organisations](#) and has been conducted between 4 November – 16 December 2019.

24 PGEU members (1 response per country) provided their responses to the survey coming from the following countries:

Austria	Cyprus	Germany	Latvia	Poland	Slovenia
Belgium	Czech Republic	Greece	Malta	Portugal	Spain
Bulgaria	Denmark	Ireland	Netherlands	Romania	Sweden
Croatia	France	Italy	Norway	Slovak Republic	United Kingdom

For the purpose of this survey, the term “medicine shortage” was defined as *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*. 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:

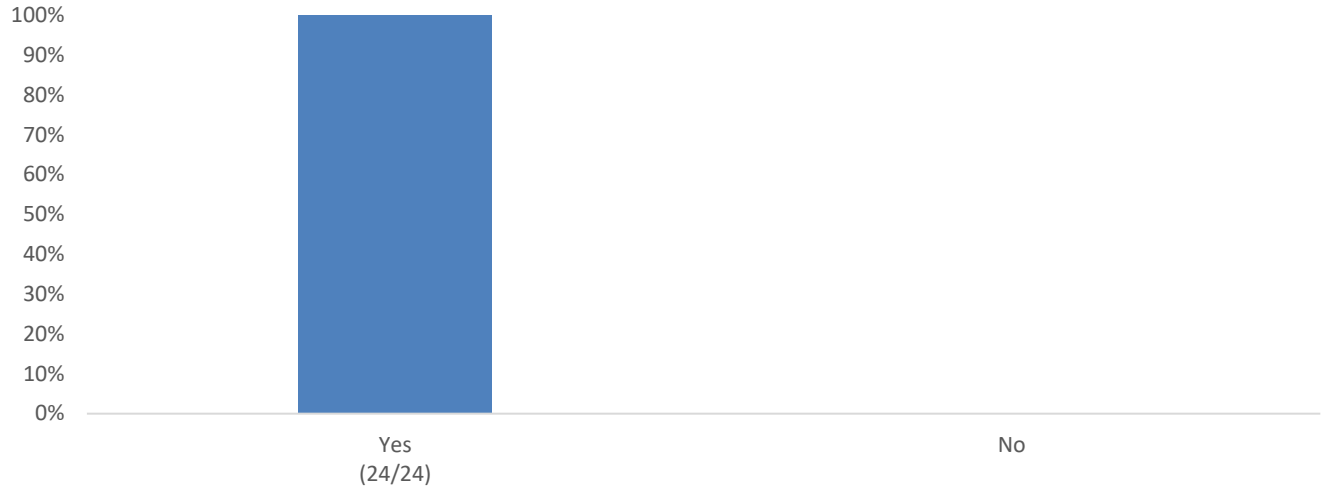
- The high incidence and ongoing rise of the number of medicine shortages in most European countries;
- The daily and burdensome impact of medicine shortages on patients and pharmacy practice across Europe;
- The existing gap in needed information, tools and legal solutions available to community pharmacists in many European countries for providing solutions to patients in case of a shortage.



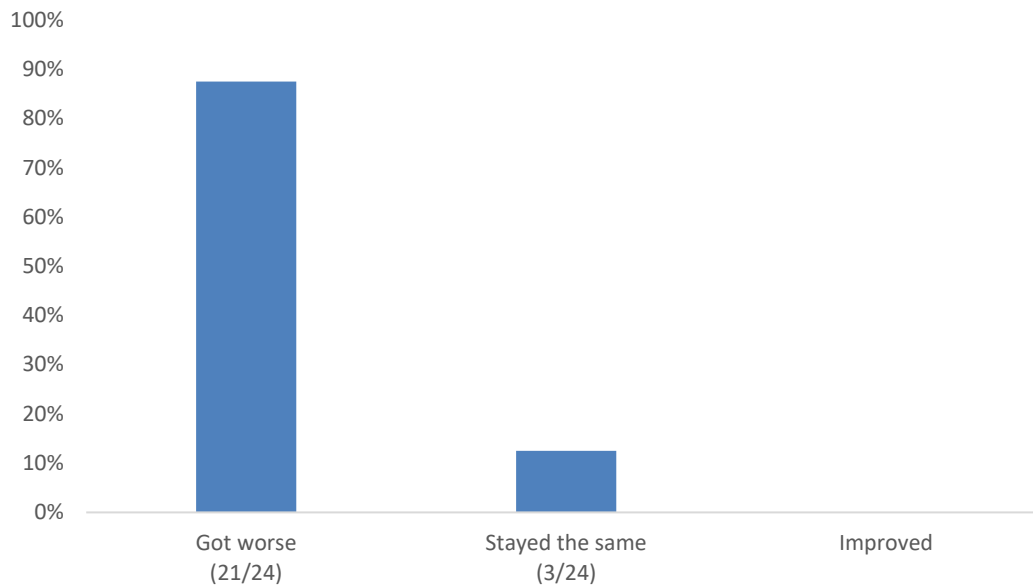
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1. In the last 12 months, have you experienced medicines shortages in your country?
(% of responding countries)



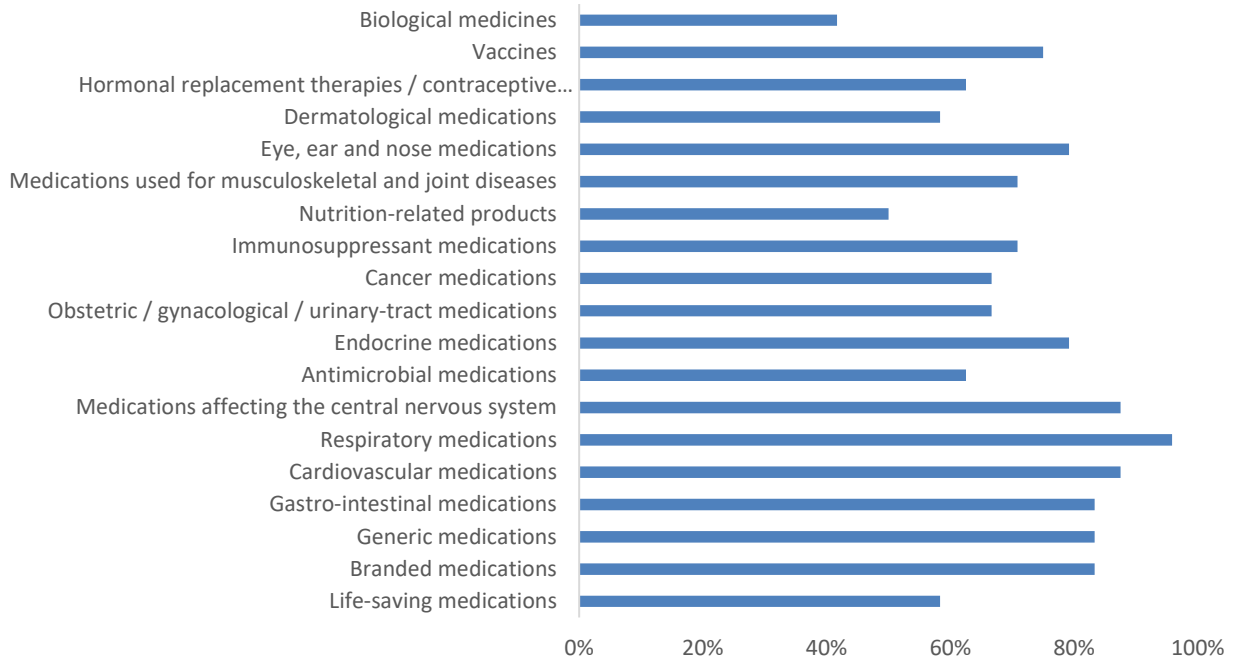
2. If yes, compared to the previous 12 months, the situation has:
(% of responding countries)





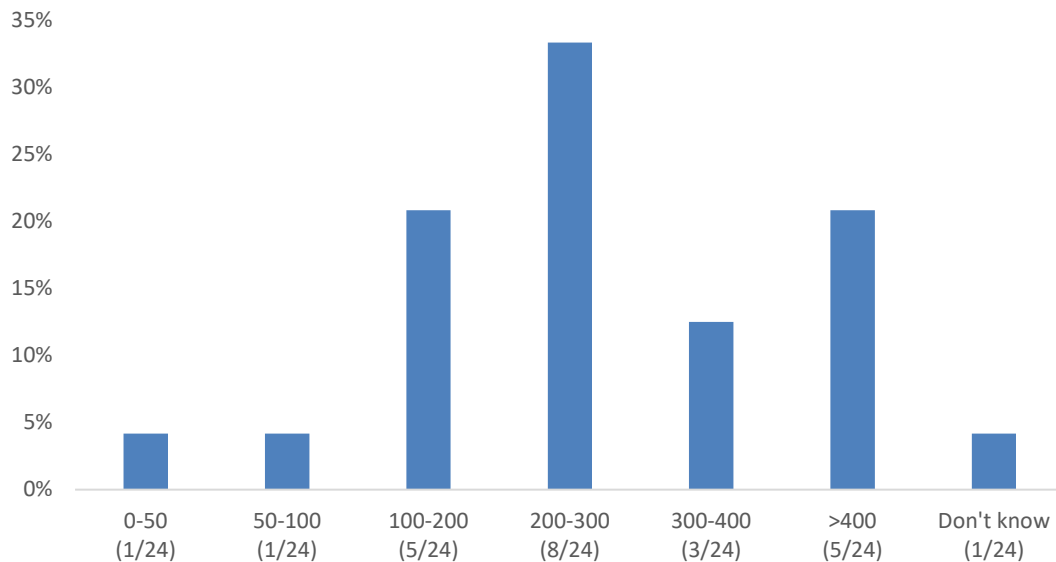
3. If yes, which medicines have been in short supply?

Tick all that apply (% of responding countries)



4. How many medicines are short in supply at the time of completing this survey?¹

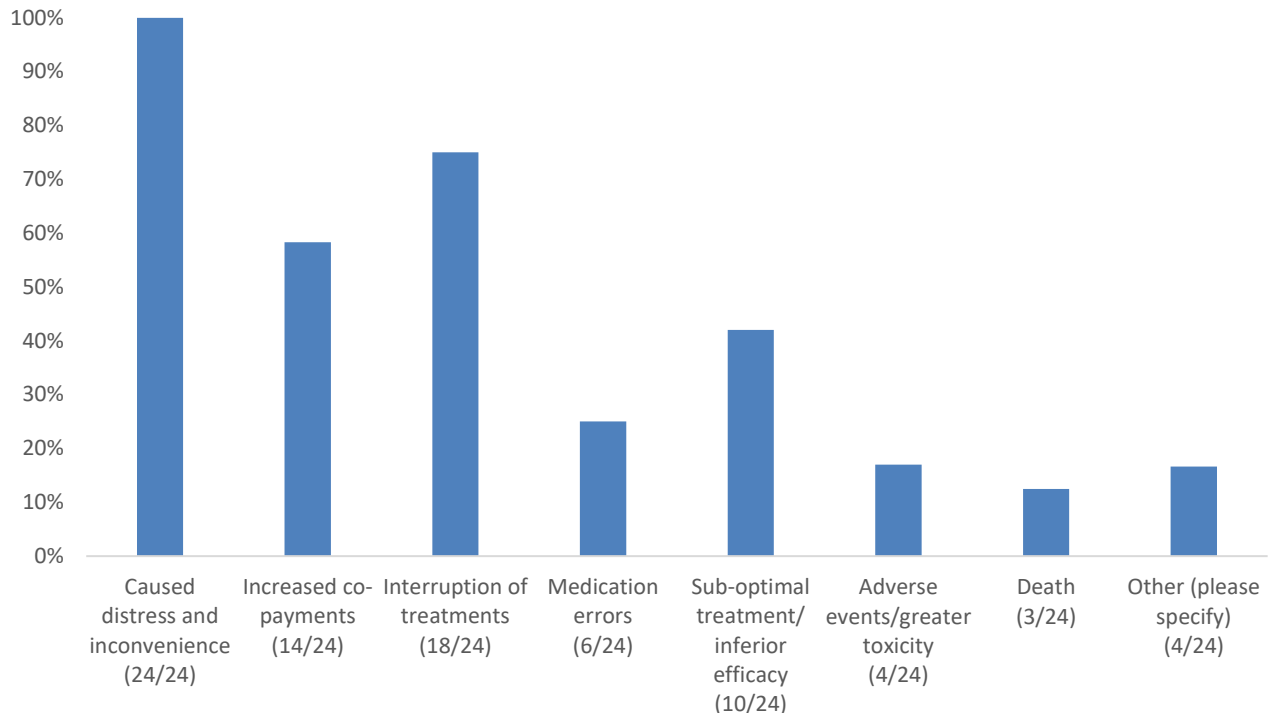
(% of responding countries)



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.



5. In your opinion, how have medicines shortages adversely affected patients in your country? Tick all that apply (% of responding countries)

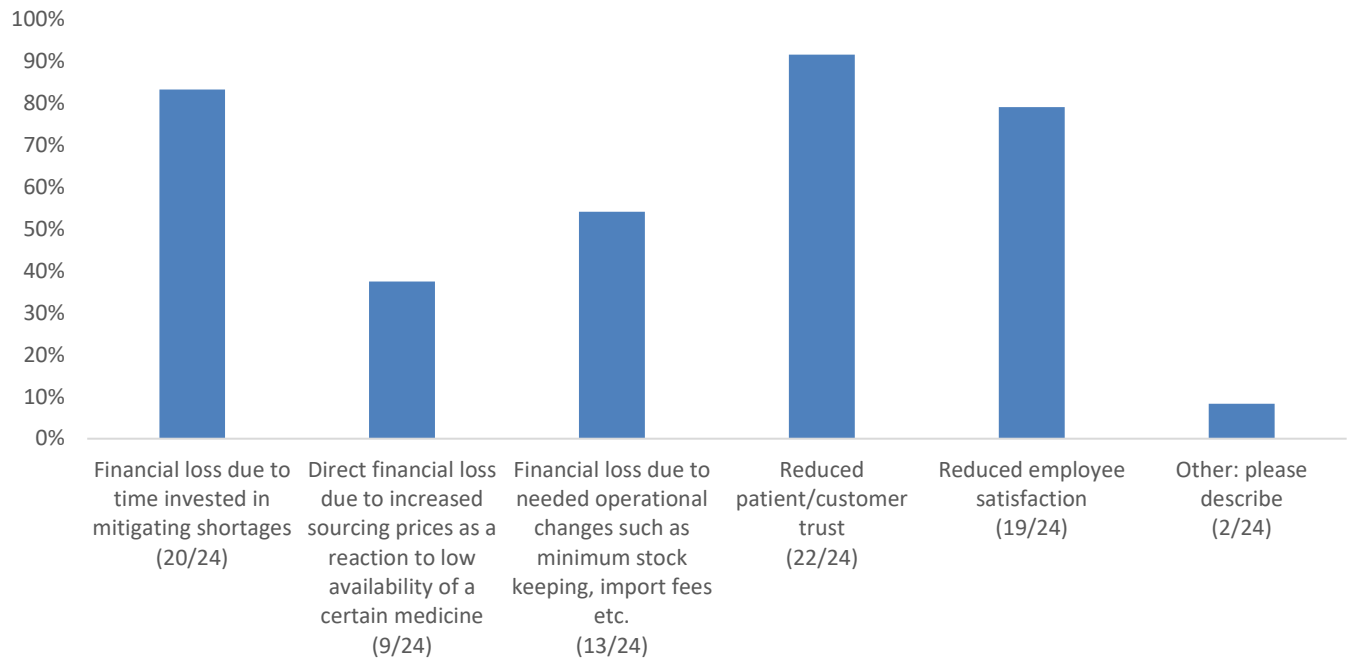


Comments received:

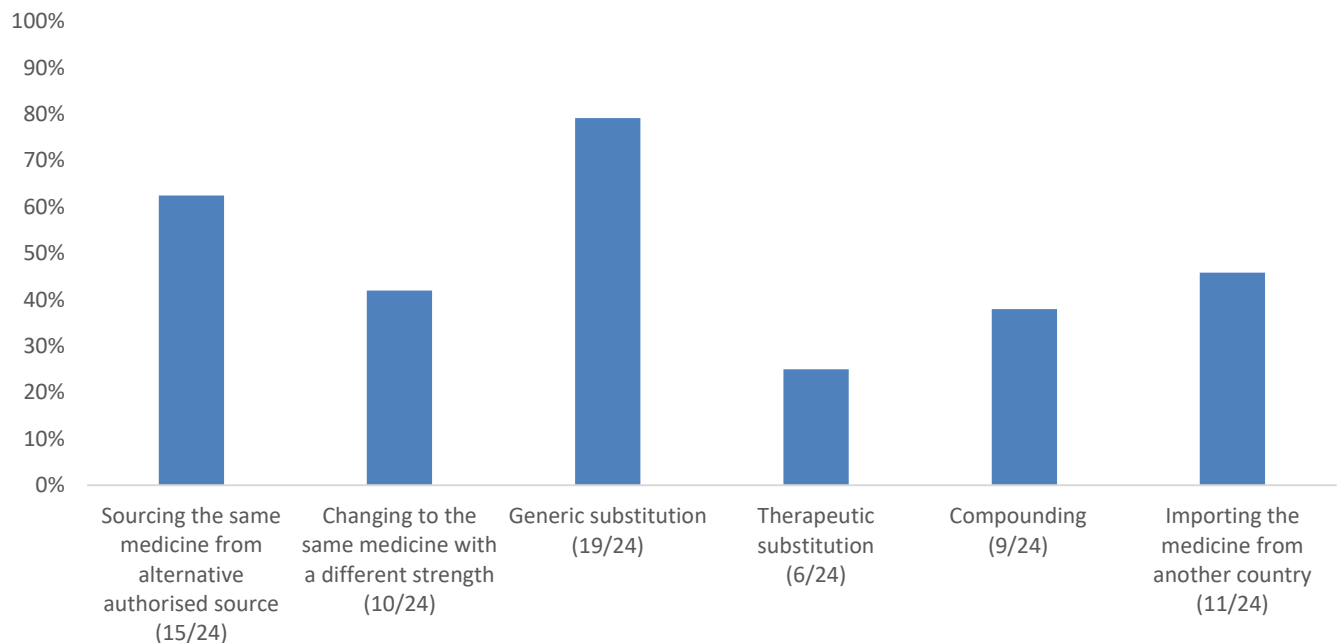
- **Belgium:** It is hard to prove or measure what the consequences of actual shortages have been in recent years on patients. However, it is obvious that the burden on pharmacists and patients became more and more problematic. It is probable that continued and unpredictable shortage of essential medicines such as diuretics and anticoagulants have caused destabilization in compromised patients, hospital admissions and likely also early deaths in a limited number of complex and severely compromised patients.
- **Bulgaria:** In Bulgaria, pharmacists are not permitted to provide substitutes for medicines and the patient should make a visit to a GP for a new prescription.
- **France:** Increased payments as a result of new basic medical consultation to change therapy due to medicines unavailability.
- **Spain:** Some medicines have to be imported from an EU country when it is not available. Once the medicine is received, patients should go to approved establishments by the Spanish Autonomous communities to pick up their medication. This situation have a sheer impact on patients in terms of access to medicines and time invested by the patient.



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



7. Which solutions can legally be offered by pharmacists in case of a shortage Tick all that apply (% of responding countries)



7. Comments:

- Austria: Generic Substitution is not allowed in Austria
- Belgium: Sourcing the medicines from other pharmacies systematically is not permitted. It is accepted in urgencies of exceptional circumstances such as shortages.
- Bulgaria: None from listed above options. In Bulgaria pharmacists are not permitted to provide substitutes for medicines in short supply.
- Germany: Most of the above mentioned solutions may only be offered in correspondence to the prescriber and potential amendments to the prescription.
- Greece: Importing through the Institute of Pharmaceutical Research and Technology.
- Slovenia: Patients seek medicine in another country and get reimbursed by the insurance. Therapeutic substitution is possible, but only by the prescriber.
- Spain: In Spain only approved establishments by the Spanish Autonomous communities are allowed to dispense medications imported from European countries when the substitution or switching by the pharmacist / prescriber is not possible. At this point it is important to highlight that there are some kind of medications whose substitution is not permitted, such as those medicines with a narrow therapeutic index or inhaled therapy in respiratory diseases (see Order SCO / 2874/2007, of September 28th)
- Sweden: Importing medicines are made after a special approval for a non-licensed medicine by the Swedish Medical Product Agency. Preparing compounded formulation is only permitted if there are no other alternatives. The formulation is normally made by special pharmacies as APL (<https://www.apl.se/in-english.html>) specialised in ex tempore preparations.
- United Kingdom: We now have the serious shortage protocol set in legislation, which will be utilised through the Department of Health in instances of a serious shortage of a specific named product. These protocols are fixed with a start and end date. So far, the UK has had two protocols in place.



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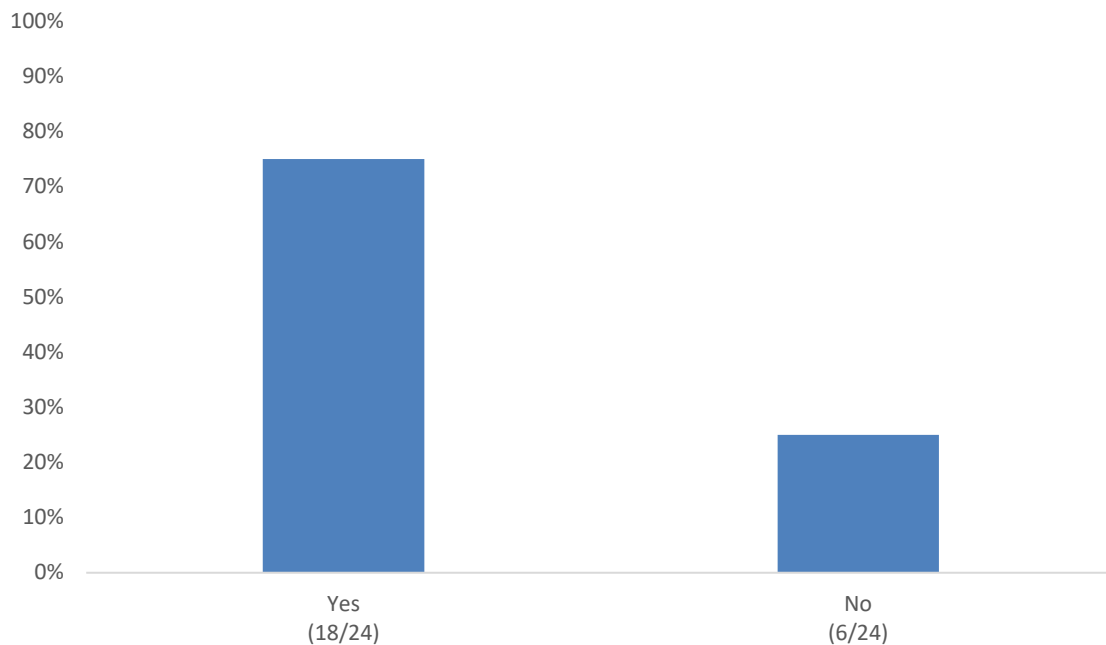
8. On average, per week, how much time does pharmacy staff spend dealing with medicine shortages?



6,6 hours/week on average

(Answers ranged from 2 hours/week to 15 hours/week)

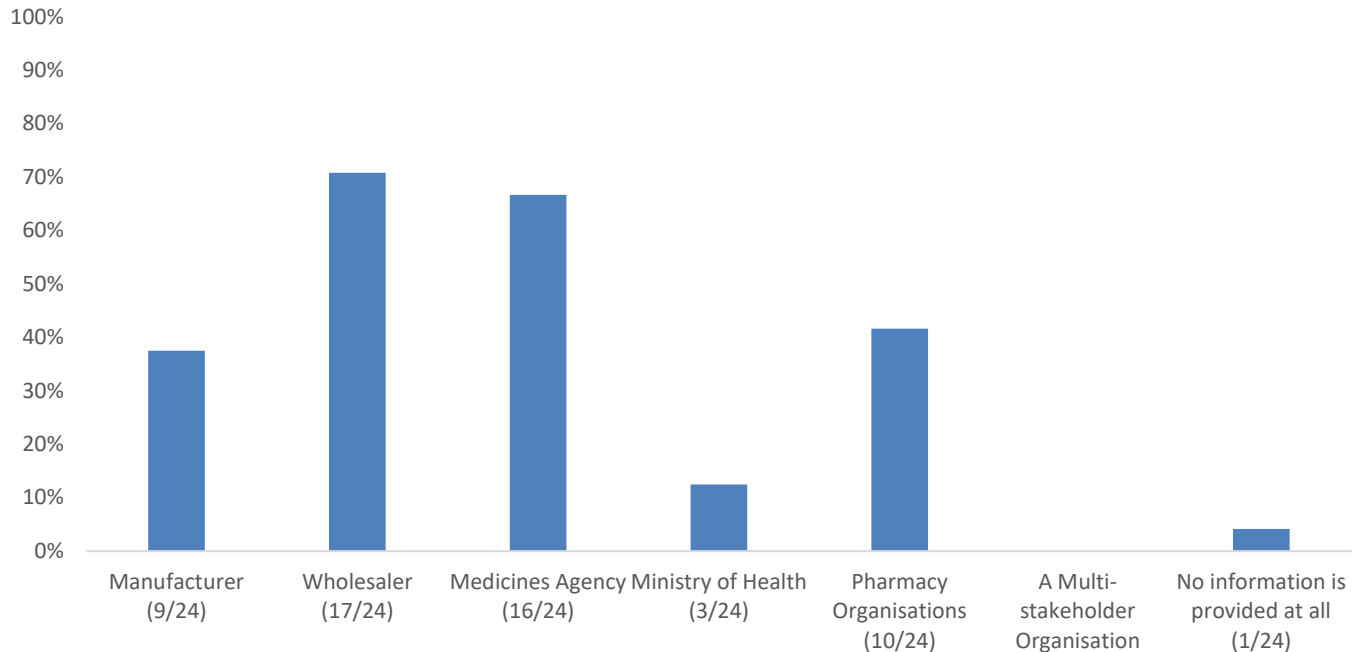
9. Does your country have a reporting system for shortages in place which can be used by community pharmacists?
(% of countries)





10. Who provides data / information on medicines shortages to pharmacists in your country?

Tick all that apply (% of countries)



Comments:

- Poland: There is no legal obligation to provide public information about shortages. In crisis situation information is provided by different parties.
- Portugal:
 - a) Manufacturers are obliged to notify INFARMED (regulator) on the cause and estimated length of production problems
 - b) Pharmacies report to ANF (daily), on a voluntary basis, information regarding the medicine (name, strength, pharmaceutical form), package and price, name of the market authorization holder, name of the supplier (wholesaler) and number of units in shortage. The registry of shortages is undertaken during the verification of the orders received from the wholesalers in the Pharmacy. The pharmacy software generates a file which is sent by e-mails to the IT department of ANF. The report produced is shared with Authorities on a monthly basis
 - c) Pharmacies must notify all medicines on shortage to INFARMED; the Portuguese Medicines Agency, automatically through a webservice. Wholesalers should notify shortages to an email address from INFARMED, while the webservice is being developed.
- Romania: Although this information is provided to the authority, the information doesn't reach the pharmacy on a regular basis or systematically. In most cases it is transmitted locally by one pharmacy to another, or by wholesalers when you place an order.



MAIN FINDINGS

- **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.
- **All classes of medicines are affected by medicine shortages** in community pharmacies across the different responding European countries. **Respiratory medications** have been short in supply in the highest percentage of countries (87%) whilst **biological medicines** have been short in supply in the lowest percentage of countries (42%).
- In the majority of responding countries (67%), **over 200 medicines** were listed as in short supply at the time of completing this survey, with 5 countries indicating that there were even **more than 400 medicines** short in supply.
- **All responding countries** indicated that they believe medicine shortages cause **distress and inconvenience** to patients. **Interruption of treatments** (75% of countries), **increased co-payments** as a result of more expensive/non-reimbursed alternatives (58%) and **suboptimal treatment/inferior efficacy** (42%) are also perceived as negative consequences of medicine shortages on patients.
- Medicine shortages are believed to affect community pharmacy businesses in most countries by **reduced patient trust** (92% of countries), **financial loss** due to time invested in mitigating shortages (82%) and **reduced employee satisfaction** (79%).
- Across European countries, **strong differences** exist in terms of **legal solutions** community pharmacists can offer in case of a shortages. **Generic substitution** (79 % of countries), **sourcing the same medicine from alternative authorised sources** (such as other pharmacies) (63%), and **importing the medicine** from a country where it is available (46%) 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 has increased from 5,6 hours per week (2018) to **6,6 hours per week** on average.
- **25%** of responding countries indicated that there is still **no reporting system for shortages** in place which can be used by community pharmacists in their country, despite that pharmacists often experience or foresee supply difficulties before the industry or wholesalers are aware that there is, or will be, a problem.
- Community pharmacists receive their **needed information** on shortages in most countries from **wholesalers** (71%), **medicines agencies** (67%) and **pharmacy organisations** (42%).