# PGEU Medicine Shortages Survey 2020 Results





### **PGEU Medicine Shortages Survey 2020**

- Each year PGEU conducts a survey among their membership to map the impact of medicine shortages across Europe from the community pharmacists' perspective.
- The 2020 Survey was open to <u>all PGEU member organisations</u> and has been conducted between 9 November 11 January 2021.
- >> 26 PGEU members (1 response per country) provided their responses to the survey coming from the following countries:

### Countries that participated in the survey





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 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.

### **Survey Results**



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



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



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

Medicines	Responding countries (%)
Cardiovascular medications	92.31%
Vaccines	88.46%
Nervous system	84.62%
Respiratory system	84.62%
Gastro-intestinal medications	80.77%
Antiinfectives for systematic use (e.g. antibiotics)	76.92%
Systemic hormonal preparations	76.92%
Genito-urinary system and sex hormones	73.08%
Antineoplastic and immunomodulatings agents	69.23%
Musculo-skeletal system	65.38%
Dermatologicals	65.38%
Blood and blood forming organs	61.54%
Various	57.69%
Antiparasitic products, insecticides and repellents	50.00%
Sensory organs	50.00%

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



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<sup>1</sup>The 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 your opinion, how have medicine shortages adversely affected patients in your country? Tick all that apply. (% of responding countries)

96.15%	80.77%	57.69%	50.00%
Cause distress and inconvenience (25/26)	Interruption of treatments (21/26)	Increase copayments (15/26)	Sub-optimal treatment /inferior efficacy (13/26)
23.07%	11.54%	11.54%	3.84%
Medication errors (6/26)	Adverse events/ greater toxicity (3/26)	Other (3/26)	Death (1/26)







See Said A, Goebel R, Ganso M, Zagermann-Muncke P, Schulz M. Drug shortages may compromise patient safety: Results of a survey of the reference pharmacies of the Drug Commission of German Pharmacists. Health Policy. 2018 Dec;122(12):1302-1309. DOI: 10.1016/j.healthpol.2018.09.005



#### Spain

Major medicines supply problems have been reduced during the first half of 2020. As stated in the half-yearly report on supply problems published by AEMPS, there has been a decrease to 6.1% in the number of medicines provoking the greatest problems for patients, compared to the total number of presentations affected (0.14% of the total number of authorized presentations). Despite the unprecedented impact of SARS-CoV-2 on the medicines supply chain, these problems have not only been reduced but also resolved in a shorter time. Engaging pharmacists, in all professional settings, has been key to ensuring that the supply of medicines has not been affected during the pandemic.

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

Financial loss due to time invested in mitigating shortages (24/26)

Reduced patient/customer trust (21/26)

Reduced employee satisfaction (20/26)

Financial loss due to needed operational changes such as minimum stock keeping, import fees, etc. (14/26)

Direct financial loss due to increased sourcing prices as a reaction to low availability of a certain medicine (6/26)

Other (3/26)



Comments received:



#### Spain

The overloaded healthcare system due to COVID-19 has not led to major problems of shortage. This was partly due to the establishment of the home medicine dispensing service, in place during the pandemic, which helped to ensure that patients had their medication, while avoiding hoarding of medicines. Since the beginning of the pandemic, Pharmacy Representative Bodies (Provincial Pharmacists' Chamber) as well as the General Pharmaceutical Council of Spain (through CISMED information system) have continuously monitored the availability of medicines in community pharmacies.



Question 7. Which solutions can legally be offered by pharmacists in case of a shortage?<sup>2</sup> Tick all that apply (% of responding countries)





Comments received:

#### Belgium

Systematically sourcing medicines from other pharmacies is not permitted. It is permitted in exceptional circumstances such as shortages.



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



#### Cyprus

Only generic substitution is legally allowed. Therapeutic substitution, change of strength, or compounded formulation is only allowed after a new prescription is issued. Sourcing directly from manufacturers or from another country is legally prohibited.



"Changing to the same medicine with a different strength when still available, and adjusting therapy posology accordingly": in that case, the pharmacist must get the consent of the prescriber and note "replaced after medical advice" on the prescription. "Therapeutic substitution": this is done for some medicines, following a specific recommendation from health authorities. "Preparing a compounded formulation": this can happen, e.g. when there were shortages of corticoids.

#### Germany

Most of the above mentioned solutions can only be offered in correspondence to the prescriber and potential amendments to the prescription. During the SARS-CoV-2-Pandemic, where a possible worsening of drug supply is 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.

<sup>&</sup>lt;sup>2</sup> 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.



#### **Portugal**

It is possible to import medicines, but it has to be approved by the national health and medicines authority (INFARMED), through a special authorisation.



Slovenia

Patients can buy a medicine in another EU country and get reimbursement by the insurance.



#### Sweden

Many pharmacists also makes changes to the same medicine with a different strength or formulation and adjusting the therapy posology. However, the regulation are a bit unclear in what extent this is allowed.

**Spain** 

In Spain, virtually all the Regions only allow authorised centres attached to the Regional Government to dispense medicines imported from European countries when substitution or change by the pharmacist/prescriber is not possible. There are already programmes in some Regions agreed between the regional authorities and the Regional Pharmaceutical Councils, in which the participation of pharmacies in the dispensing of these imported medicines has been authorised to address situations of shortage, thus facilitating access to them for patients. It is important to note that some medicines cannot be replaced, such as those with a narrow therapeutic margin or medicines for the respiratory system administered by inhalation (see Order SCO/2874/2007 of 28 September).



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



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





Question 10. Who provides data / information on medicines shortages to pharmacists in your country? Tick all that apply (% of countries)



#### Comments received: $\mathbf{x}$



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### Denmark

In Denmark the pharmaceutical wholesalers report supply failure to the Danish Medicines Agency and they inform the community pharmacies.



#### Slovakia

State Institute for Drugs Control.



#### Poland

There is no procedure for providing public information about shortages.



Royal Pharmaceutical Society.

### Main Findings



All responding countries experienced medicine shortages in community pharmacies in the past 12 months, and in the majority (65%) of countries, respondents indicated that the situation got worse compared to 2019.



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 (92%).



In the majority of responding countries (65%), **over 200 medicines were listed as in short supply** at the time of completing this survey, with 8 countries indicating that there were even more than 400 medicines short in supply.



Almost all responding countries indicated that they believe medicine shortages cause distress and inconvenience to patients (96%). Interruption of treatments (80% of countries), increased co-payments as a result of more expensive/non-reimbursed alternatives (57%) and suboptimal treatment/inferior efficacy (50%) are also perceived as common negative consequences of medicine shortages on patients.



Medicine shortages are believed to affect community pharmacy businesses in most countries by **financial loss** due to time invested in mitigating shortages (92% of countries), **reduced patient trust** (80%) and **reduced employee satisfaction** (76%).

### **Main Findings**



Across European countries, **strong differences** exist in terms of **legal solutions** community pharmacists can offer in case of a shortages. Generic **substitution** (80% of countries), **importing the medicine** from a country where it is available (50%) and **sourcing the same medicine from alternative authorised sources** (such as other pharmacies) (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 is **6,3 hours per week on average.** 



23% 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 **medicine agencies** (65%), **manufacturers** (57%), and **wholesalers** (50%).

### Pharmaceutical Group of European Union

Rue du Luxembourg 19, 1000 Brussels - Belgium T: +32 (0)2 238 0818 Email: pharmacy@pgeu.eu <u>www.pgeu.eu</u>

