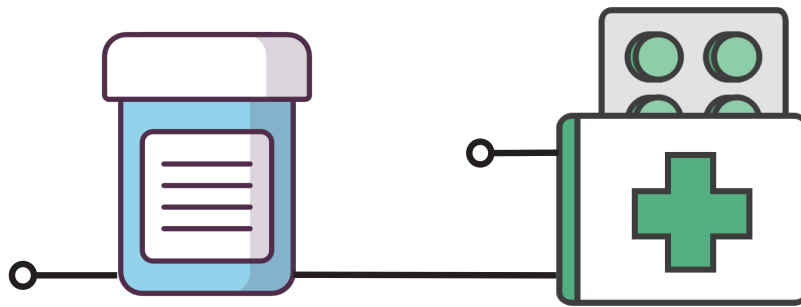


2018 EAHP Survey on Medicines Shortages



MEDICINES SHORTAGES IN ROMANIAN HOSPITALS



- 75% of hospital pharmacists are currently experiencing problems with medicines shortages.
- 71% of hospital pharmacists report that medicines shortages are a weekly, sometimes monthly, occurrence.
- 89% of hospital pharmacists agreed, or strongly agreed, that medicines shortages in their hospital are having a negative impact on patient care.

With medicines shortages becoming a growing issue in the pharmaceutical world year after year, the European Association of Hospital Pharmacists (EAHP) continued its “Medicines Shortages Survey” in 2018 in order to renew the available evidence on the medicines shortage situation in European hospitals. The survey covered 38 countries and amassed a total number of 1,666 responses. 24 Romanian hospital pharmacists provided responses, with an increase of 22 individuals compared to the 2014 EAHP Medicines Shortages Survey, when two responses were received from Romania.

75% of Romanian respondents are currently experiencing problems with medicines shortages

When asked if the shortage of medicines is a current problem in the hospital, especially in terms of delivering the best care for patients, 75% of Romanian respondents participating in the survey answered with “yes”.

** The numbers in this country report relate to the Romanian hospital pharmacists that participated in the 2018 EAHP Medicines Shortage Survey.*

*** The country report uses original quotes provided by survey respondents during the consultation period. These quotes have not been altered.*



In which area of medicines do Romanian hospitals experience shortages most commonly?



52% anaesthetic agents



48% oncology medicines



33% cardiovascular medicines



33% emergency medicines

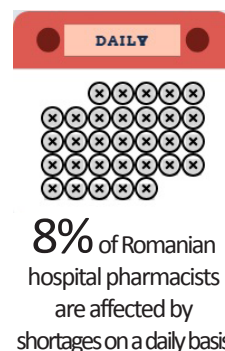


29% preventative medicines

71% of Romanian respondents report that medicines shortages are a weekly, sometimes monthly, occurrence

It is important to assess the occurrence of shortages in a timely manner in order to know if shortages for specific medicines come in waves or if they usually manifest themselves in the hospitals. When asked how often their hospital pharmacies experienced shortages of medicines, 8% (N=2) of respondents replied with “daily”, while 17% (N=4) experienced shortages on a “weekly” basis. Shortages are a monthly occurrence in 54% (N=13) of Romanian hospital pharmacies.

When a shortage is detected, hospital pharmacists work on overcoming it as soon as possible, although the timeframe depends on the nature of the shortage. In Romania, shortages usually last for up to 8 months, a worrying amount of time in terms of patient care. Nevertheless, sometimes they are resolved within 3 months.



In order to find out the answers to questions on the availability of shortage information in Romania, respondents were asked if they are aware of a reporting system for shortages being in place at the national level. Those who replied positively were encouraged to provide further feedback on the functionality of the system. The respondents pointed out that there is a system where Romanian hospital pharmacists can submit information on shortages, but 63% (N=10) believe that this system is not effective. The Ministry of Health and National Agency for Medicines and Medical Devices are the entities responsible for shortage reporting in Romania (<http://medicamentelipsa.ms.ro>, <https://www.anm.ro>).

The following free text comments were shared by the Romanian respondents on the functionality of the reporting system:

- “Health professionals and patients can use this site to report medicine shortages. This site is correlated with a daily stock reporting system for pharmacies and medical wholesalers. Unfortunately, medicines reported missing are inexplicably found in daily stock reports, but they are not actually available for patients, but rather meant for parallel export. However, this makes government officials say there are no medicine shortages.”
- “in our country is a tax problem (clawback tax) involved in many shortages and also parallel export (unregulated legislation.)”



89% of respondents agreed, or strongly agreed, that medicines shortages in their hospital are having a negative impact on patient care

In the hospital environment, medicines shortages affect patient care on different levels. The survey took into consideration **budget** and **time**. Results show that, due to shortages, Romanian hospital staff is diverted from their usual tasks for up to 5 hours (50% | N=9). In the worst-case scenario, hospital pharmacy staff must compensate the time lost due to medicines shortages with more than 10 or even 15 hours per week (34% | N=6). Furthermore, 67% (N=12) of respondents in Romania agree, or strongly agree, that medicines shortages have a negative impact on the overall hospital budget.

In regard to the steps taken to minimise the negative impact on patient care in Romania, the survey results showed that in 72% (N=13) of the cases, hospital pharmacists informed the prescriber about the shortage and recommended an alternative medicine. Other actions included investigating when the supply will be restored and planning accordingly (56% | N=10), informing the prescriber of a shortage (56% | N=10) or attempting to source the medicine from an alternative supplier (including another country) (17% | N=3).

Action from European and national entities is needed to combat the growing threat of medicines shortages and its impact on patient care

When presented with already existing solutions at the European level, four out of five respondents were in favour of the initiatives taken by the European Medicines Agency (EMA), the Heads of Medicines Agency* and the activities of COST Action CA 15105**. The remaining 17% (N=3) of Romanian respondents chose “none of the above” when asked which policy solution they personally supported. This particular answer may indicate, on the one hand, that Romanian hospital pharmacists are well informed and satisfied with the pan-European actions, but, on the other hand, that they are also calling for policy improvements.

61% (N=11) requested a more comprehensive database, run by the EMA, listing all medicines shortages together with advice on the shortages timeframe and available replacement therapies. The same percentage of respondents (61%) favour an annual reporting system providing information on the extent of medicines shortages within Europe. 33% (N=6) would personally support greater legal clarity on the need to oblige manufacturers to report a forthcoming disruption of supply, as well as a high-level investigation, led by the European Commission, to determine the causes of medicines shortages in Europe (e.g. production issues, pricing impact and parallel trade) and their impact on both patient care and healthcare delivery.

The following comments were received from respondents in relation to policy options on both national and European level:

- *“I think EU could ask for a report from every Ministry of Health in EU member countries about this topic (to be compulsory and maybe verifiable, being known that some countries like Romania tend to make fake reports in order to not give explanations about shortages). And parallel export policies with harsh consequences if the regulations are not respected.”*
- *“Make some special reports when the agency ANMDM of our country can’t solve the medicines shortages problems. I think that the supply of medicines for our hospitals needs changes and some other rules.”*

*Further information on EMA/HMA task force is provided here: <https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/heads-medicines-agencies>

**More on COST Action CA 15105 can be found here: http://www.cost.eu/COST_Actions/ca/CA15105