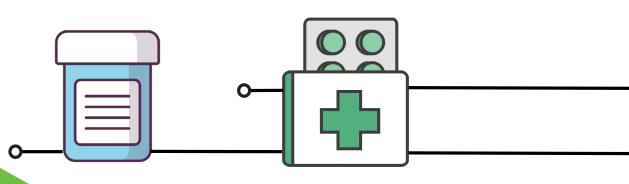
2018 EAHP Survey on Medicines Shortages



MEDICINES SHORTAGES IN ITALIAN HOSPITALS



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- 79% of hospital pharmacists are currently experiencing problems with medicines shortages.
- 70% of hospital pharmacists report that medicines shortages are a weekly, sometimes monthly, occurrence.
- 75% 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 and 73 responses were obtained from Italian hospital pharmacists, with an increase of 32 individuals compared to the 2014 EAHP Medicines Shortages Survey, when 41 responses were received from Italy.

79% of Italian 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, 79% of Italian respondents participating in the survey answered with "yes".

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



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

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



78% antimicrobial agents



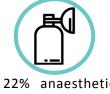
36% preventative medicines



36% cardiovascular medicines



28% oncology medicines



anaesthetic agents

70% of Italian 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 a 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, 22% (N=16) of respondents replied with "monthly", while 48% (N=35) experienced medicines shortages on a "weekly" basis. In 11% (N=8) of hospital pharmacies based throughout Italy, shortages are a daily occurrence. 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 Italy, shortages usually last for a number of months (3 months on average) or are resolved in a matter of weeks (approximately 5 weeks), according to the data collected by the EAHP Medicines Shortages Survey.



hospital pharmacist are affected by shortages on a daily basis



48% of Italian hospital pharmacists are affected by shortages on a weekly basis



22% of Italian hospital pharmacists are affected by shortages on a monthly basis

In order to find out the answers to questions on the available information vis-à-vis shortages in Italy, respondents were asked if they are aware of a reporting system for shortages being in place at the national level. Those who responded positively were encouraged to provide further feedback on the functionality of the system. The respondents pointed out that there is a system where Italian hospital pharmacists can submit information on shortages and 91% (N=29) believe this system is effective. Italian Medicines Agency (AIFA) is the entity responsible for shortage reporting in the Apennine Peninsula (http://www.aifa.gov.it/). The following free text comments were shared by the Italian hospital pharmacists describing the reporting system:

- "Sometimes, we obtain information partially, no alternative solutions are proposed, the problems are always the same: no meds."
- "We get the information of a shortage by e-mail, but this does not include all the shortages (for example no information about buspirone shortage). You get the information, but it seems that nothing is done to reduce the shortages."



75% of Italian 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 has taken into consideration **budget** and **time**. Results show that, due to shortages, hospital staff is diverted from their usual tasks for up to 5 hours (39% | N=14) or even up to 10 hours (17% | N=6) during an average working week. In the worst-case scenario, hospital pharmacy staff must compensate the time lost due to medicines shortages with more than 15 hours per week (17% | N=6). Furthermore, 72% (N=26) of respondents 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 Italy, the survey results showed that in 60% (N=21) 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 (57% | N=20), informing the prescriber of a shortage (54% | N=19) or attempting to source the medicine from an alternative supplier (including another country) (49% | N=17).

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 European level, over half of the 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 44% (N=15) of respondents chose "none of the above" when asked which policy solution they personally supported. This could mean that the system in Italy is providing enough information on pan-European initiatives and that they are well accepted by the hospital pharmacists. However, it may also indicate, on the one hand, individuals who do not support any of the proposed policies and, on the other hand, that respondents might not be aware that these policies exist or what they entail. Consequently, there is a clear need to improve communication on European and national policy responses and strategies vis-à-vis medicines shortages. 53% (N=18) of respondents opted for a more comprehensive database, run by the EMA, listing all medicines shortages linked with advice on how long the shortage may last and available replacement therapies. Moreover, 50% (N=17) would personally support a greater legal clarity on the need to oblige manufacturers to report a forthcoming disruption of supply, while 50% (N=17) favoured 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 patient care and healthcare delivery. Lastly, one fifth favour an annual reporting system on the extent of the medicines shortages problem within Europe.

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

- "Drugs shortage affects our work too much and the consequences are that we do not have the time to do other important things"
- "More responsibility of producers to assure the presence of their medicines in commerce, even if they
 have other countries where they commerce these medicines, where perhaps they gain more."

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



^{*}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