

EAHP Position Paper on Medicines Shortages

The problems caused by medicines shortages are serious, threaten the well-being of patients and have far reaching consequences for European health systems. Consequently, the European Association of Hospital Pharmacists (EAHP) started in 2013 to analyse in more detail the challenge posed by medicines shortages. Two pan-European surveys on medicines shortages in the hospital sector were conducted by the Association in 2014¹ and 2018² to investigate the prevalence and nature of shortages as well as direct impact on patient care. The percentage of hospital pharmacists reporting shortages to be an issue in particular in terms of delivering the best care to patients has seen a significant increase in 2018 with 91.8% respondents – compared to 86.2% in 2014 – stressing that medicines shortages constitute a problem in their hospital pharmacy.³ Such reports are alarming and demonstrate the urgent need to draft and implement corrective policies at all decision-making and professional levels across Europe. Multi-stakeholder action is urgently needed since only joint efforts can help diminish the impact of medicines shortages on patients. Consequently,

EAHP advises national governments to evaluate if their shortages measures and management systems are fit for purpose and to rectify shortcomings where and when needed.

EAHP urges national governments and healthcare organisations to evoke appropriate staffing levels in order to lower the impact that medicines shortages currently have on the overall patient services provided by hospital pharmacists.

EAHP calls on the European Commission to urgently commence an investigation of the medicines shortage problem looking at the causing factors and propose solutions that will help alleviate or solve shortages.

EAHP appeals for improved information exchange between authorities and supply chain actors as well as best practice sharing and implementation support on shortage management strategies between relevant national regulatory bodies to support patient safety.

EAHP urges the EMA and the HMA to consider the development of a comprehensive communication strategy on medicines shortages.

ACTION IN THE SUPPLY CHAIN

To minimise patient impact, all supply chain actors, including hospital pharmacists, wholesalers, manufactures and national competent authorities, have the obligation and responsibility to collaborate more closely in terms of resolving the shortages problem. When it comes to medicines availability, hospital pharmacists are the key information holder inside the hospital. They are responsible for sharing relevant notices on forthcoming shortages with colleagues, including the hospital management and prescribers. However, in order to fulfil this role, all supply chain actors, especially wholesalers and manufacturers, must communicate more effectively to hospital pharmacies about likely and current shortages. Such communication should be carried out in a timely manner and contain insights on how imminent the issue is, the expected duration of the shortage and whether alternatives are available. Communication between supply chain actors should be facilitated by national competent authorities to make sure that each entity works diligently and with urgency on bringing to an end the shortage difficulties that are currently experienced throughout Europe. The

overarching objective of these collaborative actions must be that the entire supply chain works together in minimising the detrimental effects on patients.

Managing medicines shortages and ensuring continuity of supply can cause the diversion of significant amounts of time⁴ and attention from other important tasks that a hospital pharmacist must perform in the provision of high quality, safe and efficacious care. It can also add to already high levels of stress experienced at the workplace. As shown in the results of the 2018 EAHP Medicines Shortages Survey, medicines shortages have the potential to result in increased medication error rates and lead to the delay or even the cancellation of therapies. Furthermore, efforts to reduce costs in health systems are very often undermined by having to opt for either a more costly or a less effective alternative that, in the long term, augments the use of financial resources by increasing the likelihood of hospital stay or readmission. Consequently, **EAHP urges** national governments and healthcare organisations to evoke appropriate staffing levels in order to lower the impact that medicines shortages currently have on the overall patient services provided by hospital pharmacists.

Hospital pharmacists in particular should remain vigilant and alert to the issue of medicines shortages as well as fully engage with prescribers and managers. To this end, they should raise awareness about the issue at local level and ensure the development and implementation of appropriate contingency plans. To better address the impact caused by shortages on patients and their therapy, hospital pharmacists should use and keep up to date their pharmacy skills in order to identify other solutions which can include small scale production of a medicine without a marketing authorisation.

ACTION AT NATIONAL LEVEL

The results of the 2018 EAHP Medicines Shortages Survey showed that many European countries have reporting systems in place. However, the views on their effectiveness were mixed with only 56% of participants judging their systems to be functional. Given the high degree of divergency throughout Europe, efforts should be made to strengthen the robustness and functionality of these reporting systems.⁵ Consequently, **EAHP appeals for** improved information exchange between authorities and supply chain actors as well as best practice sharing and implementation support on shortage management strategies between relevant national regulatory bodies to support patient safety. Ideally, it should be an expectation in each country that medicines are available to pharmacies within 24 hours of having ordered them.

The demand by hospital pharmacists for more timely and accurate information is increasing.⁶ To achieve higher quality of information, authorities and pharmacy practices should invest in combining their sourced shortages data. Such a measure would safeguard the timely detection of both temporary and permanent shortages since different signals on potential medicines shortages are being picked up by authorities and hospital pharmacists.⁷ In addition, national regulatory bodies should ensure action is taken against elements of the supply chain found to be in breach of legal and ethical obligations in relation to supply.⁸ Consideration should also be given to putting in place more rigorous rules on issuing timely alerts about shortage problems. **EAHP advises** national governments to evaluate if their shortages measures and management systems are fit for purpose and to rectify shortcomings where and when needed. This includes the removal of legal barriers that prevent compounding by hospital pharmacists in case of a medicine shortage.

ACTION AT PAN-EUROPEAN LEVEL

The problems created by medicines shortages have been widely reported by healthcare professionals^{9,10} as well as patients¹¹ and acknowledged at the European level by the European Medicines Agency (EMA), the European Commission and the Heads of Medicines Agencies (HMA). This

acknowledgement manifested itself on the one hand in the creation of a dedicated task force on the availability of authorised medicines for human and veterinary use¹² and on the other hand through dedicated research funding in the field of medicines shortages from the European Cooperation in Science and Technology (eCOST). Despite the efforts of the European Medicines Shortages Research Network¹³, funded by eCOST, the problem of medicines shortages continues to persist. The issues caused by medicines shortages are understood to be multifactorial. However, robust data on the causes are missing. To fill this information gap, **EAHP calls on** the European Commission to urgently commence an investigation on the medicines shortage problem by focusing on the causing factors and propose solutions that will help alleviate or solve shortages.

Closer collaboration between Member States is crucial for the pan-European solution finding process. The EMA and the European Commission are the most suitable actors to coordinate such action since they can build on their previous work, experience, expertise and involvement to date in this area. Further efforts should however be invested in the development of a comprehensive communication strategy, including the introduction of a unified European medicines identification system. Only a comprehensive communication strategy on shortages targeting all European states will ensure that all supply chain actors, including hospital pharmacists, receive adequate information on the shortage of medicines in their countries. National early reporting systems that exist in a number of countries should be complemented by a European-wide database that lists reasons and estimated durations of shortages. In addition, this system should include advise on alternatives which includes the expertise is provided by hospital pharmacists.

EAHP urges the EMA and the HMA to consider the development of a comprehensive communication strategy on medicines shortages.

¹ European Association of Hospital Pharmacists. Medicines shortages in European hospitals. The evidence and case for action. Brussels: European Association of Hospital Pharmacists (EAHP), 2014. Available from:

http://www.eahp.eu/sites/default/files/shortages_report05online.pdf.

² European Association of Hospital Pharmacists. EAHP's 2018 Survey on medicines shortages to improve patient outcomes. Brussels: European Association of Hospital Pharmacists (EAHP), 2018. Available from:

http://www.eahp.eu/sites/default/files/report_medicines_shortages2018.pdf.

³ Miljković N, Gibbons N, Batista A, et al Results of EAHP's 2018 Survey on Medicines Shortages Eur J Hosp Pharm 2019;26:60-65.

⁴ In some hospital pharmacies, many hundreds of hours. Drugs available in the EU – Future shortages? EJPB Practice. Volume 13. 2007/3.

⁵ Bochenek T et al (2018) Systemic Measures and Legislative and Organizational Frameworks Aimed at Preventing or Mitigating Drug Shortages in 28 European and Western Asian Countries. Front. Pharmacol. 8:942. Available from:

[https://www.frontiersin.org/articles/10.3389/fphar.2017.00942/full?utm_source=Email&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers in Pharmacology&id=323253](https://www.frontiersin.org/articles/10.3389/fphar.2017.00942/full?utm_source=Email&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers%20in%20Pharmacology&id=323253).

⁶ European Association of Hospital Pharmacists. EAHP's 2018 Survey on medicines shortages to improve patient outcomes. Brussels: European Association of Hospital Pharmacists (EAHP), 2018. Available from:

http://www.eahp.eu/sites/default/files/report_medicines_shortages2018.pdf.

⁷ Postma DJ, De Smet PAGM, Gispens-de Wied CC, Leufkens HGM and Mantel-Teeuwisse AK (2018) Drug Shortages From the Perspectives of Authorities and Pharmacy Practice in the Netherlands: An Observational Study. Front. Pharmacol. 9:1243. Available from:

<https://www.frontiersin.org/articles/10.3389/fphar.2018.01243/full>.

⁸ De Weerd E, Simoens S, Hombroeckx L, Casteels M, Huys I. Causes of drug shortages in the legal pharmaceutical framework. Regul Toxicol Pharmacol. Elsevier Inc.; 2015;71: 251–258.

⁹ The Economist Intelligence Unit. Cancer medicines shortages in Europe. Policy recommendations to prevent and manage shortages.

London: the Economist Intelligence Unit Limited, 2017. Available from: <http://www.eiu.com/graphics/marketing/pdf/ESMO-Cancer-medicines-shortages.pdf>.

¹⁰ Postma DJ, De Smet PAGM, Gispens-de Wied CC, Leufkens HGM and Mantel-Teeuwisse AK (2018) Drug Shortages From the Perspectives of Authorities and Pharmacy Practice in the Netherlands: An Observational Study. Front. Pharmacol. 9:1243. Available from:

<https://www.frontiersin.org/articles/10.3389/fphar.2018.01243/full>.

¹¹ EURORDIS. Common position between patients', consumers, and healthcare professionals' organisations involved in the activities of the European Medicines Agency on Supply Shortages of Medicines. Paris: EURORDIS, 2014. Available from:

<http://download2.eurordis.org.s3.amazonaws.com/documents/pdf/common-position-supply-shortages-final-10-2013.pdf>.

¹² Heads of Medicines Agencies. European Medicines Agency EU regulatory network reflection paper on the availability of authorised medicinal products for human and veterinary use. 2018. Available from: [http://www.hma.eu/fileadmin/dateien/HMA_joint/00-About_HMA/03-](http://www.hma.eu/fileadmin/dateien/HMA_joint/00-About_HMA/03-Working_Groups/TF_Availability/2018_08_TF_AAM_Reflection_paper_on_the_availability_of_authorised_medicinal_products_for_human_and_veterinary_use.pdf)

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¹³ eCOST. European Medicines Shortages Research Network – addressing supply problems to patients (Medicines Shortages) CA15105. Brussels: European Cooperation in Science and Technology (eCOST). Available from: <http://www.medicinesshortages.eu/>.