

EAHP STATEMENT ON MEDICINES SHORTAGES

JULY 2012

The European Association of Hospital Pharmacists (EAHP) is deeply concerned at reports from hospital pharmacists across Europe of increasing experience of medicines shortages in their hospital. EAHP has agreed through its 2012 General Assembly the following statement on the problem, which outlines measures to improve the current difficulties.

The problem

Medicines are not simple items of commerce, they are an essential component of patient care and in the hospital sector they must be administered to the patient in a timely manner. This is particularly the case for patients taking medicines which have a significant clinical consequence when doses are missed, such as anti-psychotics, anti-epileptics, immunosuppressives and anti-cancer drugs. Shortages of such medicine place the ability to provide timely administration of a particular medicine under threat.

Managing medicines shortages and ensuring continuity of supply can also cause the diversion of significant amounts of the time¹ and attention of a hospital pharmacist from other tasks important in the provision of high quality, safe and efficacious care. It can also add to already high levels of stress that can be experienced in the workplace. EAHP is concerned that this, combined with use of alternative medications, has the potential to have detrimental impacts on medication error rates.

Furthermore, the medicines shortage problem can undermine efforts to reduce costs in health systems as often, in the case of shortage, a more costly alternative must be used – or worse, a less effective alternative, a perverse scenario in relation to a hospital pharmacist's instinctive drive to improve patient outcomes.

Finally a theoretical risk to the safety of the supply chain is posed by medicines shortages as unscrupulous individuals or organisations could take advantage of an increasingly difficult situation through the sale into the supply chain of counterfeit medicinal products².

Therefore reports that hospital pharmacies across Europe are increasingly experiencing medicines shortage are alarming and demonstrate the urgency of remedial policies being enacted at all levels and across Europe.

¹ In some hospital pharmacies, many hundreds of hours <http://eahp.eu/Media/Home-page/EJHP-BMJ/EJHP-Practice-archive/Issue-3-2007/Cover-story/DRUGS-AVAILABLE-IN-THE-EU-a-FUTURE-SHORTAGES>

² <http://www.securingspharma.com/drug-shortages-raising-supply-chain-risk-says-fda/s40/a1166/>

Action in the supply chain

EAHP recognises that every member of the medicines supply chain has obligations and responsibilities in terms of resolving the shortage problem and therefore makes the following calls:

- For prescribers
 - to be aware of the problem;
 - to discuss with hospital pharmacists potential changes to prescribing policies if necessary; and,
 - to take due notice of hospital pharmacy communications on the issue.
- For hospital pharmacists:
 - to be vigilant and alert to the issue of medicines shortage;
 - to share relevant information of forthcoming shortages with colleagues, including hospital management and prescribers;
 - use, and keep up to date, pharmacy skills to identify other solutions when a shortage occurs, which might eventually include small scale production of medicine without a marketing authorisation; and,
 - consider contingency arrangements for theoretical shortages.
- For wholesalers:
 - communicate effectively to hospital pharmacies about likely and current shortages, and in a timely manner;
 - make appropriate use of quotas as a tool to ensure fair distribution when demand exceeds supply; and,
 - prioritise replenishment of supplies over routine delivery when a shortage is relieved.
- For manufacturers:
 - provide adequate notice and alert of manufacturing problems;
 - provide within such notifications information on how imminent the shortage is, the expected duration of the shortage, whether alternatives are available, and the size of the manufacturer's share of the market for the product;
 - provide active assistance to hospital pharmacies in the management of shortage problems, such as maintaining dedicated helplines;
 - ensure maintenance of adequate "buffer stocks" of medicines, especially for critical medicines such as those used by emergency departments in hospitals;
 - conduct customer audits and surveys to assess the performance of supply arrangements and to identify any potential improvements; and
 - otherwise work with urgency to bring to an end the shortage difficulties currently being experienced across Europe, including root cause analysis of why the problems are occurring and how they might be resolved most quickly.

At the national level

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 and contributing to the shortage problem. Consideration should also be given to putting in place more rigorous rules on the issuing of timely alerts about shortage problems.

EAHP also call for improved national information, vigilance and monitoring systems in relation to shortages, and the sharing of information and best practice on shortage management between relevant national regulatory bodies.

Ideally it should be an expectation in each country that medicines should be delivered to pharmacies within 24 hours of order.

At the international level

At a European level, EAHP considers that in reference to Article 168 of the Treaty on the Functioning of the European Union which states that, *'Union action [...] shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health'* the European Commission should:

- Actively contribute to the coordination of EU-wide actions to respond to the medicines shortage problem
- Commence a European wide investigation of the medicines shortage problem including looking at:
 - the issue of free movement of goods, and whether or not this is a factor in undermining national medicines supply chains, and if so, how can the conflict best be resolved at a European level;
 - the extent to which European Guidelines on Good Distribution Practice of Medicinal Products for Human Use (94/C 63/03)³ are being adhered to; and,
 - the extent to which this Guideline may need to be updated in view of the shortage problem.
- EAHP consider that the future European medicines identification system should be introduced in the context of joined-up thinking on European-wide medicines related issues, and not address counterfeit issues solely without reference to other solutions of public benefit that it might be able to provide. EAHP therefore urge that the Commission give serious consideration to how the forthcoming Delegated Act on a Unique Identifier for medicines might be used to help tackle the medicines shortage problems in future for example by:
 - use of information about where medicines are going;
 - where short supply medicines might be available from;
 - understanding medicines demand patterns; and,
 - assisting forecasting and supply chain inventory management and efficiency.

³Especially the requirement that *"the quality system should ensure that the right products are delivered to the right addressee within a satisfactory time period"*
<http://ec.europa.eu/health/files/eudralex/vol-4/gdpguidelines1.pdf>

EAHP also calls for the European Heads of Medicines Agencies to jointly consider what new European-wide actions can assist the shortage problem, and develop a strategic joint position on medicines shortages, reviewing its 2007 Task Force Report in the process⁴, many of the recommendations of which have now been implemented.

Finally, EAHP calls for the European Medicines Agency to have involvement in the pan-European solution-finding process, building on some of its work, experience, expertise and involvement to date in this area.

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EAHP is a Federation of national associations of hospital pharmacists. Its European membership includes more than 21,000 professionals. EAHP represents and develops the hospital pharmacy profession within Europe in order to ensure the continuous improvement of care and outcomes for patients in the hospital setting. This is achieved through science, research, education, practice, as well as sharing best-practice and responsibility with other healthcare professionals..

⁴http://www.hma.eu/fileadmin/dateien/HMA_joint/02- HMA_Topics/05-Availability_Medicines/2007_11_ReportTF.pdf