

13 June 2016

The European Association of Hospital Pharmacists (EAHP) has advised the European Heads of Medicines Agencies ^[1] to work together to improve the information available about medicines shortages, assign responsibilities and learn from replicable actions on shortages taken by medicines regulators in other parts of the globe.

The Heads of Medicines Agencies (HMA) is a network of both human and veterinary medicines agencies of the European Economic Area ^[2]. The network provides a forum for the co-ordination and the exchange of views and proposals on issues concerning the European regulatory system and the role of the national authorities within that system.

The HMA recently adopted a Multi-Annual Work Plan to 2020 ^[3], in which "*availability of appropriately authorised medicines*" is the second described business priority of the network. It was in this context that EAHP was invited to speak about the experiences of medicines shortages in the hospital sector.

EAHP described real life case studies, shared the results of surveys of its membership on the topic and made 5 key recommendations to the network:

1. A common definition for a medicine shortage is needed to ensure all medicines agencies and stakeholders in Europe are speaking the same language on the problem.

This should be patient-centred, focusing on the experience at the end of the supply chain. When a patient cannot receive the medicine they need and have been prescribed within a reasonable timeframe, this is a shortage.

2. Information systems for medicines shortages across Europe should operate to common standards

Information on confirmed shortages should be publicly available. Patients and healthcare professionals need to know how long a shortage is likely to last, and what alternatives might be available in the interim.

3. Improve reporting requirements

It is questionable the extent to which current EU requirements for manufacturers to report likely disruptions to supply (Art. 81 of Directive 2001/83/EC ^[4]) is meeting its purpose. Experience of legislation in the USA (FDASIA 2012 ^[5]) has shown clarifying these requirements can improve management of problems and better enable contingencies to be put in place.

4. Monitor and analyse the shortage situation at the European and international level

Many shortages can be said to have cause at the international level, for example as a result of globalisation of production, demand spikes, or parallel trade. If common European standards for shortages information systems can be put in place, then a European level system for monitoring, oversight and cooperation can be put in place.

5. Assign responsibilities

As well as an "information gap", EAHP identifies a "responsibility gap" at the European level on the topic of medicines shortages. EAHP has suggested the remit of the European Medicines Agency to be active in this area be enhanced. Experience of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 suggests assignment of responsibility helps to alleviate inertia. A pan-European health threat merits an EU response.

Commenting on the meeting, Aida Batista, EAHP Director of Professional Development and policy lead on medicines shortages, said:

"At the meeting, I detected a strong desire from European medicines regulators to cooperate and take action on medicines shortages. I believe the recommendations we provided offer a sensible, realistic and achievable way forward by which the process of amelioration on shortages can begin. Once we have improved information and assigned responsibilities we can really start to pinpoint more precisely causes and solutions. I thank the Heads of Medicines Agencies for their invitation to engage, and congratulate them on making availability of medicines one of their key priorities to 2020."

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NOTES TO EDITORS:

1. The European Association of Hospital Pharmacists (EAHP) is an association of national organisations across 34 countries representing hospital pharmacists at European and international levels. More information about the EAHP and its history [here](#) [7].

2. More information about the Heads of Medicines Agency is available [here](#) [1].

3. The EU Medicines Agencies Network Strategy to 2020 is available [here](#) [3].

4. The meeting between HMA and EAHP took place on Tuesday 31st May in Rotterdam.

5. More information about EAHP's policy activity in the area of medicines shortages, including the report of its 2014 pan-European survey on the topic, is available [here](#) [8].

6. Further reflections about why improving information about shortages assists in managing the problem is available in the article "Drug Shortages in the US: Causes and What the FDA Is Doing to Prevent New Shortages" by Dr Erin Fox, available [here](#) [9].

7. Requests for interviews with Aida Batista can be made by contacting [info\[at\]eahp\[dot\]eu](mailto:info[at]eahp[dot]eu) [6] | 00 322 741 2436

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Links

[1] <http://www.hma.eu/> [2] https://en.wikipedia.org/wiki/European_Economic_Area [3] http://www.hma.eu/fileadmin/dateien/HMA_joint/00-__About_HMA/01-

HMA_MG_and_PS/2016_02_HMA_Joint_Mult_Annual_Work_Plan.pdf [4]

http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf
[5]

<http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/ucm313121.htm>

[6] <https://www.eahp.eu/contact/info/eahp/eu> [7] <http://www.eahp.eu/about-us> [8]

<http://www.eahp.eu/practice-and-policy/medicines-shortages> [9]

<https://login.medscape.com/login/sso/getlogin?urlCache=aHR0cDovL3d3dy5tZWZyY2FwZS5jb20vdmld2FydGljbGU>