The EAHP EU Monitor is a regular round up of news relevant to hospital pharmacy in Europe.

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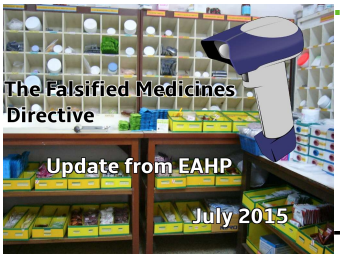
New EAHP President Joan Peppard: Building on firm foundations for the future

The European Association of Hospital Pharmacists (EAHP) is delighted to welcome Ireland's Joan Peppard as its new President following the recent annual General Assembly in Porto, Portugal (12-13 June 2015).

The event also saw elections to the EAHP Board, with Aida Batista (Portugal), Petr Horak (Czech Republic), Rob Moss (Netherlands) and András Süle (Hungary) all elected to serve 3-year terms.

More information here. [2]



The Falsified Medicines Directive: July 2015 update from EAHP

With the clock ticking until the 2018 deadline to implement medicines verification procedures in European hospital pharmacies, EAHP presents a general update to its membership on recent developments in respect of the Falsified Medicines Directive.

See previous update here [3].

The Delegated Act: inching towards finalisation

The 2011 Falsified Medicines Directive sets out very basically described requirements for all EU Member States to implement a system for verifying the authenticity of medicines before the medicines reach the patient. The details of how such a system should operate in practice was left to be described in secondary piece of legislation, to be drafted by the European Commission, known as a 'Delegated Act'.

While the process by which the Commission is developing this Delegated Act operates to strict rules of confidentiality, EAHP understands that the drafting is almost complete, and that the Act should be 'adopted' (i.e. made final) by either late August or early September 2015. After this, a stage of translation to EU languages will be conducted, and by the end of 2015 the Commission will publish a public version.

EAHP and its members have made numerous representations seeking to ensure that facilities will exist within the final system for aggregated check out of medicines. This will help to reduce the potentially significant impact for hospitals in terms of individually scanning every single packet of medicine that the hospital receives. In large hospitals, where millions of medicine boxes can be received every year, the resource impact on staff time threatens to be severely onerous unless it can be made possible to conduct check out scans at the bulk container level.

EAHP has also expressed concern about a suggested short 10-day period between a medicine being checked out at the pharmacy level and the possibility of return to the manufacturer being eliminated.

As the drafting process remains confidential it is not yet known if these concerns will be addressed in the final delegated act. It is also not yet known whether the Delegated Act will be given any final opportunity for stakeholder consultation before becoming final EU law. EAHP has pushed strongly for the need for a final consultation with those stakeholders expected to implement the regulations in order to avoid foreseeable implementation problems caused by unconsidered issues, especially in respect of the great diversity and difference between medicines supply chains and hospital practices across Europe.

In the final instance, the Delegated Act must also be approved via a straight yes/no vote of the European Parliament, likely to take place either at the end of 2015 or in early 2016. There is however little precedent so far for the European Parliament rejecting a Delegated Act.

Creating national systems for implementation of the Directive

The principal emerging provider of a system for implementing the Falsified Medicines Directive in pharmacies is the European Medicines Verification Organisation (EMVO). This is a collaboration of the EFPIA (the European Federation of Pharmaceutical Industries and Associations – representing pharmaceutical originator companies), the EGA (the European Generic and Biosimilar medicines Association), PGEU (the Pharmaceutical Group of the European Union – representing community pharmacy), GIRP (the European Association of Pharmaceutical Full-line Wholesalers) and EAEPC (the European Association of Euro-Pharmaceutical Companies – representing the parallel trade industry).

The broad concept of EMVO is to create an overall set of principles and system architecture for medicines verification at the European level that can then be employed at a national level as a template or 'blueprint' system.

Whilst waiting for publication of the Delegated Act, EMVO is pressing ahead with preparations for the 2018 implementation deadline, recently announcing three preferred IT providers for national medicines verification systems to select from when putting in place any verification systems that make use of the EMVO system.

The three preferred providers are Aegate, Arvato and Solidsoft Reply. More information here [4] .

Elsewhere, the European Medicines Verification Organisation has recently appointed Sonia Ruiz Moran as the organisation's new President. Ms Moran has been the European Public Affairs lead at the General Pharmaceutical Council of Spain since 2008. More information here. [5]

EAHP continues to monitor FMD developments closely and, in partnership with its membership, to make representations on hospital pharmacy concerns and recommendations.

Some further information about the Falsified Medicines Directive and current matters is also available via a recent interview piece in Pharma World Magazine here. [6]

EAHP members with questions and requests for additional information about the Falsified Medicines Directive may contact info [@] eahp [dot] eu.

EAHP presents medicines access challenge to European Parliament Group

The European Association of Hospital Pharmacists recently presented evidence to a workshop hearing of the Socialists and Democrat (S&D) Group of the European Parliament on the topic of access to medicines. EAHP focused on the matters of availability and affordability of medicines and made suggestions for how improvement might be achieved at the European level.

EAHP was presenting on behalf of the European Public Health Alliance of which EAHP is an active member. The invitation to present was received from the Socialist and Democrat Group as the Group is developing a position paper on the topic of access to medicines. The Socialist and Democrat Group is the political group in the European Parliament of the Party of European Socialists (PES), and is the second largest grouping of Members of the European Parliament (MEPs) after the centre-right European People's Party (EPP).

Chaired by German MEP Matthias Groote, the workshop heard from many perspectives, including the pharmaceutical industry, regulatory perspectives, and from pharmacists and doctors.

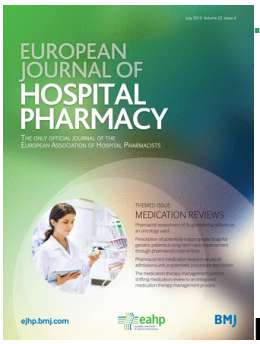
On availability of medicines, EAHP set out the scale of current medicines shortages across the European hospital sector, as evidenced in EAHP's November 2014 report [7] on the topic. EAHP made suggestions as to how information systems for reporting shortages across Europe could be improved, learning from regulatory action taken in the USA [8] in this respect. This includes improved clarity on the legal obligations of manufacturers to report forthcoming disruptions to supply at an early stage in order to assist contingency arrangements. EAHP also supported the recommendation of the Matrix Insight study on availability of medicines [9] in Europe that highlighted the need to clarify the obligations on companies, contained within Article 81 of Directive 2001/83/EC [10], to meet an obligation to supply.

On affordability of medicines, EAHP explored the non-regulatory tools currently emerging as a means to meet the challenge, including joint procurement processes by two or more EU countries and risk-sharing pricing models. The development of access indicators, and the value of pharmacist roles in achieving improved adherence and more rational use of medicines were also promoted in the presentation.

The overall event also explored how the European Medicines Agency's evaluation activities could be better streamlined to assist early Health Technology Assessments for new medicines. A spokesperson from the European Commission outlined current initiatives to encourage enhanced cross-country coordination around drug pricing, looking at methods for price information and consensus building on price standardization. Richard Torbett from the European Federation of Pharmaceutical Industry Associations (EFPIA) presented thoughts on moves towards more value based pricing models, while Doctors of the World raised the need for Governments to consider compulsory licensing as a potential remedy to the affordability challenge.

The S&D Group intend to develop a position paper on the issue of access to medicines in Europe, drawing from the discussion at the 1 July workshop, with the possibility of it being the basis of further activity in the European Parliament. EAHP will continue to monitor and input where possible to the process and outcomes.

More information here. [11]



EJHP: July 2015 issue now available, special theme medication reviews

The July 2015 edition of the European Journal of Hospital Pharmacy is now available! The issue has a special focus on the topic of medication reviews, highlighting the various aspects of such reviews in a variety of patient populations, including the elderly, nursing home patients, oncology patients and other hospitalised patients. Studies from six European countries are included.

More information here. [12]

23 July 2015

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