

european association of
hospital pharmacists

Rue Abbé Cuyppers, 3
1040 Brussels
Belgium

tel: +32 2 7416829
fax: +32 2 7347910

e-mail: sec@eahp.eu
internet: www.eahp.eu

VAT No.: BE0836.539.876

Brussels, 7 December 2015

Dear EAHP Member Presidents and Delegates,

2016: An important year for implementation of the Falsified Medicines Directive

As 2015 comes to a close, and our attentions turn to the challenges and opportunities for hospital pharmacy in 2016, I am writing to you in relation to the ever-pressing issue of the Falsified Medicines Directive and its impact for hospital pharmacy.

2015: The European Commission's development and publication of a Delegated Act

As you will be aware from editions of the EU Monitor this year, as well as presentations at EAHP meetings, the 2011 Directive on Falsified Medicines will lead to major impact to hospital pharmacy workflows in all EU and European Economic Area countries.

Hospitals will be under legal obligation to conduct verification scans of each package of medicine received by a 2019 deadline.

2015 saw the publication of the European Commission's Delegated Act on the Directive that sets out how countries are expected to implement these requirements, including some detail about hospital implementation.

More information about the Delegated Act, including hospital-specific reflections and key points, is available via the EAHP EU Monitor's August edition:

<http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-25-august-2015>

2016: The need now for national level engagement in implementation discussions

Following the publication of the Delegated Act, implementation issues related to the Directive will now be largely dictated at a national level. **Therefore the primary reason for my communication is to encourage all EAHP member associations to be active participants in the discussions taking place in your country on how this Directive will be implemented in practice.**

2016 will be a year in which "national medicines verification organisations" (NMVOs) will be constructed to create and oversee the electronic systems used to implement the verification-scanning requirements. Thereafter, the NMVOs will select vendors and carry out other implementation activity. Your association may already have been invited to participate in some of these early meetings.

As your association plans its year ahead, I would like to personally encourage each of you to:

1. ensure familiarity at your Board level with the Falsified Medicines Directive and its likely impacts for hospital pharmacy;
2. reach out to EAHP with lingering queries and questions about the Directive that we may be able to assist with; and,
3. ensure your association is engaging in the national level dialogues on FMD implementation in 2016, and that the voice of hospital pharmacy is being heard.

From EAHP's perspective, we are:

- conducting discussions with the preferred system suppliers to heighten their awareness of hospital pharmacy perspectives on implementation;
- liaising with the European Medicines Verification Organisation on the possibilities and consequences of "associate membership" in order to improve hospital pharmacy representation with the system design; and
- raising hospital pharmacy concerns, and seeking solutions, via all appropriate forums we can identify.

The Directive must be carefully implemented in order to avoid disproportionate burden being placed on already resource-constrained health facilities. It will require representation from hospital pharmacy to militate against this risk.

From this point forward, the best means to achieve proportionate implementation is to proactively ensure hospital pharmacy representation on the issue occurs at **both** the national and European level.

Whilst our next Members' Meeting in Vienna on Tuesday 15th March provides a chance for pan-European exchange on all these matters, I do hope members will also take action on the 3 points described above before we meet.

I wish you all a restful holiday season ahead of another important year for all us involved in hospital pharmacy advocacy and I thank you once more for the efforts you always make with EAHP on this.

Yours sincerely,



Joan Peppard

President

The European Association of Hospital Pharmacists (EAHP)