

# eahp euMonitor

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

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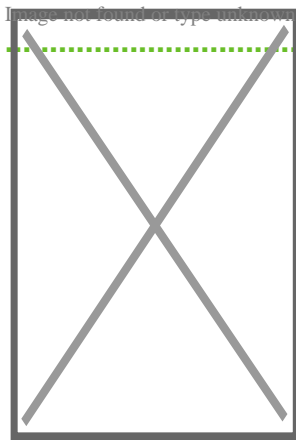


## **EAHP's Hamburg Congress puts patient safety at the heart of the hospital pharmacist's agenda**

For those who couldn't attend, or couldn't attend all sessions, EAHP is delighted to share a summaries of its recent annual Congress in Hamburg. The Congress took patient safety as its central theme.

All copies of the EAHP Congress Daily Dose, including the post-Congress edition, are now available [here](#) [2].

A press release summarising the Congress key messages, announcements and prize-winners is available [here](#) [3].



## **EAHP BRIEFING: New details emerge about the implementation of**

### **the Falsified Medicines Directive**

All hospital pharmacies in Europe will be under a legal obligation to implement medicines verification practices in 2018. The new requirements come as a result of the 2011 Falsified Medicines Directive. Further details of what this is likely to mean in practice for hospital pharmacists have recently been emerging.

EAHP and its members remain seriously concerned about the implications and burden such obligations will place on hospital pharmacy, which across Europe already operates in resource-restrained environments.

The [2011 Directive](#) [4] gives only headline attention to what the pan-European verification system for medicines might consist of: a verification system based on unique identifiers linked to a repository. All of the details relating to the technical specifications, modalities and management of the new verification system are instead left to the European Commission to propose via a second set of regulations called a "Delegated Act".

Negotiations on the contents of this Delegated Act have been conducted in private between the European Commission and the EU Member State Governments with strict rules on confidentiality. However, EAHP understands the negotiations are nearing a conclusion. A

document prepared for the EU's Pharmaceutical Committee has also recently been made public, and gives an indication of what can be expected in the Delegated Act. The document is available [here](#). [5]

A confidential impact assessment has so far provided the primary guide to the European Commission in developing the content of the Delegated Act. Key points from this assessment highlighted in the recently published paper to the EU's Pharmaceutical Committee include:

1. The "unique identifier" that will underpin the verification system will take the form of a 2D barcode and contain the product code, a serialisation number, a national reimbursement number (if requested by Member States), the batch number and the expiry date.

**EAHP comment:** To be aware that this 2D barcode will only feature on the **outer** (or secondary) packaging of the medicine, and NOT the primary packaging (e.g. the foil blister package). EAHP has campaigned for many years for barcoding to the single unit in order to facilitate the practice of bedside scanning to prevent medication error in hospitals (more information [here](#) [6]). Sadly the Directive will **not** achieve this objective, **but it will mean all hospitals in Europe must operate scanning procedures, at least in respect of medicines entering the hospital.**

2. The system to be introduced will be an "end-to-end" medicines verification system supplemented by risk-based verifications by wholesale distributors (i.e. the system will **NOT** be a full track-and-trace system where the location of a medicine package throughout the supply chain is recorded)

**EAHP comment:** This "end-to-end" system of verification means that **BOTH** community **AND** hospital pharmacy **MUST** ensure that a final check (in practice a scan of the barcode) of a medicine's authenticity is conducted before it reaches the patient.

EAHP and its members remain **seriously concerned** about the implications and burden such obligations will place on hospital pharmacy, which across Europe already operates in resource-restrained environments. Large hospitals can receive many millions of packets of medicine each year, and the staff time involved in scanning every single packet received would be immense. **EAHP and its members advocate that the forthcoming Delegated Act enable hospital pharmacists to conduct the verification scan of received medicines at a bulk level (i.e. by a single scan of large bulk container holding dozens of individual packages).**

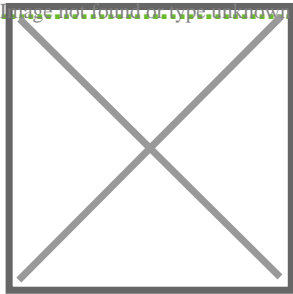
3. The repository containing the unique identifiers (i.e. the database that links to the conducted scan to check that the scanned item is indeed legitimate) should be set up and managed by stakeholders ("a stakeholder's model"). National competent authorities are expected to be able to access and supervise the database.

**EAHP comment:** This final point of advice that the Commission has received via its impact assessment suggests that the model for medicines verification under development by the "[European Medicines Verification Organisation](#) [7]" (EMVO) is likely to be treated favourably by the Commission and national Governments. EMVO (previously referred to as 'the European Stakeholder Model') is a collaboration of European medicines supply chain organisations working together to create a stakeholder managed and driven system for medicines

verification.

Members of the EMVO are:

- the European Federation of Pharmaceutical Industries and Associations (EFPIA);
- the European Generic and Biosimilar Medicines Association (EGA);
- the European Association of Pharmaceutical Full-line Wholesalers (GIRP);
- the European Association of Euro-Pharmaceutical Companies (EAEPIC); and,
- the Pharmaceutical Group of the European Union (PGEU).



**European Medicines Agencies launches several consultations of**

### **hospital pharmacist interest**

In the past number of weeks the European Medicines Agency has launched a number of consultations of interest to the hospital pharmacy profession, mostly in the area of risk minimization.

#### ***1) Good practice guide on risk minimisation and prevention of medication errors***

The Agency has launched a public consultation until 14th June 2015 on European guidance on optimising risk minimisation and prevention of medication errors. The draft guidance document includes:

- Measures that Marketing Authorisation Holders should take in reducing risk of medication error during product development stages (e.g. simulated use testing and 'perception-cognition-action' analysis), including in the creation and maintenance of Risk Management Plans (RMPs), and creation of Periodic Safety Update Reports (PSURs);
- Suggestions on risk minimization measures during clinical trials, as well as collection of early indicators on risk during a trial
- Key considerations for risk minimization by prescribers, including support for eliminating hand written prescriptions, and available e-prescribing tools to prevent prescribing error
- Suggestions on the role of the pharmacist in preventing medication error, including consulting dispensing records and asking questions to the patient
- Particular considerations on risk minimization in respect of older patients and patients with visual impairment or low literacy
- Recommendations on the conduct of Root Cause Analysis by multidisciplinary teams at the local level

The guidance is supported by many case examples and references to other international sources of good practice.

More information [here](#) [8].

## **2) Risk minimisation strategy for high strength and fixed combination insulin products**

A number of high strength insulins (i.e. higher than EU-wide standard 100 units/ml concentration) have recently been approved in EU, prompting some concerns about potential medication errors by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC). Accordingly, the PRAC has developed a suggested strategy on preventing errors with such medicines and is consulting publicly on its contents. The deadline for comments and responses is 14th June 2015.

The guidance includes recommendations that:

- high strength/fixed combination insulin product should be manufactured in a pre-filled insulin injector device only
- the insulin injector device should be a multiple-dose, disposable insulin pen injection system for single patient use for either self-injection or to be operated by a healthcare professional, patient relative or carer
- the insulin injector device should be discarded when the insulin container is empty
- the maximum insulin dose per injection should be limited to avoid serious overdose.

The guidance goes on to make recommendations in the areas of product design and labeling, information to be included in the Summary of Product Characteristics (SmPC), and additional measures for Manufacturing Authorisation Holders to take within specific Risk Management Plans (RMPs)

More information [here](#) [9].

## **3) Good practice guide on recording, coding, reporting and assessment of medication errors**

The European Medicines Agency has developed a draft good practice guide on the recording, coding, reporting and assessment of medication errors associated with suspected adverse reaction(s) in the context of EU pharmacovigilance obligations, and seeks comments on its content. The deadline for responses is 14th June 2015.

The guidance reflects on the benefit of recording 'potential errors' as well as actual errors and also errors that do not result in harm. The guidance also provides definition and classification for a common typology of medication error in order to improve information sharing and analysis on the point. The guidance gives suggestion on how such information sharing should take place and which agencies should be involved. The guidance also makes recommendation on the fields of information to be included within various types of error reports.

More information [here](#) [10].

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## EJHP: May 2015 edition now online!

The May 2015 edition of the European Journal of Hospital Pharmacy is now online! The edition includes:

- a review of the role of pharmaceutical care in the oncology department;
- a comparison of antibiotic use in three specialist paediatric hospitals in France, Latvia and the UK;
- an article on the identification and categorisation of drug-related problems on admission to an adult intensive care unit;
- a cohort study investigating medication management by pharmacists to prevent drug-related problems in pain therapy; and,
- a 2-year retrospective review of vial sharing options for the compounding of cytotoxics.

More information [here](#). [11]

22 May 2015

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### Links

[1] <http://www.eahp.eu/newsletter/subscribe> [2] <http://issuu.com/eahp/docs> [3] <http://www.eahp.eu/press-room/eahp%E2%80%99s-hamburg-conference-puts-patient-safety-heart-hospital-pharmacist%E2%80%99s-agenda> [4] [http://ec.europa.eu/health/human-use/falsified\\_medicines/index\\_en.htm](http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm) [5]

<http://ec.europa.eu/health/files/committee/74meeting/pharm682.pdf> [6] <http://www.eahp.eu/practice-and-policy/bar-coding-medicines-to-the-single-unit#> [7] <http://www.esm-system.eu/about-us/what-we-do.html> [8]

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[11] <http://ejhp.bmj.com/content/22/3.toc>