eahp euMonitor

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

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Hospital pharmacists from across Europe gather in Prague for EAHP General Assembly

Hospital pharmacists from across Europe are gathering in Prague today (9th June) for the annual General Assembly of the European Association of Hospital Pharmacists (EAHP). Topics on the agenda include implementation of the 44 European Statements of Hospital Pharmacy and the development of a common training framework for hospital pharmacy in Europe.

More information here [2].

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World Health Assembly agrees actions on medicines shortages

Delegates to the Sixty-ninth World Health Assembly have agreed a range of measures aimed at addressing the global shortage of medicines and vaccines, especially for children.

Delegates agreed to develop ways to forecast, avert and reduce shortages. These include notification systems, better ways of monitoring supply and demand, improving financial management of procurement systems to prevent funding shortfalls, and improving affordability through price negotiations and voluntary or compulsory licensing of high-priced medicines.

Other highlights from the World Health Assembly meeting include the adoption of a "WHO Framework on Integrated, People-Centred Health Services", which calls for a fundamental shift in the way health services are funded, managed and delivered. Delegates requested WHO to develop indicators to track progress toward integrated people-centred health services.

More information here [3]. The full text of the agreed resolution is available here. [4]

Commission launches 4 consultations on application of clinical trials regulation

The European Commission has opened 4 separate public consultations, each examining a distinct issue, or set of issues, related to implementation of EU Regulation 536/2014 ("the Clinical Trials Regulation").

1. Consultation on risk proportionate approaches to clinical trial regulation

The first consultation seeks stakeholder opinions on how best to apply the "risk proportionate" approach to regulation of clinical trials envisaged in Regulation 536/2014. Regulation 536/2014 provides for less stringent rules or adaptations with regards to monitoring, traceability of the Investigational Medicinal Product (IMP) and content of the Trial Master File (TMF), to those clinical trials which pose only a minimal additional risk to subject safety (as defined in Article 2(3) of the Regulation) compared to normal clinical practice. The consultation covers such issues as how identification of risk levels should be conducted and the application of risk proportionate approaches to safety report. The deadline for response is 31 August 2016.

2. Public consultation on "Summary of Clinical Trial Results for Laypersons"

A second consultation interrogates the application of Article 37 of the Clinical trial Regulation (EU) No 536/2014 which requires that sponsors provide a summary of clinical trial results in the EU Portal and Database, in a format understandable to laypersons.

The consultation seeks stakeholder opinion on the recommendations formed by an expert group on what primary elements should be covered in a lay summary, and other guidelines such as format, language and a recommended template.

The deadline for response is 31 August 2016.

3. Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs)

A third consultation examines the definition of "Investigational Medicinal Product" with a particular focus given to how common understanding about the term and concept of "Auxiliary Medicinal Products" can be established. Different types of AMP are explored, such as rescue medication and challenge agents.

The deadline for response is 31 August 2016.

4. Public consultation on the revision of "Ethical Considerations for Clinical Trials on Medicinal products conducted with Minors"

A fourth consultation is now published exploring aspects of change that Regulation (EU) No 536/2014 ushers in in respect to the participation of children in clinical trials. This includes greater emphasis on understanding informed consent as a continual process, new recommendations in respect to consent in emergency situations and the provision of age appropriate information.

The deadline for response is 31 August 2016.

All four consultations are available here [5] and here [6].

In other clinical trial news, the European Medicines Agency has announced a review of the guidelines that describe first-inhuman clinical trials and the data needed to enable their appropriate design and allow initiation. This is being done in cooperation with the European Commission and the Member States of the European Union (EU).

The review will identify which areas may need to be revised in the light of the tragic incident which took place during a Phase I first-in-human clincial trial in Rennes, France, in January 2016. The trial led to the death of one participant and hospitalisation of five others.

More information here [7].

EJHP: Cleaning validation for blister packaging machines in an Austrian pharmacy

The Online First edition of the European Journal of Hospital Pharmacy this week published an original study investigating the cleaning procedures of blister machines in an Austrian hospital pharmacy.

Article here [8].

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