eahp euMonitor

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

You can subscribe to receive the EAHP EU Monitor by email ***HERE*** *[1].* *[1]*

European Statements of Hospital Pharmacy – Moving from statement to implementation

The Statement implementation project began with the adoption of the European Statements of Hospital Pharmacy [2] in May 2014 and has reached another milestone.

Last week during the 22nd congress of EAHP, Joan Peppard, the EAHP President – officially launched the Statements website [3]. It is an addition to the EAHP website that offers an overview of why the European Statements of Hospital Pharmacy are so important.

The Statements website provides stakeholders – such as hospital pharmacists, patients, policy makers, healthcare practitioners, academics or our many partners in industry – with access to a variety of different resources which should help individual hospitals throughout Europe with the implementation of the Statements. These resources include an evidence base for each of the Statements and are complemented by general material aimed at assisting EAHP's member associations with implementation.

And there is still more to come. At the moment, EAHP is working on an online self-assessment tool that will allow hospital pharmacists to assess the level of Statement implementation within their countries. Such a tool was first developed for the American Society of Healthcare-System Pharmacists (ASHP). EAHP's self-assessment tool will complement the information collected through our regular statement surveys. Its primary purpose is to help individual hospitals show progress with implementation. Users will be provided with a tailored action plan to assist them in further advancing the implementation of individual Statements in the hospital setting.

A beta version of the self-assessment tool was tested by interested stakeholders during EAHP's Congress in Cannes last week. The finalised version is expected to be made available on the Statement website by June 2017.

Do you want to stay up-to-date on the Statement implementation project? Subscribe to the Statement Newsletter **HERE** [4].

Joint HMA/EMA Task Force on Big Data established

To further evaluate the role of Big Data in the healthcare system, the Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMA) have established a new task force on Big Data. The group, which is headed by the Dutch Medicines Agency and EMA – will be exploring how medicines regulators in the European Economic Area (EEA) can use big data to support research, innovation and robust medicines development to benefit both human and animal health.

Within the next 18 month the task force will be working on establishing a roadmap and recommendations for the use of Big Data in the assessment of medicines. Preparatory work will include the mapping of sources and characteristics of big data and the exploration of the potential applicability and impact of big data on medicines regulation. The task force will also collaborate with other regulatory authorities and partners outside the EEA to consider their insights on big data initiatives.

Once the work is concluded the task force is planning to present

- A roadmap for the development of big data capabilities for the evaluation of applications for marketing authorisations or clinical trials in the national competent authorities; as well as,
- Recommendations on necessary changes to legislation, regulatory guidelines or data security provisions.

Background information on the task force is available **HERE** [5]

Further information on the activities of the task force will be published soon by EMA on its **website** [6].

In the interest of patients, Commission recommends improvements to package leaflets

Package leaflets are contained in each medicine that is marketed within the EU. These leaflets include amongst other elements the name of the product, the manufacturer as well as information on therapeutic indications, dosage, shelf life and adverse reactions.

The European Commission noted in its report to the European Parliament and the Council shortcomings in the summary of product characteristics and the package leaflets. Recommendations have thus been put forward within the report to better meet the needs of patients and healthcare professionals.

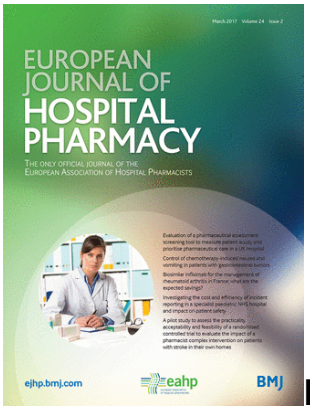
The recommendations of the European Commission centre around the following:

- Improving the readability and comprehensibility of package leaflets, especially for the elderly and individuals with low literacy skills;
- Modifying the layout (font size, line spacing and length) of package leaflets;
- Increasing the utilization of user-testing, a feature that ensures patient input is considered during the leaflet development process;
- Sharing best practices by making available good examples of package leaflets to pharmaceutical companies;
- Exploring the possibility to make product information available in electronic form.

Amendments to existing legislation such as Directive 2001/83/EC [7] of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use are not planned. Instead the European Commission seeks to update existing regulatory guidelines in collaboration with the European Medicines Agency (EMA) and competent authorities of Member States.

The full report of the European Commission to the European Parliament and the Council is available **HERE** [8].

[8] More information regarding EU action on medicinal products for human use is available **HERE** [9].



EJHP: Falsified Medicines Directive in Poland – background, implementation and recommendations

The online first edition of the European Journal of Hospital Pharmacy (EJHP) has published an open access article on the European Falsified Medicines Directive in Poland which discusses its background and implementation as well as provides potential recommendations for hospital pharmacists.

The article is available **HERE** [10].

Image not found or type unknown

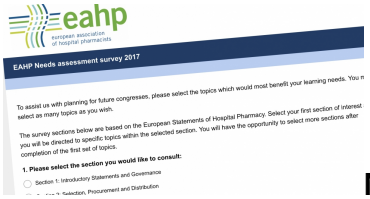
Have your say! 1 open consultation of hospital pharmacy relevance

The European Commission seek stakeholder input for a new 5-year European Union (EU) Action Plan to tackle antimicrobial resistance (AMR).

Deadline for reply 28th April 2017

See EAHP EU Monitor 2 February 2017 [11] for more information.

Consultation **HERE** [12].



Needs Assessment Survey

Help EAHP plan for its next congress by filling in the needs assessment survey.

The survey is available **HERE** [13]**.**

31 March 2017

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://ejhp.bmj.com/content/21/5/256 [3] http://statements.eahp.eu [4] http://statements.eahp.eu/newsletter/subscribe [5] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/03/WC500224262.pdf [6] http://www.ema.europa.eu/ema/ [7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF [8] https://ec.europa.eu/health/sites/health/files/files/documents/2017_03_report_smpc-pl_en.pdf [9] http://ec.europa.eu/health/human-use_en [10] http://ejhp.bmj.com/content/early/2017/03/27/ejhpharm-2016-000970 [11] http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-2-february-2017 [12] http://ec.europa.eu/dgs/health_food-safety/amr/consultations/consultation_20170123_amr-new-action-plan_en.htm [13] https://www.surveymonkey.com/r/22EAHP