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]*

EAHP extends open learning environment for hospital pharmacists

Earlier this year, the European Association of Hospital Pharmacists (EAHP) launched its open learning environment, a new educational module for the further development of the hospital pharmacy profession within Europe in order to ensure the continuous improvement of care and outcomes for patients in the hospital setting. Two new courses were added to the open learning environment over the summer. Now hospital pharmacists can follow courses on biologics and on biosimilars in cancer care in addition to the pre-existing one on anticoagulants.

The open learning course ‘Biosimilars in cancer care’ aims at providing participants with the key information on biosimilar approval in the EU as applied to cancer therapy. By understanding the concepts and facts, hospital pharmacists will be enabled to provide a scientific, unbiased approach with a focus on patient care in a world of limited resources. By gaining insights on into the regulatory assessment process and the clinician's perspective in prescribing biosimilars the ability of hospital pharmacists to advise on how to implement biosimilars of monoclonal antibodies used in cancer therapy will be strengthened.

‘The essentials of biologicals – past, present and future’ will offer insights into the evolution of biologicals which are an essential treatment option for a variety of diseases in current medicine. Course participants will learn about the development and authorisation of biosimilars as well as the quality criteria of biologicals. In addition, issues of switching and interchangeability of biologicals will be addressed to provide an in-depth understanding of key principles regarding quality, safety and efficacy.

EAHP is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants of the open learning courses will be entitled to 1.5 to 2 ACPE credits, depending on the length of the course. These credits can be obtained after the completion of the course and a short survey.

More about the open course learning on biologics HERE [2].

More about the open course learning on biosimilars in cancer care HERE [3].

Study on cross-border health services

The European Commission has published a study on cross-board health services in the EU which aims at proposing recommendations for improving the current level of information provision to patients by National Contact Points (NCPs). Overall, the study found a general lack of awareness about the existing measures that were introduced by the Cross Border Healthcare Directive (2011/24/EU), including the NCPs.

Even though NCPs made considerable progress since the publication of an evaluative study in 2014 further improvements are needed. In particular, information provided via NCP websites in relation to patient's rights, quality and safety standards, and reimbursement of cross-border healthcare costs are a concern. Moreover, the report found considerable organisational differences between the NCPs of Member States. A practice-oriented toolbox as well as training materials aim at helping to improve the shortcomings. Additionally, a set of guiding principles was developed to ensure that NCP services throughout the Union become more uniform, patient-centred and adhere to legal requirements.

Read the study HERE [4].

HTA – outlook to the month ahead

Prior to the summer break, the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) discussed the amendments to the draft report on the Proposal for a regulation of the European Parliament and of the Council on health technology assessment (HTA) by MEP Soledad Cabezón Ruiz. In particular the discussion focused on the scope of the Commission's proposal and the coverage of medical devices by the Regulation.

New developments are expected in mid-September, once the ENVI Committee votes on the draft report. The opinions of the Committee on Industry, Research and Energy (ITRE) and the Committee on the Internal Market and Consumer Protection (IMCO) will feed into this discussion.

EAHP published its response to the proposal for a Regulation on HTA in early August. It welcomes the Commission's efforts to strengthen the cooperation between Member States in

the field of HTA. Moreover, the association urges the Council and the Parliament to enhance the involvement of stakeholders. In particular the role of healthcare professionals, including hospital pharmacists, should be strengthened to ensure that their extensive experience and knowledge in medicine use is utilised in HTA processes.

Follow the legislative procedure HERE [5].

Read EAHP's response to the proposal HERE [6].

nes information

The 'Hands on medicines information' section of the European Journal of Hospital Pharmacy (EJHP) aims at presenting clinical queries arising from medicines information practice, in particular those that are complex or unusual and could be of interest to other hospital pharmacists.
Hospital pharmacists are encouraged to send submissions for this EJHP section. They should present a clearly defined clinical question and answer which should be supported with scientific evidence. The inclusion of patient-specific information and an outcome assessment is strongly encouraged. Submissions should be structured in the following manner:

- Summary of up to 150 words;
- Introduction, including the case presentation and any clinical or background information relevant to the query;
- Clinical question;
- Recommended answer, including the problem-solving approach used (if applicable);
- Outcome and discussion; and,
- Key message/learning outcome of one sentence.

The article should be no longer than 1500 words, include a maximum of 1 table and/or figure and up to 10 references. It can be uploaded via the 'submit a paper' button on the EJHP website [7].

FIP-The potential for pharmacists to support women in their often overlooked role as informal caregivers

The International pharmaceutical Federation has released a report on how pharmacists, as the most accessible healthcare professionals, can empower women in their role as informal caregivers. The report, “Pharmacists supporting women and responsible use of medicines” aims to provide a platform for a change & collaborations in women empowerment and better care for their own health. The report revealed that due to their direct link to patients and caregivers, hospital as well as community pharmacists are ideally placed in the healthcare system to empower women in their role as informal caregivers, communicate to women the need to be informed and support women’s health literacy. Supporting evidence that underpinned these findings was collected via a literature review as well as by means of a survey activity undertaken among FIP member organisations.

Read the report HERE [8].

EJHP: September issue published

The September edition of the European Journal of Hospital Pharmacy (EJHP) contains six distinct original articles including the ones on junior doctors' communication with hospital pharmacists about prescribing and health information technology for the management of cancer chemotherapies. The editorials of this issue focus on the goals of EAHP's new President Petr Horák and the achievements of EAHP's Immediate Past President Joan Peppard. Reviews cover electronic medication reconciliation in hospitals as well as the 2017 European Statements Survey.

Read more HERE [9].

[EAHP Statement Corner]

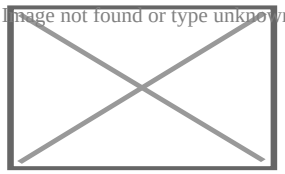
implementation of the european statements of hospital pharmacy

right for the patient, right for the profession

Check out our SILCC hosts!

Ever thought about leaving your hospital pharmacy for a few weeks to learn more about methods that are applied abroad? The Statement Implementation Learning Collaborative (SILCC) programme is your chance to explore the work processes of another hospital pharmacy in Europe. SILCC provides hospital pharmacists (SILCC Fellows) with the

opportunity to visit hospitals (SILCC hosts) from other EAHP member countries to learn about pharmacy procedures linked to the European Statements of Hospital Pharmacy. Seven SILCC hosts are currently awaiting applications from their first fellows. Have a look at our website [10]to learn more about these hospitals and the SILCC application procedure. In case you have questions or need assistance don't hesitate to contact us via Statements[at]eahp[dot]eu [11]



Consultations

Commission - Targeted stakeholder consultation on duplicate marketing authorisations for biological medicinal products

The consultation seeks the views of interested parties on the specific issue of the impact of duplicate marketing authorisations of biological medicinal products on the availability of biosimilars to healthcare professionals and patients.

Deadline – 10th September 2018

More information HERE [12]

Concept paper on preparation of a revised guideline on the evaluation of medicinal products indicated for treatment of bacterial infections

This concept paper proposes the development of a single guideline on the clinical evaluation of medicinal products indicated for treatment of bacterial infections. The development of this single guideline is intended to merge, revise and add to the guidance that is currently included in two separate documents.

Deadline – 13th September 2018

More information HERE [13]

EMA- Draft guideline on clinical evaluation of vaccines

This guideline addresses the clinical evaluation of vaccines intended for the prevention of infectious diseases. It includes considerations for trials intended to document the safety, immunogenicity and efficacy of new candidate vaccines and to support changes in the prescribing information of licensed vaccines. It also considers the need for and use of vaccine effectiveness studies.

Deadline – 30th October 2018

More information HERE [14]

4 September 2018

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://www.eahp.eu/events/open-learning/courses/essentials-biologicals [3] http://www.eahp.eu/events/open-learning/courses/Biosimilarscancercare [4] https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2018_crossborder_frep_en.pdf [5] http://www.europarl.europa.eu/legislative-train/theme-deeper-and-fairer-internal-market-with-a-strengthened-industrial-base-products/file-health-technology-assessment [6] http://www.eahp.eu/press-room/eahp-response-proposal-regulation-hta [7] http://ejhp.bmj.com/ [8] https://fip.org/files/fip/publications/Pharmacists-supporting-women-responsible-use-medicines.pdf [9] https://ejhp.bmj.com/content/25/5?current-issue=y [10] http://statements.eahp.eu/statement-implementation-learning-collaborative-centres-silcc [11] https://www.eahp.eu/contact/Statements/eahp/eu [12] https://ec.europa.eu/health/human-use/consultations/20180518_biologicalmedicinalproducts_en [13] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V [14] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V