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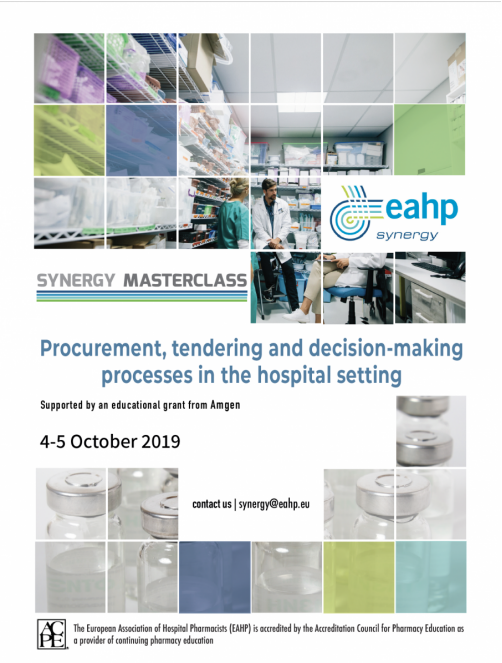
The EAHP EU Monitor is a regular round up of news relevant to hospital pharmacy in Europe.

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

2019 Synergy Masterclass: Broaden your knowledge about procurement and tendering



Hospital pharmacists due to their knowledge and skills are specialists in the field of all medicines procurement. They should lead in all phases of the procurement processes and practices to ensure the continuity of supply of cost-effective and quality medicines to patients. To foster the engagement of hospital pharmacists in procurement processes, the European Association of Hospital Pharmacists (EAHP) is organising its second Synergy Masterclass around the topic of procurement.

The Synergy Masterclass titled “Procurement, tendering and decision making processes in the hospital setting” – which is sponsored by an educational grant from Amgen – will be held on 4th and 5th October 2019 in Brussels, Belgium. EAHP invites to healthcare professionals, representatives from industry and all other interested parties working in the field of procurement and tendering in the hospital environment to sign up for this educational event.

The speaker, James Kent (National Health Service, United Kingdom), Dorte Glintborg (Danish Medicines Council, Denmark), Francis Arickx (Belgian Social Insurance Institute INAMI, Belgium) John Yfantopoulos (University of Athens, Greece), Hanne Plet (North Denmark Region, Denmark), Jo Swartenbroekx (University Hospital Antwerp, Belgium) and António Gouveia (Instituto Português de Oncologia de Lisboa, Portugal), will take participants through the key developments. The 2-day programme – through a mix between workshops and lectures – will ensure that participants are able to recall important EU-legislation with regard to procurement, list elements of value-based procurement and recognise the pros and cons of doing procurement and tenders at national, regional and hospital level, respectively.

Join the event by registering HERE [2]

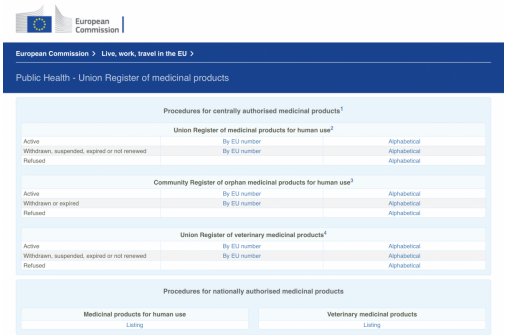
Learn more about the programme HERE [3]

Webcasts and presentations of the 24th EAHP Congress are out!

EAHP has made available the video recorded presentations as well as the slides of each of the presentations given at the 24th Congress of the Association – "Personalised Hospital Pharmacy – meeting the needs of every patient".

Webcasts and presentations can be accessed HERE [4]

European Commission launched new version of Union Register



The European Commission has released a new version of its Union Register of Medicinal Products which lists all medicinal products for human and veterinary use that have been authorised through the centralised procedure. At the moment the register contains information about more than 1.300 medicines. In addition, it also covers designation of orphan medicinal products, refused authorisations and reviews related to nationally authorised medicinal products. The update offers a more simplified navigation, greater compatibility with mobile devices and allows users to filter and export functionalities.

Access the Register HERE [5]

Updates from the European Medicines Agency

In early May, the European Medicines Agency (EMA) released its 2018 annual report. In addition, the Agency shared information on a new long-lasting implant to treat opioid dependence as well as on the re-analysis of data on use of breast cancer medicine Tyverb following treatment with trastuzumab.

EMA 2018 Annual Report

The annual report provides an overview of EMA's activities in 2018. It includes information on the Brexit preparations, the key milestones as well as facts and figures about achievements in the field of human and veterinary health.

Access the EMA annual report here [6]

New long-lasting implant to treat opioid dependence

EMA's human medicines committee (CHMP) has recommended granting a marketing authorisation in the EU for Sixmo (buprenorphine) as a substitution treatment for opioid dependence. Sixmo is an implant that releases low levels of buprenorphine into the patient's body for six months. It is indicated in clinically stable adult patients who require no more than 8 mg per day of sublingual (i.e. administered under the tongue) buprenorphine, within a framework of medical, social and psychological treatment.

The active substance of Sixmo is buprenorphine. It consists of four small rods that are implanted in the patient's upper arm by a trained physician under local anaesthetic and continuously deliver buprenorphine for six months. This new method of administration could enhance adherence to the treatment and reduce the potential for misuse or accidental overdoses in the home, as well as the risk of accidental ingestion of buprenorphine by others, especially children.

The safety and efficacy of Sixmo were studied in three pivotal trials, in a total of 626 adult patients. One of the trials enrolled OUD adults who were considered clinically stable by their treating physician. The results demonstrated that 96.4% of patients in the Sixmo group responded to treatment, compared to 87.6% of patients treated with sublingual buprenorphine.

The applicant is required to perform an additional study in patients in Europe to further evaluate the risks associated with the insertion and removal of the implants.The opinion adopted by the CHMP is an intermediary step on Sixmo's path to patient access. The opinion

will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once the marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Further information is available here [7]

Re-analysis of data on use of breast cancer medicine Tyverb following treatment with trastuzumab

EMA is updating the prescribing information for Tyverb (lapatinib) following detection of errors in results of a study involving postmenopausal women who had 'HR+/HER2+' breast cancer and whose disease had worsened despite previous treatment with trastuzumab. The results had indicated a benefit of Tyverb over trastuzumab when each medicine was used together with an aromatase inhibitor.

The detected errors were included in the prescribing information for Tyverb on 30 July 2018. However, these will now be removed while data are being re-analysed. In the meantime, the prescribing information will be amended to state, as before, that no data are available on the effectiveness of Tyverb compared with trastuzumab in this combination in patients previously treated with trastuzumab.

In the light of this new information, doctors currently treating patients with Tyverb in combination with an aromatase inhibitor, whose disease had worsened despite previous treatment with trastuzumab, should decide whether to continue with the same therapy or consider an alternative treatment.

Further information, including specific information for patients and healthcare professionals, is available here [8]

EJHP: May issue is available!

The May issue of the European Journal of Hospital Pharmacy (EJHP) has been released. The issue contains original articles on medication reconciliation in a Swiss hospital, antibiotic utilisation in adult and children patients in Kosovo hospitals as well as a content analysis of Twitter in relation to biological treatments for chronic inflammatory arthropathies. The reviews section covers approaches to outpatient pharmacy automation. In addition, EAHP's position papers on procurement and antimicrobial resistance are included.

Read the May issue HERE [9]

Follow EAHP during the Statement Implementation Month!

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Statement Implementation
Learning Collaborative Centres

The month of May marks the occasion of the Statement Implementation Month for EAHP. Have a look at EAHP's social media channels (Facebook [10], Twitter [11], LinkedIn [12] and Instagram [13]) in order to learn more about the self-assessment tool and the fellows that are currently participating in the Statement Implementation Learning Collaborative Centres (SILCC) programme. Don't forget to also review EAHP's Statements website [14] which is a great resource and provides you with all relevant information about the implementation of the European Statements of Hospital Pharmacy.

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Consultations

Public consultation on EMA Regulatory Science to 2025

The purpose of this public consultation is to seek views from EMA's stakeholders, partners and the general public on EMA's proposed strategy on Regulatory Science to 2025 and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, participants have the opportunity to jointly shape a vision for regulatory science that will in turn feed into the wider EU network strategy in the period 2020-25.

Deadline – 30th June 2019

Access consultation HERE [15]

EMA - Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections

The EMA has launched a consultation on the revision of its guideline on the evaluation of human medicines indicated for the treatment of bacterial infections. Antimicrobial resistance is a global public health problem. Regulators in the European Union, the United States and Japan have had extensive discussions over the last few years to explore and agree how to align as much as possible their respective data requirements so that medicine developers can design clinical trials that meet the evidence needs of multiple regulatory agencies. The revised guidance reflects the outcome of these discussions.

Deadline – 31st July 2019

Access consultation HERE [16]

EMA – Public consultation on key principles for the electronic product information of EU medicines

The European Medicines Agency (EMA), together with the European Commission (EC), has launched a public consultation on draft key principles which will form the basis on which the electronic product information [17] (ePI) for human medicines will be developed and used throughout the European Union. The rationale behind the ePI is that digital platforms open additional possibilities to disseminate the PI electronically. This can address some of the current limitations and better meet patients' and healthcare professionals' needs for accessible, up-to-date information on medicines. The draft key principles are the result of extensive discussions and consultations carried out by EMA, the Heads of Medicines Agencies (HMA) and the EC throughout 2018, with representatives of all stakeholder groups.

Deadline – 31st July 2019

Access consultation **HERE** **[18]**

14 May 2019

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://www.eahp.eu/synergy-masterclass/events/procurement/registration19 [3] http://www.eahp.eu/synergy-masterclass/events/procurement/%20Masterclass%20programme [4]

https://events.eahp.eu/cmgateway/webcast2019.html#!sessionschedule [5] http://ec.europa.eu/health/documents/community-register/html/index_en.htm [6] https://www.ema.europa.eu/en/documents/annual-report/2018-annual-report-european-medicines-agency_en.pdf [7] https://www.ema.europa.eu/en/news/new-long-lasting-implant-treat-opioid-dependence [8] https://www.ema.europa.eu/en/news/re-analysis-data-use-breast-cancer-medicine-tyverb-following-treatment-trastuzumab [9] https://ejhp.bmj.com/content/26/3?current-issue=y [10] https://www.facebook.com/eahp.eu/?ref=settings [11] https://twitter.com/EAHPtweet [12] https://www.linkedin.com/company/5087133/admin/ [13] https://www.instagram.com/eahpofficial/ [14] http://statements.eahp.eu/ [15] https://ec.europa.eu/eusurvey/runner/EMARS2025PublicConsultation2019 [16] https://www.ema.europa.eu/documents/scientific-guideline/draft-guideline-evaluation-medicinal-products-indicated-treatment-bacterial-infections-revision-3_en.pdf [17] https://www.ema.europa.eu/en/glossary/product-information [18] https://www.ema.europa.eu/en/news/public-consultation-key-principles-electronic-product-information-eu-medicines