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 successfully launches first Synergy Masterclass

On 5th and 6th October, the European Association of Hospital Pharmacists (EAHP) organised its very first Synergy Masterclass on Management and Leadership. The event was hosted in Brussels and focused on innovative medicines management strategies, decision-making and individual as well as team development. It was open to hospital pharmacists and other professionals working the healthcare sector.

The international faculty ensured through a mix between lectures and small working group sessions that the newly learned techniques could be applied in practice throughout the intensive 2-day training. Open workshop sessions encouraged the group to comment on the practical examples given by the lecturers and to share information about their own management projects in the hospital setting. After the event, participants highlighted that they welcomed the unique opportunity to get acquainted with different management techniques in a very interactive atmosphere.

EAHP's Synergy Masterclasses are ACPE accredited one or two-day mini congresses that are focused on the most ground-breaking topics and topics most needed by hospital pharmacists and healthcare professionals. Those that missed this unique opportunity to participate in 2018 should not worry, since the Synergy Masterclasses will continue in 2019. The next event is scheduled for the 4th and 5th October 2019. Professionals that want to hear more about procurement, tendering and decision making processes in the hospital setting should already mark their calendars. During the two-day training event insights on EU legislation, procurement and tenders at national, regional and hospital level as well as on the elements of value-based procurement will be shared.

Learn more about EAHP's 2019 Synergy Masterclass HERE [2]

EDQM – consultation linked to European Paediatric Formulary

The European Directorate for the Quality of Medicines & HealthCare (EDQM) has launched a public consultation on the first two pilot monographs and on two general texts for its European Paediatric Formulary. European pharmacists and paediatricians are invited to share their

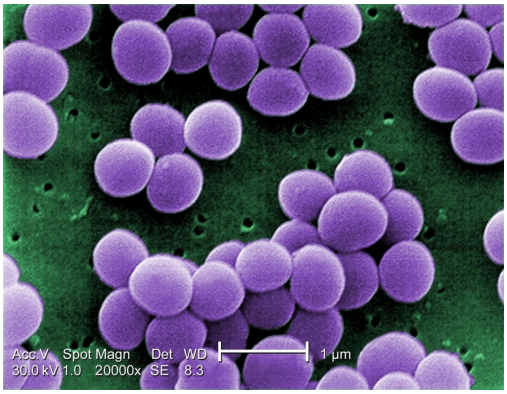
feedback on the draft monographs on Hydrochlorothiazide oral solution and on Sotalol oral solution.

The European Paediatric Formulary is a project created by the European Committee on Pharmaceuticals and Pharmaceutical Care (CD-P-PH) and the European Pharmacopoeia Commission. It seeks to collect monographs on formulations for extemporaneous preparations that are currently described in national formularies centrally on European level. Overall, it aims at providing pharmacists and clinicians with specific formulations of appropriate quality to allow preparation when no licensed alternative is available on the market.

Monographs to be included in the European Paediatric Formulary are selected on the basis of criteria for inclusion and evaluation adopted by the CD-P-PH end of 2015. These include quality criteria, for example that the preparation process is prescribed in a way to ensure reproducibility, and criteria for therapeutic relevance and clinical justification of the preparation, for example following the therapeutic needs identified by the European Medicines Agency. The verification also includes the excipients to ensure they comply with Ph. Eur. requirements, are not harmful and suitable for their intended use.

Access the consultation HERE [3]

EMA antibiotic in animal sales



In mid-October, the European Medicines Agency (EMA) released a report on the sales of veterinary antimicrobials. It shows that between 2011 and 2016, the sale numbers decreased across Europe by over 20%. This trend is partially attributed to the success of EU guidance efforts, including actions contained the One Health Action Plan, and national campaigns that aimed at promoting the prudent use of antibiotics in animals. The report is a component of the EMA's project on the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC).

The study covers 2016 data collected from the EU28, Norway, Iceland and Switzerland and data from 25 EU Member States for the period 2011 to 2016. Even though sales of polymyxins went down by almost 40% and sales of quinolones declined by 13.6% the situation is not homogenous across Europe. While 16 of those 25 countries that provided data for 2011 to 2016 saw a drop in sales of veterinary antimicrobials of 5% or more, six countries recorded an increase of more than 5% in sales during the same period.

The ESVAC project, which aims at harmonising the collection and reporting of data from EU Member States on the use of antimicrobials in animals, was launched in 2010. Each year a report is produced which is used by risk assessors and risk managers in Member States as a reference for antimicrobial policies and for guidance on responsible use of antimicrobials.

Read the report HERE [4]

EAAD 2018 – keeping antibiotics working

The European Centre for Disease Prevent and Control (ECDC) is currently preparing for the European Antibiotic Awareness Day (EAAD) 2018. The EAAD celebrated its 10th anniversary last year and focuses on raising awareness about the threat to public health of antibiotic resistance and the importance of prudent antibiotic use.

The EAAD takes place on 18th November and falls within the World Antibiotic Awareness Week of the World Health Organisation (WHO). The theme of this year's EAAD will continue to illustrate how hospital pharmacists, doctors, nurses, hospital managers, farmers, veterinarians, policymakers, professional and patient organisations, governmental institutions, and the general public keep antibiotics working. The ECDC encourages healthcare professionals, patients and other interested parties to share stories, pictures or videos during the week 12—18 November 2018, using the hashtag #KeepAntibioticsWorking.

More information see HERE [5]

Commission consultation on orphan drugs

European Commission

The European Commission has launched a public consultation on the evaluation of the legislation on medicines for children and rare diseases. Healthcare professionals as well as private citizens are encouraged to share their experiences with and perspectives on access to orphan medicines in general, and on the role the EU Orphan Regulation plays in the development of orphan medicines.

The EU Orphan Regulation [6] is closely linked to the Paediatric Medicines Regulation [7] which was recently evaluated through in the Commission Report on the Paediatric Regulation (for more information see EU Monitor of 7 November 2017 [8]). Consequently, the consultation is not only touching on orphan medicines but also paediatric ones. Comments should be submitted by 4th January 2018.

Access consultation HERE [9]

EJHP: Release of the October online issue

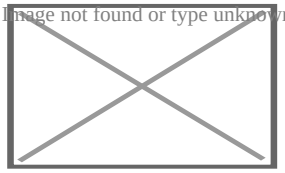
In October, the second online issue of the European Journal of Hospital Pharmacy (EJHP) was published focusing on formulation, compatibility and stability issues of medicines. The special online issue contains for example original articles on the physicochemical stability of voriconazole in elastomeric devices, on the validation of a procedure to mix homogenous solutions in bags and syringes and on the physical compatibility of MCT/LCT propofol emulsions with crystalloids during simulated Y-site administration.

Read more HERE [10]

[EAHP Statement Corner]

Launched during the 24th EAHP Congress in Gothenburg, the SILCC programme is a new initiative allowing hospital pharmacists to visit hospitals (SILCC Hosts) from other EAHP member countries in order to receive training in procedures linked to the European Statements of Hospital Pharmacy. EAHP has set up a reward system for SILCC Hosts and limited financial help for SILCC Fellows.

Do you want to become a SILCC Hosts and provide training to other pharmacists? Or do you want to become a SILCC Fellow and visit other hospitals to learn about new procedures in order to share that knowledge with your colleagues? Then click HERE [11] and visit our website. Don't hesitate to contact the EAHP Implementation team at Statements[at]eahp[dot]eu [12] to learn more about SILCC.



Consultations

*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 [13]

European Commission - Public consultation on the draft Guidelines on Good Clinical Practice for Advanced Therapy Medicinal

The European Commission is currently consulting on Good Clinical Practice for Advanced Therapy Medicinal Products. In particular, the Commission would like to hear from stakeholders involved in the clinical trials of advanced therapy medicinal products ("ATMPs"). Comments from the hospital sector are welcomed.

Deadline – 31st October 2018

More information HERE [14]

EMA- Draft guideline on the use of minimal residual disease as a clinical endpoint in multiple myeloma studies

The guideline aims to address the use of undetectable minimal residual disease (MRD) as an intermediate efficacy endpoint in controlled randomised clinical studies in patients with multiple myeloma (MM), adequately designed to demonstrate efficacy by relevant hard endpoints. MRD as an endpoint in this context would allow earlier approval of new drugs pending final confirmatory data.

Deadline – 31st October 2018

More information HERE [15]

Survey on patients opinion about drug shortages

COST Action CA 15105 on medicines shortages invites you to participate in a qualitative study regarding patients' perspective about medicine shortages during hospital stay. Hospital pharmacists are encouraged to question interested patients who are willing to share their experience with medicines shortages. Questions in relation to this survey activity can be address by email to Darija Kuruc Poje (darijakuruc21[at]gmail[dot]com [16]).

Deadline – 1stDecember 2018

Access the survey HERE [17]

EMA - Draft guideline on clinical investigation of medicinal products in the treatment of epileptic disorders

The present document is a third revision of the existing guideline. The main changes to the existing guideline include incorporation of the new classification / definitions of seizure types and epilepsies, the acceptance of add-on studies in support of a monotherapy claim on a case-by-case basis, the inclusion of new sections on neonates and status epilepticus and other changes related to paediatric developments. The scope of this document is restricted to treatment of seizures in epileptic disorder although there are some remarks concerning non-seizure features of epilepsy syndromes.

Deadline – 17th February 2019

More information HERE [18]

23 October 2018

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://www.eahp.eu/synergy-masterclass/events/procurement [3] https://paedform.edqm.eu/home [4] https://www.ema.europa.eu/documents/report/sales-veterinary-antimicrobial-agents-30-european-countries-2016-trends-2010-2016-eighth-esvac_en.pdf [5] https://antibiotic.ecdc.europa.eu/en/get-involved/social-media-2018 [6] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000R0141&from=EN [7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1901&qid=1507134956441&from=EN [8] http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-7-november-2017 [9] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-6059807/public-consultation_en [10] https://ejhp.bmj.com/content/25/e2?current-issue=y [11] http://statements.eahp.eu/statement-implementation-learning-collaborative-centres-silcc [12] https://www.eahp.eu/contact/Statements/eahp/eu [13] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V [14] https://ec.europa.eu/health/human-use/consultations/2018_gcp_atmp_en [15] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V [16] https://www.eahp.eu/contact/darijakuruc21/gmail/com [17] https://ec.europa.eu/eusurvey/runner/PatientsPerspectivesOnMedicinesShortagesV2 [18] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V