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 launches open learning environment for hospital pharmacists

The European Association of Hospital Pharmacists (EAHP) has launched 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. The new open learning module aims at improving the applied knowledge and problem-solving skills of hospital pharmacists, with the first edition focusing on anticoagulants. The learning material is offered to hospital pharmacists in collaboration with BMJ Learning [2].

The first open learning module of EAHP – *Anticoagulants – show me the evidence!* – will provide hospital pharmacists with information on new anticoagulant drug developments. Specific emphasis will be put on the differences in pharmacokinetics, efficacy, safety between newer anticoagulant drugs and warfarin. Through training on optimal oral anticoagulant therapy participants of the online course will be enabled to better educate patients about their drugs and the importance of adhering to their anticoagulant therapy.

The Open Learning Course on anticoagulants shows recordings of a Synergy satellite event held at the 2017 Congress of the EAHP. The event was supported by means of an unrestricted educational grant from Bayer. The EAHP Scientific Committee developed the educational program of the satellite event totally independent of industry involvement.

The EAHP is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants of the 2-hour Open Learning Course on anticoagulants will be entitled to 2 ACPE credits. These credits can be obtained after the completion of the course and a short survey.

In the future, the EAHP plans on expanding its open learning offer through the inclusion of additional synergy satellite sessions. Like the anticoagulants session, all other open learning courses will be linked to the different Sections of the European Statements of Hospital Pharmacists [3]. Follow us an Twitter [4] and Facebook [5] to hear first about new open learning sessions.

More about the new open course learning anticoagulants HERE [6]

EDQM - Automatic drugs dispensing report

The European Directorate for the Quality of Medicines (EDQM) released Automated Dose Dispensing (ADD) guidelines. Their content was agreed upon during an open consultation involving stakeholders, which was held this past year and concluded on February 2017. Overall, the ADD guidelines aim at harmonising the standards and approaches to ADD across Europe for the safe supply of medicines to patients.

The ADD guidelines, published this year, have been developed by a working group of experts from industry, academia, pharmacy and government from across the region of the Council of Europe. These guidelines harmonise the standards and approaches to automated dose dispensing across Europe and are intended to be used by pharmacies and manufacturers involved in automated dose dispensing, as well as by national authorities in countries where this service is provided. They include standards regarding the ADD sites and operations, as well as patient care activities associated with the ADD process.

The guidelines include detailed instructions on issues such as product liability and ADD suitability information from manufacturers, responsibility and training of personnel, traceability of medicinal products, suitable packaging materials for ADD, stability of medicinal products, automated dose dispensing process, and many other aspects related to ADD. Finally, the report encourages national governments to establish legal frameworks and develop standards or guidance to support the regulation of ADD.

Guidelines can be downloaded HERE [7]under the pharmaceutical care section.

WHO -World leaders join new drive to beat noncommunicable diseases who

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The World Health Organisation (WHO) has announced the constitution of a new high-level commission comprised of heads of state and ministers, leaders in health and development and entrepreneurs, with the objective of finding innovative solutions for the prevention and control of noncommunicable diseases (NCDs), such as heart and lung disease, cancers, and diabetes.

According to the WHO, NCDs are the world's leading avoidable killers, accounting to 7 out of 10 deaths, and more than 15 million between the ages of 30 and 70 years die from NCD's every year. This shows not enough is being done to prevent and control them, as for the first time in history, more people are dying of NCDs than from infectious diseases. In combatting NCDs, the World Health Assembly has endorsed WHO cost-effective interventions to prevent or delay most premature NCD deaths, with the objective of scaling up these actions in countries while raising awareness.

The high-level commission will run until October 2019 and will provide actionable recommendations to contribute to the Third United Nations General Assembly High-level Meeting on NCDs scheduled for the second half of 2018. The first report on the proceedings will be published in June 2018.

More HERE [8]

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ECDC, EFSA report - antimicrobial resistance in zoonotic bacteria still high in humans, animals and food

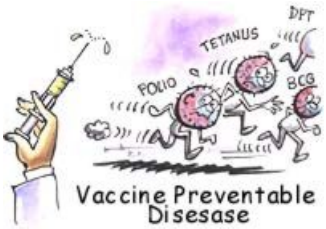
The European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA) have published a summary report on antimicrobial resistance in zoonotic bacteria. The report which touches upon humans, animals and food highlights emerging issues and confirms the threat that antimicrobial resistance poses to public health.

Zoonoses infections are transmissible between animals and humans, via direct infection from animals or ingestion of contaminated food. The report focuses on antimicrobial resistance of salmonella, E. coli and meticillin-resistant Staphylococcus aureus (MRSA), and provides details on multidrug resistance (MDR), as well as complete susceptibility and combined resistance patterns in both human and animal isolates at the EU level and country level.

The findings of the report highlight that *Salmonella* bacteria cause one out of four infections in humans which show resistance to three or more antimicrobials commonly used in human and animal medicine. The resistance levels of *Campylobacter* bacteria which are responsible for the most common foodborne disease in the EU also increased in two of the three analyzed antibiotics. ESBL-producing S. Kentucky with high resistance to ciprofloxacin – that cannot be treated with critically important antibiotics – was found for the first time in four countries.

According to Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents, Member States (MSs) are obliged to monitor and report antimicrobial resistance (AMR) in Salmonella and Campylobacter isolates obtained from healthy food-producing animals and from food. Commission Implementing Decision 2013/652/EU of 12 November 20131 [9] sets up priorities for the monitoring of AMR from a public health perspective, drafts a list of combinations of bacterial species, food-producing animal populations and foodstuffs and lays down detailed requirements on the harmonised monitoring and reporting of AMR.

Report available HERE [10]



WHO - 12 European countries commit to greater efforts to protect people from vaccine-preventable diseases

On 20 February 2018, health ministries from 12 south-eastern European countries met in Podgorica, Montenegro to endorse the need to speed up progress towards the goals and strategic objectives of the European Vaccine Action Plan 2015–2020 (EVAP). The EVAP was made to complement the Global Vaccine Action Plan on a European level, parallel to Health 2020 and other regional health strategies and policies. It sets goals for immunization and control of vaccine-preventable diseases.

The health ministries agreed to a tailored roadmap focusing on common challenges and opportunities to increase individual and community protection against diseases like measles, rubella, diphtheria and others. They also called upon the WHO to: propose options for the joint procurement of vaccines, to support capacity-building on resource mobilization for sustained financing of immunization programmes, to establish a sub-regional centre on vaccine demand, and to strengthen the role and responsibilities of the National Immunization Technical Advisory Groups. Additionally, the ministerial meeting focused on priority topics for south-eastern Europe, such as integrating immunization programmes into strong health systems by coordinating with other programmes, the private sector, partners and communities.

The outcomes from the Montenegro meeting will feed into the discussion on the mid-term progress review of the EVAP, to be held at the 68th session of the WHO Regional Committee for Europe in September 2018.

There is an ongoing public consultation by the European Commission on strengthened cooperation against vaccine preventable diseases, which is open for input until 15th March 2018. Citizens, administrations, associations and other organisations with an interest in vaccination and health policy can participate in this consultation. Its results will feed into the Council Recommendation on Strengthened Cooperation against Vaccine Preventable Diseases.

More HERE [11]

European vaccine action plan 2015-2020 available HERE [12]

Consultation available HERE [13]

ema

Image not found or type unknown **EMA – Human Medicines Highlights 2017 report now available**

The European Medicines Agency (EMA) has published the Human Medicines Highlights 2017 report, with intuitive infographics and a comprehensive overview of medicines authorisations, recommendations and assessments.

In a nutshell, in 2017 the EMA emitted authorisation reviews encompassing: 92 positive opinions, 35 new active substances, 6 negative opinions, 2 advanced therapy medicinal products, 19 orphan medicines, 7 accelerated assessments, and 3 conditional marketing authorisations. The report also highlights new safety advice based on its quality and

benefit/risk analysis. Regarding medicines authorisations that are an outstanding contribution to their therapeutic areas, various medicines for children are included, such as Brineura and Spinraza for neurology, and Alkindi and Crysvita for endocrinology.

Also, for rare diseases, and following the encouragement of the EU framework for orphan medicines, new orphan medicines include Oxervate for neurology, Qarziba for cancer, and Xermelo for endocrinology. The report continues with conditional marketing authorisation holders such as Bavencio for cancer, medicines that were approved under exceptional circumstances, such as Brineura for neurology, new uses for existing medicines, such as Truvada for infections, and negative opinions on Onzeald, Masipro, Fanaptum and others.

Report available HERE [14]

EJHP – Electronic medication reconciliation in hospitals: a systematic review and meta-analysis

The online first edition of the European Journal of Hospital Pharmacy (EJHP) has published an original article focusing electronic medication reconciliation (MedRec) in hospitals. MedRec is recognised as a multiprofessional process for the prevention of medication discrepancies. The study evaluates available eMedRec tools and their effect on unintended discrepancies that occur in hospital institutions and demonstrates how they can reduce the incidence of medication with unintended discrepancies and improve medication safety.

More HERE [15]

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Consultations

Commission – Public consultation on strengthened cooperation against vaccine preventable diseases

Due to the cross-border nature of vaccine preventable diseases and the challenges to national vaccination programmes, the European Commission saw the need to look into common EU actions and an increase of coordination. The information collected via the public consultation is intended to feed into the adoption of a proposal of a Council Recommendation on Strengthened Cooperation against Vaccine Preventable Diseases.

Deadline – 15th March 2018

More information HERE [13]

Survey on multidisciplinary and integrated heart failure care

The Heart Failure Policy Network is conducting an investigation to better understand how multidisciplinary and integrated programmes in heart failure have been planned and implemented across Europe. The study seeks to analyse the success factors, challenges and how collaboration was achieved by those leading the way.

Deadline – 30th March 2018

More HERE [16]

EMA-Draft qualification opinion - The European Cystic Fibrosis Society Patient Registry

The qualification opinion provides a draft context of use of the registry for public consultation, describing where this registry is deemed by CHMP as an appropriate data source for post-authorisation studies to support regulatory decision making on medicines for the treatment of cystic fibrosis, together with CHMP's response to the questions posed by the Consortium.

Deadline – 9th April 2018

More information HERE [17]

EMA- Concept paper on the development of a reflection paper on new analytical methods/ technologies in the quality control of herbal medicinal products

Quality control is a prerequisite to assure safe and effective use of (traditional) herbal medicinal products, which are complex mixtures of numerous phytochemical constituents. For the majority of herbal substances, herbal preparations and (traditional) herbal medicinal products the active constituents are not known or are only partly understood. Consequently, EMA is planning to develop a reflection paper that addresses new analytical methods and technologies for the quality control of herbal medicinal products.

Deadline – 30th April 2018

More information HERE [18]

EMA- Draft guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products

This draft consultation offers the opportunity for proving input regarding the replacement of the 'Guideline on safety and efficacy follow-up - risk management of Advanced Therapy Medicinal Products', which provides dedicated and specific guidance for ATMPs with regards to the pharmacovigilance system, the identification of risks, the risk minimisation measures, the post-authorisation S&E studies, the management and the reporting of adverse reactions and of the evaluation of the effectiveness of the risk management system.

Deadline – 30th April 2018

More information HERE [19]

EMA- Reflection paper on investigation of pharmacokinetics and pharmacodynamics in the obese population

The specific aims of this reflection paper are to describe how the effects of obesity can be investigated during clinical drug development, provide recommendations on when investigations of the effect of obesity on the PK of a drug should be considered, provide information on specific important considerations for these investigations and discuss how to reflect PK findings in weight/size based dosing recommendations.

Deadline – 31st July 2018

More information HERE [20]

1 March 2018

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://learning.bmj.com/learning/home.html [3] http://statements.eahp.eu/statements/final-statements [4] https://twitter.com/EAHPtweet [5] https://www.facebook.com/eahp.eu/ [6] http://www.eahp.eu/events/open-learning/courses [7] https://register.edqm.eu/freepub [8] http://www.who.int/mediacentre/news/releases/2018/world-leaders-ncds/en/ [9] http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5182/full#efs25182-note-1005 [10] http://www.efsa.europa.eu/en/efsajournal/pub/5182 [11] http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/news/news/2018/2/12-european-countries-commit-to-greater-efforts-to-protect-people-from-vaccine-preventable-diseases [12] http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/publications/2014/european-vaccine-action-plan-20152020-2014 [13] https://ec.europa.eu/info/consultations/open-public-consultation-strengthened-cooperation-against-vaccine-preventable-diseases_en [14] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/01/WC500242079.pdf [15] http://ejhp.bmj.com/content/early/2018/02/08/ejhpharm-2017-001441 [16] http://www.hfpolicynetwork.eu/callforinformation [17] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=W [18] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=W [19]

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