eahp euMonitor

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

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EAHP 2017: Recap, 2018 outlook

Like every year, also in the previous year the European Association of Hospital Pharmacists (EAHP) carried out a number of activities, including but not limited to our annual Congress, member events – such as the General Assembly and the Academy Seminar - and our key projects.

The European Statements of Hospital Pharmacy – which were adopted in 2014 – express commonly agreed objectives which every European health system should aim for in the delivery of hospital pharmacy services. Since 2016, motivated and enthusiastic hospital pharmacists are helping their countries and others move towards Statement Implementation under the guidance of EAHP. The implementation ambassadors, which are very vital to the success of the project, held their second meeting in autumn 2017, where they exchanged their progress with each other and learned about the Self-Assessment Tool. Moreover, the Statement website [2] was launched during the annual EAHP congress in Cannes in March 2017.

Major progress was also made in relation to EAHP's second key project – the Common Training Framework [3] (CTF). In spring 2017, the association conducted a Delphi Consultation on the draft competency framework to secure voluntary agreement across countries about the knowledge, skills and attitudes/behaviours that underpin advanced practice in the hospital sector. With the help of hospital pharmacists, other healthcare professionals, patients/ representatives of patient organisations and regulatory bodies participated, EAHP managed to finalise the draft competency framework. Additionally, the literature review of CTF Working Group 2 was published in the online first edition of the European Journal of Hospital Pharmacy.

EAHP's General Assembly saw the voting on a new president-elect Petr Horak (Czech Republic), who will take office in June 2018 as well as the discussion on policy matters. The 34 member countries present at the meeting, agreed to revise the existing position paper on eHealth and mHealth due to rapid changes in this policy field. In addition, due to increasing interest in the opinion of hospital pharmacists on biosimilar medicines, EAHP's members adopted a position on this topic. The position paper addresses the role of the hospital pharmacist as well as other matters relevant to EAHP, such as the naming of biosimilar medicines; extrapolation of indications; interchangeability, switching and substitution of biosimilar medicines; and, information about biosimilar medicines.

The two parallel EAHP Academy Seminars [4] held on the 29th and 30th of September 2017 in Vienna, Austria, focused on "Hospital Pharmacy Practice Research - Scientific Quality" and "Antibiotic Stewardship for Beginners".

To further advance research skills, the first seminar included presentations of best practices on pharmacy research, encompassing the formulation of the research question, the study design, outcome measurements and qualitative research. Practical workshops and

considerations on the involvement of patients, statistics and medical ethics concluded the two-day training. Antimicrobial stewardship, one of EAHP's key policy priorities featured prominently in the second seminar which touched upon consumption surveillance methods, antibiotic therapy and usage data. Workshops on rational antibiotic therapy as well as training on the implementation of antibiotic stewardship teams and awareness raising for medical professionals equipped interested hospital pharmacists with the basic knowledge on these topics.

EAHP is already preparing to release information on further milestones in the upcoming month. At the end of January, the results of the Labour Mobility Survey – a project that was undertaken by Working Group 2 of the Common Training Framework project – will be presented to the public and made available on our website. Furthermore, news on the European Statements of Hospital Pharmacy will be revealed during our annual Congress in March.

This year's Congress will take place from 21st to 23rd March in Gothenburg, Sweden. In accordance with the theme 'Hospital Pharmacists – Show us what you can do!' participants can learn more about the challenges that economic restrictions and increased demands pose. In addition, the Congress provides an opportunity to demonstrate what hospital pharmacists have achieved and it aims at serving as an inspiration for future development. Until 31st of January 2018 a reduced registration rate is available.

More information about the registration for the 23rd EAHP Congress HERE [5]

EMA

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EMA recommendations: Contraception in men and women and CMDh endorses suspending the marketing of modified- or prolonged-release paracetamol.

The European Medicines Agency (EMA) has updated recommendations for contraception in men and women taking mycophenolate medicines, used to prevent rejection of transplanted organs, and the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) [6] has endorsed by majority EMA's Pharmacovigilance Risk Assessment Committee's (PRAC) [7] December 2017 recommendation [8] to suspend marketing of modified- or prolonged-release products containing paracetamol.

The updated recommendations follow a periodic review of mycophenolate medicines by EMA's Pharmacovigilance Risk Assessment Committee (PRAC). Mycophenolate medicines [9] are known to increase the risk of malformations and miscarriages during pregnancy if the fetus is exposed to them in the womb. EMA has now concluded that current evidence does not indicate a risk of malformations or miscarriages when the father has taken

mycophenolate, although the risk of genotoxicity cannot be completely ruled out. For male patients, EMA now recommends that either the male patient or his female partner use reliable contraception during mycophenolate treatment and for at least 90 days after stopping treatment. For female patients, the risk is unchanged. These medicines must not be used in pregnant women unless there are no suitable alternatives to prevent transplant rejection.

The Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) has endorsed by majority a European Medicines Agency recommendation to suspend marketing of modified- or prolonged-release products containing paracetamol (designed to release paracetamol slowly over a longer period than the usual immediate-release products).

CMDh agreed with the Agency's advice that the advantages of a longer-acting product did not outweigh the complications of managing an overdose of the medicine, since the treatment procedures for immediate-release products are not appropriate for modified-release paracetamol. Products containing modified release paracetamol alone or combined with the opioid medicine tramadol will remain suspended unless the companies that hold the marketing authorisations can provide evidence of appropriate and practical EU-wide measures to help prevent overdose with these products and adequately reduce its risks. The CMDh decision will now be sent to the European Commission which will issue a final legally binding decision valid throughout the EU.

Updated recommendations on mycophenolate medicines HERE [10]

CMDh endorsement of modified- or prolonged-release products containing paracetamol recommendations HERE [11]

European Commission proposes ban of seven new psychoactive substances

In the fight against illegal drugs, the European Commission has issued a proposal on the ban of new psychoactive substances (NPS) in December 2017. This proposal concerns seven NPS which are not covered by international drugs controls and remain a serious challenge to European public health.

The seven new psychoactive substances, including those commonly known as "spice", "herbal incense" and "legal weed", belong to two categories: four of them are synthetic cannabinoids, with effects similar to cannabis but much more toxic, while the other three substances are synthetic opioids closely related to fentanyl, a substance controlled at international level. According to the European Monitoring Centre for Drugs and Drug Addiction

(EMCDDA [12]), these toxic substances are associated with over 170 deaths across the EU and a number of acute intoxications.

The Commission therefore considers that there are grounds for subjecting all seven substances to control measures across the EU. The Commission's proposal will now be discussed in the Council, which, in consultation with the European Parliament, will decide whether to adopt the measures.

Proposal available HERE [13]

EPHA - Joi  all to action on antimicrobial resistance

The European Public Health Alliance (EPHA) presented a Joint Statement and Call to Action on antimicrobial resistance (AMR) at the 2017 meeting of the Health Policy Platform. Both documents go together – the Call to Action being a shorter executive summary of the Joint Statement. EAHP, alongside other European and international organisations active in the health sector, has endorsed the statement.

The Health Policy Platform [14] is a collaborative initiative that was set up in after the mandate of the EU Health Policy Forum ended in December 2013 to ease the communication between the European Commission services and health stakeholders. It is aimed to be inclusive and to reflect geographical and professional diversity of the participants.

The Joint Statement contains eleven key points for action that its authors and signatories (representing a diverse group of public health stakeholders including organisations representing the interests of healthcare and animal health professionals and students, patients and disease-specific groups, health groups active at the national level and many others involved in tackling AMR's many dimensions) would like to see addressed by the European Commission and the relevant Executive Agencies working on AMR.

Some points are the involvement of civil society in AMR One Health policymaking, supporting the development and implementation of National Action Plans and allocation of adequate European funds to actions against AMR, make full use of EU legislative powers in AMR relevant sectors and nurture and actively involve healthcare professionals, including students. The Statements' objective is to highlight areas where the signatories feel that more action is required than what is outlined in the One Health Action Plan. Specifically, the eleven points include an increased involvement of civil society, students and health professionals, the sufficient allocation of EU funds to actions against AMR, the monitoring and benchmarking of AMR data throughout Europe, supporting and promoting rapid diagnostic tests and in general empowering patients and raising public awareness.

Joint Statement HERE [15]

Call to Action HERE [16]

Endorse the Statement HERE [17]

EJHP: January Issue now available!

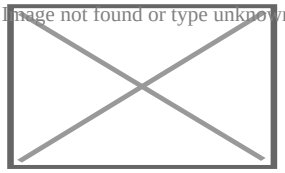
The January issue of the European Journal of Hospital Pharmacy (EJHP) is now available, featuring articles regarding the Common Training Framework (CTF), the Falsified Medicines Directive (FMD) and an editorial on the 'end' of antibiotics.

In the editorial, titled Apocalypse: the end of antibiotics? the focus is placed on the report by England's chief medical officer on antimicrobial resistance, pointing out the decrease in antibiotic prescriptions and the increase in resistance, citing the E.Coli resistance of up to 50% in many eastern and southern European countries.

The review article carried out by EAHP Working Group 2, analysed the impact of educational interventions on health outcome to determine the value that can be created in forming a CTF for hospital pharmacy. Despite no specific mentions of hospital pharmacists in the analysed literature reviews, the ones used showed that higher education levels of healthcare professionals improve patient outcomes. Therefore, furthering hospital pharmacy education could significantly impact the professional status and ensure the best use of medicines by patients in hospitals. In addition, a common framework could provide an appropriate benchmark for all European countries to strive for.

In the FMD article, the Polish case study is presented, with explanations on how Poland is planning to comply with the new EU regulations, the actions that have been taken so far to incorporate the FMD into Polish Pharmaceutical Law and whether or not these actions are sufficient. It concludes that Poland is only partially compliant with the FMD and further actions need to be undertaken to fully meet the Delegated Regulation (DR) requirements. Moreover, there is lack of awareness in Poland about the prevalence of falsified medication and the time scale required for implementation of the DR. The article suggests a public awareness campaign.

More HERE [18]



Consultations

EMA – Reflection paper on the pharmaceutical development of medicines for use in the older population

The reflection paper describes aspects that medicines developers may consider when designing medicines for older people, such as selecting appropriate routes of administration and dosage forms, dosing frequency, excipients, container closure systems, devices and technologies, and user instructions in the product information. It is intended to communicate the current status of discussions on the pharmaceutical development of medicines that may be used in the older population.

Deadline – 31st January 2018

More information HERE [19]

EMA – Concept paper on the need for a paediatric addendum of the guideline on clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolic disease

A number of new EMA guidelines related to clinical investigation of medicinal products for the treatment and prophylaxis of venous thromboembolism (VTE) are already available, but recommendations are applicable only to adults. In contrast to adults, VTE in children is a rare event, but represents a significant management dilemma that requires therapeutic intervention. The concept paper thus has been drafted since a paediatric addendum to the guidelines on clinical investigation of medicinal products for the treatment and prophylaxis of VTE is considered necessary to discuss and make methodological recommendations adapted to children.

Deadline – 31st January 2018

More information HERE [20]

Commission – Public consultation on pharmaceuticals in the environment

The consultation by the European Commission seeks views on possible actions to address the risks from pharmaceuticals in the environment. Its overall aim is to obtain views and information to support the development of the European Commission's strategic approach to pharmaceuticals in the environment.

Deadline – 21st February 2018

Access survey HERE [21]

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 [22]

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 [23]

12 January 2018

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://statements.eahp.eu/ [3] http://www.hospitalpharmacy.eu/ [4] http://www.eahp.eu/events/academy/EAHP-Academy-Seminars [5] http://www.eahp.eu/congresses/registration#node_congress_registration_group_reg_geninfo [6] http://www.hma.eu/abouthma.html [7] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000537.jsp [8] http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Paracetamol_31/Recommendation_p [9] http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000882/human_med_000913.jsp [10] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/12/news_detail_002871.jsp&am [11]

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