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

Catch up with EAHP Webinar

EAHP has introduced a new and exciting concept to keep you updated with our latest projects and initiatives: the Catch up with EAHP Webinar. Make the most of our resources and learn about our latest projects, initiatives and ways of collaboration. Whether you are already very familiar with EAHP or a newcomer, this webinar is for everyone. It will take place on the 14th of December at 6.00 PM CET on the online platform ZOOM.

Register in advance for this meeting HERE. [1]

CAS on “Medicines and medical devices in emergency and disaster situations”

The crises of the recent years have concretely highlighted the key role of pharmacists in health crisis management. This experience also underlined the value of preparedness to respond to such situations. In this context, the Specialised Centre for Emergency and Disaster Pharmacy opens the registration for its third edition of the CAS "Medicines and medical devices in emergency and disaster situations", starting at the end of January 2024. The objective of this CAS is to provide a recognised interprofessional post-graduate university training in emergency and disaster pharmacy. Indeed, in crisis contexts, including humanitarian crises and daily emergencies in (pre-)hospital and hospital settings, the role of drugs and medical devices is obvious in treating victims and guaranteeing the survival of most individuals. In this respect, specific pharmaceutical and pharmacological knowledge is essential for every health professional involved in emergency and disaster situations.

This program provides qualified pharmacists, physicians, paramedics and other health professionals with new skills and/or updated knowledge, thus strengthening their expertise in this specific field. Courses are taught mainly in English and international participants are welcome. They consist of 6 thematic modules of 2-3 days each and a small final thesis. They

will be organized in the Geneva, Lausanne and Bern areas in Switzerland. The registration deadline for the entire CAS is 30 November 2023 (but can be extended on request). The modules are also be offered on an individual basis.

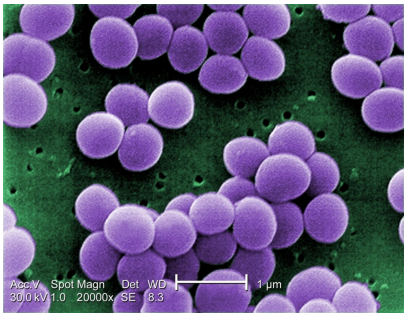
Learn more about the CAS on "Medicines and medical devices in emergency and disaster situations" HERE [2].

Adapting EMA's New Mandate: Hospital Pharmacists' and Pharmacy Managers Data Sharing Survey

EHMA and EAHP are conducting a survey targeting hospital pharmacists and pharmacy managers, focusing on the collection and sharing of data related to medication demand and stocks. The survey aims to identify how hospitals currently gather and share data on medication stock and demand, identify any barriers to collecting information on medicines stocks, and explore the workload implications and digitalisation requirements for hospital pharmacy workflows in relation to data collection. The survey will remain open for three months. The results will be collected and published in a briefing paper that will be shared with EU policymakers and the European Medicines Agency.

Find the survey HERE. [3]

Annual Epidemiological report about Antimicrobial Antimicrobial consumption in the EU/EEA for 2022



In light of the Antimicrobial Awareness Week, ECDC released the Annual Epidemiological Report about Antimicrobial Antimicrobial Consumption in the EU/EEA for 2022. The total consumption of antibacterials for systemic use has decreased by 2.5% since 2019, indicating slow progress towards the EU target reduction of 20% by 2030. In the hospital sector, the EU/EEA mean consumption of antibacterials for systemic use (ATC group J01) was 1.61 DDD

per 1,000 inhabitants per day (country range: 0.75 (Netherlands) –3.15 (Czechia). During 2013–2022, a statistically significant decrease was observed at the EU/EEA level. However, the EU/EEA hospital sector has also seen a rise in the percentage of AMC from the ‘Reserve’ group (i.e. antibiotics for the treatment of confirmed or suspected infections due to multidrug-resistant organisms). Among 21 countries for which 10-year trend analyses were performed, 17 (81%) countries had increasing trends in the percentage of hospital AMC from the ‘Reserve’ group of antibiotics. Not one EU/EEA country has a decreasing trend in the percentage of ‘Reserve’ group AMC in the hospital sector.

Learn more about it HERE. [4]

First electronic Product Information available for a selection of medicines

The Heads of Medicines Agencies (HMA), the European Commission (EC) and the European Medicine Agency have published the first electronic product information (ePI) for a selection of human medicines. They are part of a pilot that aims to improve accessibility for healthcare professionals and patients by transitioning from traditional PDF documents to real-time, electronically accessible information. The one-year pilot involves 25 medicines from Denmark, the Netherlands, Spain, and Sweden and is testing the integration of ePIs into regulatory procedures. The project is expected to finish in July 2024, and depending on the outcomes, it will inform us to integrate the ePIs into common practice and expand their use across the EU.

The ePI’s for the selected medicines within the project can be found HERE. [5]

7th Biosimilar Multistakeholder event

On the 13th of December 2013, from 9.00 to 16.30, the European Commission organised the 7th Biosimilar Multistakeholder Event in Brussels (it is also possible to attend the event online). The event will discuss several topics related to the development and use of biosimilars: How to address the challenges and lack of biosimilar competition in certain areas of the biologic pipeline, Disparities in biosimilar uptake and access (across EU Member States within countries and regions), Consequences of product formulation and administration for patients, healthcare professionals and systems (both in terms of opportunities and challenges).

Learn more about it HERE. [6]

European Commission looking for independent scientific experts for EMA’s Pharmacovigilance Risk Assessment Committee (PRAC)

The European Commission is looking for six independent scientific experts for EMA's Pharmacovigilance Risk Assessment Committee (PRAC) for a three-year mandate starting on 2 July 2024. The deadline for submission of applications is on the 7th of December before 12:00 CET.

Find more information HERE. [7]

EJHP: Medication adherence reporting in pivotal clinical trials: overview of oral oncological drugs

Medication adherence is essential to collect reliable outcomes in clinical trials. A recent article published in the European Journal of Hospital Pharmacy (EJHP) aimed to assess how and to what extent medication adherence is reported in pivotal clinical trials of oral cancer drugs. 56 clinical trials concerning 30 oral cancer drugs authorised by the European Medicines Agency were analysed. Eleven articles (19.6%) contained a mention of medication adherence in the main document, 26 (46.4%) in the supplementary material, and 19 (33.9%) did not contain any reference to adherence. Seven studies reported medication adherence between the results, expressed as the number of patients discontinuing treatment for non-compliance and mean or median percentage. It can, therefore, be concluded that medication adherence in pivotal clinical trials of oral oncological drugs is poorly represented. A greater level of reporting in the results is needed and should be included among the minimum set of recommendations in reporting health research.

Read the article [8]HERE. [9]

[Consultations]

EMA Consultation: Concept paper on the development of an addendum to the Guideline on clinical development of vaccines for immunocompromised individuals.

EMA launched a concept paper on the development of an addendum to the Guideline on Clinical Development of Vaccines on clinical trials for vaccines for immunocompromised individuals. The Guideline on clinical evaluation of vaccines EMEA/CHMP/VWP/164653/05 Rev. 1 (3) does not provide detailed guidance on the design of clinical trials to assess the safety, immunogenicity and efficacy of vaccines in immunocompromised individuals. There is a need to provide some guidance on potentially suitable sub-populations of immunocompromised individuals for trials to improve the extrapolation of the findings to other sub-populations. Moreover, there is a need to consider designing studies in immunocompromised individuals that also indicate alternative doses and/or regimens that could provide adequate levels of protection against infectious diseases. All interested parties are invited to comment on the concept paper. The public consultation is open until 1 January 2024.

Contribute HERE [10]

EMA Consultation: Draft the 3rd revision of the guideline on clinical investigation of medicinal products in the treatment of epileptic disorders.

EMA published the draft of the 3rd revision of the Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders. The public consultation is open until the 1st of January 2024.

Contribute HERE [11]

EMA Consultation: Guideline on the clinical requirements for non-replacement therapy in haemophilia A and B.

The Guideline on the clinical requirements for non-replacement therapy in haemophilia A and B describes the main clinical data needed to support an application for a marketing authorisation for non-replacement therapy for use in the prevention of bleeding in patients with haemophilia A and/or haemophilia B. The public consultation is open until the 1st of January.

Contribute HERE [12]

EMA consultation: A concept paper on the revision of the Non-clinical and Clinical Module of the influenza vaccines guideline.

The current influenza vaccines guideline covering non-clinical and clinical modules (EMA/CHMP/VWP/457259/2014) was adopted in July 2016. Developments in the field of influenza vaccines and experience with applications for scientific advice and marketing authorisation since 2016 have pointed to the need for additions to and revisions of the current text. The proposed guideline will replace the Guideline on influenza vaccines and non-clinical and clinical modules (EMA/CHMP/VWP/457259/2014). The public consultation is open until the 1st of January 2024.

Contribute HERE [13]

European Commission Public Consultation: assessing the performance and impacts of the Health Emergency Preparedness and Response Authority (HERA).

The Health Emergency Preparedness and Response Authority (HERA) was set up by the Commission in 2021 to respond to the COVID-19 pandemic. The Commission has opened up a public consultation to gather views from a broad range of stakeholders on the performance and wider impacts of HERA. This consultation will assess whether HERA effectively and efficiently contributed to the political objective of strengthening the EU's health emergency preparedness and response and fulfilling its assigned tasks. Furthermore, the aim is to look at the complementarity with work carried out by other EU bodies, the extent to which HERA's mandate fits the current health challenges and if any changes to this mandate are needed. The public consultation is open until the 19th of February 2024.

Contribute HERE [14]

29 November 2023

Links
[1] https://us02web.zoom.us/meeting/register/tZUvc-6upzwiGdcsHHXa5YznwA4GRv39G9bm [2] https://eur01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.unige.ch%2Fformcont%2Fcours%2Fmedi emergency-disaster&data=05%7C01%7Cepsa%40eahp.eu%7Cba05208f467646f9733308dbf4b1ed51%7C2504c6a78226 [3] https://forms.office.com/e/j0E641ac3W [4] https://www.ecdc.europa.eu/sites/default/files/documents/AER-antimicrobial-consumption.pdf [5] https://plm-portal.ema.europa.eu/ePIAll/ [6] https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5190 [7]

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