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

Submit your abstract to the 28th EAHP Congress!

From 20 to 22 March 2024, the European Association of Hospital Pharmacists (EAHP) will be hosting the largest European gathering of hospital pharmacists in Bordeaux, France. The 28th Congress of EAHP will bring together healthcare professionals from all over the globe that are seeking to improve their level of training. Submit your abstract for review to the Congress by 1 October.

• Submit your abstract for EAHP's 28th Congress HERE [1]

Addressing environmental challenges at all healthcare levels is paramount while ensuring the continuity and quality of pharmaceutical therapy and patient safety. Consequently, EAHP's 28th Congress will be focusing on the theme "Sustainable Healthcare – Opportunities & strategies". EAHP's Scientific Committee, under the lead of Prof. Dr. Thomas De Rijdt, has prepared an interesting and innovative Congress programme that caters to the educational needs of the profession and looks to the future to better prepare the profession for current and future challenges.

Three keynote lectures and over 20 seminars, interactive sessions, and workshops will be presented with topics related to stakeholder involvement in sustainable healthcare, green hospitals, carbon footprint, stability studies, cross-border collaboration, patient involvement in clinical pharmacy, and patient safety. It is also foreseen a Pharmacotherapy Session on the theme of Medication management after bariatric surgery. Furthermore, an interactive Young professional Session will be organised as a panel discussion in order to share experience and expertise.

Learn more about the programme of EAHP's 28th Congress HERE [2]
Early bird registration rate available up to end November HERE [3]

Stakeholder event on the implementation of the HTA Regulation

 On 18 September 2023, the European Commission, the Heads of Health Technology Assessment (HTA) Agencies and the national HTA agencies, will jointly host an event in Athens (Greece) on the implementation of the HTA Regulation.

Held from 8h00 to 11h30 a.m. CEST, this English-speaking event will provide an overview of the new EU HTA Regulation by the European Commission, and will be followed by panel discussions, featuring local speakers who will discuss important issues related to the implementation of the regulation.

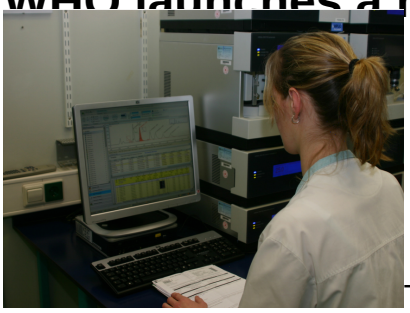
The panels will cover topics such as: (i) understanding key elements of the EU HTA Regulation; (ii) challenges and opportunities in the implementation process; and (iii) involving stakeholders in EU HTA implementation.

Having entered into force in January 2022 and which will apply as of January 2025, this legislation covers joint clinical assessments, joint scientific consultations, the identification of emerging health technologies, and voluntary cooperation. Ultimately, it will contribute to the availability of new innovative technologies for EU patients.

The programme will be available closer to the date of the event.

Register for this event HERE [4]
More information HERE [5]

WHO launches a new Global Initiative on Digital Health

 The World Health Organisation (WHO) and the G20 Indian Presidency released a new Global Initiative on Digital Health (GIDH) at the G20 Summit hosted by the Government of India on 19 August 2023.

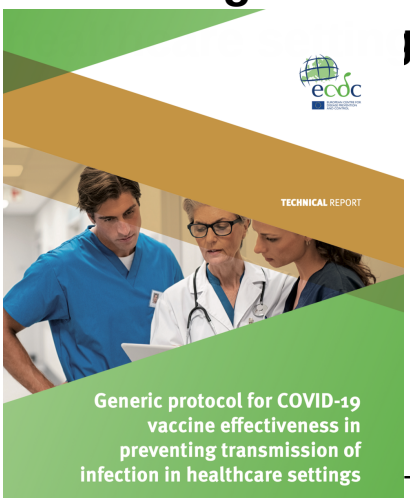
This new GIDH initiative will operate as a WHO-managed network and platform in order to the implementation of the Global Strategy on Digital Health 2020-2025. The initiative aims to develop clear priority-driven investment plans for digital health transformation, improve reporting and transparency of digital health resources. It will also facilitate knowledge

exchange and collaboration across regions and countries to accelerate progress and increase technical and financial support to the implementation of the Global Strategy on Digital Health 2020-2025 and its next phase.

The above-mentioned global strategy 2020-2025 will strengthen health systems through the application of digital health technologies for consumers, healthcare professionals, and industry towards empowering patients and achieving the vision of health for all.

More information is available HERE [6]

Preventing transmission of COVID-19 infection in [illegible]s



The European Centre for Disease Prevention and Control (ECDC) published a generic protocol for COVID-19 vaccine effectiveness in preventing transmission of infection in healthcare settings.

As part of the ECDC's 'Assessment of COVID-19 vaccine effectiveness among healthcare workers' project, the aim of the study protocol is to measure product-specific COVID-19 vaccine effectiveness in preventing transmission of SARS-CoV-2 infection from healthcare workers to their contacts, which can be either other patients or healthcare workers, in healthcare settings.

This document presents the core protocol of a cohort study and outlines a generic method to establish the study, collect data, undertake analysis, and allow for necessary local adaptions. Sections of this generic protocol require further local modification.

Read the report HERE [7]

EU-Innovation network multi-stakeholder meeting on 26 September!

The EU-Innovation Network (EU-IN) and the Spanish Agency of Medicines and Medical Devices are organising a multi-stakeholder meeting under the Spanish 2023 EU Presidency to promote research and development of innovative medicines and related technologies and methodologies in the European Union.

The meeting aims to (i) inform stakeholders on EU-IN activities and available EU regulatory support to developers and to gather feedback on how to further optimise these support tools; (ii) exchange knowledge, experience and good practices among stakeholders involved in medicines research and development, and explore opportunities for collaboration; and (iii) collect inputs from multiple stakeholders, in particular from academic innovators, to identify gaps in regulatory science and discuss options to address them.

The input collected during the meeting will be used to inform recommendations with the aim of fostering innovative medicines development in the EU.

More information is available HERE [8]

The EJHP September issue is available!

The September issue of the European Journal of Hospital Pharmacy (EJHP) is out with an editorial on choosing carefully where to publish your research. This latest edition also includes a systematic review, a case report, and EAHP Position Papers on Access to medicines and Hazardous medicinal products. With the help of the original research articles, you can learn more about the effectiveness of antithrombotic prophylaxis in hospitalised patients with SARS-CoV-2 infection, real-world outcomes of abiraterone and enzalutamide in first-line treatment of metastatic castration-resistant prostate cancer, implementation and effectiveness of pharmacist-led interviews at patient hospital admission in a rheumatology department and medicine shortages in France: a 6-year retrospective study in a university medical centre.

Read the September edition of the EJHP HERE [9]

[Consultations]

European Commission: Survey for the study on the implementation of Europe's Beating Cancer Plan

The European Commission launched a Survey for the study on mapping and evaluating the implementation of the Europe's Beating Cancer Plan with one dedicated to health professionals. The study aims to assess the state of play of the Cancer Plan, identify further actions to support, coordinate and complement Member States' efforts against cancer, and build a monitoring framework to assess the outcomes of Europe's Beating Cancer Plan. The deadline for comments is 22 September 2023.

Contribute HERE [10]

European Commission: Pharmaceuticals – changes to marketing authorisations (review of EU rules)

The European Commission launched a call for evidence on "Pharmaceuticals – changes to marketing authorisations (review of EU rules)". This initiative, announced in the 2020 pharmaceutical strategy for Europe, aims to review the current rules setting out the procedures for post-authorisation changes to a marketing authorisation for medicines for human use. The purpose is to make the lifecycle management of medicines more efficient. The deadline for providing feedback is 26 September 2023.

Contribute HERE [11]

EMA Consultation: Draft ICH E6 (R3) guideline on good clinical practice – step 2b

EMA has published a consultation on the International Conference on Harmonisation (ICH) Good Clinical Practice Guideline to provide a unified standard to facilitate the mutual acceptance of clinical trial data for ICH member countries and regions by applicable regulatory authorities. The guideline builds on key concepts outlined in ICH E8 (R1) General Consideration for Clinical Studies. This includes fostering a quality culture and proactively designing quality into clinical trials and drug development planning, identifying factors critical to trial quality, and engaging stakeholders, as appropriate, using a proportionate risk-based approach. Comments should be provided by 26 September 2023.

Find the document HERE [12]

EMA Consultation: ICH Reflection Paper on international harmonisation of RWE terminology

EMA published an International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)'s Reflection Paper on "Proposed international harmonisation of real-world evidence (RWE) terminology and convergence of general principles regarding planning and reporting of studies using real-world data, with a focus on effectiveness of medicines", co-authored by EMA, US FDA and Health Canada. The deadline for comments is 30 September 2023.

Contribute HERE [13]

EMA Consultation: Concept Paper on the development of a Guideline on the quality aspects of mRNA vaccines

The Concept Paper addresses the need to establish a guideline on the quality aspects of mRNA vaccines. The scope of the guideline focuses on the mRNA vaccines against infectious diseases (including self-amplifying mRNA). It is not intended to address specific requirements

for mRNA vaccines to be used in clinical trials, but the scientific principles described may also be applicable during pharmaceutical development. The deadline for comments is 30 September 2023.

Contribute HERE [14]

European Paediatric Formulary: Furosemide oral solution monograph

The European Directorate for the Quality of Medicines & HealthCare (EDQM) has just released Issue 7 of Pharmeuropa PaedForm, in which the draft text for Furosemide 2 mg/mL Oral Solution is published for public consultation with a view to its later inclusion in the European Paediatric Formulary. This is the second round of public consultation for this text that was first published in issue 2 of Pharmeuropa PaedForm. The EDQM welcomes all comments on the revised monograph from users and interested parties. The deadline for comments is 30 September 2023.

Contribute HERE [15]

EMA Consultation: reflection paper on the use of artificial intelligence in the lifecycle of medicines

EMA launched a draft reflection paper outlining the current thinking on the use of artificial intelligence (AI) to support the safe and effective development, regulation and use of human and veterinary medicines. The document reflects on principles relevant to the application of AI and machine learning (ML) at any step of a medicine's lifecycle, from drug discovery to the post-authorisation setting. All interested parties are invited to comment on the consultation. The public consultation is open until 31 December 2023.

Contribute HERE [16]

EFCCA Patient Preference Survey

The European Federation of Chron's & Ulcerative Colitis Associations (EFCCA) together with the University of Leuven launched the "Patient Preference Survey". It aims to find out which aspects, factors, and characteristics are important for patients when choosing a treatment for inflammatory bowel disease. The survey has been translated into several languages.

Contribute HERE [17]

7 September 2023

Links
[1] https://www.eahp.eu/congresses/28th-congress-eahp/abstract [2] https://www.eahp.eu/congresses/28th-congress-eahp/programme [3] https://www.eahp.eu/congresses/28th-congress-eahp/registration [4] https://athens.hta-info-day.eu/registration/ [5] https://health.ec.europa.eu/events/theory-practice-implementing-eu-health-technology-assessment-regulation-2023-09-18_en [6] https://www.who.int/news/item/19-08-2023-who-launches-a-new-global-initiative-on-digital-health-at-the-g20-summit-in-india [7] https://www.ecdc.europa.eu/sites/default/files/documents/Generic-protocol-COVID-19-vaccine-effectiveness-preventing-transmission-healthcare-settings.pdf [8] https://www.ema.europa.eu/en/events/shaping-european-innovation-ecosystem-eu-innovation-network-multi-stakeholder-meeting [9] https://ejhp.bmj.com/content/30/5 [10] https://ec.europa.eu/eusurvey/runner/c019de64-6b43-c73a-e54e-f9c55f39bd2b [11]

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13561-Pharmaceuticals-changes-to-marketing-authorisations-review-of-EU-rules-_en [12] https://www.ema.europa.eu/en/documents/scientific-guideline/draft-ich-e6-r3-guideline-good-clinical-practice-gcp-step-2b_en.pdf [13] https://www.ema.europa.eu/en/documents/scientific-guideline/ich-reflection-paper-proposed-international-harmonisation-real-world-evidence-terminology_en.pdf [14] https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-development-guideline-quality-aspects-mrna-vaccines_en.pdf [15] https://www.edqm.eu/en/-/european-paediatric-formulary-furosemide-oral-solution-monograph-published-for-public-consultation-in-pharmeuropa-paedform-1 [16] https://ec.europa.eu/eusurvey/runner/93c5397b-b904-76ca-a54d-3873e177e87d [17] https://ibdpatientpreferencesurvey.sawtoothsoftware.com/cgi-bin/ciwweb.pl?hid_studyname=IBD_preference_survey&hid_pagenum=0&hid_link=1&hid_javascript=