

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

EAHP's General Assembly adopted a new Position Paper on Digital Health!



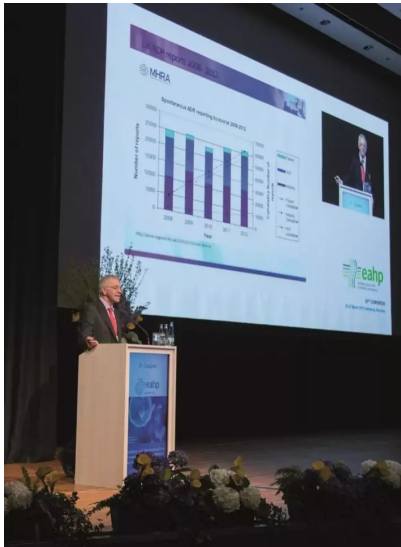
This year's General Assembly of the European Association of

Hospital Pharmacists (EAHP) adopted a new Position Paper on Digital Health. The role of hospital pharmacists is changing and so is the environment they work in. Digitalisation is impacting a vast spectrum of healthcare services ranging from electronic prescribing, medical records, and automation, text message prompts that remind patients to take their medicine, and artificial intelligence revolutionising treatment.

The Position Paper encourages national governments, hospital administrations, and European institutions to take all necessary steps to ensure that a uniform informatic structure for health data and clear standards for the interoperability of information technology systems used in healthcare is in place. In this sense, decision-makers at both national and European levels need to ensure the involvement of hospital pharmacists in the design, development, and specification of parameters as well as the evaluation and maintenance of information communication technology within the medicines processes. Furthermore, the European Commission and Member States need to establish funding programmes that support hospitals in updating their digital infrastructure.

To ensure that no one is left behind, there should be the complementary use of paper and electronic patient information leaflets where access of patients to the information cannot be ensured otherwise. Also, a recommendation is given to raising awareness among users and appropriate regulatory oversight mechanisms for digital health applications to ensure that they have a positive impact and adequately protect patient data.

Have a look at the Position Paper on Digital Health [HERE](#) ^[1]



David Cousins

In May 2023, David Cousins, an outstanding former hospital

pharmacist, passed away. In the United Kingdom, he was most known for his work around patient safety, while in Europe many recognised him as a member of the inaugural EAHP Congress Scientific Committee. David Cousins researched and published on medication error prevention since 1990. He authored the national guidance on safe medication practice for primary, secondary and tertiary healthcare providers and pharmaceutical and the medical devices industry in the United Kingdom. There he also worked as the Chief Pharmacist at the Derby Hospital, the Head of Safe Medication Practice and Medical Devices at the National Patient Safety Agency and Head of Safe Medication Practice and Medical Devices for NHS England.

Within EAHP he will always be remembered as a passionate advocate for patient and medication safety that contributed greatly to EAHP's education programme and the modernisation of the Congress Scientific Programme during his time on the Scientific Committee from 1995 to 2002. He engaged in many EAHP Congresses, was also a speaker, and help push for the expansion of the clinical role of the hospital pharmacist. As a member of the Special Interest Group (SIG) focused on the Use of Prefilled Syringes in Intensive Care Units and Operating Theatre he helped gather data from hospital pharmacists, nurses and physicians as well as different European and national associations on the value of prefilled syringes. He was involved in the SIG from autumn 2021 to spring 2023.

Spain took over the Presidency of the Council of the EU!



The Spanish Council Presidency started on 1 July and will run

until 31 December 2023. Amongst its priorities are ensuring the open strategic autonomy of Europe in areas such as health and advancing the green transition and environmental adaption.

The presidencies are organised in trios to have an agreement on some overarching goals and to ensure continuity of the work between them. The Spanish presidency marks the beginning of the trio of presidencies – Spain, Belgium, and Hungary – that will work to further strengthen the EU Health Union and the resilience of health systems that are accessible to all and build preparedness for future health emergencies. The trio will continue working on antimicrobial resistance and on the accessibility of medicines that meet public health needs.

The Spanish main priorities in health are improving the protection of the vulnerable population in the EU, promoting initiatives to prepare for and respond to new health crises, and aligning the European health agenda with the 2030 agenda, and the One Health approach. Continuing the work of Sweden, cancer will be a topic on the agenda during the presidency.

Regarding policy files, Spain intends to advance the European Health Data Space discussion, due to its potential to improve the effectiveness of health and research policies. Also, the Substances of Human Origin proposal will be another dossier to be moved forward, since it will be essential to supervise the operation of the centres involved in obtaining the different substances and their use.

Another important file will be the strengthening of the financial base of the European Medicines Agency (EMA). Specifically, through the process that has already begun to establish the fees and expenses based on the costs to be charged by the Agency, but also regarding the remuneration according to the costs of the competent authorities of the Member States for the services they provide in the execution of the EMA's statutory tasks. Finally, Spain is planning to work on the adoption of conclusions on mental health.

Have a look at the trio programme [HERE](#) ^[2]

More information regarding the Spanish Presidency can be found [HERE](#) ^[3]

**EMA's Healthcare Professionals' Working Party
celebrated 10 years!**



June 2023 marked the 10th anniversary of the formal

establishment of the Healthcare Professionals Working Party (HCPWP) which is essential to connect the EMA with healthcare professionals. It provides recommendations to EMA and its human scientific committees on all matters of interest regarding medicines.

HCPWP is key for understanding the needs and challenges of the use of medicines in the real world and the impact of regulatory decisions. EAHP joined the HCPWP in 2013 when it was created. By being an active member of the working party, the Association provided recommendations to EMA and its human scientific committees on all matters of interest concerning medicines, such as medicine shortages and vaccines. EAHP is represented in the HCPWP by Piera Polidori and Despoina Makridaki, both Directors of Professional Development.

Throughout the last decade, representatives of EAHP have actively participated in a wide variety of EMA activities, including but not limited to exchanging views with other stakeholders during the meetings of the HCPWP, contributing to different workshops and sharing the views of the profession via consultations issued by the Agency. Improving patients' outcomes, the availability of medicines, tackling the problems caused by medicines shortages and combatting antimicrobial resistance are among the key concerns of the hospital pharmacy profession. Communication is therefore key to making a difference in medication and the delivery of valuable services to patients. Playing an active role in this platform for the exchange of information and discussion of issues of common interest between EMA and healthcare professionals is valuable.

Find more information [HERE](#) ^[4]

TEHDAS forum discussed the EHDS proposal



The joint action Towards European Health Data Space

(TEHDAS) initiative had its Stakeholder forum last month where different experts in the field of digital health discussed the state of play of the European Health Data Space (EHDS) file. The need to make the most of health data sharing and use in Europe was highlighted.

The debate centred on the individuals' right to their data, trust as an enabler of data sharing and use and the importance of ensuring data quality. Having a secure environment where data processing takes place after a data permit has been granted is a key element for the EDHS architecture. The European health data stakeholders underlined that to take the best

advantage of wider health data sharing and use, people's trust and communication on the benefits of data should be enhanced. It was also underlined that data plays a crucial role in shifting health systems towards personalised healthcare.

This was the third and last forum organised by TEHDAS and a follow-up joint action is planned to begin in 2024.

More information is available [HERE](#) ^[5]

Mental Health Strategy is out!



The European Commission adopted on 7 June the

Communication on a comprehensive approach to mental health to help member states and stakeholders tackle mental health challenges. It is a broad, prevention-oriented, and multi-stakeholder approach to mental health that puts it on par with physical health.

The Communication proposes a holistic approach to mental health, based on adequate and effective prevention, access to high-quality and affordable mental healthcare and treatment and reintegration into society after recovery. It foresees integrating mental health across policies, boosting the mental health of children and young people and helping those most in need.

The strategy is supported by 1.23 billion in EU funding from different financial instruments and 20 flagship initiatives that will be implemented in the upcoming years until 2028. These planned activities include for example building capacity already in 2023 for an approach that promotes mental health across all policies together with the World Health Organization and launching in 2024 a blueprint (toolkit) for a multi-disciplinary approach to mental health capacity building.

Reinforcing mental health systems and improving access to treatment and care, with some initiatives for more and better-trained professionals in the EU, technical support for mental health reforms across sectors, and gathering data on mental health.

Read the Communication [HERE](#) ^[6]

The EJHP July issue is available!



The July issue of the European Journal of Hospital Pharmacy (EJHP) is out

and with an editorial on the Granada Statements: an impact boost to clinical and social pharmacy publications. The newest edition of the EJHP includes a systematic review, a case report, and news with hospital pharmacists' first impressions on the revision of the General Pharmaceutical Legislation. With the help of the original research articles, you can learn more about the expanding role of pharmacy technicians and foundation rotation pharmacists in delivering patient-centred care at a mental health trust, a pilot study of a European oncology regimen reference library and matching algorithm, the accuracy of an electronic prescribing system for standard treatments and the impact of automated dispensing cabinets on dispensing errors, interruptions and pillbox preparation time.

Read the July edition of the EJHP [HERE](#) ^[7]

[Consultations]

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](#) ^[8]

EMA Consultation: revision of the Guideline for the evaluation of medicines targeting acute respiratory distress syndrome

EMA launched a consultation on a concept paper on the revision of the Guideline on clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome. This consultation aims to address the need to re-consider the EU regulatory expectations regarding the data that should be generated to support the approval of novel agents, like e.g. (co)primary and secondary endpoints, time of assessment, stratification and functional assessment indices recorded in confirmatory studies. Comments should be provided by 31 July 2023.

Find the document [HERE](#) ^[9] and contribute [HERE](#) ^[10]

Bedside clinical pharmacists in Europe

In this research, organized by the Semmelweis University, Hungary the position of bedside clinical pharmacists in hospitals will be assessed to gain insight into the routine practices and the provided clinical pharmacy services. The researchers would like to hear your opinion based on your experiences, so there are no correct or incorrect answers. It takes about 15 minutes to complete the questionnaire.

Contribute [HERE](#) ^[11]

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](#) ^[12]

5 July 2023

Links

[1] https://www.eahp.eu/sites/default/files/position_paper_on_digital_health_june_2023.pdf [2] <https://data.consilium.europa.eu/doc/document/ST-10597-2023-INIT/en/pdf> [3] <https://spanish-presidency.consilium.europa.eu/en/> [4] <https://www.ema.europa.eu/en/events/10th-anniversary-european-medicines-agency-ema-healthcare-professionals-hcpwp-working-party-meeting> [5] <https://tehdas.eu/news/european-stakeholders-determined-to-advance-the-use-of-health-data-for-the-benefit-of-all/> [6] https://health.ec.europa.eu/publications/comprehensive-approach-mental-health_en [7] <https://ejhp.bmj.com/content/30/4> [8] https://www.ema.europa.eu/en/documents/scientific-guideline/draft-ich-e6-r3-guideline-good-clinical-practice-gcp-step-2b_en.pdf [9] https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fdocuments%2Fguideline%2Fconcept-paper-revision-guideline-clinical-investigation-medicinal-products-treatment-patients-acute_en.pdf&data=05%7C01%7Cdiogo.teixeira.pereira%40eahp.eu%7C6122e92f464e49fa628008db65e1181 [10] <https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fec.europa.eu%2Feusurvey%2Frunner%2F86c4f1-e66d-1b60-5c9749e1f16b&data=05%7C01%7Cdiogo.teixeira.pereira%40eahp.eu%7C6122e92f464e49fa628008db65e1181> [11] https://eur01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fmailinglinks.eahp.eu%2Fis%2Fclick%3Fupn%3Fw-2FuG00n7m3G5Tke6TIJMhsCuhpPjGgnO0l6zVJwl0hXooofO46q2yz3R9Uxe-2B64a74s0jukU0oYJuhpxeTpzIzkd-2FyQdCRYkSxWh0UfUoEw8ETVtzWotYgCFtaZqYSMQ-3D-3DIXeM_MAMh3hPQ5NTYCAU3RkWbQPXmu9PGksQR8AGCe7Lwx-2B4kMb4oVms7z39WQGrAwPt4PpKksy-2FKEthOcTk1bWdlvXsmAZmEqCRQ3uG2i9dvX6iullwiKti-2BhuYo4JcZtZhZysk6F4nWLIYpYyLN7aOQJttXMSRWcVhqBSkulsDy5ArK67BGQNb-2Ftqb9MCUZGP4OaCJu9fXA6bVFMPkIMs0OO3KmeEKyUyoTpgYV4rIBQkk3REBICbh3KpEz-2BQ26-2BpWIARq8sZR76uQKEOfsZW8Yci3Qk4dnm4dB0jLWiZvprp7pRvicguAZ0PHJdJYM20nB1aLGUz47PObbgbfBASs2FIClbfPM-2FPp2-2Bs4ZBNvafBrXX-2BTbsbxUX13IDn6yTm5zcE6fiTVREsHmMYZ5vgzIVib5vPy3qNUPC2e6wqR0-3D&data=05%7C01%7Cdiogo.teixeira.pereira%40eahp.eu%7C4e7eff09924942fd4da808db612d66fd%7C2504 [12] <https://www.edqm.eu/en/-/european-paediatric-formulary-furosemide-oral-solution-monograph-published-for-public-consultation-in-pharmeuropa-paedform-1>