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

EAHP celebrated World Patient Safety Day!

On the 18th of September, EAHP joined forces with the International Hospital Federation, GS1 Healthcare, ISQua Organisations to advocate for the involvement of patients in ensuring patient safety.

The objective was to inspire all stakeholders, encompassing patients, their families policymakers, healthcare leaders, healthcare professionals, and patient advocacy groups, to join forces in co-creating healthcare policies and safety measures that genuinely align with patients' requirements and choices. Such a collective effort intends to enhance global healthcare safety standards significantly.

Hospital pharmacists play a critical role in ensuring patient safety by managing medication processes. They are responsible for verifying prescriptions, checking for potential drug interactions, educating patients on proper medication usage, and monitoring for adverse reactions. Their expertise helps reduce medication errors and enhances the overall quality of care, making them indispensable in safeguarding patient well-being within healthcare settings. They are vital in facilitating seamless care transitions from primary care to hospitals.

Find out more HERE [1] and HERE [2]

ACT EU multi-stakeholder platform report is out

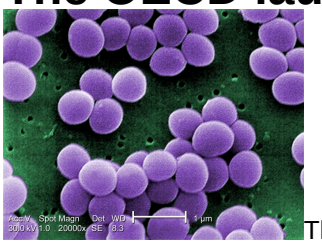
The European Medicines Agency (EMA) released the report of the Kick-off workshop of the ACT EU multi-stakeholder platform that took place between 22 and 23 June 2023.

Accelerating Clinical Trials in the EU (ACT EU) is a joint initiative of the European Commission, Heads of Medicines Agencies, and EMA. ACT EU's vision is to make the EU a competitive centre for innovative clinical research, building on the new Clinical Trials Regulation and the Clinical Trials Information System launched on 31 January 2022.

The workshop organised on June 2023 was an opportunity for the European Commission, HMA and EMA to present the scope of this platform and listen to stakeholder feedback on the EU clinical trials landscape. The event aimed to gain a stronger understanding of stakeholders' priorities and perspectives on how to transform the EU environment for clinical trials, and to present and discuss a proposed model for the establishment of the multi-stakeholder platform.

Find the document HERE [3]

The OECD launched a study on AMR



The Organisation for Economic Cooperation and Development (OECD) released on 14 September a study on "Embracing a One Health Framework to Fight Antimicrobial Resistance (AMR)".

The report analyses critical policy levers to inform future AMR initiatives. It shows that tackling the detrimental health and economic impact of AMR requires embracing a One Health approach – a multidisciplinary, collaborative, and multi-sectoral effort that envisages human and animal health, agri-food, and the environment.

There are some national action plans to tackle AMR, but this policy analysis identified some priorities for action, such as (i) best practices across human and animal health, as well as agri-food systems; (ii) investing in more robust surveillance systems, particularly in specific areas of human health; (iii) ensuring greater compliance with regulatory frameworks and (iv) increasing investments in research and development for new antibiotics, vaccines, and diagnostics. The report also identified as essential to strengthening antimicrobial stewardship programmes, and better environmental and hand hygiene practices in healthcare settings.

Find the report HERE [4]

Join the RWE webinar on the lifecycle of ATMPs

RWE4Decisions is organising on 10 October (15:00 – 16:30 CEST) a webinar on how Real-World Evidence (RWE) over the lifecycle of Advanced Therapeutic Medicinal Products (ATMPs) could support the EU Joint Health Technology Assessment (HTA).

Under the EU HTA Regulation, oncology medicines and ATMPs will be the first to undergo Joint Clinical Assessments, starting in January 2025. As there is often a paucity of clinical evidence available for these highly innovative treatments, the RWE4Decisions webinar will consider the potential for the use of Real-World Evidence (RWE) generation or use.

RWE4Decisions is a multi-stakeholder initiative commissioned by the Belgian National Institute of Health and Disability Insurance and comprising policy makers, HTA bodies, payers, regulatory agencies, clinicians, patient groups, researchers, registry-holders, data analysts, industry and academic experts. It brings stakeholders together to agree what real-world data could be collected for highly innovative technologies in order to generate real-world evidence that informs decisions by healthcare systems, clinicians and patients.

Find more information and register HERE [5]

The World Mental Health Day Conference is coming

To mark World Mental Health Day on 10 October 2023, the European Commission is holding a high-level conference "An EU Comprehensive approach that prioritises sound mental health for all" in Brussels on that day between 09:00 and 13:00 (CEST).

The event will bring together several representatives from the EU institutions, national governments, international organisations, and other interested partners to raise awareness of the new approach, hear from experts and those with lived experience, and exchange on good practices linked to topics such (i) Mental health across all policies; (ii) promotion and prevention; and (iii) equal access for all.

Find more information and register available HERE [6]

EJHP: Effectinesse of antithrombotic prophylaxis in hospitalised patients with SARS-CoV-2 infection

A recent online first article published in the European Journal of Hospital Pharmacy (EJHP) aims to assess the effectiveness of antithrombotic prophylaxis in patients admitted with COVID-19 and 30 days after discharge. The main outcome measure was the global incidence of symptomatic venous thromboembolism (VTE) related to hospitalisation. The incidence of hospital acquired VTE was lower than that described in the literature. Although it cannot be certain that it is directly related to the instituted protocol, the data can show that the management of prevention of VTE is being optimally performed at the hospital.

Read the article HERE [7]

[Consultations]

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 [8]

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 [9]

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 [10]

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 [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]

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 [13]

EMA Consultation: guideline on clinical investigational of medicinal products in the treatment of depression

EMA launched a draft "Guideline on clinical investigation of medicinal products in the treatment of depression". The document recognises that the emergence of new antidepressants with rapid onset of effect and the repurposing of psychedelics require

separate design strategies. It goes on to address key issues for the development of psychedelic-assisted psychotherapy in the field of major depressive disorder. The public consultation is open until 31 March 2024.

Contribute HERE [14]

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 [15]

25 September 2023

Links
[1] https://www.linkedin.com/feed/update/urn:li:activity:7109560035143254016 [2] https://lnkd.in/exeSP5Sm [3] https://www.ema.europa.eu/en/documents/report/meeting-report-act-eu-multi-stakeholder-platform_en.pdf [4] https://www.oecd.org/health/embracing-a-one-health-framework-to-fight-antimicrobial-resistance-ce44c755-en.htm [5] https://rwe4decisions.com/event/rwe-over-the-lifecycle-of-atmps-to-meet-the-htarneeds/ [6] https://health.ec.europa.eu/events/world-mental-health-day-conference-eu-comprehensive-approach-prioritises-sound-mental-health-all-2023-10-10_en [7] https://ejhp.bmj.com/content/30/5/264 [8] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13561-Pharmaceuticals-changes-to-marketing-authorisations-review-of-EU-rules-_en [9] https://www.ema.europa.eu/en/documents/scientific-guideline/draft-ich-e6-r3-guideline-good-clinical-practice-gcp-step-2b_en.pdf [10] https://www.ema.europa.eu/en/documents/scientific-guideline/ich-reflection-paper-proposed-international-harmonisation-real-world-evidence-terminology_en.pdf [11] https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-development-guideline-quality-aspects-mrna-vaccines_en.pdf [12] https://www.edqm.eu/en/-/european-paediatric-formulary-furosemide-oral-solution-monograph-published-for-public-consultation-in-pharmeuropa-paedform-1 [13] https://ec.europa.eu/eusurvey/runner/93c5397b-b904-76ca-a54d-3873e177e87d [14] https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-clinical-investigation-medicinal-products-treatment-depression-revision-3_en.pdf [15] https://ibdpatientpreferencesurvey.sawtoothsoftware.com/cgi-bin/ciwweb.pl?hid_studyname=IBD_preference_survey&hid_pagenum=0&hid_link=1&hid_javascript=