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

Webcasts and presentations of EAHP's 25th Congress are

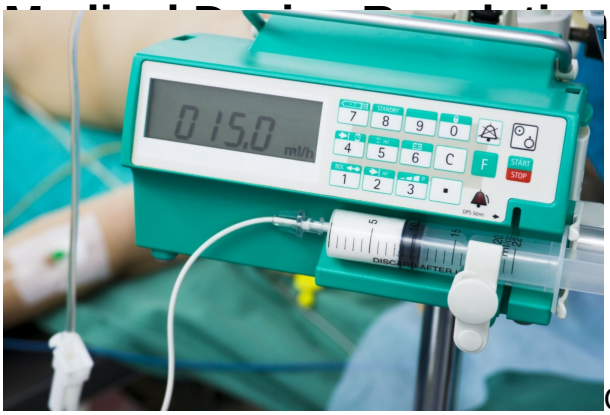
Did you miss the 25th Congress of the European Association of Hospital Pharmacists (EAHP)? Don't worry EAHP has got you covered. The video recorded presentations as well as the slides of each of the presentations given at the 25th Congress of the Association – " Hospital Pharmacy 5.0 - the future of patient care (2021)" have been made available online.

The 25th anniversary congress of EAHP did not only provide participants with a look forward but also looked back at the impact that the COVID-19 pandemic has had and still has on the profession. In addition, it covered some of the ongoing challenges faced by hospital pharmacists, like tackling antimicrobial resistance, delivering seamless care, raising the quality of hospital pharmacy compounding, moving forward advances in clinical pharmacy and increasing the role of hospital pharmacists in the multidisciplinary teams in hospitals and on the interface with community or outpatient settings.

Those of you already looking forward to next year can circle the 23rd to the 25th March in your calendars. EAHP is inviting you to Vienna, Austria to explore the changing roles of hospital pharmacists in a changing world. Registration and abstract submission will open on the 1st of August.

Access the webcasts and presentations of EAHP's 25th Congress HERE [1]

Learn more about EAHP's 26th Congress HERE [2]



On the 26th of May 2021, the new EU rules on medical devices entered into application. They establish a modern and more robust regulatory framework by increasing transparency and bringing EU legislation in line with technological advances and progress in medical science. Also, clinical safety is improved.

Medical devices play a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. Their safety is paramount as acknowledged by EAHP in an Opinion focusing on the application of the Medical Device Regulations. The MDR's application will bring the following improvements:

- Increasing the quality, safety and reliability of medical devices: it imposes tighter controls on high-risk devices such as implants and requires the consultation of a pool of EU level experts before placing medical devices on the market. Clinical evaluations, investigations and the notified bodies that approve the certification of medical devices will be subject to tighter controls.
- Strengthening transparency and information for patients, so that vital information is easy to find. The European database of medical devices (EUDAMED), will contain information about each medical device on the market, including economic operators and certificates issued by notified bodies. Each device will have a unique device identifier so that it can be found in EUDAMED. More detailed labelling and electronic manuals will increase user-friendliness. Implant patients will receive an implant card with all the essential information.
- Enhancing vigilance and market surveillance: Once devices are available on the market, manufacturers have to collect data about the devices' performance. EU countries will closely coordinate their vigilance and market surveillance.

The MDR is complemented by the Regulation on in vitro diagnostic medical devices (2017/746/EU) with a date of application of 26 May 2022. In vitro diagnostic medical devices are used to perform tests on samples, include HIV blood tests, pregnancy tests, COVID-19 tests and blood sugar monitoring systems for diabetics.

Access the questions & answers on the application of MDR HERE [3]

Read EAHP's Opinion focusing on the application of the Medical Device Regulations HERE [4]

[illegible]ebinar

On the 16th of June 2021, the European Directorate for the Quality of Medicines & HealthCare (EDQM) will be hosting a freewebinar on the 'Council of Europe Resolution on good reconstitution practices'. The event will take place from 10.30 AM to 12.00 PM CET and it is aimed at healthcare professionals, in particular, pharmacists working in hospital pharmacies, nurses and physicians, healthcare and patient associations, as well as national competent authorities and ministries of health.

The Resolution on good reconstitution practices was adopted by the Committee of Ministers of the Council of Europe in 2016, with a view to improving the safety of patients receiving reconstituted injectable medicines. The 90-minute, free webinar will provide some practical examples of how the provisions in the resolution can be transposed into national legislation and implemented in a hospital pharmacy setting. It will also help attendees learn how to overcome possible challenges affecting implementation.

Register for the webinar HERE [5]

Learn more about the webinar on EDQM's event web page HERE [6]

Read the Resolution HERE [7]

EMA: ePI public consultation & workshops

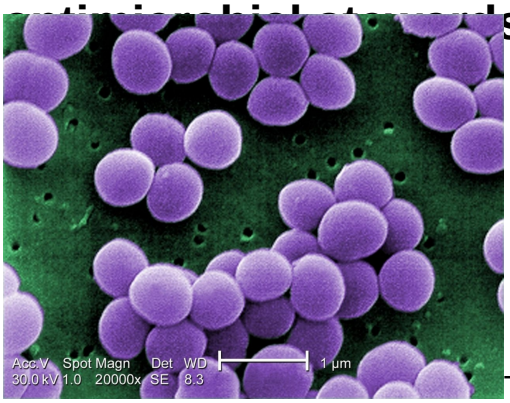
The European Medicines Agency (EMA) has opened a public consultation on the draft EU common standard for electronic product information (ePI) that is intended to be adopted for future use for ePI across the EU. The public consultation is completed by several workshops held throughout July that are designed to inform

stakeholders on the electronic standard.

Feedback from the workshops will contribute to ensuring that the adopted EU common electronic standard meets the future needs of stakeholders to access, view and disseminate product information in electronic format. The draft EU common standard for ePI is part of the ePI set-up project, started by EMA, national competent authorities and the European Commission in 2021. It aims at developing a common electronic standard for product information, carrying out a proof-of-concept exercise for implementing the standard and creating a roadmap for implementation across the EU. EMA will publish progress updates and details of stakeholder consultations and share these with patients, healthcare professionals, academia and the pharmaceutical industry.

Learn more about the workshops and the consultation HERE [8]

WHO published policy guidance on integrated antimicrobial stewardship activities



The World Health Organization (WHO) has published policy guidance on integrated antimicrobial stewardship activities that is addressed to national policy-makers at ministries of health and national antimicrobial resistance (AMR) coordinating bodies who are responsible for the development, implementation and monitoring of the national action plans, policies and standards for mitigating AMR in the human health sector.

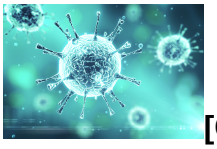
This WHO guidance was requested by Member States. It offers advice on how to facilitate the implementation of national antimicrobial stewardship (AMS) activities in an integrated and programmatic approach. The guidance is anchored in public health guiding principles in human health and provides a set of evidence-based and pragmatic recommendations to drive comprehensive and integrated AMS activities under the purview of a central national coordination unit, national AMR steering or coordinating committees or other equivalent national authorities. It complements the Global Action Plan, the WHO practical toolkit for AMS programmes in healthcare facilities in low- and middle-income countries and other WHO guidance on this topic.

Access the guidance HERE [9]

EJHP: Treatment of high-risk bleeding with susoctocog alfa in a patient with acquired haemophilia A and a nosocomial severe acute respiratory syndrome coronavirus 2 infection

The case report published in the online edition of the European Journal of Hospital Pharmacy (EJHP) studies the case of a man in his early 70s with idiopathic acquired haemophilia A and persistent high-titre type II inhibitors on immunosuppressive treatment to eradicate the inhibitor. Considering the high risk of thrombosis in this patient as a result of non-anticoagulated AF during hospital admission, SARS-CoV-2 infection with increased DD and being bedridden, treatment was re-evaluated after an increase was seen in the size of the haematoma and FVIII:C 19.0 IU/dL. In view of this situation, it was decided to request the use of susoctocog alfa, a B-domain deleted, recombinant porcine sequence FVIII concentrate that is licensed for AHA. It acts as a cofactor of activated factor IX, accelerating factor X conversion into activated factor X, which ultimately converts prothrombin into thrombin. Thrombin then converts fibrinogen into fibrin and a clot can be formed. These results show that susoctocog alfa is a safe and effective treatment in controlling severe acute AHA bleeding. In our clinical case, potential bleeding control involved a high risk of thromboembolic events owing to non-treated AF during hospital admission, a prolonged period in bed and SARS-CoV-2 disease with acute phase reactants and elevated DD.

Read the article here [10]


[COVID-19 Updates]

EAHP's COVID-19 Resource Centre

To assist its member associations and individual hospital pharmacists in this critical time with the provision of the best possible care for patients, EAHP has decided to gather and make available information on COVID-19 relevant for the hospital pharmacy profession.

Access the Resource Centre HERE [11]

Prader-Willi Syndrome Association UK | Prader-Willi Syndrome (PWS) – Information for Accident and Emergency (A&E) and other hospital staff

The UK's PWS Association has made available a general care guideline for individuals with PWS that are hospitalised.

Access the guideline HERE [12]

British Society of Haematology | Clinician Frequently Asked Questions (FAQs) and guidance on COVID- 19 vaccine for patients receiving Systemic Anti-Cancer Therapy

This document has been produced in response to questions raised by cancer health care professionals relating to the administration of COVID-19 vaccine in patients receiving systemic anti-cancer therapy (SACT).

Access the guidance HERE [13]

Endocrine - International Journal of Basic and Clinical Endocrinology - Clinical management of patients with genetic obesity during COVID-19 pandemic: position paper of the ESE Growth & Genetic Obesity COVID-19 Study Group and Rare Endo-ERN main thematic group on Growth and Obesity

This article aims to provide guidance on the prevention and treatment of COVID-19 in patients with genetic obesity.

Read the article HERE [14]

Journal of Hypertension - Adherence to anti-hypertensive treatment on the COVID-19 pandemic

The study evaluates the adherence to antihypertensive treatment during the COVID-19 pandemic and associated variables.

Read the article HERE [15]

Evidence map

EAHP's Statement website contains an evidence map that helps hospital pharmacists to identify case studies, Statement Implementation Collaborative Learning Centres (SILCCs) and Good Practice Initiatives (GPIs). The evidence map is available via the following LINK [16].

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Consultations

European Commission – Public Consultation: Digital health data and services – the European health data space

To ensure that all possible views are considered in the design of a legal framework for a European Health Data Space (EHDS), the European Commission invites all interested individuals and stakeholders to share their views and experiences. Your contribution can help provide important insights, opinions and evidence to support the impact assessment accompanying the EHDS proposal on the problems to be tackled, the policy options to be considered and their likely impacts.

Deadline – 26 July 2021

Access the consultation HERE [17]

European Commission – Public Consultation: Cross-border healthcare – evaluation of patients' rights

The Directive on patients' rights in cross-border healthcare (2011/24/EU) aims to facilitate access to safe and high quality healthcare in another EU country. The European Commission invites all interested individuals and stakeholders to share their views and experience in seeking planned healthcare across the EU or in EU cooperation in the area of rare diseases.

Deadline – 27 July 2021

Access the consultation HERE [18]

European Commission – Public Consultation: Medicines for children & rare diseases – updated rules

This initiative will explore several options to address the shortcomings identified in the evaluation of the Regulations on medicines for children and rare diseases, in view of a revision of the existing legislation. With this public consultation, citizens and stakeholders are invited to share their views and experiences on the main obstacles they are facing concerning treatments for rare diseases and children, on possible ways to overcome these obstacles and on how to make the current legislation future-proof.

Deadline – 30 July 2021

Access the consultation HERE [19]

8 June 2021

Links
[1] https://www.eahp.eu/content/webcast-eahp-congress-2021-1 [2] https://www.eahp.eu/congresses [3] https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_2619 [4] https://www.eahp.eu/sites/default/files/2021_eahp_opinion_focusing_on_the_application_of_the_medical_device_re [5] https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fattendee.gotowebinar.com%2Fregister%2F80 [6] https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.edqm.eu%2Fen%2Fevents%2Fwebinar-council-europe-resolution-good-reconstitution-practices-major-contribution-safety&data=04%7C01%7CStephanie.Kohl%40eahp.eu%7C05e2b2b0d90a481d10e208d919d0777e%7C2504 [7] https://rm.coe.int/09000016809cdf26 [8] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/product-information-requirements#electronic-product-information-initiative-section [9] https://www.who.int/publications/i/item/9789240025530 [10] https://ejhp.bmj.com/content/early/2021/05/19/ejhpharm-2021-002805 [11] https://www.eahp.eu/hp-practice/hospital-pharmacy/eahp-covid-19-resource-centre [12] https://irp-cdn.multiscreensite.com/1b38aac2/files/uploaded/PWSA%20UK%20-%20Information%20for%20A%26E%20and%20other%20hospital%20staff.pdf [13] https://b-s-h.org.uk/media/19241/clinician-faqs-and-guidance-on-covid19-vaccine-for-patients-receiving-sa_.pdf [14] https://link.springer.com/article/10.1007/s12020-021-02619-y [15] https://journals.lww.com/jhypertension/Abstract/2021/04001/ADHERENCE_TO_ANTI_HYPERTENSIVE_TREATME [16] http://statements.eahp.eu/evidence-map [17] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space/public-consultation_en [18] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Cross-

border-healthcare-evaluation-of-patients%E2%80%99-rights/public-consultation_en [19] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12767-Medicines-for-children-&-rare-diseases-updated-rules/public-consultation_en