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

EAHP starts to investigate the future potential of electronic product information (ePI)

With the digital transformation of healthcare in Europe in full swing, EAHP has decided to analyse the use of (electronic) patient leaflets and the future potential of electronic product information (ePI) with its newest survey targeting hospital pharmacists. Over the next 5 weeks, EAHP's ePI survey seeks to collect information on both the use of printed package leaflets and the prevalence of the application of product information in a digital format. Also, the future use of ePI in European hospitals will be looked at.

Inspired by a project carried out in Belgium and Luxembourg evaluating the effectiveness of the electronic patient information leaflet and the key principles created by the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) to guide the development and use of ePI in the EU, EAHP has embarked on a journey to collect input from its membership.

As outlined by the EMA in connection to its work on the ePI key principles, the product information of a medicine includes the package leaflet for patients and the summary of product characteristics (SmPC) for healthcare professionals. These documents accompany every single medicine authorised in the EU and explain how it should be prescribed and used. The package leaflet is provided in the medicine's box and can also be found, often as a pdf document, on the websites of EU regulators. In light of the digital transformation of healthcare, digital platforms open additional possibilities to disseminate the PIs electronically and to facilitate the work of healthcare professionals.

EAHP's ePI survey is available in English and 20 other European languages covering the majority of EAHP's membership. The survey will remain open until the 15th of April.

Access EAHP's ePI survey HERE [1]

EAHP launches first Special Interest Group

Last month, EAHP's first Special Interest Group (SIG) focusing on hazardous medicinal products started its activity. Throughout 2021, this SIG will work on better understanding the classification landscape for hazardous medicinal products in Europe. It is one of many initiatives of EAHP that seeks to advance specific areas of knowledge, learning and technology for improving patient outcomes.

Hospital pharmacists together with other members of the multidisciplinary team are dealing with hazardous medicinal products in their daily work. Their safe handling is of uttermost importance for the safety of healthcare workers and patients treated with these medicines. Their classification plays an essential role in determining suitable handling procedures. However, unlike the United States, Europe does not have one single body similar to the National Institute for Occupational Safety and Health (NIOSH) that addresses all questions linked to the classification of hazardous medicinal products. Supported by Amgen, EAHP's first SIG brings together hospital pharmacists from different European regions as well as industry representatives to investigate the classification systems that are used throughout Europe for hazardous medicinal products.

To optimise patient care not only in the field of hazardous medicinal products, EAHP is also working on establishing other SIGs that will specifically address various conditions, therapies or technologies needed through collaboration with healthcare professionals, patients' organisations and industry. Stay tuned for more insights into EAHP's SIGs in the coming editions of the EU Monitor!

EAHP Opinion focusing on the application of the Medical Device Regulations

Earlier this week, the second Synergy Certification Course was held to share more about the added value of medical devices for hospital pharmacists.

The event was organised by Euro-Pharmat. EAHP used this occasion to reiterate some of the considerations raised by hospital pharmacist in EAHP's Statement on the Medical Device Regulation adopted in 2014 and EAHP's Opinion on this topic released in 2019.

EAHPs Opinion focusing on the application of the Medical Device Regulations touches on the reporting of serious incidents, the European Database on Medical Devices (EUDAMED), the unique device identification (UDI) system as well as on the role of hospital pharmacists in the procurement of devices and the importance of collaboration between healthcare professionals and with authorities. In relation to serious incident reports, EAHP underlines the value of healthcare professional and patient reporting, while for EUDAMED the Association addresses the European Medical Device Nomenclature which should be mapped to the Global Medical Device Nomenclature prior to the application of the Medical Device Regulation in May this year to facilitate the work of hospital pharmacists. As for UDI systems, it is mentioned in the Opinion that confusion between other UDI systems used in the hospital should be avoided and that hospitals should be encouraged to facilitate the integration of the UDI system into their existing information systems and working processes. The section on procurement and collaboration emphasises the importance of multi-disciplinary cooperation and the use of specialist knowledge for procuring medical devices which both contribute to improving patient outcomes.

Read EAHP's newest Opinion HERE [2]

updates from the EMA

The European Medicines Agency (EMA) has shared the newest safety updates for COVID-19 vaccines and announced the date of its upcoming public stakeholder meeting focusing on the approval, safety monitoring and impact of COVID-19 vaccines in the EU.

For both the Comirnaty vaccine and the one of Moderna, EMA has shared in early March the latest safety updates. These touch on updates on safety, other information for the vaccine and how the vaccine's safety is monitored.

Access the March 2021 safety update for Comirnaty HERE [3]

Access the March 2021 safety update for Moderna HERE [4]

The third public stakeholder meeting will provide an update to EU citizens about the continued assessment, approval and safety monitoring of COVID-19 vaccines, as well as their expected impact at the community level. Participants of the virtual meeting will learn about:

- COVID-19 vaccines approved in the EU and those currently under review;
- post-authorisation activities, including emerging safety data since EU authorisation of the first COVID-19 vaccines, and ongoing work to address new variants;
- the expected impact of COVID-19 vaccination on our society; and
- transparency and the publication of clinical data for COVID-19 vaccines.

The meeting will be broadcasted live on Friday, 26th of March from 1 to 3.30 PM (CET).

Learn more about EMA's third public stakeholder meeting HERE [5]

Dose banded antimicrobials for children - European survey

A French pharmacy resident working at the Evelina London Children's Hospital is conducting a research project about the feasibility of dose banded antimicrobials for children. Hospital pharmacists working in paediatric areas are invited to contribute by the 19th of March 2021.

Since dose banded antimicrobials preparation could assist the paediatric emergency department in improving patient's treatment, the survey seeks to review the current practice of other paediatric centres in order to propose a list of antimicrobials suitable for dose banding and propose the bands. The collected responses will remain confidential and the questionnaire should take no more than 5 to 10 minutes to complete.

Access the survey HERE [6]

Investigator Initiated Studies – Series of Webinars

EUROPEAN CENTRE FOR
CLIINICAL RESEARCH TRAINING If your organisation is supporting Investigator Initiated Studies

(IIS), this proposal will be of interest to you. As you know, in IIS, investigators setting up (academic) clinical trials within their organisation act as sponsors. Consequently, physicians and their clinical research staff must be trained accordingly.

By supporting their training, you will offer them the possibility to be up-to-date about how to implement mandatory clinical trials rules for sponsors in practice in order to ensure patient safety and data quality. ECCRT, the European Centre for Clinical Research Training, is

offering a unique online training programme composed of 14 live webinars of 1-2 hours each and supported by 10 experienced expert trainers.

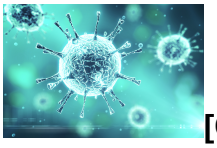
A new webinar series is scheduled in spring 2021 and will allow site staff to spread the training over a given period to prevent from disturbing their day-to-day work.

Know more about these webinar sessions HERE [7]

EJHP: Review of studies examining microbial contamination of vials used for preparations done with closed-system drug transfer devices

The original research published in the online edition of the European Journal of Hospital Pharmacy (EJHP) identifies all studies that present data regarding microbial contamination of vials used for preparation with closed-system drug transfer devices (CSTDs) and compares the reported contamination of vials punctured with a CSTD versus no CSTD and evaluates the quality of data reporting as defined by the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) criteria. In conclusion, vials punctured in ISO5 conditions with a CSTD presented a low frequency of microbial contamination. No study showed a significant difference between vials punctured with a CSTD and with a conventional method.

Read the article HERE [8]



[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 [9]

The National Institute for Health and Care Excellence (NICE) - Antibiotics for pneumonia in adults in hospital

The purpose of this guideline is to ensure the best antibiotic management of suspected or confirmed bacterial pneumonia in adults in the hospital during the COVID?19 pandemic.

Read the guideline HERE [10]

Therapeutic strategies for severe COVID-19: a position paper from the Italian Society of Infectious and Tropical Diseases (SIMIT)

Summary of the available literature on the management of COVID-19 in order to combine current evidence and interpretation of the data by experts who are treating patients in the frontline setting.

Read the position paper HERE [11]

Thrombosis and Haemosthasis - Pharmacologic Thromboprophylaxis and Thrombosis in Hospitalized Patients with COVID-19: A Pooled Analysis

The article aims to determine the pooled incidence of thrombosis/bleeding in hospitalized patients with COVID-19 for standard-dose, intermediate-dose, therapeutic anticoagulation, and no pharmacologic thromboprophylaxis.

Read the article [12]HERE [12]

Farmacia hospitalaria - Pharmaceutical care to hospital outpatients during the COVID-19 pandemic. Telepharmacy

The purpose of this article is to describe and analyse the experience of hospital pharmacy services with out-patient telepharmacy during the COVID-19 pandemic and expose the lessons learned.

Read the article HERE [13]

Get ready for the EAHP annual congress!

EAHP's annual Congress is around the corner. The Statement Implementation team will be present from 23rd to 28th March 2021 at EAHP's virtual booth. Register online for the biggest hospital pharmacy Congress in Europe and visit us at the EAHP booth. The Statement Implementation team is looking forward to answering all of your questions related to the 44 European Statements of Hospital Pharmacy, the self-assessment tool and the Statement Implementation Learning Collaborative Centres (SILCC).

More information about EAHP's Congress HERE [14]

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Consultations

EDQM – Pharmeuropa PaedForm, Issue 3

The European Directorate for the Quality of Medicines & HealthCare (EDQM) released Issue 3 of Pharmeuropa PaedForm, in which the draft text for Phosphate 60 mg/mL Oral Solution is published for public consultation prior to its inclusion in the European Paediatric Formulary. This is the fourth monograph elaborated by the PaedForm Working Party.

Deadline – 31st March 2021

Find more information HERE [15]

European Commission – Public Consultation on Blood, tissues and cells for medical treatments & therapies

This consultation concerns an initiative for an improved EU legal framework for the safety and quality of blood, tissues and cells used in transfusion, transplantation and medically assisted reproduction. These are healthcare services that impact on the lives of millions of EU citizens, both as donors of essential substances or patients that need treatment with those substances.

For this reason, this public consultation is collecting the views of all interested citizens and organisations.

Deadline – 15th April 2021

Access the consultation HERE [16]

10 March 2021

Links
[1] https://www.eahp.eu/practice-and-policy/ehealth-and-mhealth/ePIsurvey [2] https://www.eahp.eu/sites/default/files/2021_eahp_opinion_focusing_on_the_application_of_the_medical_device_re
[3] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-comirnaty-march-2021_en.pdf [4] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-covid-19-vaccine-moderna-march-2021_en.pdf [5] https://www.ema.europa.eu/en/events/public-stakeholder-meeting-approval-safety-monitoring-impact-covid-19-vaccines-eu [6] https://docs.google.com/forms/d/e/1FAIpQLSfBgJU0zXsywAHm8RSAyV9PgrsGjNPLY76HBzRnRZX8f6Gqag/viewfo
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