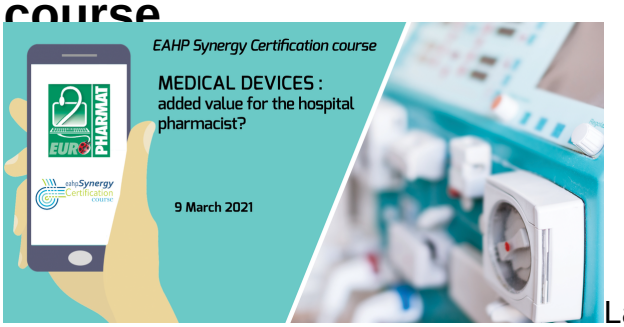
The EAHP EU Monitor is a regular round up of news relevant to hospital pharmacy in Europe.

Last chance to register for EAHP's Synergy Certification course



Last days to register for the EAHP Synergy

Certification Course, organised by our colleagues from Euro-Pharmat, on medical devices. The event will take place online due to the on-going developments with COVID-19. Join colleagues from across the world on the 9th of March 2021 from 9.00 AM to 4.30 PM CET.

During the online event, panellists will discuss the basics of medical devices for the provision of healthcare to citizens and their role in both the European and global economy. The afternoon session is dedicated to the pharmacists' role in the management of the patient by medical devices. Interested hospital pharmacists are encouraged to sign up for this online event!

See the programme HERE [1]

Register HERE [2]

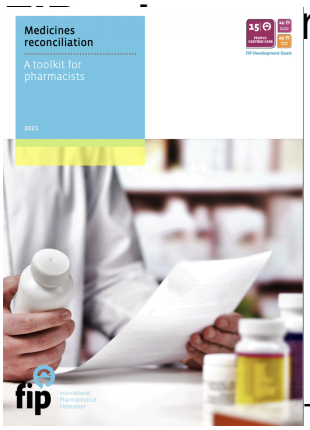
Webinar: COVID-19 vaccination - What you need to know as a health professional?

 In-mid February, the European Commission hosted a

webinar titled “COVID-19 vaccination - What you need to know as a health professional?”. The presentations shared during this webinar by the Directorate-General for Health and Food Safety (DG SANTE), the European Medicines Agency and the European Centre for Disease Prevention and Control can be accessed and downloaded via the website of DG SANTE.

Download the presentations HERE [3]

medicines reconciliation toolkit



To support pharmacists’ contributions to the World Health Organization’s

third Global Patient Safety Challenge — “Medication without harm” – the International Pharmaceutical Federation (FIP) created a toolkit on medicines reconciliation for its members.

The medicines reconciliation toolkit outlines the principles and important processes that pharmacists should follow when providing this professional service. It summarises the definitions, impact and procedures for the implementation of pharmacist-led medicines reconciliation in both community and hospital healthcare settings, and offers a set of tools to support practice. A webinar will be organised by FIP in the next month to present the toolkit.

Access the toolkit HERE [4]

opean Medicines Agency

The European Medicines Agency (EMA) published new communications on its latest additions to the dedicated COVID-19 webpage and the precautionary marketing suspension of the thalassaemia medicine Zynteglo.

Latest updates on COVID-19 vaccines

EMA's latest updates on COVID-19 included the publication of the AstraZeneca European Public Assessment Report (EPAR), information on the application for conditional marketing authorisation of COVID-19 Vaccine Janssen that EMA had received and the start of the rolling review of CureVac's COVID-19 vaccine (CVnCoV). EMA also shared a clarification on the Sputnik V vaccine in the EU approval process and is preparing guidance to tackle COVID-19 variants.

All of these updates can be accessed via EMA's dedicated webpage on COVID-19 – see HERE [5]

Precautionary marketing suspension of thalassaemia medicine Zynteglo

The company that markets the gene therapy medicine Zynteglo for treating the rare blood condition beta thalassaemia has suspended sales pending investigation of a safety concern. The company, bluebird bio, notified EMA that a related medicine it was developing, which uses the same technology as Zynteglo, may have been associated with a case of cancer. Although no cases of cancer have been reported with Zynteglo itself, the company suspended marketing of Zynteglo until the possibility that the same risk might apply to the licensed medicine has been investigated.

The concern arose with the medicine, bb1111, intended to treat another blood disorder, sickle cell disease. This medicine uses the same viral vector as Zynteglo, based on a type of virus known as a lentivirus, to insert a working gene into the patient's blood cells. One patient treated with bb1111 developed acute myeloid leukaemia, a cancer of the blood, that might have been related to treatment, and a different blood disorder, myelodysplastic syndrome, was reported in another patient.

Cancer caused by this type of treatment (insertional oncogenesis) was already identified as a potential risk with Zynteglo, so patients who receive the medicine are followed up and monitored in a registry. So far no cases of cancer have been reported with Zynteglo treatment. Nonetheless, since bb1111 works in the same way, it was thought prudent to suspend clinical studies with bb1111 and pause sales of Zynteglo while the evidence is

examined more thoroughly.

EMA is liaising closely with the company and experts within the regulatory network, and will now examine the evidence at EU level and decide on any relevant regulatory action for Zynteglo or any similar medicines under evaluation. No other authorised medicines use the same viral vector so no direct implications are foreseen for other licensed medicines.

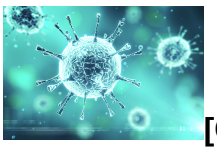
Zynteglo was granted conditional marketing authorisation on 29 May 2019. Currently it is only marketed in Germany, and because of limited availability and the rarity of the condition it is intended to treat, only a very small number of patients have received or would have been eligible to receive treatment. However, if treated patients do have any concerns they should contact the specialist supervising their Zynteglo treatment. EMA will communicate further once additional information becomes available.

More information is available HERE [6].

EJHP: Read the March issue!

The latest issue of the European Journal of Hospital Pharmacy (EJHP) is available. The editorial invites you to attend the next EAHP Congress, while the systematic review shares insights on the clinical and economic value of automated in-hospital pharmacy services. Other features include several original research articles, short and case reports and electronic pages. Among other things included in the EU & EAHP news section, the March issue gathers the EAHP opinion on COVID-19 vaccine programmes and their implementation and the new COVID-19 vaccines and vaccinations section in EAHP's COVID-19 Resource Centre.

Read the March issue HERE [7]

 **[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 [8]

ESCMID Study Group for Legionella Infections (ESGLI) - ESGLI guidance for managing legionella in hospital water systems during the COVID-19 pandemic

This guidance is aimed at hospitals, temporary and converted buildings or parts of buildings and field hospitals used for treating COVID-19 patient.

Consult the guidance HERE [9]

Society of Breast Imaging - SBI Recommendations for the Management of Axillary Adenopathy in Patients with Recent COVID-19 Vaccination

The guidance shares insights on the incidence and appearance of axillary lymphadenopathy following COVID-19 vaccination.

Consult the guidance HERE [10]

American Journal of Health-System Pharmacy - Accuracy and safety of medication histories obtained at the time of intensive care unit admission of delirious or mechanically ventilated patients

Project to assess the accuracy of alternate-source medication histories obtained for critically ill patients who were delirious or mechanically ventilated at the time of intensive care unit admission.

Read the study HERE [11]

European Review for Medical and Pharmacological Sciences - Impact of the COVID-19 pandemic on clinical research in hospitals: observational study in the first epicenter of the epidemic during the general lockdown in France

This study aims to assess the impact of the strict COVID-19 lockdown on non-COVID-19 clinical research at the French University Hospital of Strasbourg.

Read the study HERE [12]

Have you already assessed the level of Statement Implementation within your hospital?

The online self-assessment tool is an initiative allowing hospital pharmacists to check the level of implementation of the European Statements of Hospital Pharmacy within their hospitals. By assessing their hospital pharmacies, hospital pharmacists are not only able to understand the Statement implementation level within their hospitals, but the tool also helps them to find out where they stand in comparison to others in their own country and abroad. The tool allows pharmacies to show progress as it can be updated at any time. Remember that the official assessment needs to be done with the Chief Pharmacist! Please find HERE [13] a video explaining how you can use the tool to move towards implementation.

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Consultations

European Commission – Inception Impact Assessment: European Health Emergency Preparedness and Response Authority (HERA)

The COVID-19 pandemic demonstrated the need for coordinated EU level action to respond to health emergencies. It revealed gaps in foresight, including demand/supply dimensions, preparedness and response tools. A European HERA is a central element for strengthening the European Health Union with better EU preparedness and response to serious cross-border health threats, by enabling rapid availability, access and distribution of needed countermeasures.

Deadline – 24th February 2021

Access the consultation HERE [14]

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]

23 February 2021

Links
[1] https://www.eahp.eu/sites/default/files/programme_1.pdf [2] https://www.eahp.eu/page/eahp-synergy-certification-course-online [3] https://ec.europa.eu/health/policies/events/ev_20210210_en [4] https://www.fip.org/file/4949 [5] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19#what's-new-section [6] https://www.ema.europa.eu/en/news/precautionary-marketing-suspension-thalassaemia-medicine-zynteglo [7] https://ejhp.bmj.com/content/28/2 [8] https://www.eahp.eu/hp-practice/hospital-pharmacy/eahp-covid-19-resource-centre [9] https://www.escmid.org/fileadmin/src/media/PDFs/3Research_Projects/ESGLI/ESGLI_Guidance_for_managing_Leg [10] https://splf.fr/wp-content/uploads/2021/02/Society-of-breast-imaging-Recommendations-for-the-Management-of-Axillary-Adenopathy-in-Patients-with-Recent-COVID-19-Vaccination-Mis-en-ligne-par-la-Societe-francaise-de-radiologie-le-10-02-21.pdf [11] https://academic.oup.com/ajhp/advance-article-abstract/doi/10.1093/ajhp/zxab040/6134522?redirectedFrom=fulltext [12] https://www.europeanreview.org/article/24686 [13] https://www.youtube.com/watch?v=BmDBahJGpBQ [14] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Response-Authority [15] https://www.edqm.eu/en/news/european-paediatric-formulary-phosphate-oral-solution-open-public-consultation-issue-3 [16] https://ec.europa.eu/info/law/better-

regulation/have-your-say/initiatives/12734-Revision-of-the-Union-legislation-on-blood-tissues-and-cells-/public-consultation