

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

eahp euMonitor

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EAHP online learning – bringing education to your home!



The open learning courses of the European Association of Hospital Pharmacist (EAHP) offer healthcare professionals an exciting new opportunity to learn online about new developments. The portal was opened in spring 2018 and has since then been expanded. It now offers five different courses focusing on anticoagulation and biosimilar medicines.

Biosimilars in breast cancer – the next challenge [2] takes a closer look at biosimilars like trastuzumab, the key treatment option in HER2 positive breast cancer patients. This open learning course is particularly interesting for hospital pharmacists involved in oncology as it will equip them with specific knowledge on the quality and clinical background of the approval process. At the same time the course will be exploring the role of biosimilars in budget management in the breast cancer setting, considering all the new therapeutic options available for this disease.

The introduction of new anticoagulants means new options in the prevention and treatment of thromboembolic events. *Anticoagulation - from theory to practice* [3] seeks to strengthen the role of the hospital pharmacist in maintaining the awareness of new agents, their management, adverse effects and educating the patients about their drugs and importance of adherence. After the open learning course, participants will have an increased awareness about the differences between anticoagulants, their pharmacodynamics and pharmacokinetics. In addition, they will be enabled to describe the management of different anticoagulants in perioperative settings.

Biosimilars in cancer care - the next challenge [4] is approaching the subject of biosimilar medicines from the regulatory angle by presenting participants with the key facts on their approval in the EU as applied to cancer therapy. By understanding the concepts, hospital pharmacists will be enabled to provide a scientific, unbiased approach with a focus on patient care in a world of limited resources. Moreover, open learning course participants will be equipped with the tools to advise how to implement biosimilars of monoclonal antibodies used in cancer therapy.

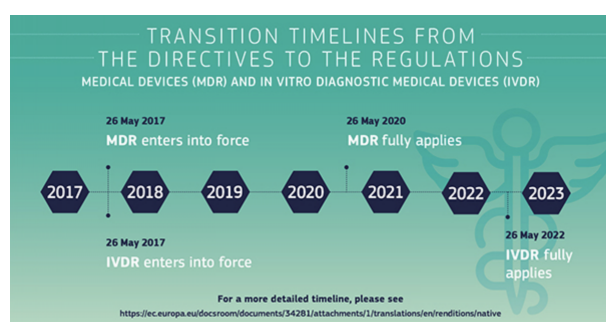
The evolution of biologicals which are an essential treatment option for a variety of diseases in current medicine is being explored by the course *“The essentials of biologicals – past, present and future* [5]. Since hospital pharmacists are responsible for selecting and assessing biologicals and biosimilars and monitoring their use, they need to have an in-depth understanding of key principles regarding quality, safety and efficacy. Open learning course participants will learn about the development and authorisation of biosimilars as well as the quality criteria of biologicals. In addition, issues of switching and interchangeability of biologicals will be addressed.

The second open learning course focusing on anticoagulant agents, “*Anticoagulants - Show me the evidence!*” [6], explains the complications of anticoagulation therapy and provides information that help hospital pharmacists review the differences in pharmacokinetics, efficacy and safety between newer anticoagulant drugs and warfarin. Since adherence plays an important role key patient counselling points will be conveyed that help hospital pharmacists in educating their patients about their drugs and the importance of their therapy.

All of EAHP’s open learning courses are accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. Participants are entitled to receive between 1.5 to 2 ACPE credits, depending on the length of the course. These credits can be obtained after the completion of the course and a short survey.

Access EAHP’s open learning environment [HERE](#) [7]

Medical device information portal launched

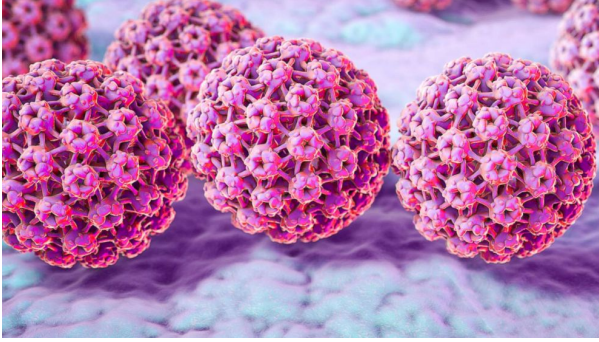


The European Commission recently released its revamped medical device information website which aims at improving the understanding of stakeholders about the differences between the currently applicable Medical Device Directives and the Medical Device Regulations. In addition, the portal provides resources as well as information on the implementation timeline for the transition between these two instruments.

The two new Regulations, covering medical devices and in vitro diagnostic medical devices, entered into force in May 2017. They intend to improve the quality and safety of medical devices available in the EU by setting up control mechanisms and processes for the oversight of these devices. In addition, the creation of a new system of unique device identifiers is foreseen in order to increase the identification and traceability of medical devices. Also transparency is being improved by making available summaries of safety and clinical performance for high risk medical devices via the European database on medical devices (EUDAMED). During the transition period, which for the Medical Devices Regulation will last until 26 May 2020 and the for In Vitro Diagnostic Medical Devices Regulation until 26 May 2022, both the Regulations and the Directives will apply.

Visit the portal [HERE](#) [8]

Consultation on HPV vaccines in EU countries



The European Centre for Disease Prevention and Control (ECDC) has opened a public consultation on human papillomavirus (HPV) vaccines in EU countries. Citizens, organisations and public authorities are encouraged to contribute their views on the guidance document developed by ECDC. This document is the result of a systematic review and grading of the available evidence of the efficacy and effectiveness of the nine-valent HPV vaccine. In addition, it looks at the cost-effectiveness of adding boys to the girls-only HPV vaccination strategy. Input should be included in a [specific template](#) ^[9] and submitted by 29th April 2019 to [ECDC.HPVguidance\[at\]ecdc.europa\[dot\]eu](mailto:ECDC.HPVguidance[at]ecdc.europa[dot]eu) ^[10].

Further information available [HERE](#) ^[11]

Assessing the efficiency of health care services



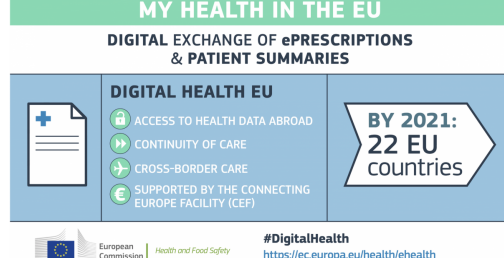
In mid-April, the European Commission's Expert Group on Health System Performance Assessment (HSPA) published its report titled "*Tools and methodologies to assess the efficiency of health care services in Europe: an overview of current approaches and opportunities for improvement*". The document is the result of the work of HSPA which examined the tools and methodologies at the disposal of Europe countries to assess health

care efficiency.

The findings of HSPA revealed the shortcomings caused by the limited number of tools available to health policy-makers. To ensure patient safety and improved efficiency, a first step should be to invest in the development of more instruments targeting the analysis, measurement and assessment of efficiency of care. Only with the help of the correct tools will health policy-makers be enabled to correctly detect inefficient practice and design policy interventions that can enhance efficiency without unintended consequences on the access to quality care. The authors of the report have identified several promising improvement opportunities. Suggestions include increasing the quality and granularity of cost data, improving measurement of health outcomes, expanding the scope for efficiency measurement beyond hospital care and designing communication of results with stakeholders in mind.

Read the report [HERE](#) ^[12]

ePrescription network continues to grow



In January 2019, the European Commission announced

the implementation of its ePrescription initiative which aims at facilitating the exchange of patient between different European countries (see [EU Monitor of 24th January 2019](#) ^[13]). Estonia and Finland were the first countries that started collaborating with each other. This summer, Croatia will join.

Finnish citizens travelling to Croatia will be enabled to obtain their ePrescriptions in Croatia, while Croatians travelling to Estonia can get their ePrescriptions dispensed there. In the past 3 months, 1000 Finnish patients have already benefited from the initiative and retrieved medicines prescribed electronically by their doctor in Finland in pharmacies in Estonia.

In addition to enabling the exchange of ePrescriptions, the European Commission is also fostering the exchange of patient summaries. Two other countries, Czechia and Luxembourg, received the approval from the eHealth Network earlier this year to start exchanging patient summaries of citizens coming from other European countries. Both will start with the practical implementation in the coming months. Croatia will join in as well and allow the access of Czech patient summaries.

Read more [HERE](#) ^[14]

EJHP: The impact of implementing a pharmacy technician role as part of a nursing team in an acute admissions unit



The online first edition of the European Journal of Hospital Pharmacy (EJHP) recently published a short report evaluating the impact of pharmacy technicians incorporated in the nursing team in an acute admissions unit. The pilot carried out in a large district hospital located in North-East England showed that the introduction of pharmacy technicians results in fewer omitted doses and also addresses persistent staffing issues by ensuring better use of nursing time.

Read the report [HERE](#) ^[15]



[EAHP Members Corner]

In April 2019 the following events will be organised by EAHP's member associations:

- 26th+ 27th April – Austrian Association of Hospital Pharmacists: [Spring meeting](#) ^[16] (St. Pölten, Austria)

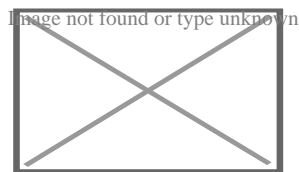
[EAHP Statement Corner]

Have you completed your SAT?



To help you with the implementation of the European Statements of Hospital Pharmacy, the EAHP has developed a self-assessment tool (SAT) which helps you understand the level of Statement implementation in your pharmacy. The tool has been rolled out across Europe. Different language versions (English, French, Hungarian, Italian, Polish, Romanian, Serbo-Croatian, Spanish and Turkish) have been made available to enable as many hospital pharmacists as possible to use the tool. Talk to your chief pharmacist and encourage him/her to work with the SAT. In case you are the head of the pharmacy get your team together and complete your assessment today with the help of the SAT.

Learn more about SAT [HERE](#) ^[17]



Consultations

European Commission Consultation: Phthalates in medical devices

The European Commission is consulting on preliminary guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates, which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties. These guidelines describe how a benefit-risk assessment for the justification of the presence of CMR 1A or 1B and/or ED phthalates (CMR/ED phthalates) in medical devices should be performed by relevant stakeholders. In addition, the document also considers steps for the evaluation of possible alternatives for these phthalates used in medical devices.

Deadline – 29th April 2019

Access consultation [HERE](#) ^[18]

Public consultation on EMA Regulatory Science to 2025

The purpose of this public consultation is to seek views from EMA's stakeholders, partners and the general public on EMA's proposed strategy on Regulatory Science to 2025 and whether it meets stakeholders' needs. By highlighting where stakeholders see the need as greatest, participants have the opportunity to jointly shape a vision for regulatory science that will in turn feed into the wider EU network strategy in the period 2020-25.

Deadline – 30th June 2019

Access consultation [HERE](#) ^[19]

EMA - Guideline on the evaluation of medicinal products indicated for treatment of bacterial infections

The EMA has launched a consultation on the revision of its guideline on the evaluation of human medicines indicated for the treatment of bacterial infections. Antimicrobial resistance is a global public health problem. Regulators in the European Union, the United States and Japan have had extensive discussions over the last few years to explore and agree how to align as much as possible their respective data requirements so that medicine developers can design clinical trials that meet the evidence needs of multiple regulatory agencies. The revised guidance reflects the outcome of these discussions.

Deadline – 31st July 2019

Access consultation [HERE](#) ^[20]

EMA – Public consultation on key principles for the electronic product information of EU medicines

The European Medicines Agency (EMA), together with the European Commission (EC), has launched a public consultation on draft key principles which will form the basis on which the electronic product information ^[21] (ePI) for human medicines will be developed and used throughout the European Union. The rationale behind the ePI is that digital platforms open additional possibilities to disseminate the PI electronically. This can address some of the current limitations and better meet patients' and healthcare professionals' needs for accessible, up-to-date information on medicines. The draft key principles are the result of extensive discussions and consultations carried out by EMA, the Heads of Medicines Agencies (HMA) and the EC throughout 2018, with representatives of all stakeholder groups.

Deadline – 31st July 2019

Access consultation [HERE](#) ^[22]

17 April 2019

Links

[1] <http://www.eahp.eu/newsletter/subscribe> [2] <http://www.eahp.eu/events/open-learning/courses/breast-cancer-next-challenge> [3] <http://www.eahp.eu/events/open-learning/courses/anticoagulation-theory-practice> [4] <http://www.eahp.eu/events/open-learning/courses/Biosimilarscancercare> [5] <http://www.eahp.eu/events/open-learning/courses/essentials-biologicals> [6] <http://www.eahp.eu/events/open-learning/courses/anticoagulants> [7] <http://www.eahp.eu/events/open->

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<http://ecdc.europa.eu/sites/portal/files/documents/Template-submission-comments-HPV-Guidance.docx>
[10] <https://www.eahp.eu/contact/ECDC.HPVguidance/ecdc.europa.eu> [11]
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https://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/2019_efficiency_en.pdf
[13] <http://www.eahp.eu/news/EU-monitor/eu-monitor-%E2%80%93-24-january-join-1st-eahp-synergy-certification-course> [14] <https://ec.europa.eu/digital-single-market/en/news/croatia-start-exchange-eprescriptions-and-patient-summaries> [15] <https://ejhp.bmj.com/content/early/2019/03/06/ejhpharm-2018-001685> [16] <https://www.aahp.at/component/eventbooking/veranstaltungen/84-fruehjahrensversammlung-2019?Itemid=92> [17] <http://sat.eahp.eu/en/home> [18]
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