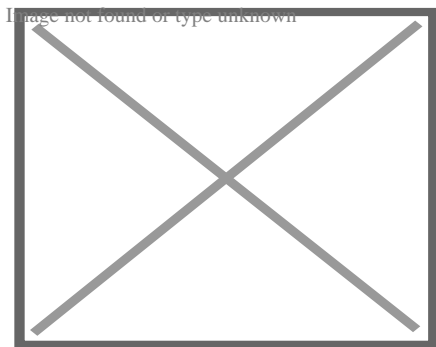


# eahp euMonitor

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

*You can subscribe to receive the EAHP EU Monitor by email [HERE](#) <sup>[1]</sup>. [\[1\]](#)*



## **EAHP's position on biosimilar medicines**

In June, the European Association of Hospital Pharmacists (EAHP) published its position paper on biosimilar medicines outlining the Associations views on the role of the hospital pharmacist, naming of biosimilar medicines, extrapolation of indications, information about biosimilar medicines as well as interchangeability, switching and substitution of biosimilar medicines.

Biological medicines have become indispensable in the treatment of patients with serious diseases such as cancer and inflammatory diseases. An increasing number of biological medicines are biosimilar medicines which are medicines. These are developed to be similar to already existing biological medicines. The European Medicines Agency (EMA) is the body responsible for their approval in the European Union.

The position paper of EAHP closely follows the line of EMA on matters concerning naming of biosimilar medicines and extrapolation of indications. The evidence acquired over 10 years of clinical experience has shown that biosimilar medicines approved through EMA can be used as safely and effectively in all their approved indications as other biological medicines. Thus, EAHP has expressed confidence in EMAs regulatory pathway for biological reference products and biosimilar medicines.

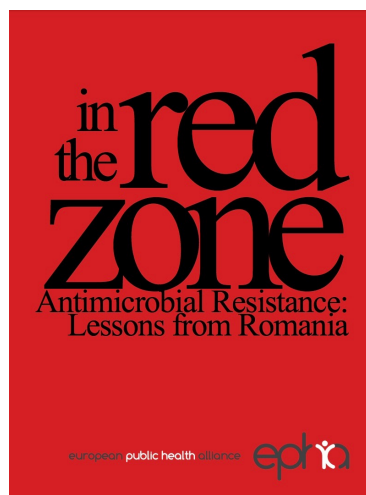
Hospital pharmacists are stewards of appropriate selection, procurement, logistics and use of medicines as well as key players in pharmacovigilance. Consequently, they are uniquely positioned and capable to promote the appropriate utilisation of biosimilar medicines. Their knowledge is therefore particularly relevant with regard to switching and providing the evidence on patient safety and treatment quality.

In terms of interchangeability, switching and substitution of biosimilar medicines, EAHP supports the view that a reference product and its biosimilar(s) are interchangeable and therefore can be switched. EAHP holds the same view for biosimilars to the same reference product. These views are based on evidence presented in the position paper. Nevertheless, due to patient specific issues, EAHP acknowledges that there are instances where it is not appropriate to make a switch. It should therefore be ensured that the considerations of the prescriber, the pharmacist and the patient whether to choose the reference product or its biosimilar are taken into account. Provided that the above safeguards are in place, EAHP supports substitution at hospital pharmacy level.

The decisions regarding switching and substitution may be taken on either national or local level. The key positions of EAHP on biosimilar medicines are summarised on the first page of the position paper. Each position does however not stand by itself and thus should be read in

conjunction with the corresponding supportive information presented in the position paper.

Read the position paper [HERE](#) [2]



## AMR initiatives on the rise

The launch of the [One Health Action Plan](#) [3] by the European Commission coincided with two other developments in the field of antimicrobial resistance (AMR), namely the adoption of the first deliverable of the action plan - the EU Guidelines on the prudent use of antimicrobials in human health - and the publication of a study that gives a compelling insight into the current AMR situation in Romania.

### ***EU Guidelines for the prudent use of antimicrobials in human health***

The Guidelines for prudent use of antimicrobials in human health issued by the European Commission are based on a proposals prepared by the European Centre for Disease Prevention and Control (ECDC) with input from EU Member States' experts and stakeholders. They complement the [guidelines for the prudent use of antimicrobials in veterinary medicine](#) [4] which were released in 2015.

The guidelines aim to reduce inappropriate use and promote prudent use of antimicrobials in people. They are complementary to infection prevention and control guidelines which may exist at national level. The measures included therein target all actors who are responsible for or play a role in antimicrobial use. Different chapter are addressing national, regional and local governments, healthcare professionals, patients and others who play a role in antimicrobial use. The elements of good practice to be followed by pharmacists include:

- Dispensing antimicrobials with prescription, unless specific provisions allow for regulated dispensation in specific circumstances;
- Ensuring that the patient and/or the carer understands the dosage and duration of treatment as this can improve adherence and increase treatment success;

- Promoting appropriate disposal of leftover antimicrobials;
- Notifying adverse-events related to antimicrobials in accordance with regulations;
- Participating in local, regional or national public health campaigns promoting the prudent use of antimicrobials; and
- Providing advice to patients and health professionals with regard to contraindications, drug interactions and food–drug interactions.

Besides measures, the guidelines suggest good clinical practices, systems and processes for EU countries to consider when developing and implementing their national strategies. They also include activities that may be taken by international organisations and agencies in support of national strategy development and implementation.

The guidelines have been published in English <sup>[5]</sup> as well as in all other official languages <sup>[6]</sup> of the European Union.

### ***In the red zone***

"In the red zone – Antimicrobial Resistance: Lessons from Romania" is a study by the European Public Health Alliance (EPHA) which provides insights into the AMR situation in Romania. It demonstrates the challenges of the Romanian health system in combatting AMR.

The study is based on interviews with experts from healthcare practice and policy in Romania. It discusses how a combination of factors, including inadequate infection control and prevention protocols, lack of human and financial resources for tackling AMR and hospital-acquired infections, and insufficient surveillance data combine to reduce a country's ability to ward off AMR. Bacteria are not contained by borders, wherefore AMR is not only an issue in Romania but has become a global threat. Consequently, Europe needs to work together in the fight against AMR. Thus, the study also illustrates the urgent need for coordinated, well-resourced and effective EU policy action and programmes to tackle AMR. Based on this report, EPHA makes the following EU policy recommendations:

- Deploy EU policies and programmes including legislation, to reduce drug-resistance, reduce excessive antimicrobial use and tackle other causes of AMR across all relevant sectors (human, animal, industrial, environmental);
- Expand the remit and resources of the ECDC, deepen the country visits and produce tailored targets and recommendations for Member States / regions;
- Expand ECDC's role in technical cooperation between the EU and Member States on AMR, including the take-up of best practice;
- Include recommendations in the European Semester as a policy tool to motivate national progress on AMR and healthcare associated infections;
- Design future EU funding opportunities and conditionalities to boost national policy and implementation capacity, improve facilities to tackle AMR and HAIs, e.g. use of rapid diagnostic tests, upgrade laboratory equipment, isolation units, etc.;
- Identify EU experts to train inter-sectoral "AMR champions" at national level; and
- Develop a European curriculum for AMR, to be integrated into health workers' education programmes.

Study available [HERE](#) <sup>[7]</sup>

Read more about the One Health Action Plan in the [EU Monitor of 29 June](#) <sup>[8]</sup>

## **Estonian presidency promoting eHealth and mHealth**

The Estonian Council Presidency is due to its focus called a digital presidency. Every aspect of our society is influenced by digital solutions, including our health. Consequently, Estonia will start discussions on the free movement of data in the health sector.

Prior to its presidency, the Government Office of Estonia had commissioned a study "Mapping out the obstacles of free movement of electronic health records in the EU in light of the digital single market <sup>[9]</sup>". The study compares the Estonian eHealth system with five Member States (Finland, Germany, Poland, Sweden and the United Kingdom) that were chosen to have a better understanding of the diversity of eHealth systems that are being used in the EU.

The study mapped the obstacles as well as enablers of movement of health data, including expectations of the population and the patients' possibilities of using their own health data in the surveyed Member States and across borders. In addition, it provided recommendations to overcome the obstacles identified in the study. Overall, the report shows that necessary preconditions for the free and safe movement of health data across the borders of Member States exist in the EU. It concludes that the main barriers for free movement of health data are not information technology or legislation, but rather so-called soft aspects such as people's attitudes, awareness and cooperation.

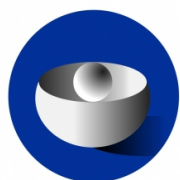
Overall, Estonia is of the opinion that calculated use of e-health solutions supports the general targets of the health policies of Member States, so that people will be healthier, and health systems will be sustainable and more manageable. Consequently, its presidency will also focus on eHealth aspects. There are plans to launch a discussion on the promotion of cooperation and coordination on e-health in order to create the necessary preconditions for the wider use and cross-border movement of health data for the purposes of treatment, research and innovation and to promote data-based innovation in healthcare.

Moreover, it has been acknowledged by the Estonian presidency that due to the increased role of smart devices and mobile applications, a large volume of health and lifestyle data is currently created. An important aspect in this regard is the safe use and the secure sharing of this data. Attention should be paid to the issues of data protection and cybersecurity, so that health data can be used in a safe and secure way and not to be held from use. Estonia is thus planning to discuss eHealth issues with Health ministers at both an informal meeting and at a high-level conference.

"Health in the digital society and the digital society for health <sup>[10]</sup>" will address how digital technologies and the wider use of health data are changing our lives and also methods of healthcare. Through a combination of educational sessions, interactive workshops and valuable networking opportunities, the conference will not only showcase already existing digital health solutions, but also use-cases and technologies to demonstrate that citizen-centric health services and systems are genuinely valuable.

It has further been announced that Estonia will be proposing Council Conclusions on digital health for the adoption at the December Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) Council. The EU Monitor will keep you updated on all the above activities.

More information on the Estonian presidency and its aims HERE <sup>[11]</sup>



EUROPEAN MEDICINES AGENCY  
SCIENCE · MEDICINES · HEALTH

## EMA – Public Hearing

The European Medicines Agency (EMA) would like to let you know it is going to hold a Public Hearing on 26 September 2017. The hearing is part of an ongoing review of valproate <sup>[12]</sup>-containing medicines in the treatment of women or girls who are pregnant or of childbearing age. Citizens are invited to share their experience with valproate – a medicine that treats epilepsy, bipolar disorder and migraine. This review (a so-called Article 31 referral) is being carried out by the Agency's experts in medicines safety, the Pharmacovigilance Risk Assessment Committee (PRAC).

Those wishing to participate at the hearing, which will take place at the EMA offices in London, need to register in advance and may request to speak in front of the Committee or simply observe the proceedings. An application form <sup>[13]</sup> needs to be filled in and submitted to EMA, no later than 25 August 2017.

Those unable to attend the hearing in person can follow the live broadcast on EMA's website.

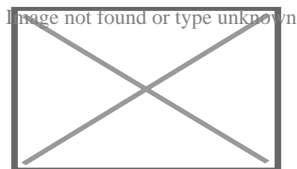
More information HERE <sup>[14]</sup>



## **EJHP: Accuracy of best possible medication history documentation by pharmacists**

The online edition of the European Journal of Hospital Pharmacy [15] has published an original article on the accuracy of best possible medication history documentation by pharmacists at an Australian tertiary referral metropolitan hospital. It determines the quality of best possible medication history taking activities and identifies factors which impact upon erroneous documentation.

More HERE [16]



## **Consultations**

### ***EMA – Concept paper on a guideline on the evaluation of medicinal products indicated for treatment of influenza***

EMA consults on a concept paper proposing the development of a guideline on the clinical evaluation of medicinal products indicated for the treatment of influenza for which there is no regulatory guidance currently available within the EU.

**Deadline – 31st July 2017**

More information HERE [17]

### ***EMA - Concept paper on the revision of the guideline on the role of pharmacokinetics in the development of medicinal products in the paediatric population***

The guideline was issued in 2007. Over the last 10 years, the EMA Paediatric Committee has approved a large number of Paediatric Investigational Plans and an increasing number of applications for paediatric indications have been submitted to EMA and the national regulatory agencies. A revision to the guideline is therefore proposed to reflect the experience gained over the last decade and developments in science.

**Deadline – 31st July 2017**

More information [HERE](#) <sup>[18]</sup>

### ***EMA - concept paper on the need for the development of a reflection paper on regulatory requirements for the development of medicinal products for chronic non-infectious liver diseases (PBC, PSC, NASH)***

Based on the need for further guidance, EMA would like to work on a reflection paper outlining requirements for the development of medicinal products for chronic non-infectious liver diseases. The consultation aims at determining the scope of this paper.

**Deadline – 31st August**

More information [HERE](#) <sup>[19]</sup>

### ***EMA - Clinical Data Publication Survey***

The survey aims at collecting the views of the users of the clinical data website and gathering feedback on the usability of the website. The survey should take no more than 10 minutes to complete.

**Deadline – 31st August**

The survey is available [HERE](#) <sup>[20]</sup>

### ***European Commission - Stakeholder consultation for the evaluation of EU legislation on blood, tissues and cells***

The purpose of this consultation is to support a comprehensive evaluation of the Union legislation on blood and tissues and cells - Directives 2002/98/EC and 2004/23/EC respectively and their implementing (technical) Directives, examining their functioning across the EU. In particular, the consultation aims to gather views on the extent to which the Directives have met their original objectives and whether they remain fit for purpose. The evaluation is expected to provide a sound evidence base which will be used to consider the need for any changes to the legislation.

**Deadline – 31st August**

More information [HERE](#) <sup>[21]</sup>





## Upcoming events

### 7th September – EPHA 8th Annual Conference: Make Health Your Business [22]

Brussels, Belgium

Despite the existence of a strong evidence base for effective policy action on health promotion and disease prevention too little has been achieved. Policy-makers already know what needs to be done to overcome barriers to good health so the focus of this conference will be to explore how new levers and different levels of power can break through to real action on chronic diseases – by making health everyone's business.

17 July 2017

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#### Links

[1] <http://www.eahp.eu/newsletter/subscribe> [2]

[http://www.eahp.eu/sites/default/files/eahp\\_position\\_paper\\_on\\_biosimilar\\_medicines\\_0.pdf](http://www.eahp.eu/sites/default/files/eahp_position_paper_on_biosimilar_medicines_0.pdf) [3]

[https://ec.europa.eu/health/amr/sites/amr/files/amr\\_action\\_plan\\_2017\\_en.pdf](https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf) [4]

[http://ec.europa.eu/health/sites/health/files/antimicrobial\\_resistance/docs/2015\\_prudent\\_use\\_guidelines\\_en.pdf](http://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf)

[5] [https://ec.europa.eu/health/amr/sites/amr/files/amr\\_guidelines\\_prudent\\_use\\_en.pdf](https://ec.europa.eu/health/amr/sites/amr/files/amr_guidelines_prudent_use_en.pdf) [6] [http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C\\_.2017.212.01.0001.01.ENG&toc=OJ:C:2017:212:TOC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2017.212.01.0001.01.ENG&toc=OJ:C:2017:212:TOC) [7]

<https://epha.org/wp-content/uploads/2017/06/In-the-red-zone-EPHA.pdf> [8] <http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-29-june-2017> [9] [https://www.eu2017.ee/sites/default/files/inline-files/final\\_inglk\\_etervise\\_uuring.pdf](https://www.eu2017.ee/sites/default/files/inline-files/final_inglk_etervise_uuring.pdf) [10] <http://www.ehealthtallinn2017.ee/ehome/252892/ehealthtallinn/>

[11] <https://www.eu2017.ee/> [12]

[http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Valproate\\_and\\_related\\_substances](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Valproate_and_related_substances)

[13] [http://www.ema.europa.eu/ema/pages/includes/document/open\\_document.jsp?webContentId=WC500231026](http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500231026)

[14] [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2017/07/news\\_detail\\_002774.jsp&am](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/07/news_detail_002774.jsp&am)

[15] <http://ejhp.bmj.com/> [16] <http://ejhp.bmj.com/content/early/2017/07/11/ejhp/harm-2016-001177> [17]

[http://www.ema.europa.eu/ema/doc\\_index.jsp?curl=pages/includes/document/document\\_detail.jsp?webContentId=V](http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V)

[18] [http://www.ema.europa.eu/ema/doc\\_index.jsp?curl=pages/includes/document/document\\_detail.jsp?webContentId=V](http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V)

[19] [http://www.ema.europa.eu/ema/doc\\_index.jsp?curl=pages/includes/document/document\\_detail.jsp?webContentId=V](http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V)

[20] [https://ec.europa.eu/eusurvey/runner/clinical\\_data\\_publication\\_survey](https://ec.europa.eu/eusurvey/runner/clinical_data_publication_survey) [21]

[https://ec.europa.eu/health/blood\\_tissues\\_organ/consultations/implementation\\_legislation\\_en](https://ec.europa.eu/health/blood_tissues_organ/consultations/implementation_legislation_en) [22]

<https://epha.org/epha-2017/>