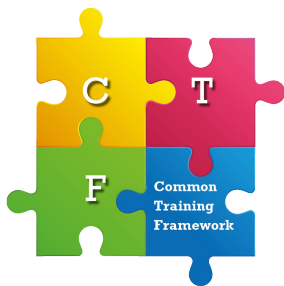


# eahp euMonitor

*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>. [\[1\]](#)*



## CTF Working Group 2 - Literature review published

The Common Training Framework (CTF) project <sup>[2]</sup> of the European Association of Hospital Pharmacists (EAHP) has a new milestone to report. Working Group 2 which was tasked with the compilation of supporting evidence published a literature review. This review analysed the impact of educational interventions on health outcome to determine the value that can be created in forming a CTF for hospital pharmacy. The findings of Working Group 2 were published in the online first edition of the European Journal of Hospital Pharmacy <sup>[3]</sup> (EJHP).

Members of Working Group 2 analysed 9 primary research studies and one literature review which were selected due to their relation to education and impact of pharmacists, medical doctors or nurses on patient outcomes. The literature search was carried out by two teams of researchers to ensure inter-rater reliability at each stage of screening and data extraction. However, the search was limited on the one hand to two databases and restricted on the other hand by the limited number of studies published in the English language.

Almost one-third of the selected studies targeted pharmacists in their research. The importance of a CTF was not specifically discussed. Nonetheless, the review carried out by Working Group 2 showed that higher education levels of healthcare professionals improve patient outcomes. Since, higher degrees or extended training positively affected patient outcomes, including mortality rates, it was concluded by Working Group 2 that further hospital pharmacy education could significantly impact the professional status and services reimbursement.

The literature review also touched upon labour mobility, one of the EU's four freedoms. Currently, hospital pharmacists have difficulties to use this freedom due to the different systems that are employed by the national bodies responsible for the recognition of professional qualifications. A CTF could not only improve labour mobility of hospital pharmacist, but also increase the prospect of cooperation in specialisation education provision between different countries, always with the aim of providing the same standards of care to all patients. As the foundation stone for ensuring the best use of medicines by patients in hospitals, a CTF for hospital pharmacy could become the benchmark for all European countries to strive for.

EAHP would like to thank both the chair of Working Group 2, Roberto Frontini, and its individual members (Cornelia Vetter Kerkhoff, Eduardo Echarri, Ian Bates, Jos Kosterink, Jose Manuel Martinez Sesmero, László Horváth, Lorna Marie West, Nenad Miljkovic and Stephanie Belaiche) for their contribution to the CTF project.

The literature review is available [HERE](#) <sup>[4]</sup>

## **ECDC – Toolkit for professionals in hospital and other healthcare settings**

In preparation of the 10th anniversary of the European Antibiotic Awareness Day (EAAD) the European Centre for Diseases Prevention and Control <sup>[5]</sup> (ECDC) redesigned its EAAD website and launched a new toolkit for hospital professionals. The EAAD – which takes place every year on 18th November – will focus on healthcare professionals and their efforts to keep antibiotics working.

The new EAAD website is a more dynamic and easy-to-access hub for resources to raise awareness about prudent use of antibiotics and about antibiotic resistance. It features a full set of informative resources aimed at the general public and at healthcare professionals, including factsheets, videos and infographics. A set of communication tools that can be used to raise awareness about prudent use of antibiotics is available for free, together with a guidance document on how to develop a social media campaign on the topic. Stories of patients who battled infections by antibiotic-resistant bacteria and an overview of awareness campaigns on prudent antibiotic use and antibiotic resistance developed throughout Europe are also on display.

To further guide professionals in hospitals and other healthcare settings, the ECDC also released a new toolkit which contains materials to help these professionals influence the use of antibiotics in their work environment. It includes factsheets, infographics, posters and leaflets that can be adapted. The toolkit addresses healthcare professionals such as prescribers, nurses and also hospital pharmacists by highlighting a series of actions that should be taken to prevent the spread of resistant bacteria as well as the misuse of antibiotics.

Hospital pharmacists are encouraged by ECDC to keep antibiotics working through

- Participating in antibiotic stewardship teams, as a key member of the team;
- Collaborating with the infectious disease specialist and the clinical microbiologist to implement the antibiotic stewardship programme;
- Improving the quality of antibiotic prescribing (e.g. checking for drug interactions, optimising dosage and route of administration, preventing adverse events);
- Consulting with hospital prescribers and providing them with feedback to ensure the quality of antibiotic prescribing;
- Implementing interventions on formulary restrictions, such as pre-approval and post-authorisation requirements, and assessing compliance with these restrictions;
- Analysing data on antibiotic use and costs for the purpose of surveillance and benchmarking;
- Supporting evidence-based hospital antibiotic guidelines for common infections and for surgical prophylaxis; and

- Managing your hospital's antimicrobial formulary (i.e., list of drugs available for prescribers).

By covering a number of professionals working at hospitals and other healthcare settings the new toolkit aims at creating a sense of individual responsibility in tackling antibiotic resistance and at empowering professionals to take action.

To mark the 10th anniversary of the EAAD, ECDC has also launched a social media call-to-action initiative called [#KeepAntibioticsWorking](#). This initiative prompts all EAAD stakeholders, professionals and members of the general public to share a message on social media to explain what they are doing to ensure antibiotics remain effective. On 15th November, the new toolkit will be launched officially during the [world antibiotic awareness wee](#) <sup>[6]</sup>k. EAHP will participate in the launch event.

Key messages for hospital pharmacists [HERE](#) <sup>[7]</sup>

Communication toolkit for healthcare professionals [HERE](#) <sup>[8]</sup>

Information on social media initiative [HERE](#) <sup>[9]</sup>



## EMA/ DG SANTE – action plan to foster development of ATMPs

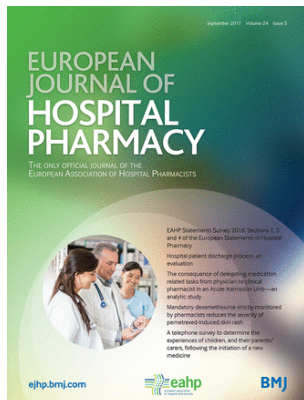
The European Medicines Agency (EMA) and the European Commission's Directorate-General for Health and Food Safety (DG SANTE) have adopted a joint action plan to foster the development of advanced therapy medicinal products (ATMPs).

ATMPs are medical products for human use based on genes or cells that offer potentially ground-breaking opportunities for the treatment of injury and disease, particularly in cases of severe, untreatable or chronic diseases which do not respond adequately to conventional treatments. They can be categorised into four main groups: gene therapy medicinal products, somatic cell therapy medicinal products, tissue engineered medicines and combined ATMPs.

These products are governed by [Regulation 1394/2007 on advanced therapy medicinal products](#) <sup>[10]</sup> which mandates that a marketing authorisation must be obtained prior to the marketing of ATMPs. The evaluation of these products is led by the Committee for Advanced Therapies – a specialised committee within EMA. The Regulation also empowers Member States to permit the use of advanced therapies that have not been authorised by the

Commission under certain conditions (so-called "hospital exemption"). The joint new action plan does not foresee changes to this regulatory framework, instead it identifies initiatives designed to optimise the regulatory environment. These include a European Commission guideline on good manufacturing practice for ATMPs; the initiation of dialogue with national competent authorities; new EMA scientific guidelines on ATMPs; as well as awareness raising.

Joint action plan available [HERE](#) [11]

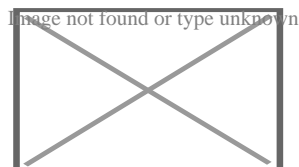


**EJHP: Identification and prioritisation of risks in a**

## **hospital pharmacy using healthcare failure mode and effect analysis**

The online first edition of the European Journal of Hospital Pharmacy (EJHP) has published an original article focusing on the identification and prioritisation of risks in a hospital pharmacy. Risks were identified by failure mode and effect analysis and prioritised according to their risk priority index (RPI) and criticality.

More [HERE](#) [12]



## **Consultations**

## ***EMA – Reflection paper on the use of extrapolation in the development of medicines for paediatrics***

The reflection paper aims to provide guidance on the main regulatory requirements that are expected to be met for the evaluation of extrapolation approaches in development of medicines for children. However, indicating preferences for the use of particular quantitative methods to address specific objectives of paediatric development is not within the scope of this document. The principles outlined should encourage further exploration of potentially suitable methods for specific situations, and choice of strategies should be justified.

**Deadline – 14th January**

More information [HERE](#) <sup>[13]</sup>

## ***EMA – Reflection paper on the pharmaceutical development of medicines for use in the older population***

The reflection paper describes aspects that medicines developers may consider when designing medicines for older people, such as selecting appropriate routes of administration and dosage forms, dosing frequency, excipients, container closure systems, devices and technologies, and user instructions in the product information. It is intended to communicate the current status of discussions on the pharmaceutical development of medicines that may be used in the older population.

**Deadline – 31st January 2018**

More information [HERE](#) <sup>[14]</sup>



## **Upcoming events**

**22<sup>nd</sup> November – Game Changers for better and affordable medicines for Europe <sup>[15]</sup> - Brussels, Belgium**

*The 2017 Universal Access and Affordable Medicines Forum of the European Public Health Alliance (EPHA) organised under the auspices of the Bulgarian Health Ministry aims at setting out a positive agenda of actionable policy recommendations to be implemented at the European and national level. The one-day event will provide participants with stimulating and lively discussions on the hottest topics in pharmaceuticals.*

26 October 2017

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## Links

- [1] <http://www.eahp.eu/newsletter/subscribe> [2] <http://www.hospitalpharmacy.eu/> [3] <http://ejhp.bmj.com/>  
[4] <http://ejhp.bmj.com/content/early/2017/03/02/ejhpharm-2016-001185> [5] <https://ecdc.europa.eu/en> [6]  
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[15] <https://epha.org/game-changers-for-better-and-affordable-medicines-for-europeans/>