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*** *[1]. [1]*

The EAHP-EPSA Int tudents learn more about hospital pharmacy!

The European Association of Hospital Pharmacists (EAHP) is collaborating with the European Pharmaceutical Students' Association (EPSA) on many different areas. The aim of the collaboration between the two associations is to familiarise students with the hospital pharmacy profession. One of the three projects that the associations cooperate on is the EAHP-EPSA Internship Platform. Through the platform, students and young professionals are given the opportunity to intern in hospital pharmacies around Europe for a period up to three months.

EAHP liaised with EPSA in 2012 to establish the platform. The first students found their internships in the same year. The project has been developing since, with the official name being adopted in 2016. Currently, interested candidates can apply for internships in 21 different hospitals located in 8 European countries. Gaining international experience and being provided with the opportunity to learn from one another by exchanging good practices, encouraged 24 students in 2017 to apply for an internship through the platform.

The feedback from both hospital pharmacies and applicants has been excellent so far. Motivated by students, such as Nataša from Serbia who interned in Spain in 2016, both EAHP and EPSA are fiercely working on the enlargement of the platform. Begin asked about her experience Nataša reported: "*During my 2-month-long internship I rotated through different areas of hospital pharmacy - from dispensing, TDM and parenteral nutrition design to clinical trials, oncology and external patients. In every area, there was a pharmacist guiding me. As a person who wants to dedicate herself to clinical pharmacy, I find this experience very valuable. I am especially satisfied with my improvement in oncology area. Generally, I now understand how the hospital pharmacy should work. In addition, I met new friends and made valuable contacts - it was a great networking opportunity!*"

Feedback from students like Nataša confirms that "pharmacists in training" are very excited about these kinds of opportunities. It gives them the possibly to explore and learn about different areas of hospital pharmacy, and at the same time provides them with the opportunity to visit another country with a different healthcare system and work environment.

With the number of interested students rising steadily over the past years, the 21 hospital pharmacies currently enrolled in the programme will soon not be enough. To enable more curious pharmacy students to gain the same experience as Nataša, EAHP is seeking additional hospital pharmacies interested in joining the Internship Platform.

If you are interested in hosting an intern contact intern[at]eahp[dot]eu [2]

More about the EAHP-EPSA internship platform HERE [3]

FMD – the one-year countdown has started

The European Commission released a report on the transposition of part of the Falsified Medicines Directive (2011/62/EU) [4] as well as an updated version of the Question & Answer (Q&A) document on safety features concerning falsified medicines. The report analyses how Member States have implemented the article which mandates the adoption of proportionate, effective and dissuasive penalties for those involved in the production and circulation of falsified medicines.

The FMD strengthens good distribution practices and requirements for wholesale distributors, reinforces rules on importation, controls and inspections of active substances and their manufacturers, and establishes an EU-wide logo to allow the identification of legal online retailers of medicines. Part of these provisions have been applicable since 2013. In addition, the FMD introduces mandatory safety features on prescription medicines. Details on the rules for the safety features appearing on the packaging of medicinal products for human use have been laid down in a Delegated Regulation (2016/161) [5] which will be applicable from 9th February 2019 onwards.

The report [6] of the Commission indicates that Member States have adopted a wide variety of penalties, ranging from one year (Sweden, Finland and Greece) to 15 years (Austria, Slovenia and Slovakia). Similarly, also the levels of fines differ from country to country, starting at 4300 Euros in Lithuania and going as high as an unlimited amount in the United Kingdom. The report deems the measures adopted by Member States satisfactory. Nonetheless, it suggested to consider the introduction of additional criminal penalties or administrative sanctions in relation to falsified medicines, active substances or excipients to strengthen the overall effectiveness of the measures taken.

Moreover, the European Commission has published an updated version of the Q&A on safety features concerning falsified medicines. Version 9 of the Q&A document addresses in addition to general questions, enquiries relating to the technical specifications of the unique identifier, verification and decommissioning activities and the repository system.

To assist hospital pharmacists and hospitals with the implementation of the Delegated Regulation the EAHP, the European Hospital and Healthcare Federation (HOPE) [7] and the European Medicines Verification Organisation (EMVO) [8] have set up a hospital platform on European level that looks into the development of communication strategies and the collection and sharing of best practices in order to better understand and solve common issues in the hospital sector.

Commission report HERE [6]

Study on the transposition measures of Member States in relation to the pharmaceutical legislation HERE [9]

Updated Q&A document on safety features HERE [10]

More about falsified medicines and FMD HERE [11]

Commi  blishes 3 opinions to help guide policy makers

The Expert Panel on effective ways of investing in health of the European Commission has adopted three Opinions related to **access to healthcare, innovative payment models for high-cost innovative medicines** and **performance of primary care**. The Expert Panel provides advice in the form of opinions in response to questions submitted by the European Commission, with the aim of supporting EU countries in delivering high quality care and making their health systems more effective, accessible and resilient.

The *Opinion on innovative payment models for high-cost innovative medicines* [12] explores possible new ways of setting prices for specialty medicines by improving access, setting out some broad principles to guide the definition of specific payment models. These include greater price and cost transparency, looking at patent law and market exclusivity rules to promote and reward high-value innovations, and developing and using methods to measure the social value of pharmaceutical products, such as in the context of Health Technology Assessment (HTA).

The *Opinion on benchmarking access to healthcare in the EU* [13] is based on the data from the EU annual Survey of Income and Living Conditions (EU-SILC) [14], drawing attention to evidence of relatively high rates of unmet healthcare needs in some EU countries. The Panel proposes a mechanism for setting an ambitious but achievable target for unmet needs based on the median achievements of the best performing Member States and advises on how to identify the distribution of unmet needs and how to address challenges by mobilising resources available at national and European level.

The *Opinion on tools and methodologies for assessing the performance of primary care* [15] translates multiple dimensions into comparative key indicators, and descriptive additional indicators, related to the 10 identified domains of primary care. It also sets out some procedural steps necessary for a performance assessment system, including multi-dimensionality, shared design, evidence-based benchmarking of results, timeliness and transparent disclosure. Finally, it recommends some criteria to ensure relevant performance indicators are selected, for example: alignment of indicators with objectives of the health system, ability to routinely collect the indicator, the validity and reliability of information. The Opinion will feed into the work of the Member States' group on Health Systems Performance Assessment (*HSPA)* [16] on primary care, which will publish in the first quarter of 2018 a report on measuring primary care.

More information HERE [17]

Commission Synopsis report: ‘Transformation Health and Care in the Digital Single Market’

The European Commission has released the summary results of the consultation on the transformation of health and care in the Digital Single Market. The public consultation on transformation of health and care in the Digital Single Market investigated the need for policy measures that will promote digital innovation for better health and care in Europe. The results will feed into a new policy Communication by the European Commission.

A total of 1400 people participated in the consultation, and their overwhelming response, with over 93% of respondents agreeing, was that they would like patients to be able to manage their own health-related data. Also, 83% of respondents believe the interoperability of data throughout the EU Member States and digital innovation would improve patient safety.

The main obstacles to the realisation of this cooperation, according to the respondents, are the risks regarding privacy breaches, cybersecurity risks, lack of infrastructure, lack of awareness and legal restrictions within Member States. As a way to overcome these barriers, many respondents believe it is important to support health care professionals, and 64% expressed their support for developing cross border infrastructure in order to pool access to health data and scientific expertise across the EU.

On the basis of the responses received as well as from input gathered through the eHealth Network, the Council Conclusions on Health in the Digital Society, eHealth Stakeholder Group, the Workshop on GDPR implementation and health data, the European Commission drew five conclusions. In accordance with these conclusions the European Commission should work on

1. Enabling citizens to use and have access to data concerning health across borders;
2. Ensuring that data security and privacy remains a key concern;
3. Lowering barriers, such as the lack of interoperability and the lack of heterogeneity of electronic health record (EHR) systems;
4. Developing actions to minimise barriers relating to health data access and sharing; and
5. Addressing the low level of adoption of digital health solutions in health care.

Full report HERE [18]

Survey fo  and disaster pharmacy – deadline extended

In 2016, the International Pharmaceutical Federation (FIP) published pharmacy guidelines for responding to natural disasters [19] which aims at helping pharmacists to prepare and manage natural disasters situations. Moreover, FIP has issued a policy statement [20] about the role of the pharmacist in disaster management. Also, a survey is being conducted to determine how hospital pharmacies in Europe are prepared for a natural or manmade disaster and whether they have specifically followed these guidelines since their publication. The survey tries to make an inventory of hospital pharmacies that already faced disaster situations and to collect information on how these hospital pharmacies have managed the disaster situation.

This survey was initiated by Prof Pascal Bonnabry (Chief-pharmacist at the pharmacy of Geneva University Hospitals) and Dr Nicolas Widmer (Chief-pharmacist at the pharmacy of Eastern Vaud Hospitals), who have been mandated by the Swiss Confederation to develop a Centre for Emergency and Disaster Pharmacy at the University of Geneva, Switzerland. Its objectives are to offer research and teaching in this field.

Participation in the survey should not take more than 10-15 minutes to fill in case major events were not experienced in the last 5 years. For hospital pharmacies that were faced with a disaster situation the completion of the survey will take less than 30-40 minutes. All answers are welcome even if your hospital pharmacy doesn't have any special preparedness plan, because every answer is important.

Answers should be submitted by **16th March 2018**.

The survey can be accessed HERE [21]

For any questions you can contact the Centre (info[at]disaster-pharmacy[dot]ch) [22]

EJHP: March Issue now available!

The latest issue of the European Journal of Hospital Pharmacy (EJHP) is now available, featuring articles regarding parenteral nutrition wastage, nanosimilars, on-call hospital pharmacy services and two editorials, one on deprescribing, and an open call for peer reviewers. The issue also includes various short reports, such as ‘Dispensing errors from look-alike drug trade names’ and ‘Medication reconciliation activities among pharmacists in

Europe'.

The editorial, titled 'Deprescribing one year on: challenging the first iatrogenic epidemic', addresses the topic of potentially inappropriate medication prescription, presenting various tools related to deprescription, as well as recent developments in this area.

The review article addresses the accuracy of intravenous and enteral preparations involving small volumes for paediatric use, specifically challenges arising from neonatal drug delivery.

This issue includes much more content, such as articles and reports offering a comprehensive overview of recent developments, such as the path towards measuring safe medication practices in Portuguese hospitals or the introduction of pharmacy technicians into the oncology ward as part of the nursing team.

More HERE [23]

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Consultations

Commission – Public consultation on strengthened cooperation against vaccine preventable diseases

Due to the cross-border nature of vaccine preventable diseases and the challenges to national vaccination programmes, the European Commission saw the need to look into common EU actions and an increase of coordination. The information collected via the public consultation is intended to feed into the adoption of a proposal of a Council Recommendation on Strengthened Cooperation against Vaccine Preventable Diseases.

Deadline – 15th March 2018

More information HERE [24]

EMA-Draft qualification opinion - The European Cystic Fibrosis Society Patient Registry

The qualification opinion provides a draft context of use of the registry for public consultation, describing where this registry is deemed by CHMP as an appropriate data source for post-authorisation studies to support regulatory decision making on medicines for the treatment of cystic fibrosis, together with CHMP's response to the questions posed by the Consortium.

Deadline – 9th April 2018

More information HERE [25]

EMA- Concept paper on the development of a reflection paper on new analytical methods/ technologies in the quality control of herbal medicinal products

Quality control is a prerequisite to assure safe and effective use of (traditional) herbal medicinal products, which are complex mixtures of numerous phytochemical constituents. For the majority of herbal substances, herbal preparations and (traditional) herbal medicinal products the active constituents are not known or are only partly understood. Consequently, EMA is planning to develop a reflection paper that addresses new analytical methods and technologies for the quality control of herbal medicinal products.

Deadline – 30th April 2018

More information HERE [26]

EMA- Draft guideline on safety and efficacy follow-up and risk management of advanced therapy medicinal products

This draft consultation offers the opportunity for proving input regarding the replacement of the 'Guideline on safety and efficacy follow-up - risk management of Advanced Therapy Medicinal Products', which provides dedicated and specific guidance for ATMPs with regards to the pharmacovigilance system, the identification of risks, the risk minimisation measures, the post-authorisation S&E studies, the management and the reporting of adverse reactions and of the evaluation of the effectiveness of the risk management system.

Deadline – 30th April 2018

More information HERE [27]

EMA- Reflection paper on investigation of pharmacokinetics and pharmacodynamics in the obese population

The specific aims of this reflection paper are to describe how the effects of obesity can be investigated during clinical drug development, provide recommendations on when investigations of the effect of obesity on the PK of a drug should be considered, provide information on specific important considerations for these investigations and discuss how to reflect PK findings in weight/size based dosing recommendations.

Deadline – 31st July 2018

More information HERE [28]

23 February 2018

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] https://www.eahp.eu/contact/intern/eahp/eu [3] http://www.eahp.eu/students/eahp-epsa-internship-platform [4] http://eur-lex.europa.eu/legal-content/DE/TXT/?uri=uriserv:OJ.L_.2011.174.01.0074.01.ENG [5] http://eur-lex.europa.eu/eli/reg_del/2016/161/oj [6] https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/com2018_49_final_en.pdf [7] http://www.hope.be/ [8] https://emvo-medicines.eu/ [9] https://publications.europa.eu/en/publication-detail/-/publication/a1201026-fb39-11e7-b8f5-01aa75ed71a1/language-en/format-PDF/source-62239868 [10] https://ec.europa.eu/health/sites/health/files/files/falsified_medicines/qa_safetyfeature_v9.pdf [11] https://ec.europa.eu/health/human-use/falsified_medicines_en [12] https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/opinion_innovative_medicines_en.pdf [13] https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/opinion_benchmarking_healthcareaccess_en [14] http://ec.europa.eu/eurostat/web/microdata/european-union-statistics-on-income-and-living-conditions [15] https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/docsdir/opinion_primarycare_performance_en.pdf [16] https://ec.europa.eu/health/systems_performance_assessment/overview_en [17] https://ec.europa.eu/health/expert_panel/home_en [18] https://ec.europa.eu/health/sites/health/files/ehealth/docs/2018_consultation_dsm_en.pdf [19] http://www.fip.org/files/fip/publications/2016-07-Responding-to-disasters-Guideline.pdf [20] https://www.fip.org/www/uploads/database_file.php?id=385&table_id [21] https://fr.surveymonkey.com/r/Disaster_Pharmacy [22] https://www.eahp.eu/contact/info/disaster-pharmacy/ch) [23] http://ejhp.bmj.com/content/25/2 [24] https://ec.europa.eu/info/consultations/open-public-consultation-strengthened-cooperation-against-vaccine-preventable-diseases_en [25] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V [26] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V [27] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V [28] http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=V