

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

# eahp euMonitor

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## **2017 EAHP Statements Survey results are**

### **online**

The European Association of Hospital Pharmacists (EAHP) released the results of the 2017 Statements Survey which measured the progress of the implementation of the European Statements of Hospital Pharmacy. The 2017 edition of the survey focused on Sections 2, 5 and 6 of the Statements linked to selection, procurement and distribution, patient safety as well as education and research.

The European Statements of Hospital Pharmacy <sup>[2]</sup> express commonly agreed objectives which every European health system should strive for in the delivery of hospital pharmacy services. Since 2015, EAHP is evaluating the barriers and drivers of Statement implementation by means of the Statement surveys. The Results of the 2017 survey activity revealed that while education opportunities are sought by hospital pharmacists, many still struggle with the participation in and the publication of research. Concerning patient safety activities the reduction of medication errors through the use of computer decision support proved difficult, mainly due to the lack of capacity and capability or because the hospital management did not consider such activity as a priority.

The least positive responses in section 2 were however received in relation to the question inquiring about reason to contact the medicines authority because of medicines shortages. Around 60% of the respondents had to contact their national competent authority to inform them of a medicine shortage, to ask for details about the reasons for a shortage or to acquire details about the likely timeframe of the shortage

Overall, the survey results showed that awareness and the importance given to the Statements is beginning to increase significantly. This trend can partially also be attributed to the work of the EAHP Statement Ambassadors and the successful realisation of the implementation strategy.

EAHP would like to thank all hospital pharmacists that supported the publication of the 2017 EAHP Statements Survey by inputting to the survey activity. The contributions received are essential for the development of the hospital pharmacy profession in Europe.

Survey results [HERE](#) <sup>[3]</sup>

Survey questions [HERE](#) <sup>[4]</sup>

## **COST Action – Prospective Risk Assessment Practices in Medicine Shortages**

Working Group 4 members of COST Action CA15105 (European Medicines Shortages Research Network) [5] have developed a survey and are looking for healthcare professionals interested in sharing information on any possible insights into introducing alternative medicines and classifying the criticality of shortages.

COST Action CA15105 is part of the European Cooperation in Science and Technology [6]. The initiative is seeking to address supply problems to patients. To this end the research cooperation is encouraging systematic sharing of information and research about past, ongoing and future shortages of medicines and nutritional products. The action was launched in 2016 and will for the next 2 years continue its activities alongside the supply chain of medicines linked to landscape analysis, manufacturing, wholesaling, procurement, and measuring the impact of shortages on outcomes.

Working Group 4 members are interested in gathering information on risk assessment procedures that are used as a medicine-shortage mitigation strategy. In particular, they are searching for information on the implementation of such procedures in everyday practice and on their implications concerning the medicine-shortage mitigation process. Survey participants are also encouraged to recommend researchers working on the evaluation of risk assessment practices that are willing to contribute as co-authors in the expected publication.

Interested healthcare professionals should complete the questionnaire by no later than 1<sup>st</sup> July 2018. The members of Working Group 4 highly appreciate your time and willingness to participate in this research project. The completion of your contribution should not take longer than 15 minutes. Questions can be addressed by email to Nenad Miljković ( [nenad.hedren\[at\]gmail\[dot\]com](mailto:nenad.hedren[at]gmail[dot]com) [7] or [nenad.miljkovic\[at\]iohbb.edu\[dot\]rs](mailto:nenad.miljkovic[at]iohbb.edu[dot]rs) [8]).

Access survey [HERE](#) [9]



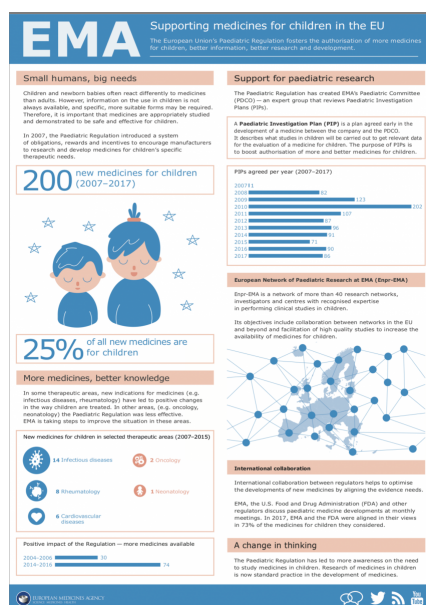
**ECDC – Towards One Health preparedness**

The European Centre for Disease Prevention and Control (ECDC) published the results of an expert consultation on One Health preparedness in Europe. The report addresses the challenges of the One Health approach and seeks to identify priority areas for action to help strengthen it. One Health encompasses human and veterinary health as well as the environment.

Consultation participants suggested to reinforce ECDC's role related to information exchange and coordination of surveillance data by improving cooperation with the European Food Safety Authority (EFSA), supporting the development of One Health action plans at national level, conducting integrated risk assessments and fostering simulation exercises to improve coordination and networking across sectors. A number of additional measures aiming at enhancing the One Health preparedness in Europe were also identified. These recommendations advised to invest into early warning and surveillance and to close research gaps. Moreover, the duplication of efforts should be avoided through better coordination. Communication should be improved to facilitate risk management.

ECDC is currently evaluating how these recommendations can be incorporated in forthcoming actions to encourage cross-sectoral preparedness planning as well as in future annual work plans. Close cooperation with the European Commission, EFSA and the World Health Organisation (WHO) is crucial for the for the implementation of measures that strengthen the One Health preparedness in Europe.

Read report [HERE](#) [10]



## EMA – Supporting medicines for children in the EU

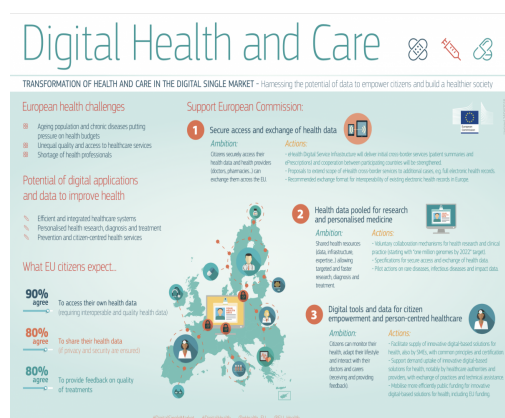
In March 2018, the European Medicines Agency (EMA) conducted a workshop to seek input on the better application of the Paediatric Regulation [11]. This exercise aimed at boosting the development of medicines for children. In the workshop report EMA summaries the outcomes of the meeting during which patients and carers, academics, healthcare professionals, and pharmaceutical industry representatives, as well as clinical trial assessors provided their

thoughts about ways to improve the implementation of the Paediatric Regulation.

The workshop participants centred their discussions around 5 key topics linked to the identification of paediatric medical needs, international cooperation, the timely completion of paediatric investigation plans (PIPs), improving the handling of PIP applications and increasing transparency around paediatric medicines. For each of these topics different proposal for concrete actions were put forward. The considerations of the workshop participants will be reflected in a new action plan that is currently being developed by the European Commission and EMA. Both institutions plan to share it by mid-2018.

The Paediatric Regulation was adopted to encourage and enable high-quality research into the development of medicines for children. Ten years after its entry into force in 2017 the European Commission conducted a review which showed an increase in medicines for children in many therapeutic areas. The report however also revealed that little progress has been made in diseases that only affect children or where the disease shows biological differences between adults and children. For more information on the ten-year report see the [EU Monitor of 7 November 2017](#) <sup>[12]</sup>.

Read EMA workshop report [HERE](#) <sup>[13]</sup>



## Commission – Communication on the future of digital health

In a communication that was published last month, the European Commission provided insights on the digital transformation of health and care in the Digital Single Market. Measures identified by the communication aim at increasing the availability of data in the EU and at building on previous initiatives to boost the free flow of non-personal data. This publication basis itself on the [result of a public consultation](#) <sup>[14]</sup> concluded in September 2017.

The initiative by the European Commission, which provides direction for EU-level activities in the field of digital health for the coming years, was welcomed by many stakeholders such as patient and healthcare professional associations. Three main areas of action were identified focusing on securing access to health data for citizens, personalised medicine and citizen empowerment with digital tools for user feedback and person-centred care.

Concrete actions for each of the three key areas have been put forward by the European Commission including but not limited to the development of an eHealth Digital Service Infrastructure, the creation of voluntary collaboration mechanisms for health research and clinical practice, the implementation of pilot exercises for rare and infectious diseases as well as the facilitation of the supply and uptake of innovative digital-based solutions for health.

Communication available [HERE](#) <sup>[15]</sup>

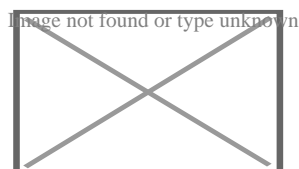
EAHP's position paper on eHealth and mHealth [HERE](#) <sup>[16]</sup>



## **EJHP: A UK hospital survey to explore healthcare professional views and attitudes to patients incorrectly labelled as penicillin allergic**

The article published in the online first edition of the European Journal of Hospital Pharmacy (EJHP) reports on the results of a study that analysed the views, beliefs and attitudes of hospital staff towards incorrect penicillin allergy records. In particular the motivation for the implementation of a penicillin de-labelling antibiotic stewardship intervention at the study hospital was measured. The results of this survey activity showed that such an intervention programme is well supported by the majority of the healthcare workers that provided feedback to the study.

Read [more](#) <sup>[17]</sup>



## **Consultations**

***EMA - Questions and answers on Bovine Spongiform Encephalopathies (BSE) and vaccines***

The document contains an update of the information in the Public Statement on the Evaluation of Bovine Spongiform Encephalopathies (BSE). Since 2001, understanding of the risks associated with BSE has progressed significantly and a routine review of EMA guidelines identified this document as requiring updating. It includes information on the use of bovine derived materials in vaccine manufacture.

**Deadline – 31<sup>st</sup> July 2018**

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

***EMA- Guideline on quality aspects included in the product information for vaccines for human use***

The guideline describes the information on the quality aspects to be included in the Product Information of vaccines for human use.

**Deadline – 31st July 2018**

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

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

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

**Deadline – 31st July 2018**

More information [HERE](#) <sup>[20]</sup>

***EMA- Draft addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections to address paediatric-specific clinical data requirements***

This addendum to the Guideline has been developed to provide specific guidance on paediatric clinical development programmes that are required to support the authorisation of antibacterial agents for treatment of infectious diseases in paediatric patients. This Addendum provides guidance on clinical data requirements to support the approval of an antibacterial agent to treat infectious diseases in paediatric patients, both when extrapolation of efficacy from adults (source population) to paediatric patients (target population) is possible, and when this is not the case.

**Deadline – 30th August 2018**

More information [HERE](#) [21]

### ***EMA- Draft guideline on clinical evaluation of vaccines***

This guideline addresses the clinical evaluation of vaccines intended for the prevention of infectious diseases. It includes considerations for trials intended to document the safety, immunogenicity and efficacy of new candidate vaccines and to support changes in the prescribing information of licensed vaccines. It also considers the need for and use of vaccine effectiveness studies.

**Deadline – 30th October 2018**

More information [HERE](#) [22]

5 June 2018

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#### **Links**

[1] <http://www.eahp.eu/newsletter/subscribe> [2] <http://statements.eahp.eu/statements/final-statements> [3] [http://www.eahp.eu/sites/default/files/eahp\\_survey\\_report\\_2017-18.pdf](http://www.eahp.eu/sites/default/files/eahp_survey_report_2017-18.pdf) [4] [http://www.eahp.eu/sites/default/files/eahp\\_statements\\_survey\\_2017.pdf](http://www.eahp.eu/sites/default/files/eahp_statements_survey_2017.pdf) [5] <http://www.medicinesshortages.eu/> [6] <http://www.cost.eu/> [7] <https://www.eahp.eu/contact/nenad.hedren@gmail.com> [8] <https://www.eahp.eu/contact/nenad.miljkovic/iohbb.edu/rs> [9] <https://docs.google.com/forms/d/e/1FAIpQLSdVaEZoV3UdW-40iRt0AzosxlGeEB2QtMytjhB5nGVH0aSpKQ/viewform> [10] <https://ecdc.europa.eu/sites/portal/files/documents/One-Health-preparedness-24-May-2018.pdf> [11] [https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg\\_2006\\_1902/reg\\_2006\\_1902\\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2006_1902/reg_2006_1902_en.pdf) [12] <http://www.eahp.eu/news/EU-monitor/eahp-eu-monitor-7-november-2017> [13] [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2018/05/WC500249617.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2018/05/WC500249617.pdf) [14] <https://ec.europa.eu/digital-single-market/en/news/synopsis-report-public-consultation-digital-transformation-health-and-care-context-digital> [15] <https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering> [16] [http://www.eahp.eu/sites/default/files/accepted\\_position\\_paper\\_on\\_ehealthmhealth\\_revision\\_including\\_date\\_of\\_agreement](http://www.eahp.eu/sites/default/files/accepted_position_paper_on_ehealthmhealth_revision_including_date_of_agreement) [17] <http://ejhp.bmj.com/content/early/2018/05/24/ejhpharm-2017-001451> [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] [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) [21] [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) [22] [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)