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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]



### Statement implementation developments and future plans

Adopted in 2014 with the collaboration of EAHP's 34-member country associations (Montenegro joined in 2016) and more than 30 patient and professional healthcare organisations, the European Statements of Hospital Pharmacy are patient driven and represent what every European healthcare system should aim for in the delivery of hospital pharmacy services to improve patient outcomes.

EAHP is now working to implement the European Statements within its 35 member countries. Since the approval of the project by our members during the 46th General Assembly in Prague (June 2016) the Statement implementation team has progressed the following actions:

- Developing a Strategic Implementation Plan;
- Creating strong support of national implementation networks (33 national associations are represented through their national implementation ambassadors);
- Designing an awareness campaign;
- Setting up a Statement Implementation website;
- Approaching European and national relevant stakeholders;
- Designing national implementation strategies; and,
- Building up resources to help hospital pharmacists and other healthcare professionals to move towards implementation.

EAHP is also working on two major initiatives: the development of a self-assessment tool and the setting up of a network of Statement Implementation Learning Collaborative Centres (SILCC).

The self-assessment tool is an online tool that will allow hospital pharmacists to assess the level of implementation within their hospitals and will provide them with an individualised action plan to assist them during the implementation process. The online tool will be available in October. It will be officially launched during the 23rd EAHP Congress in Gothenburg (21-23 March 2018).

The set-up of SILCCs involves the identification of hospitals willing to provide training to hospital pharmacists within EAHP's member countries in procedures related to the Statements. Like the self-assessment tool the SILCC initiative will be launched during the next EAHP Congress in Gothenburg.

Do you want to learn more about the Statements and the Implementation project? Do you want to collaborate with EAHP and your national association to help your countries and others moving towards the implementation of the Statements? Send us an email at Statements[at]eahp[dot]eu [2] and visit our new website www.statements.eahp.eu [3]!



#### Final report of ARNA project published

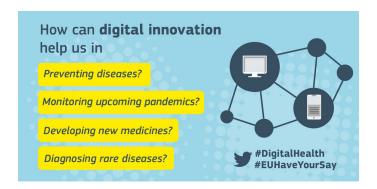
The antimicrobial resistance and the causes of non-prudent use of antibiotics (ARNA) project published its final report which estimates that 7% of antibiotics consumed in the European Union are taken without a prescription. The report marks the end of the project which overall aimed at assessing the non-prudent use of antibiotics in the EU and encouraging policies that lead to a more prudent use of antibiotics.

The highest rates of non-prescription use of antibiotics were found in Romania (20%) and Greece (16%), while the use of antibiotics without a prescription increased between 2013 and 2016 in Bulgaria, Cyprus, Croatia, Finland, Germany, Latvia, Lithuania, and Poland. Lack of knowledge among patients and pressure on healthcare professionals to provide antibiotics without prescription were highlighted as two key factors contributing to this issue. It was also found that pharmacists in smaller pharmacies seem more likely to dispense antibiotics without a prescription. Countermeasures such as the enforcement of laws banning over the counter sales of antibiotics did not seem to always be effective.

The report did not only analyse the non-prescription use of antibiotics but also explored good practice initiatives and policy measures enhancing more prudent use of antibiotics. 14 EU Member States have already published national action plans addressing antimicrobial resistance, while 26 have a surveillance system and a set of activities to promote prudent antibiotic use in place. Further efforts to improve patients' education, develop clear guidelines to healthcare professionals and promote a close collaboration between general practitioners and pharmacists are recommended by the report to tackle this issue. In addition, the report calls for multi-faceted campaigns implemented at national level as well as better enforcement of laws in EU countries where antibiotics are available over the counter without prescription.

The report is available HERE [4]

More about the ARNA project HERE [5]



#### Commission consultation on digital health

The European Commission launched a public consultation on how Europe should promote digital innovation in health and care, for the benefits of citizens and health systems in Europe. The results of the consultation will feed into a new policy Communication that is planned to be adopted by the end of 2017. This policy Communication should as mentioned by the recent Digital Single Market Mid-term Review [6] addresses the need and scope for measures on digital health and care, in line with legislation on the protection of personal data, patient rights and electronic identification.

The consultation is open to citizens, patient organisations, health and care professionals, public authorities, researchers, industries, investors, insurers and users of digital health tools. It will collect information on three main pillars:

- Citizens' secure access to their health data and the possibility to share it across borders, clarifying citizens' rights and enhancing interoperability of electronic health records in Europe;
- 2. Connecting and sharing data and expertise to advance research, personalise health and care, and better anticipate epidemics;
- 3. Using digital services to promote citizen empowerment and integrated person-centred care.

Views on digital innovation in health and care can be shared via <u>EU Survey</u> [7] until 12 October 2017.

More information about the consultation HERE [8]



EPHA – EU do more for health campaign

European Commission President Jean Claude Juncker earlier this year presented a White paper on the future of Europe [9], outlining 5 scenarios. In these scenarios, the option to "do less" on some policy areas is contemplated. This could lead to less EU action on health after 2020. The European Public Health Alliance (EPHA), the European Patients' Forum (EPF) and

a coalition of organisations which includes the European Association of Hospital Pharmacists (EAHP) have teamed up to express their concerns in a letter to European Commission President, Jean Claude Juncker.

As mentioned in the <u>EU Monitor of 21st June [10]</u>, the group calls for an enhanced EU action in the field of health that brings the EU closer to its citizens, by protecting patients and consumers and improving people's health as well as for EU action on health that fosters cross-country collaboration, integrates the action of Member States and helps them to address the unprecedented challenges we are facing.

To achieve this the authors of the letter are requesting a meeting with Commissions President Jean-Claude Juncker to discuss their concerns and ideas regarding a robust EU Health Programme and the leadership of a dedicated Directorate in the European Commission.

Read more about the #EUforHealth campaign and join it on EPHA's website [11]



### **Survey - 3D Printing in Hospital Pharmacy**

A PhD candidate of UCL School of Pharmacy whose research focuses on using 3D printing to manufacture solid oral dosage form is currently looking for hospital pharmacists interested in participating in a survey. To examine the clinical application of 3D printing, she would like to explore the opinions of hospital pharmacists about the medicines that could benefit from this technology. Information is gathered via a short questionnaire.

Further information about 3D printing in hospital pharmacy can be read in an article published in the Pharmaceutical Journal (2015), which can be accessed by clicking here [12].

The survey is available HERE [13]



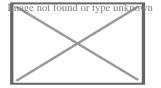
EJHP: Incompatible intravenous drug combinations in

#### routine paediatric intensive care

The online first edition of the European Journal of Hospital Pharmacy (EJHP) has published a short report on a study in routine paediatric intensive care. The study analysed intravenous drug incompatibilities in a university paediatric intensive care unit using a database. In addition, physician and nurse knowledge of incompatibilities was assessed. The report suggests the urgent implementation of quality improvement strategies by pharmacists since one in 10 patients was affected by drug incompatibility.

More HERE [14]

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#### **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 [15]

## 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 [16]

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 [17]

#### 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** [18]

# 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 [19]



### **Upcoming events**

#### 7<sup>th</sup> September – EPHA 8th Annual Conference: Make Health Your Business [20]

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.

#### 26<sup>th</sup> September – EMA: Public hearing on valproate [21]

London, United Kingdom

The hearing of the European Medicines Agency (EMA) is part of an ongoing review of valproate-containing medicines in the treatment of women or girls who are pregnant or of childbearing age. 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. Those unable to attend the hearing in person can follow the live broadcast on EMA's website.

### 1<sup>st</sup> October - 12<sup>th</sup> European meeting of Women Pharmacists [22]

The 12th European meeting of Women Pharmacists will cover all pharmacy sectors with a focus on broadening horizons and knowledge. EAHP President Joan Peppard will be part of a workshop on career advancement that will focus on new roles and qualifications required in hospital pharmacy.

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#### Links

[1] http://www.eahp.eu/newsletter/subscribe [2] https://www.eahp.eu/contact/Statements/eahp/eu [3] https://www.eahp.eu/www.statements.eahp.eu [4]

https://ec.europa.eu/health/amr/sites/amr/files/amr\_arna\_report\_20170717\_en.pdf [5]

https://www.nivel.nl/en/arna [6] https://ec.europa.eu/digital-single-market/en/content/mid-term-review-

digital-single-market-dsm-good-moment-take-stock [7]

https://ec.europa.eu/eusurvey/runner/Public\_consultation\_Transformation\_Health\_Care\_DSM[8]

https://ec.europa.eu/info/consultations/public-consultation-transformation-health-and-care-digital-single-market\_en [9] https://ec.europa.eu/commission/sites/beta-

political/files/white\_paper\_on\_the\_future\_of\_europe\_en.pdf [10] http://www.eahp.eu/news/EU-

monitor/eahp-eu-monitor-21-june-2017-0 [11] https://epha.org/eu-do-more-for-health-campaign/ [12]

http://www.pharmaceutical-journal.com/news-and-analysis/features/3d-printing-the-future-of-

manufacturing-medicine/20068625.article [13] https://www.surveymonkey.co.uk/r/X5RYKCN [14]

http://ejhp.bmj.com/content/early/2017/07/23/ejhpharm-2017-001248 [15]

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[17]

http://www.ema.europa.eu/ema/doc\_index.jsp?curl=pages/includes/document/document\_detail.jsp?webContentId=V [18] https://ec.europa.eu/eusurvey/runner/clinical\_data\_publication\_survey [19]

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https://epha.org/epha-2017/[21]

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\_and\_events/news/2017/07/news\_detail\_002774.jsp&am [22] http://vaaoe.at/events/detail/ewpm2017