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Home > EAHP EU Monitor - 24 March 2014

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 <u>here [1]. [1]</u>



EAHP launch

2014 medicines shortage survey

The European Association of Hospital Pharmacists (EAHP) has launched its **2014 survey on medicines shortages in Europe** [2].

It will be open for 7 weeks, closing at midnight CET on 7th May 2014.

More information here [3].

European Medicines Agency publishes 2014 work plan

Work programme 2014

Adopted by the Management Board on 12 December 2013

The European Medicines Agency (EMA) has published its work progamme for 2014 which includes enhancing the functionalities of the **Eudravigilance** [4] database of adverse drug reactions, addressing the issue of antimicrobial resistance and continuing implementation of its action plan on medicines shortages.

The first priority of the agency remains the evaluation of pan-European marketing authorization applications of new human medicines [5].

Defined objectives for 2014 in this area include:

- the promotion of scientific advice for innovative methodologies such as biomarker qualification; and
- the development of common clinical and methodological guidelines, trial design and modeling approaches with the aim of reducing time-to-patient of medicinal products and development costs.

Supporting parallel HTA scientific advice, and new approaches for stem-cell technology and nanotechnologies are also explicitly mentioned targets for 2014.

In a newer area of EMA activity, **its responsibilities for pharmacovigilance** [6] under a 2010 Directive, the Agency will aim to:

- develop "guidance and methodological standards for the design, conduct and analysis of post-authorisation safety and efficacy studies"
- create "evidence-based tools for the visualisation of the benefit-risk of medicinal products, to support assessment and transparency of decision-making" and
- improve "the quality of data in the EudraVigilance system, including timely updating of the database with new information".

In other areas, the EMA's workplan for 2014 commits to:

- developing clinical guidance to support development of new treatments for multiresistant bacteria; and
- •continuing "the implementation of the action plan on medicines shortages due to manufacturing deficiencies, including the development of recommendations for better and proactive risk management by Marketing Authorisation Holders, to avoid supply shortages of medicines and raw materials."

Furthermore, the Agency will seek to "improve the EU process for handling GMP noncompliance situations, including related supply shortages, and its interaction with global regulatory partners."

On the contested issue of clinical trial result transparency, the EMA undertakes to launch a new policy "on proactive publication of clinical trials, considering the outcomes of the [European] court case and legislative proposals [i.e. the proposed EU Clinical Trials regulation]."

More information here [7]:



European elections look ahead: patient

groups publish manifestos

In the first of a series of summaries, this week's EAHP EU Monitor picks out highlights from policy manifestos published ahead of the European Parliament elections in May.

We start with those communicated by European patient organisations.

European Patients Forum

The European Patients' Forum [19] is the primary umbrella representative organization for the patient interest in Europe, counting 150 million patients among its remit. It makes 3 broad calls to individuals standing for election to the next European Parliament:

- 1. Equal and timely access to safe, effective diagnosis, treatments and support
- 2. Better information and resources for patients to be partners in determining their care
- 3. A patients' voice to be heard in Brussels and throughout the European Union

More information here [9].

European Federation of Allergy and Airways Disease Patients (EFA)

The EFA [10] was established in 1991 as a European network for patient associations specialising in allergy and asthma. Their manifesto for the 2014 European Parliament elections includes calls for:

- 1. An EU strategy on chronic disease conditions with disease specific chapters
- 2. A stricter Directive on tobacco control
- 3. Reduced health inequalities as regards access to care and quality of treatment within and between Member States
- 4. Increased participation of patients in decision-making in all areas relating to their health and wellbeing
- 5. Strengthened patient safety
- 6. Improved accuracy and quality of information to patients, and increased health literacy

More information here [11].

European Liver Patients Association (ELPA)

ELPA [12] is the primary organization at the European level representing the interests of people with liver disease. Its manifesto of policy recommendations for the 2014 European Parliament elections includes:

- 1. Improved systems for the early diagnosis of a possible liver problem e.g. via enzyme testing as a mandatory component of a routine medical check up
- 2. Universal access to vaccination programmes for hepatitis A and B
- 3. Taxation and pricing measures to discourage alcohol abuse, as well as sales restrictions, warning labels and advertising controls

The manifesto also discourages external reference pricing for innovative drugs in areas of medical need, and further increases in Europe's Research and Development investment in the area of health.

More information here [13].

AGE Platform Europe

AGE Platform Europe [14] is a European network of around 167 organisations of and for people aged 50+ which aims to voice and promote the interests of the 150 million senior citizens in the EU.

On health matters, their European Parliament election manifesto calls for elected MEPs to:

- 1. Guarantee the adequacy, fairness and sustainability of Europe's social and health protection systems
- 2. Support the right to grow and age in good mental and physical health
- 3. Protect the right for all to live and die in dignity

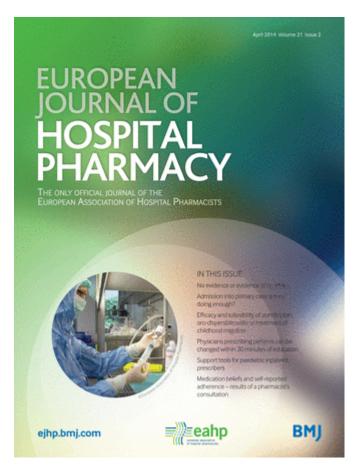
More information here [15].



Not had an opportunity to register for the 19th Congress of the EAHP [16] online?

Don't worry – its still possible to register on site.

See this short guide to find out how [17].



EJHP: Beliefs about medicines among Norwegian outpatients with chronic cardiovascular disease

An open access article in the **April 2014 edition** [18] of the European Journal of Hospital Pharmacy provides a summary of an investigation into the beliefs of Norwegian outpatients about medicines.

A survey (using the Beliefs about Medicines Questionnaire) was conducted of 150 patients from an Oslo outpatient clinic for chronic cardiovascular diseases.

The conclusion of the study drew on the finding that although the majority of patients in this study believed in the necessity of their medicines, one-third had strong concerns about their medicines: "As this may influence adherence and the outcome of therapy, this should be addressed when counselling about medicines".

More information here [19].

Links

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

https://www.surveymonkey.com/s.aspx?sm=tetwVENIJ8xiZPWj3Edo5sPr7L8%2bD44SVyz%2bqs6yYaA%3d [3] http://www.eahp.eu/press-room/eahp-launch-2014-survey-medicines-shortages-europe[4] https://eudravigilance.ema.europa.eu/highres.htm [5]

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000109.jsp[6] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000199.jsp [7]

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