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

You can subscribe to the EAHP EU Monitor ***here*** *[1]. [1]*

Hospital pharmacists signal support for centralised authorisation of high risk medical devices


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EAHP has published **a policy statement** [2] on the issue of medical device regulation in Europe offering support for a system of central authorisation for high risk (class III) medical devices as a proportionate measure to ensure high level scrutiny of device safety.

EAHP is concerned about evidence that device approval standards have been inconsistently applied by Europe's national level approval authorities (or 'notified bodies'), as well as **reported disparities in the standards of assessment for high risk devices between the USA and Europe** [3]. Whilst EAHP recognise that devices cannot necessarily be considered in the same manner as pharmaceutical products, the Association views that a distinctive case for centralised authorisation procedures for Class III devices exists (i.e. those devices that support or sustain human life).

More information here [4]

FIP announce theme of 2013 World Pharmacist day

The **International Pharmaceutical Federation (FIP)** [5]has announced that the theme of this year's **World Pharmacist Day** on 25 September is '*Pharmacists - simplifying your medicines use, no*

matter how complex'

Both FIP and EAHP encourage pharmacist organisations to create public awareness campaigns, events and press releases that educate patients and the general public on how

pharmacists are the key to making all medicines and their use more manageable.

EAHP member associations may contact the EAHP secretariat for support on ideas and materials to help promote hospital pharmacy in their country by emailing richard [dot] price [at] eahp [dot] eu.

FIP announcement **here** [6]

EFPIA ask for commercial confid n in clinical trial transparency debate

Hosting **an event in Brussels** [7] for stakeholders this week, the representative body for the pharmaceutical industry called for commercial confidentiality issues to be better appreciated when considering the issue of enhanced clinical trial result transparency.

The European pharmaceutical industry association EFPIA has recently published a set of **ethical commitments on clinical trial transparency** [8]and invited stakeholders to discuss these, alongside the current **European Medicines Agency consultation** [9] on trial result reporting, and the current proposal for **a new European clinical trial regulation** [10] making its way through the European Parliament.

On the pressing issue of how far ‘commercial confidentiality’ should be interpreted, EFPIA Director Richard Bergstrom told the audience: “We don’t want our competitors to learn too quickly about how we go about the clinical trials. We believe that a framework which is run by the industry itself is much more likely to take care of these balances.”

Ben Goldacre, author of the book Bad Pharma, also took part in the discussion and questioned the extent to which the recently published industry principles met the real and identified needs for transparency, including retrospective publication of trial results (20 years).

Hans-Georg Eichler, senior medical officer at the European Medicines Agency (EMA) discussed the benefit risk equation when thinking about greater transparency about clinical trials results and deemed the equation to be firmly on the side of benefit, with identified risks, such as misreading of data, able to be managed by regulators and others.

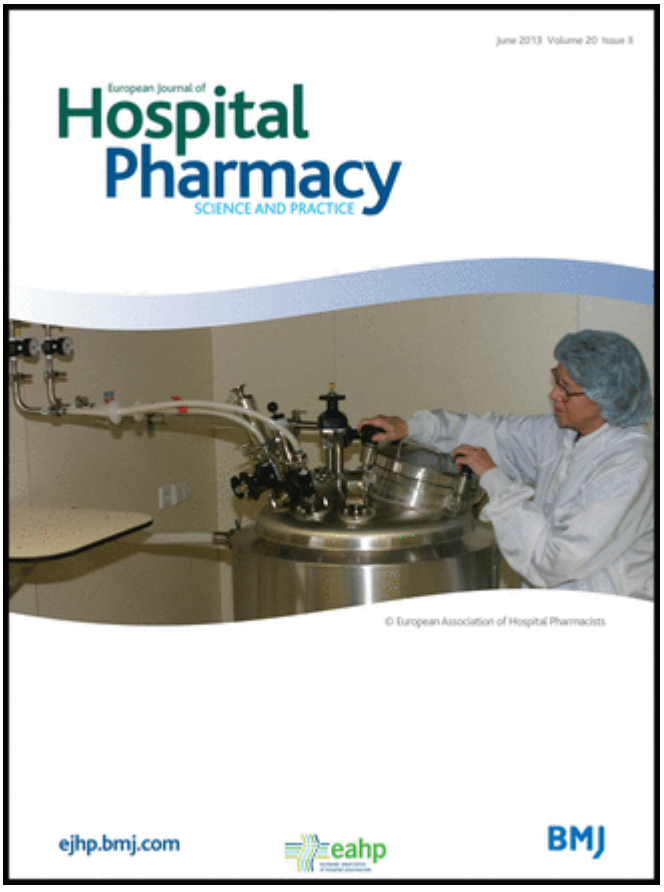
More information about the proceedings of the debate **here** [11].

Richard Bergstrom's reflection on the event **here** [12].

EFPIA also published this week the results of a patient survey on attitudes to clinical trial data publication. More information **here** [13].

The European Medicines Agency's consultation on clinical trial transparency closes on 30 September. More information **here** [9].

EAHP is a signatory to the AllTrials campaign. More information, including the petition that individuals may sign, is **here** [14].



EJHP: Doing better on anticoagulation therapy!

The **online first edition of the European Journal of Hospital Pharmacy** [15] has published an original research article which examines the results of a review of anticoagulant therapy.

The review was performed to elucidate the number and nature of medication errors with anticoagulants and to look at possibilities for improving anticoagulant therapy.

Full article **here** [16].

30 August 2013

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://www.eahp.eu/sites/default/files/files/EAHP%20Devices%20statement%20August%202013.pdf [3] http://www.elsevierbi.com/~/media/Supporting%20Documents/The%20Gray%20Sheet/38/20/FDA_EU_Devices_Rep [4] http://www.eahp.eu/press-room/hospital-pharmacists-give-support-centralised-authorisation-high-risk-medical-devices [5] http://www.fip.org/ [6] http://www.fip.org/www/index.php?page=news_publications&news=newsitem&newsitem=143 [7] http://vitaltransformation.com/2013/08/a-roadmap-for-sharing-clinical-trial-data/ [8] http://www.efpia.eu/mediaroom/114/43/EFPIA-and-PhRMA-Release-Joint-Principles-for-Responsible-Clinical-Trial-Data-Sharing-to-Benefit-Patients [9] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001825.jsp&am [10] http://ec.europa.eu/health/human-use/clinical-trials/ [11] http://www.euractiv.com/health/health-experts-critical-pharma-i-news-529991 [12] http://www.efpia.eu/blog/86/51/27-August-2013-A-Roadmap-for-Sharing-Clinical-Trial-Data [13] http://www.efpia.eu/mediaroom/117/44/Publication-of-Results-of-EFPIA-PhRMA-commissioned-Patient-Stakeholder-survey [14] http://www.alltrials.net/ [15] http://ejhp.bmj.com/content/early/recent [16] http://ejhp.bmj.com/content/early/2013/08/21/ejhpharm-2013-000295.full