eahp 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 ***here*** *[1].* *[1]*

Good Practice

Initiatives: Don’t miss the chance to share your success with European colleagues!

The EAHP reminds hospital pharmacists around Europe that they have until the **15th October** to submit Good Practice Initiatives (GPIs) they have been involved with for exhibition and exposure at the 20th Congress of the EAHP in Hamburg (25-27 March 2015).

The concept behind GPIs is to assist and inspire practice improvement in all hospital pharmacy settings in Europe by sharing the stories of improvement achieved elsewhere. With the new European Statements of Hospital Pharmacy [2] now in place, EAHP also seeks to explicitly link GPIs with individual statements in order to better illustrate how the statements can be achieved.

At the closing ceremony of the Hamburg Congress an award will be presented to the GPI submission considered to be of highest learning value and relevance to the European Statements of Hospital Pharmacy. The award prize includes free registration to the 2016 EAHP Congress.

All Good Practice Initiatives are requested – whether the improvement achievement was of a small or large nature. Indeed, the more transferable the improvement, the better!

More information about the Good Practice Initiatives programme is available here [3].

Additional to this, a range of approved GPIs from the 2014 Congress are now available to view on the EAHP website here [3].

A video explaining the background and concept of EAHP's Good Practice Initiative exercise is available here [4].

European Parliament scrutinise Juncker's proposed Commission

The European Parliament has held Committee hearings with **Jean Claude Juncker's proposed team** [5] for the European Commission 2014-19. The Commissioner delegates of highest interest to hospital pharmacy are those for Health (**DG SANCO** [6]) and the new combined Industry, Enterprise and Internal Market portfolios.

Mr Vytenis Andriukaitis, Commissioner Designate for DG SANCO

First up was the Commissioner designate for DG SANCO (Health and Consumers), Mr **Vytenis Andriukaitis** [7], on 30th September 2014. The former Lithuanian Health Minister and surgeon was inevitably questioned for his views on the significant reduction made to his portfolio by the transfer of responsibilities for pharmaceutical and medical device issues to a new joint Industry, Enterprise and Internal Market Directorate General (DG). He gave a diplomatic response, expressing confidence that cooperation between the two DGs would ensure good operation of the EU's competencies in these areas.

Asked about his priorities, he gave strong onus to the need for DG SANCO to support member states in making their health systems more efficient and innovative in order to remain financially sustainable. This would include enhancing efforts in the area of prevention, including ensuring robust implementation of the recent **Tobacco Products Directive** [8]. Other priorities will include overseeing full implementation of the **cross border healthcare directive** [9] and **cooperation between member states on health technology assessment** [10].

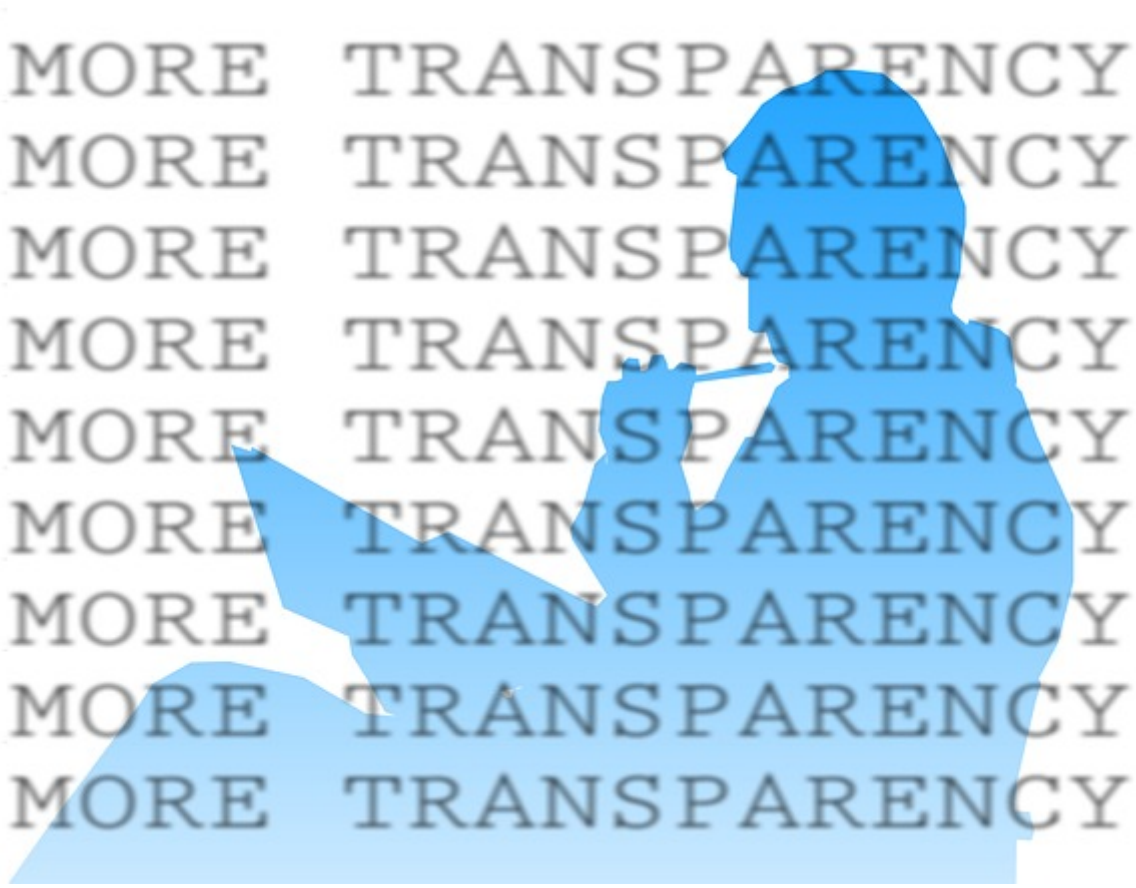
Written answers from Mr Vytenis Andriukaitis **here** [11]**.**

Ms Elzbieta Bienkowska, Commissioner Designate for DG Internal Market, Industry, Entrepreneurship and SMEs

Next up, Ms **Elzbieta Bienkowska** [12], the former Polish infrastructure minister, met with the Parliament in a hearing unsurprisingly dominated by economic questions, including the role of the European Commission in supporting small and medium enterprises.

Asked to respond to criticisms of the move of pharmaceutical and medical device technology from DG SANCO into her super-sized DG, she replied: *"Placing pharma policy in DG Enterprise was justified. It has traditionally been in DG Enterprise, but was moved to DG Sanco and has once again been instated as an Enterprise competence"*. She cited the need to protect innovation in Europe's pharmaceutical industry but also sought to reassure concerns by describing herself as *"totally and absolutely immune to lobbying"*. She went further by adding: *"In the health products sector, let me assure you that guaranteeing the health of our patients and citizens' will be my full and leading concern. Health and safety come first! And I intend to closely work on all health matters with my colleague Vytenis Andriukaitis, the designated Commissioner for Health."*

The European Parliament does not take individual votes on individual Commissioner designates, but rather takes a single plenary vote on whether to approve or reject the entire Commission team put forward by Jean Claude Juncker. With that dynamic in mind, commentators predict Juncker's proposed Commission is likely to receive an approving vote by the end of October, enabling them to assume office in November 2014.



EMA Management Board approve new clinical trials data disclosure policy

After lengthy consultation with stakeholders, **the Management Board of the European Medicines Agency** [13](EMA) has unanimously approved new policy to enable access to clinical study reports (CSRs) held by the Agency in respect of marketing authorisation applications. The new policy enters into force on 1 January 2015.

Guido Rasi, EMA Executive Director, said: *"The adoption of this policy sets a new standard for transparency in public health and pharmaceutical research and development. This unprecedented level of access to clinical reports will benefit patients, healthcare professionals, academia and industry."*

According to the policy's terms of use, the public can either browse or search the data on screen, or download, print and save the information. The reports cannot be used for commercial purposes. In general, the clinical reports do not contain commercially confidential information. Information that, in limited instances, may be considered commercially confidential will be redacted. The redaction will be made in accordance with principles outlined in the policy's annexes. The decision on such redactions lies with the Agency.

However, transparency campaigners remain concerned that too much responsibility for the redaction of information from the clinical study reports is placed with trial sponsors. Furthermore, they are concerned that the Terms of Use contract that researchers must sign opens up too much risk of legal action being taken against researchers.

More information **here** [14].

Transparency campaigners' response **here** [15].

EJHP: Special Summit edition now online!

The European Journal of Hospital Pharmacy (EJHP) has published a special edition related to **the European Summit on Hospital Pharmacy** [16] (May 2014) and the 44 **European Statements of Hospital Pharmacy** [17] it produced.

The edition includes: reflections from participants and organisers; the future of EAHP's practice development activities; and, the highlights and findings of research conducted with EAHP members on improvement implementation challenges and hospital pharmacy metrics.

Full edition **here** [18].

8 October 2014

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://ejhp.bmj.com/content/21/5/256.full.pdf+html [3] http://www.eahp.eu/congresses/gpis#node_congress_gpis_group_gips_sub [4] https://www.youtube.com/watch?v=yeq-p0KbnWE [5] http://ec.europa.eu/about/juncker-commission/ [6] http://ec.europa.eu/dgs/health_consumer/index_en.htm [7] http://en.wikipedia.org/wiki/Vytenis_Andriukaitis [8] http://ec.europa.eu/health/tobacco/products/revision/index_en.htm [9] http://ec.europa.eu/health/cross_border_care/policy/index_en.htm [10] http://ec.europa.eu/health/technology_assessment/policy/index_en.htm [11] http://www.elections2014.eu/pdfs/new-

commission/hearings/20140910CAD60724/Hearings2014_Andriukaitis_Questionnaire_en.pdf [12] http://en.wikipedia.org/wiki/El%C5%BCbieta_Bie%C5%84kowska [13] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000098.jsp [14] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/10/news_detail_002181.jsp&am [15] http://www.alltrials.net/news/ema-removes-some-restrictions-from-its-data-sharing-policy/ [16] http://www.eahp.eu/events/european-summit/intro [17] http://www.eahp.eu/events/european-summit/summit-documents [18] http://ejhp.bmj.com/content/21/5.toc