eahp euMonitor

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

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Commission, Council and European Parliament agree content of new EU trials regulation

At the end of December 2013, the European Commission, Council of Ministers (representing EU Governments), and the European Parliament **reached agreement** [2] on the terms of a new EU clinical trials regulation.

The new regulation will replace the current, and much criticized, 2001 Directive on the operation of clinical trial authorisation procedures within the EU.

The new Regulation is aimed primarily at dealing with criticisms that the 2001 Directive created a more burdensome and bureaucratic environment for conducting clinical trials, with **evidence of a reduced number of trials taking place in Europe as a result** [3]. The new regulation will therefore:

- reduce the potential for member states to interpret requirements differently, which has lead in the past to duplication in assessment and authorization procedures for multi-national trials;
- create a single EU portal for trial assessment and authorization, under the authority of the European Medicines Agency; and,
- introduce more proportionate forms of regulatory requirement where a trial is considered to be of a lower risk profile (e.g. a trial into the extended use of an already licensed product).

The proposed regulation was originally published **in late 2012** [4]and was subject to scrutiny and review by the European Parliament over the course of 2013. At the end of this process, representatives of the European Parliament, led by **Glenis Willmott MEP** [5] (UK, Labour Party), conducted extended negotiations with Governments and the European Commission to agree the final content of its terms.

The European Parliament had been particularly keen to achieve improvements in the regulation in terms of public transparency of the clinical trials process. It succeeded in gaining amendments in areas such as:

- further requirements upon clinical trial sponsors to openly publish clinical study reports;
- ensuring that ‘lay summaries’ of trials will be produced by their sponsors and published openly; and,
- requirements that trial protocols include a description about how patients were involved in the design of the trial.

The trilogue agreement must now receive final endorsement from a full plenary meeting of the European Parliament, scheduled to take place on **12 March 2014** [6].

The text of the trilogue agreement of December 2013 is available **here** [7]**.**

[8]

In late November 2013 the European Medicines Agency (EMA) made available a new online catalogue containing information on medicine shortages that affect, or are likely to affect, more than one European Union (EU) Member State, where the European Medicines Agency has assessed the shortage and provided recommendations to patients and healthcare professionals across the EU.

However the catalogue does not give a complete overview of all medicine shortages occurring in the EU as the Agency consider that most of these are dealt with at a national level.

The catalogue is available via the human medicines section of the EMA website **here** [9].

New Joint Research Framework adopted by EU countries

On 3 December 2013, the EU Member States adopted **Horizon 2020** [10], the EU's framework programme for research and innovation for 2014-2020, following the European Parliament's approval of the Regulation establishing the programme on 21 November 2013.

The programme, with a budget of nearly €80 billion over seven years, is the biggest EU research programme yet, and the European Commission claims it is one of the biggest publicly funded programmes worldwide. Horizon 2020 aims to bring all EU-level funding for research and innovation under one roof and provide a single set of rules.

Horizon 2020 is built on three pillars: (i) Excellent Science; (ii) Industrial Leadership; and (iii) Societal Challenges.

Under the third pillar of Societal Challenges, around €1.21 billion will be dedicated to researching the challenge of ***'Health, demographic change and well-being'***. Although the work programme for this area is yet to be finalised and adopted, the following topics with open calls may be of interest to hospital pharmacists involved in research:

- clinical research on regenerative medicine;
- foresight for health policy development and regulation;
- eHealth interoperability;
- comparing the effectiveness of existing healthcare interventions in the elderly;
- developing and comparing new models for safe and efficient, prevention oriented health and care systems
- understanding health, ageing and disease: determinants, risk factors and pathways;
- new therapies for chronic non-communicable diseases; and,

- advancing bioinformatics to meet biomedical and clinical needs.

Deadlines for funding applications fall in March and October 2014.

General information about Horizon 2020 is available **here** [11].

Information about currently open calls in the area of Health, Demographic Change and Wellbeing is available **here** [12].

Further information also available **here** [13].

EJHP: February edition now available!

The February edition of the European Journal of Hospital Pharmacy is now available! The edition contains articles including:

- an evaluation of the pharmacist's management of HIV patients;
- the impact on an electronic system on reducing errors related to vitamin K antagonists; and
- the production of ready to use cefuroxime syringes for opthalmology patients.

Please see also a short report on polypharmacy, especially in the elderly.

Edition available **here** [14].

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://europa.eu/rapid/press-release_MEMO-13-1190_en.htm [3] http://ec.europa.eu/health/files/clinicaltrials/2012_07/press-releases/ip-12-795_en.pdf [4] http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm#rlctd [5] http://www.europarl.europa.eu/meps/en/35743/GLENIS_WILLMOTT_activities.html [6] http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2013/0243(COD) [7] http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/dv/envi20140122_clinical_trials_/envi2014012 [8] https://www.eahp.eu/sites/default/files/files/Shortagespicture(2)(1).jpg [9] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000376.jsp&am [10] http://ec.europa.eu/programmes/horizon2020/ [11] http://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020 [12] http://ec.europa.eu/programmes/horizon2020/newsroom/548/495 [13] http://www.eahp.eu/content/horizon-2020-health-related-project-calls [14] http://ejhp.bmj.com/content/21/1.toc