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

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

EAHP President: Europe cannot be complacent about the TB challenge

Speaking in advance of World Tuberculosis (TB) day (24 March), Dr Roberto Frontini, President of the European Association of Hospital Pharmacists (EAHP), has warned European healthcare system managers and policy makers to take proactive measures now to meet the growing problem of Multi-Drug Resistant TB and the emergence of Extensively-Drug Resistant TB.

Dr Frontini highlighted 5 measures currently available to policy-makers to make a meaningful contribution to meeting the TB challenge…

More information **here** [2]

European Parliament considers the pros and cons of clinical trial data transparency

Two of the European Parliament's Committees scrutinising Commission proposals for improving clinical trial regulation voted on draft opinions this week, with transparency of result reporting a prime consideration.

Romanian ALDE MEP Dr Christian Silviu Busoi is the Internal Market Committee (IMCO)'s lead rapporteur on the subject file and delivered a draft opinion that focused on issues such as ensuring due and proper ethical assessment of a trial and the categories of information to

be included in the summary of a trial's results. The Committee supported most of the proposed amendments.

The second Committee to vote on its opinion was the Industry and Research Committee (ITRE). The lead rapporteur rMichèle Rivasi, a Green MEP from France, was unsuccessful in passing all her suggested amendments in respect of increasing transparency for and access to data gained from clinical trials involving humans. Although the Committee did not provide formal reasoning as to why her suggested amendments on transparency were rejected, critics of widespread access to clinical trials data have said that demanding too much information from researchers can overburden them unnecessarily. Critics also suggest such access could also create data protection problems, intellectual property conflicts and could harm competition between companies.

The lead Committee in the Parliament responsible for the scrutiny of the Commission proposals on clinical trial regulation is the Environment and Health Committee (ENVI), with the process being led by Glenis Wilmott (UK, PSE). The ENVI Committee will consider the opinion reports of the ITRE and IMCO Committees in the development of its final report. EAHP is working in collaboration with other health professional, patient and research organisations to scrutinize developments on this subject file and make suggestions for improvement where appropriate.

Recent Willmott and Busoi opinions reports and amendments available in European languages **here** [3].

Summary of ITRE proceedings **here** [4].

EMA CHMP gives positive opinions for new HIV & MS treatments

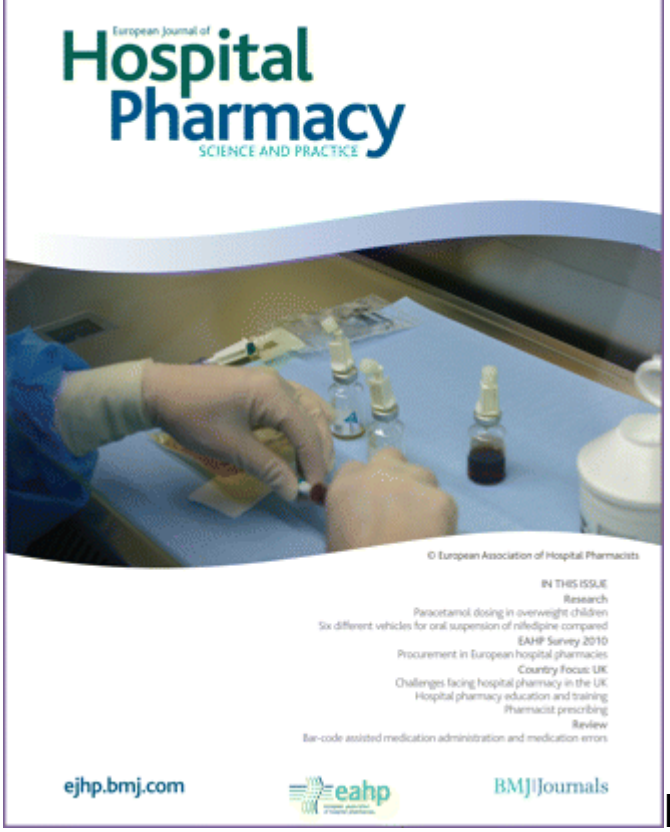
The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a number of positive recommendations for new Marketing Authorisations. It also recommended restricted use of Otsuka's Pletal (cilostazol) in the treatment of intermittent claudication.

At its March 2013 meeting the CHMP announced a positive opinion in respect of Gilead Sciences' Marketing Authorisation Application (MAA) for the once-daily, single tablet regimen Stribild® for the treatment of HIV-1 infection in adult patients who are antiretroviral-naïve or are infected with HIV-1 without known mutations associated with resistance to any of the three antiretroviral agents in Stribild.
A positive opinion was also given for Biogen's Tecfidera, or BG-12, and Sanofi's Aubagio for multiple sclerosis (MS). Both are pills, rather than injections.

The Committee also granted a Positive Opinion to Baxter for the use of HyQvia (solution for subcutaneous use) as replacement therapy for adult patients with primary and secondary immunodeficiencies. The product is a combination of human normal immunoglobulin (IGSC, 10%) and recombinant human hyaluronidase, which facilitates the dispersion and absorption of the IGSC.

The CHMP also recommended restricting use of Otsuka's Pletal (cilostazol) in the treatment of intermittent claudication. The regulator said a review, which was requested by the Spanish Agency for Medicines and Health Products (AEMPS), indicates that "the modest benefits of these medicines...are only greater than their risks" in a limited number of patients. The CHMP noted that side effects associated with the drug, which is also sold as Ekistol, include those affecting the heart and serious bleeding. As such, the regulator said that Pletal should only be used in patients whose symptoms had not improved despite lifestyle changes. In addition, the medicine should not be used in patients who have suffered severe tachyarrhythmia, or recent unstable angina, heart attack or bypass surgery, or who take two or more antiplatelet or anticoagulant drugs.

More information **here** [5].



EJHP: Quality Risk Management in Clinical Pharmacy

The online first edition of the European Journal of Hospital Pharmacy has this week published an interesting research article on quality risk management processes for the clinical pharmacy field.

The article considers:

- the purpose of risk control
- the use of risk analysis to implement suitable measures for risk reduction
- the application of guidelines from the International Conference on Harmonisation Quality Risk Management

Moreover, the article provides a useful overview of the role of the clinical pharmacist in risk management, medication safety and the prevention of errors.

Full article **here** [6].

22 March 2013

Links
[1] http://www.eahp.eu/newsletter/subscribe [2] http://www.eahp.eu/press-room/europe-cannot-be-complacent-about-tb-challenge [3] http://www.europarl.europa.eu/meetdocs/2009_2014/organes/imco/imco_20130320_0900.htm [4] http://www.researchresearch.com/index.php?option=com_news&template=rr_2col&view=article&artic [5] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/03/news_detail_001742.jsp&am [6] http://ejhp.bmj.com/content/early/2013/03/20/ejhpharm-2012-000254.full