

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

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EAHP Survey 2010 booklet now published!

EAHP SURVEY 2010

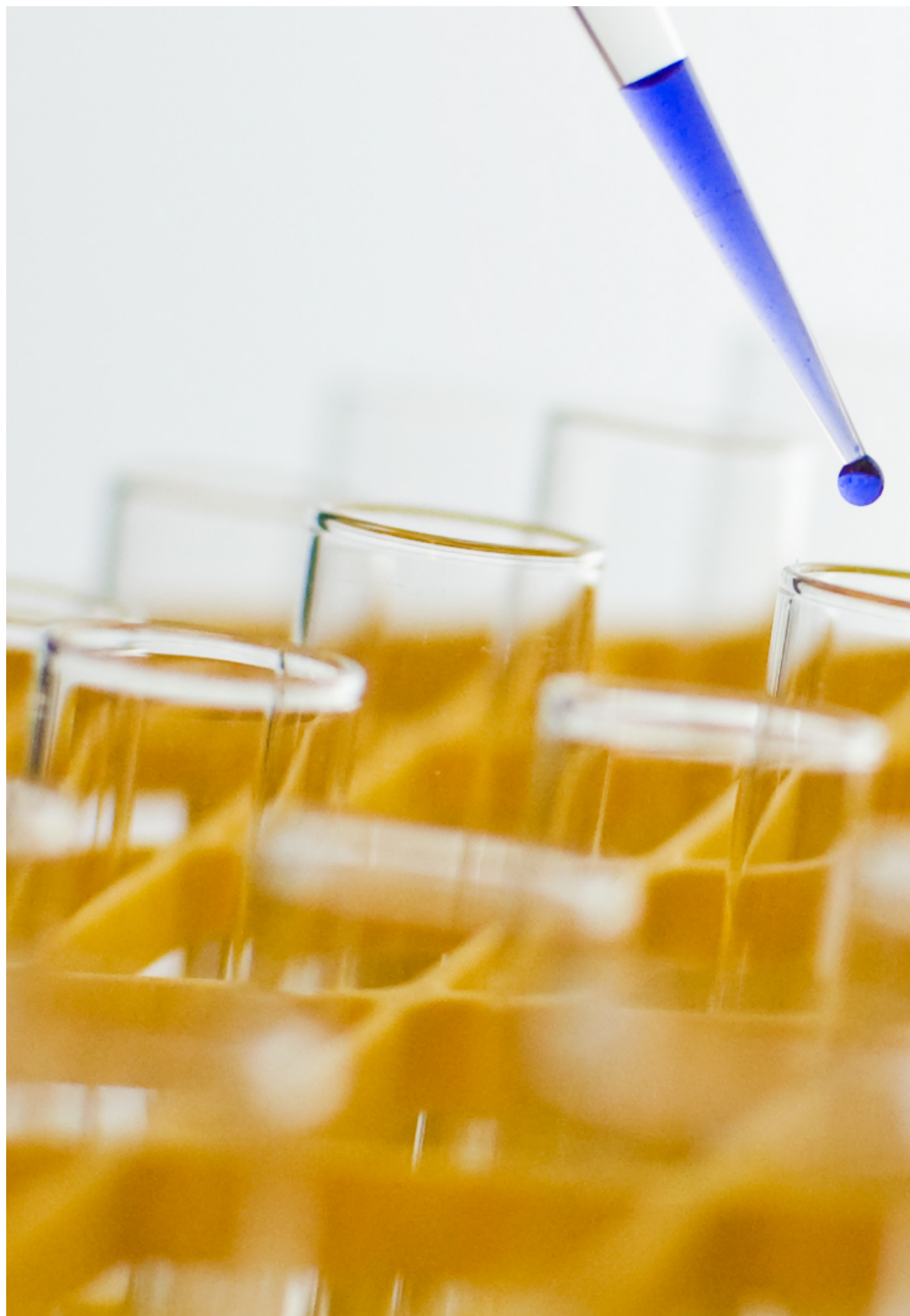
Hospital Pharmacy Practice in Europe



EAHP is proud to announce the publication of a new booklet which provides a detailed summary of the largest survey undertaken of hospital pharmacy practice in Europe.

More information [here](#) ^[2].

European Medicines Agency publishes consultation on trial transparency



The European Medicines Agency (EMA) has published a first draft of its policy on publication and access to clinical trial data and has asked for comments from stakeholders by 30th September 2013.

EMA has committed to the proactive publication of data from clinical trials submitted in support of a marketing-authorisation application, once the decision-making process has ended. EMA considers their proposed policy balances the commitment to give widest possible access to data for independent scrutiny with the need to protect personal data as well as legitimate commercially confidential information.

The consultation focuses on the categorisations and terminologies used in connection to information disclosure, especially what is, and is not, within the definitions of 'commercially confidential information', 'open access', and 'controlled access'.

Following consultation the new policy is expected to enter into force on 1st January 2014.

EAHP encourages responses from hospital pharmacists and others that support of greater transparency in the disclosure of clinical trial results.

More information [here](#) [3].

First two monoclonal antibody biosimilars receive EMA recommendation for approval



The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting of marketing authorisations for the first two monoclonal antibody biosimilars.

Remsima and Inflectra both contain the same known active substance, infliximab. In the application dossiers, they have been shown to be similar to the biological medicine Remicade, a monoclonal antibody that has been authorised in the European Union since 1999. Remsima and Inflectra are recommended for authorisation in the same indications as Remicade, covering a range of autoimmune diseases such as rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis.

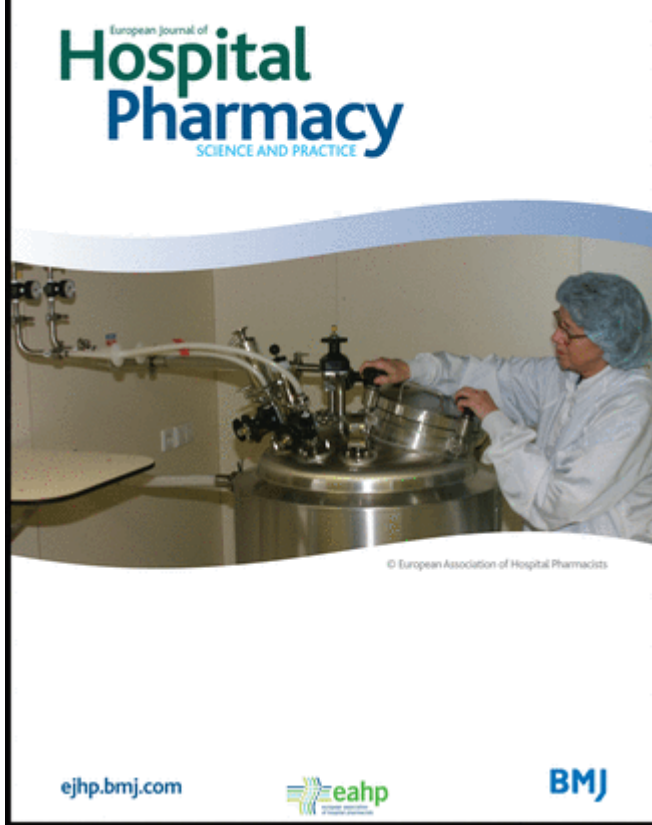
More information [here](#) [4].

The recommendation was made in the context of a meeting of the Committee of Medicinal Products for Human Use (CHMP) which met between 24 and 27 June. 8 other new medicines received positive approval, including 3 medicines for the treatment of cancer:

- Provenge, a cell-based therapy for the treatment of metastatic castrate-resistant prostate cancer
- Tafinlar, for the treatment of unresectable or metastatic melanoma with a BRAF V600 mutation
- Stivarga for the treatment of metastatic colorectal cancer

The CHMP also gave positive recommendations for the approval of Procysbi for the management of cystinosis and Lemtrada for the treatment of multiple sclerosis.

More information on all the decisions of the June 2013 CHMP meeting are available [here](#) [5].



EJHP: Implementing robotic storage

and distribution in a UK health authority

The online first edition of the EJHP has published an original research article on the implementation of robotic storage and distribution in a UK health authority.

The paper analyses the early-stage experiences (first 6 months) arising from the large-scale automation of medicines distribution, as part of a redesign programme of hospital pharmacy services within Greater Glasgow & Clyde health authority. The paper looks at how early stage implementation problems can be overcome, and the scale of benefits available from introducing such technology.

Full paper [here](#) [6].

4 July 2013

Links

[1] <http://www.eahp.eu/newsletter/subscribe> [2] <http://www.eahp.eu/press-room/european-hospital-pharmacy-survey-now-published> [3]

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001825.jsp&am [4]

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/06/news_detail_001837.jsp&am [5]

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[6] <http://ejhp.bmj.com/content/early/2013/07/04/ejhpharm-2013-000310.full>