

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

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# European Commission consult on hospital exemptions from advanced therapy regulation

**The European Commission are consulting stakeholders on the application of exemptions from regulation for advanced therapies that apply to their use in hospitals.**

The consultation follows the passage of a European Regulation relating to advanced therapies in 2007. The Regulation placed a requirement on the Commission to review the application of the Directive and produce a report. The consultation forms a part of the process for producing that report.

Importantly, the Commission are seeking views in particular on the application of exemptions from the regulation for advanced therapies in hospitals. See section 2.3.

The consultation document is available [here](#) [2].

The deadline for submitting responses is 31 March 2013.

## European Medicines Agency review Tredaptive, Pelzont and Trevaclyn

**The European Medicines Agency is commencing a review of the safety and efficacy of Tredaptive, Pelzont and Trevaclyn, identical medicines that are used to treat adults with dyslipidaemia**

The review was triggered because the Agency was informed by the pharmaceutical company Merck, Sharp & Dohme of the preliminary results of a large, long-term study comparing the clinical effects of adding these medicines to statins with statin treatment alone. The study raises questions about the efficacy of the medicine when added to statins, as this did not reduce the risk of major vascular events compared with statin therapy alone.

The Agency's Pharmacovigilance Risk Assessment Committee (PRAC) will assess the data and make a recommendation to the Committee on Medicinal Products for Human Use (CHMP), which will issue an opinion on the regulatory action required. An opinion is expected in January 2013.

While the review is ongoing, the Agency recommends that no new patients should be started on treatment with these medicines or enrolled in clinical trials involving these medicines, pending the outcome of the Agency's assessment.

Patients currently using Tredaptive, Pelzont or Trevaclyn should not stop their treatment. Patients who have any questions should speak to their doctor at their next appointment. More information [here](#) [3].

# EJHP: Editorial article on pain

The online first edition of the EJHP has published an editorial relating to a new initiative for a global year against pain.

EJHP Editor Phil Wiffen describes the opportunities within this for hospital pharmacists and discusses recent reviews of the use of analgesics and opioids.

Read the full article [here](#) [4].

## Congress Preview: Marianne Ivey discusses her keynote speech

In a special Congress Preview article, Dr Marianne Ivey talks to EAHP about her keynote speech on the hospital pharmacist's impact on patient care.

In particular, she discusses the challenges that hospital pharmacists can sometimes face in being heard by other professional colleagues, and some of the lessons from experience in overcoming such challenges.

Preview article [here](#) [5].

4 January 2013

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### Links

[1] <http://www.eahp.eu/newsletter/subscribe> [2]

[http://ec.europa.eu/health/files/advtherapies/2012\\_12\\_12\\_public\\_consultation.pdf](http://ec.europa.eu/health/files/advtherapies/2012_12_12_public_consultation.pdf) [3] [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2012/12/news\\_detail\\_001686.jsp&am](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/12/news_detail_001686.jsp&am)

[4] <http://ejhp.bmj.com/content/early/2012/12/24/ejhpharm-2012-000267.full> [5]

<http://www.eahp.eu/news/congress-preview-marianne-iveys-keynote-speech-hospital-pharmacists-impact-patient-care>