A number of recent announcements have been made by the European Medicines Agency (EMA). EAHP's EU Monitor presents a summary:

***Pharmacovigilance (1)***

On Friday 25th May the EMA held a meeting for stakeholders on the development of the Agency's role in pharmacovigilance following the passage of European legislation increasing their responsibilities in this area.
Key points from the meeting were:

- The EMA's new pan-European role in pharmacovigilance will be conducted through a Committee called the Pharmacovigilance Risk Assessment Committee (PRAC),which will hold its first meeting in July
- The Committee will operate in a transparent manner with minutes, agendas and other documents made publicly available
- It is intended that a form of measuring the impact of the Committee's work on pharmacovigilancewill be put in place. The form of measurement is not yet decided and may be subject to consultation in future
- There will be further calls for participation in this Committee from representatives from patient and health professional perspectives

***If you are a hospital pharmacist with a background in pharmacovigilance who could be interested in becoming a member of the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) please contact the Policy and Advocacy Officer Richard Price po[at]eahp[dot]eu [1].**

More information and documents from the meeting **here** [2].

***Pharmacovigilance (2)***

On Thursday31stMay the EMA beganpublishing suspected side effect reports for medicines authorised in the European Economic Area (EEA) on a new public website: www.adrreports.eu [3]. The reports come directly from the European Union (EU) medicines safety database EudraVigilance, and are one of the many types of data used by regulators to monitor the benefits and risks of a medicine once authorised. The launch of the new website is part of the Agency's continuing efforts to ensure EU regulatory processes are transparent and open and is a key step in the implementation of the EudraVigilance access policy.

More information **here** [4].

***CHMP decisions published***

On Friday 25thMay decisions of the most recent meeting of the EMA's Committee for Medicinal Products for Human Use (CHMP) were published. These included recommendations for:

- Eisai's epilepsy drug Fycompa (perampanel)
- Novo Nordisk's NovoThirteen (catridecacog) for the treatment of bleeding in patients six years and above with congenital factor XIII A-subunit deficiency
- Pfizer's Inlyta (axitinib) as a treatment for advanced renal cell carcinoma after the failure of treatment with the drug giant's own Sutent (sunitinib) or with cytokines
- BoehringerIngelheim's diabetes drug Jentadueto, which combines metformin with the DPP-4 inhibitor Tradjenta (linagliptin), which is partnered with Eli Lilly

More information **here** [5].
1 June 2012

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**Links**
[1] https://www.eahp.eu/contact/po/eahp/eu [2] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2012/05/event_detail_000582.jsp&a
[3] http://www.adrreports.eu/ [4] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/05/news_detail_001521.jsp&am
[5] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/05/news_detail_001508.jsp&am