# News from the EMA

## Activities of the CHMP

During its meeting from 11-14 April 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted:
**- two positive opinions** for the **granting of a marketing authorisation** for:

- **Bydureon** (exenatide), from Eli Lilly, intended for the treatment of type-2 diabetes in adults. The review for Bydureon began on 24 March 2010; active review time: 183 days.
- **Nulojix** (belatacept), from BMS Pharma EEIG, intended in combination with corticosteroids and a mycophenolic acid for prophylaxis of graft rejection in adults receiving a renal transplant. The review for Nulojix began on 24 February 2010; active review time: 210 days.

- **four positive opinions** for applications for **extensions of indications** for:

  - **Carbaglu** (carglumic acid), an orphan medicine from Orphan Europe S.A.R.L., to include the treatment of the following rare diseases: hyperammoniaemia due to isovaleric acidaemia, methylmalonic acidaemia or propionic acidaemia.
  - **Pradaxa** (dagibatran), from Boehringer Ingelheim International GmbH, to include the prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation.
  - **Ozurdex** (dexamethasone), from Allergan Pharmaceuticals Ireland, to include the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.
  - **Simponi** (golimumab), from Janssen Biologics B.V., to include the reduction of the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of psoriatic arthritis.

**- one positive opinion for an informed consent application for:**

- **Leganto** (rotigotine), from Schwarz Pharma Ltd, intended for the symptomatic treatment of moderate to severe idiopathic restless legs syndrome in adults and idiopathic Parkinson's disease. The review for Leganto began on 13 February 2011 with an active review time of 60 days. Reference product: Neupro from Schwarz Pharma.

**- one positive opinion for the following generic product:**

- **Rivastigmine Actavis**, from Actavis Group PTC ehf, intended for the symptomatic treatment of mild to moderately severe Alzheimer's dementia and mild to moderately severe dementia in patients with idiopathic Parkinson's disease. Reference product: Exelon from Novartis.

**- one positive opinion after the re-examination procedure for the extension of the indication for:**

- **Avastin** (bevacizumab), from Roche; the indications should be extended to include first-line treatment in combination with capecitabine of patients with metastatic breast cancer in whom treatment with other chemotherapy options, including taxanes or anthracyclines, is not considered appropriate**.**

**Pharmacovigilance:**

**Interim measures for Pandemrix:** The CHMP has recommended that the product information for Pandemrix (Influenza vaccine (H1N1)) (split virion, inactivated, adjuvanted), from GSK Biologicals S.A., should be amended to advise prescribers to take into account preliminary results from epidemiological studies on Pandemrix and narcolepsy, and to perform an individual benefit-risk assessment when considering the use of Pandemrix in children and adolescents. This is an interim measure pending the outcome of the European review expected to conclude in July 2011. After having reviewed all available data, including new findings from Sweden and France on the suspected link between narcolepsy in children and adolescents and Pandemrix the CHMP concluded that, following the earlier results of an epidemiological study from Finland, the new evidence strengthened the signal in children and adolescents, but that the data had methodological limitations. The relationship between Pandemrix and narcolepsy is still under investigation.

**Class review of bisphosphonates and atypical fractures concluded:** The CHMP concluded that rare atypical factures of the femur are a class effect of bisphosphonates. The CHMP confirmed that the benefits of bisphosphonates in the treatment and prevention of bone disorders continue to outweigh their risks, but that a warning of the risk of atypical femoral fractures should be added to the prescribing information for all bisphosphonate-containing medicines in the EU. Up to now such a warning had already been included in the product information for alendronate-containing medicines across Europe.

**Lifting of suspension of Octagam recommended:** The CHMP recommended the lifting of the suspension of the marketing authorisations for Octagam (human normal immunoglobulin 5% and 10%) and associated names, and the reintroduction of the medicine onto the market in the European Union. The lifting of the suspension is subject to changes to the manufacturing process.
Octagam is an intravenous solution used to strengthen the body's immune system to lower the risk of infection in patients with a weakened immune system.

**Update on review of Baxter's dialysis solutions:** While an in-depth review of the problem of the presence of endotoxins in Baxter's dialysis solutions manufactured at the Castlebar plant in Ireland is ongoing, the CHMP recommended that manufacturing sites located in Canada, Poland and Turkey be included into the existing marketing authorisations of Baxter's peritoneal dialysis solutions, in order to ensure the supply of endotoxin-free solutions in Europe. The CHMP will continue to investigate the root cause of the problem and the changes in the manufacturing process at Castlebar that are needed to ensure production of endotoxin-free products from this plant.

**Review of celecoxib started:** The CHMP has begun looking at the available data on the use of celecoxib in the reduction of the number of adenomatous intestinal polyps in familial adenomatous polyposis, following Pfizer's voluntary withdrawal of the marketing authorisation of its celecoxib-containing orphan medicine, Onsenal, during the medicine's annual reassessment. This review was initiated over the concern that other celecoxib-containing products may be used off-label in this indication. The CHMP will now review all available data thoroughly and will adopt an opinion on the matter.

Date of the next CHMP meeting: 16-19 May 2011.

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