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Press Office

Press release

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP)

11-14 April 2011

Interim measures for Pandemrix

The CHMP has recommended that the product information for Pandemrix (Influenza vaccine (H1N1)) (split virion, inactivated, adjuvanted), from GlaxoSmithKline 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.

The CHMP 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.

More information about this review is available in a separate press release on the Agency's website.

Positive opinions for new medicines adopted

The Committee adopted positive opinions recommending the granting of marketing authorisations for the following new medicines:

- **Bydureon** (exenatide), from Eli Lilly Nederland B.V., intended for the treatment of type-2 diabetes in adults. The review for Bydureon began on 24 March 2010 with an active review time of 183 days.
- **Nulojix** (belatacept), from Bristol-Myers Squibb 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 with an active review time of 210 days.

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Positive opinion for informed consent application adopted

The Committee adopted a positive opinion recommending the granting of a marketing authorisation 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. This application was an informed consent application referring to the dossier of the authorised medicine Neupro.

Positive opinion for generic medicine adopted

The Committee adopted a positive opinion recommending the granting of a marketing authorisation for the generic medicine **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. Rivastigmine Actavis is a generic of Exelon.

Positive opinions for extensions of therapeutic indications adopted

The Committee adopted positive opinions for applications for extensions of the therapeutic indications, adding new treatment options for medicines that are already authorised in the European Union (EU), for:

- **Carbaglu** (carglumic acid), from Orphan Europe S.A.R.L., to include the treatment of hyperammoniaemia due to isovaleric acidaemia, methylmalonic acidaemia and 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.

Re-examination procedure on Avastin concluded

Following re-examination of its previous negative opinion, the Committee adopted a final positive opinion, recommending that the therapeutic indications of **Avastin** (bevacizumab), from Roche Registration Ltd, 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**.**

More information about this re-examination procedure is available in a separate question-and-answer document on the Agency's website.

The summaries of opinion for all medicines, including their full therapeutic indications, can be found on the Agency's website.

Class review of bisphosphonates and atypical fractures concluded

The Committee 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. This extends to the whole bisphosphonate class the warning that had already been included in the product information for alendronate-containing medicines across Europe, following a review by the CHMP's Pharmacovigilance Working Party in 2008.

More information about this review is available in a question-and-answer document on the Agency's website.

Lifting of suspension of Octagam recommended

The Committee 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.

More information about this review is available in a question-and-answer document on the Agency's website.

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 Committee 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 Committee 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 Committee 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 Committee will now review all available data thoroughly and will adopt an opinion on the matter.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The review of Pandemrix is being conducted in the context of a formal review under Article 20 of Regulation (EC) 726/2004, as amended.
3. Bisphosphonates include alendronic acid, clodronic acid, etidronic acid, ibandronic acid, neridronic acid, pamidronic acid, risedronic acid, tiludronic acid and zoledronic acid. The review of centrally authorised bisphosphonates was conducted in the context of a formal review under Article 20 of Regulation (EC) 726/2004, as amended. The review of nationally authorised bisphosphonates was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, as amended.
4. The review of Octagam was conducted in the context of a formal review under Article 31 of Directive 2001/83/EC, as amended.
5. The referral for Baxter's dialysis solutions is being conducted under Article 31 of Directive 2001/83/EC, as amended.
6. The review of celecoxib is being conducted in the context of a formal review, initiated at the request of the European Commission under Article 5(3) of Regulation (EC) No 726/2004.
7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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