News from the EMA

Activities of the CHMP

During its meeting from 14-17 November 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted:

- one positive opinion for the **granting of a marketing authorisation** for:

- **Caprelsa** (vandetanib) film-coated tablets from AstraZeneca intended for the treatment of aggressive and symptomatic medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease.

- one final negative vote after re-examination of a previous negative opinion for:

- **Sumatriptan Galpharm** 50 mg tablets; the CHMP confirmed its previous negative vote from 21 July 2011, recommending the refusal of the marketing authorisation for this generic product, intended for the relief of migraine attacks in people who have been diagnosed with migraine **as an OTC product**.

- four positive opinions for the following extensions of indications:

- **Erbitux** (cetuximab), from Merck KGaA, to include treatment of patients with epidermal growth factor receptor (EGFR)-expressing, KRAS wild-type metastatic colorectal cancer in first line in combination with FOLFOX. In addition, the CHMP adopted the following new contraindication: "combination of Erbitux with oxaliplatin-containing chemotherapy for patients with mutant KRAS metastatic colorectal cancer (mCRC) or for whom KRAS mCRC status is unknown.
- **Herceptin** (trastuzumab), from Roche, to include treatment of patients with HER2 positive early breast cancer.
- **Nevanac** (nepafenac), from Alcon, to include reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.
- **Rebif** (interferon beta-1a), from Merck Serono, to include treatment of patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis.

- one negative vote – after re-examination of the previous negative opinion – to change the marketing authorisations for:

- **Ariclaim, Cymbalta and Xeristar (duloxetine),** from Lilly, to include treatment of moderate to severe chronic somatic pain in patients not taking NSAIDs regularly.

- four positive opinions for the following **generics**:

- **Desloratadine Actavis**
- **Desloratadine ratiopharm**
- **Docetaxel Mylan.**

Pharmacovigilance:
Review of pholcodine-containing medicines: The CHMP concluded that the existing risk of
putting people at risk of developing anaphylactic (severe allergic) reactions to neuromuscular blocking agents used during surgery is weak and that the benefits continue to outweigh the risks. Therefore the marketing authorisations for these products should be maintained.

Review of buflomedil-containing medicines: The CHMP concluded that the benefits of these medicines – both oral and injectable - do not outweigh their risks (serious side effects), and has recommended that all marketing authorisations should be suspended.

Update on safety of Pradaxa (dabigatran etexilate): The efficacy of Pradaxa as demonstrated in clinical trials remains unchanged. Regarding fatal cases of bleeding in patients treated with Pradaxa: The risk of bleeding with anticoagulant medicines is well-known. For Pradaxa, this has been reflected since its initial marketing authorisation in March 2008 in the product information, which recommends that doctors check for signs of bleeding and discontinue treatment in patients with severe bleeding. Pradaxa is contraindicated in a number of conditions, including in patients who are bleeding and patients with severe renal impairment, and it should be used with caution and at lower doses in elderly patients and patients with moderate renal impairment. The CHMP has recommended further changes to the product information following reports of fatal cases of bleeding coming from Japan and assessment of the latest available worldwide data on the risk of fatal bleeding.

Date of the next CHMP meeting: 12-15 December 2011.

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu