

News from the EMA

Activities of the CHMP

During its meeting from 12-15 November 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted:

- three positive opinions for the granting of a marketing authorisation for:

- **Bexsero** (meningitis B vaccine) powder and solvent for solution for injection, from Novartis, intended for active immunisation of individuals from the age of 2 months and above against invasive meningococcal diseases caused by *Neisseria meningitidis* group B.
- **Lyxumia** (lixisenatide), solution for injection, from Sanofi Aventis, intended for adults with type 2 diabetes to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin together with diet and exercise.
- **Zaltrap** (aflibercept) 25 mg/ml, concentrate for solution for infusion, from Sanofi Aventis, intended, in combination with irinotecan/5-fluorouracil/ folinic acid (FOLFIRI) chemotherapy, for the treatment of adults with metastatic colorectal cancer (MCRC) that is resistant to or has progressed after an oxaliplatin-containing regimen.

- a final negative opinion after re-examination of the negative opinion for:

- **Istodax (romidepsin)** solution for infusion, from Celgene, intended for treatment of peripheral T-cell lymphoma; since Istodax was not compared with any other treatment, it was not possible for the CHMP to establish whether the observed effects were due to the medicine or due to the disease characteristics of patients. Therefore a conclusion on the risk benefit was not possible.

- four positive opinions for the following extensions of indications:

- **Intelence (etravirine)**, from Janssen-Cilag, is also indicated in antiretroviral treatment-experienced paediatric patients from **6 years** of age.
- **Exjade (deferasirox)**, from Novartis, is also indicated for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.
- **Prevenar 13 (pneumococcal vaccine)**, from Pfizer, is also indicated for the active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks to **17** years of age.
- **Zytiga (abirateron)**, from Janssen-Cilag, is also indicated for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated.

Pharmacovigilance

Finalisation of reviews:

For the following medicines reviews were finalised:

TachoSil (human fibrinogen/human thrombin): The CHMP has recommended the following new contraindication for this medicine from Nycomed: "TachoSil must not be applied intravascularly."

Fibrin sealants Evicel and Quixil: The CHMP concluded that the benefits of these medicines given by spray application continue to outweigh their risks, but that appropriate measures have to be put in place to minimise the risk of gas embolism. For

the other fibrin sealants Tisseel, Tissucol, Artiss and Beriplast P the assessment is still ongoing.

Calcitonin-containing medicines: After re-examination the CHMP confirmed its conclusions from the July 2012 meeting that there was evidence of a small increased risk of cancer with long-term use of these medicines and that they should only be authorised for short-term use in Paget's disease, acute bone loss due to sudden immobilisation and hypercalcaemia caused by cancer. Furthermore the CHMP concluded that the benefits of calcitonin-containing medicines did not outweigh their risks in the treatment of osteoporosis and that they should no longer be used for this condition.

Potential supply issues for protamine-containing medicinal products avoided:

The CHMP concluded that protamine sulphate sourced from the Hokkaido Island fishing areas off the coast of Japan does not differ significantly from historical batches of the product derived from the traditional fishing grounds off Japan's Honshu Island. These boats and equipment of these fishing grounds had been severely damaged by the tsunami after the earthquake in March 2011.

The CHMP therefore recommends that protamine sulphate sourced from the Hokkaido fishing grounds can be used for the manufacture of medicinal products both as an active substance and as excipient. As a result, there will be no supply shortage for medicinal products containing protamine in the European Union (EU).

It is important for marketing-authorisation holders of medicinal products containing protamine to investigate alternative authorised suppliers of protamine to better manage any future supply issues.

Date of the next CHMP meeting: 10-13 December 2012.

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