News from the EMA

Activities of the CHMP

During its meeting from 16-19 January 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted:

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

- **Signifor** (pasireotide) 0.3 mg, 0.6 mg and 0.9 mg solution for injection, from Novartis Europharm, intended for the treatment of Cushing's disease of adult patients for whom surgery is not an option or has failed.

- a negative vote recommending not to grant a marketing authorisation for:

- **Folotyn** (pralatrexate) solution for infusion, an orphan medicine from Allos Therapeutics Limited, intended to be used to treat adults with peripheral T-cell lymphoma. The CHMP was concerned that the main study was designed in a way that did not allow to assess the benefit of the medicine.

- two positive opinions for the following extensions of indications:

- **Remicade** (infliximab) from Janssen Biological is also indicated for treatment of severely active ulcerative colitis in paediatric patients aged 6 to 17 years, who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.
- **RotaTeq** (oral rotavirus vaccine) from Sanofi Pasteur MSD is also indicated for the active immunisation of infants from the age of 6 weeks to 32 weeks (up to now: 26 weeks) for prevention of gastroenteritis due to rotavirus infection.

Pharmacovigilance:
Review of oral meprobamate-containing medicines: The CHMP concluded that due to the serious side effects the benefits of these medicines do not outweigh their risks any longer, and that all marketing authorisations should be suspended throughout the European Union (EU). The CHMP recommended that the suspension should be implemented gradually to avoid the risk of severe withdrawal symptoms in patients stopping treatment abruptly.

Start of safety reviews:
For the following medicines safety reviews were started:
Gilenya (fingolimod): due to information provided by Novartis on cardiovascular events. While the review is ongoing, doctors are advised to increase their level of monitoring of patients after the first dose of the medicine.
Doribax (doripenem): due to information provided by Janssen Cilag on the termination of the study DORINOS-3008.
Ergot derivatives containing medicines: France asking for reviewing the benefit-risk-balance of some products in several indications due to limited efficacy and various safety concerns.

Start of arbitration procedures:
Loraxin (loratadine): due to disagreements regarding the benefit-risk-ratio.
Affilia and Iffeza (fluticasone plus formoterol): due to disagreements regarding the benefit-risk-ratio.

Scientific advice / guidelines:
Scientific advice: For the first time the CHMP adopted an HTA parallel advice letter and two Qualifications of novel methodologies letters (quantitative disease progression model

for the design of Alzheimer's Disease; Patient-reported outcome instrument for gastro-oesophagel reflux disease (GORD)).
Guidelines: The EMA has released a guideline on non-clinical and clinical requirements for biosimilar medicines containing interferon beta for public consultation. It is open for consultation until the end of May 2012

Date of the next CHMP meeting: 13-16 February 2012.

Exclusively reported by Dr. Siegfried Throm, German Association of Research-Based Pharmaceutical Companies (e-mail: s.throm@vfa.de)
for:
Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu