News from the EMA

Activities of the CHMP

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

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

- **Forxiga** (dapagliflozin) film-coated tablet, from BMS/AstraZeneca, for the treatment of type 2 diabetes mellitus in adults as monotherapy and as add-on combination therapy with other glucose-lowering products including insulin.
- **Jakavi** (ruxolitinib) tablet, from Novartis, an orphan medicine for the treatment of chronic idiopathic myelofibrosis and treatment of myelofibrosis seondary to polycythaemia vera or essential thrombocythaemia.
- **Rienso** (Ferumoxytol) solution for injection, from Takeda, for the intravenous treatment of iron deficiency anaemia in adult patients with chronic kidney disease (CDK).

- two final opinions – after re-examination – not to recommend approval of:

- **Folotyn (pralatrexate)** solution for infusion, from Allos Therapeutics, intended for the treatment of peripheral T-cell lymphoma.
- **Glybera (alipogene tiparvovec)** solution for injection, from Amsterdam Molecular Therapeutics, a gene therapy product intended for patients with lipoprotein lipase deficiency.

- two positive opinions for the following extensions of indications:

- **Lantus and Optisulin** (insulin glargin), from Sanofi-Aventis, are also indicated for treatment of diabetes mellitus in children from 2 years of age (currently: from 6 years of age), adolescents and adults.

Pharmacovigilance

Finalisation of reviews:

For the following medicine the safety review was finalised:

Gilenya (fingolimod): The CHMP concluded that the benefits of this medicine from Novartis continues to outweigh its risks but recommended changes to the product information to strengthen the warnings and ensure close monitoring of all patients following the first dose.

For the following medicines the arbitration reviews were finalised:

Flutiform, Iffeza and other names (fluticasone propionate/formoterol fumarate): The CHMP concluded that the benefits of these asthma medicines from Napp Pharmaceuticals outweigh the risks, and that the marketing authorisation can be granted.

Yaz 24+4 and Ethinylestradiol-Drospirenone 24+4: The CHMP had been asked to consider a proposed change to the marketing authorisations for these contraceptives from Bayer to include a new indication for the treatment of moderate acne in women seeking oral contraception. The CHMP concluded that the change to the marketing authorisations cannot be granted.

Yvidually and other names (ethinylestradiol/drospirenone): The CHMP concluded that the benefits of this extended use contraceptive (for up to 120 days) from Bayer outweigh its risks, and the marketing authorisation can be granted in all EU Member States as well as Iceland and Norway.

Date of the next CHMP meeting: 21-24 May 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