News from the EMA

Activities of the CHMP

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

- four positive opinions for the following generics:

- **Docetaxel** Accord and Docetaxel Kabi 20mg/ml, concentrate for solution for infusion, from Accord Healthcare Ltd and from Fresenius Kabi Oncology, intended for the treatment of breast cancer, non-small cell lung cancer.
- **Zoledronic acid Teva Pharma and Zoledronic acid Teva** 5 mg, solution for infusion intended for the treatment of osteoporosis (in post-menopausal women and in men at increased risk of fracture), treatment of osteoporosis associated with long-term systemic glucocorticoid therapy (in post-menopausal women and in men at increased risk of fracture) and for the treatment of Paget's disease of the bone in adults.

- two positive opinions for the following extensions of indications:

- **Menveo** (meningitis vaccine), from Novartis, is also indicated for active immunisation of children (from 2 years of age), adolescents and adults at risk of exposure to Neisseria meningitidis groups A, C, W135 and Y, to prevent invasive disease. for active immunisation of children (from 2 years of age), adolescents and adults at risk of exposure to Neisseria meningitidis groups A, C, W135 and Y, to prevent invasive disease.
- **ProQuad** (measles, mumps, rubella and varicella vaccine), from Sanofi Pasteur MSD, can also be administered to individuals from 9 months of age under special circumstances (e.g., to conform with national vaccination schedules, outbreak situations, or travel to a region with high prevalence of measles.

Pharmacovigilance

Finalisation of reviews:

For the following medicines reviews were finalised:

Femara (letrozol): The CHMP has recommended that the prescribing information for these medicines from Novartis should be harmonised within the EU.

Priorix (vaccine used to protect against measles, mumps and rubella): The CHMP has recommended that the prescribing information for this vaccine from GSK should be harmonised within the EU.

Protelos/Osseor: The CHMP has confirmed the positive benefit-risk balance of these medicines, but has recommended new contraindications and revised warnings; these **m**edicines are no longer recommended for use in immobilised patients or patients with venous thromboembolism (VTE); update of warnings regarding serious skin reactions.

Start of reviews:

For the following medicines reviews were started:

M-M-RVAXPRO (measles, mumps and rubella vaccine): triggered by the European Commission to review the benefit-risk balance in pregnant women and in subjects with immune deficiencies.

ProQuad (measles, mumps, rubella and varicella vaccine): triggered by the European Commission to review the benefit-risk balance in pregnant women and in subjects with immune deficiencies.

Zostavax (zoster vaccine): triggered by the European Commission to review the benefit-risk balance in pregnant women and in subjects with immune deficiencies.

Monovalent and multivalent measles, mumps, rubella and varicella vaccines (non-centrally authorized): initiated by Belgium to review the benefit-risk balance in pregnant women and in subjects with immune deficiencies.

Mifepristone Linepharma: initiated by Sweden because of disagreements regarding the demonstration of therapeutic equivalence with the originator products.
Mometasone furoate Sandoz: initiated by the Netherlands because of disagreements regarding the demonstration of therapeutic equivalence with the originator products.
Yvidually/Flexyess (ethinylestradiol/drospirenon): initiated by the Netherlands because of disagreements regarding the benefit-risk ratio, in particular the contraceptive efficacy of the proposed dosing scheme.

GMP matters:
Caelyx and Ceplene: In its final two opinions on medicines made at Ben Venue Laboratories the EMA has recommended that the manufacturing processes for the anticancer medicines Caelyx (doxorubicin hydrochloride) and Ceplene (histamine dihydrochloride) be transferred from the Ben Venue Laboratories in Ohio, United States, to alternative facilities.

Date of the next CHMP meeting: 16-19 April 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