News from the EMA

Activities of the CHMP

During its meeting from 18-21 June 2012 the Committee for Medicinal Products for Human Use (CHMP) adopted:

- six positive opinions for the **granting of a marketing authorisation** for:

- **Cuprymina**, (copper (^{64}Cu) chloride), a radiopharmaceutical precursor, not intended for direct use in patients, but only for the radiolabelling of carrier molecules, which have been specifically developed and authorised for radiolabelling with this radionuclide from SPARKLE S.r.l.

- **Revestive** (teduglutide) powder and solution for infusion for injection intended for the treatment of adult patients with Short Bowel Syndrome from Nycomed Danmark ApS. Revestive was designated as an orphan medicinal product on 11 December 2001.

- **Enurev Breezhaler / Seebri Breezhaler / Tovanor Breezhaler (**glycopyrronium bromide) inhalation powder, hard capsules intended for the maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD) from Novartis Europharm.

- **Zinforo** (Ceftaroline fosamil) powder for concentrate for solution for infusion intended for treatment of adults with complicated skin and soft tissue infections (cSSTI) and community-acquired pneumonia (CAP) from AstraZeneca AB.

- **a negative opinion not to grant a marketing authorisation** to the following product:

Elelyso (taliglucerase alfa) intended for the treatment of type 1 Gaucher disease from Pfizer. Elelyso was designated an 'orphan medicine' (a medicine used in rare diseases) on 23 March 2010.The CHMP concluded that in spite of having demonstrated efficacy and safety Elelyso cannot be granted marketing authorisation in the EU because of the ten-year market exclusivity that had been granted for Vpriv, which was authorised in August 2010 for the same condition.

- two positive opinions for the **approval** of the following **generic products:**

- **Zyclara** (imiquimod) from Meda ABTherapeutic for topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults when other topical treatment options are contraindicated or less appropriate.

- **Zoledronic acid Mylan** for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumour-induced hypercalcaemia) in adult patients with advanced malignancies involving bone. / The treatment of adult patients with tumour-induced hypercalcaemia.

- four positive opinions for the following extensions of indications:

- **Afinitor** (everolimus), from Novartis Europharm; this may also be used for the treatment of hormone receptor-positive, HER2/neu negative advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor.

- **Cayston** (aztreonam) from Gilead Sciences; this may also be used for suppressive therapy of chronic pulmonary infections due to Pseudomonas aeruginosa in patients with cystic fibrosis (CF) aged **6 years** and older.

- **Enbrel** (etanercept) from Pfizer; this may also be used for treatment of polyarthritis (rheumatoid factor positive or negative) and extended oligoarthritis in children and adolescents from the age of 2 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.
  Treatment of psoriatic arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, methotrexate.
  Treatment of enthesitis-related arthritis in adolescents from the age of 12 years who have had an inadequate response to, or who have proved intolerant of, conventional therapy.

- **Humira** (adalimumab) from Abbott Laboratories; this may also be used for the treatment of adults with severe axial spondyloarthritis (AS) without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to nonsteroidal anti-inflammatory drugs.

Pharmacovigilance
For the following medicine a **safety review was finalised**: **Doribax (doripenem)**: The CHMP advises doctors treating patients with nosocomial pneumonia with Doribax that the current dosing recommendations may not be enough for serious cases; no change in advice for all other approved indications.

Start of reviews for non-centrally authorised medicines:
Estradiol - containing medicinal products: an Article 31 referral was started triggered by Germany asking for an opinion on the benefit-risk products for topical use due to concerns related to endometrial safety.

Start of arbitration procedures for the following products:
Glimepiride Parke-Davis: an Article 29(4) was started because of disagreements regarding the demonstration of bioequivalence between the generic and the reference product.

Deficiencies in Roche medicines-safety reporting:

The EMA is working with national medicines agencies to investigate deficiencies in the medicine-safety reporting system of Roche. This includes looking at whether the deficiencies have an impact on the overall benefit-risk profile for any of the products involved.There is at present no evidence of a negative impact for patients and while the investigations are being conducted, there is no need for patients or healthcare professionals to take any action.

The deficiencies were identified in a May 2012 report from the United Kingdom's medicines regulatory agency MHRA; at the time of the inspection, the company identified some 80,000 reports for medicines marketed by Roche in the United States that had been collected through a Roche-sponsored patient support programme, but which had not been evaluated to determine whether or not they should be reported as suspected adverse reactions to the European Union (EU) authorities. These included 15,161 reports of death of patients. it is not known whether the deaths were due to natural progression of the disease or had a causal link to the medicine. More recent information from the company indicates a smaller number of reports, but this information needs to be verified by the authorities.

Date of the next CHMP meeting: 16 – 19 July 2012.

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu