News from the EMA

Activities of the CHMP

During its meeting from 17–20 October 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted:

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

- **Ameluz** (5-amino laevulinic acid) gel from BioFrontera intended for the treatment of actinic keratosis.

- one positive opinion after re-examination of a previous negative opinion for:

- **Bronchitol** (mannitole) hard capsules from Pharmaxis Pharmaceuticals intended for the treatment of cystic fibrosis (CF) in adults aged 18 years and above as an add-on therapy to best standard of care. Bronchitol was designated as an orphan medicinal product on 7 November 2005.

- two positive opinions for the following extensions of indications:

- **Cervarix** (HPC vaccine), from GSK, to extend the indications to include subjects from the age of 9 years for the prevention of premalignant cervical lesions and cervical cancer causally related to certain oncogenic Human Papillomavirus (HPV) types;

- **Onglyza** (saxagliptin), from BMS/AstraZenecaNovo Nordisk, to include treatment in combination with insulin (with or without metformin), when this regimen alone, with diet and exercise, does not provide adequate glycaemic control.

- one final negative vote after re-examination of a previous negative opinion for:

- Glybera (alipogene tiparvovec) from Amsterdam Molecular Therapeutics intended for use in patients with lipoprotein lipase deficiency. Yet, the CHMP but maintained its recommendation from the June-meeting that Glybera should not be granted a marketing authorisation.

-- four positive opinions for the following **generics**:

- Efavirenz Teva
- Levetiracetam SUN
- Repaglinide Accord
- Topotecan Eagle.

Pharmacovigilance:
Review of angiotensin II receptor antagonists (ARBs): The CHMP concluded that there is no increased risk of cancer in patients using these medicines and that therefore the benefits continue to outweigh the risks.

Review of Takeda's Actos (pioglitazone): On the request of the European Commission the CHMP has clarified its opinion on pioglitazone-containing anti-diabetes medicines and the risk of bladder cancer: The CHMP confirmed its previous opinion, introducing some clarifications in terms of transparency towards patients and health care professionals. Pioglitazone remains a valid treatment option for certain patients with type 2 diabetes, but only when certain other treatments (metformin) have not been suitable or have failed to work adequately.

Arbitration:
The CHMP has completed an arbitration procedure following disagreement among EU Member States regarding the authorisation of **Priligy (dapoxetine)** tablets. This is a medicine used to treat premature ejaculation in men aged 18 to 64 years old. The CHMP concluded that the benefits of the 60 mg tablet (over which there was disagreement) do outweigh its risks and that the marketing authorisation for Priligy granted in Sweden can be recognised in other EU Member States.

Review of strontium-ranelate-containing medicines started: The EMA has started a review of the osteoporosis medicines Protelos and Osseor, to determine whether the cases of venous thromboembolism and drug rash with eosinophilia and systemic symptoms have an impact on their benefit-risk profile and conditions of use.

Review of non-selective NSAIDs started: The EMA is reviewing the latest available data on the cardiovascular safety of non-selective NSAIDs (non-steroidal anti-inflammatory drugs) to update its 2006 opinion in light of more recently published evidence**.**

Recall of some batches of Advagraf: The EMA has agreed to the immediate recall of some batches of 0.5 mg prolonged-release hard capsules of Advagraf (tacrolimus) from pharmacies and wholesalers across EU. This follows detection of more active substance than expected being released from the capsules. The recall is being conducted as a precautionary measure because the defect could have led to slightly higher levels of tacrolimus in the blood of patients taking the affected capsules.

Date of the next CHMP meeting: 14-17 November 2011.

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu