News from the EMEA

Activities of the CHMP

During its meeting from 19 - 22 July 2010 the Committee for Human Medicinal Products (CHMP) adopted:

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

- **Twynsta** (telmisartan/amlodipine), from Boehringer Ingelheim, intended for the treatment of essential hypertension. This review began on 23 September 2009 with an active review time of 210 days.

- **positive opinions** for the following generic medicines:

- **Clopidogrel Teva Pharma B.V.** (clopidogrel hydrobromide) for the prevention of atherothrombotic events (generic of Plavix)
- **Clopidogrel HCS and Clopidogrel Teva Generics B.V.** (clopidogrel hydrochloride), from HCS bvba and from Teva Generics, for the prevention of atherothrombotic events (generic of Plavix)
- Myclausen (mycophenolate mofetil) from Herbert Passauer GmbH & Co KG, for the prophylaxis of acute transplant rejection in combination with ciclosporin and corticosteroids (generic of CellCept).

- **positive opinions** for extensions of indications for:

- **Arixtra** (fondaparinux sodium), from Glaxo, to include treatment of acute symptomatic spontaneous superficial vein thrombosis of the lower limbs without concomitant deep vein thrombosis
- **M-M-RVAXPRO** (measles, mumps and rubella vaccine, live), from Sanofi Pasteur MSD, to include vaccination of healthy children from 9 months of age under special circumstances, in accordance with official recommendations or when early protection is considered necessary
- **Viread** (tenofovir disoproxil), from Gilead Sciences, to include treatment of chronic hepatitis B in adults with decompensated liver disease.

- new paediatric indication for:

- Xalatan eye drops (latanoprost), from Pfizer, to include the reduction of elevated intraocular pressure in the treatment of paediatric patients with elevated intraocular pressure and paediatric glaucoma (in accordance with a paediatric investigation plan, PIP)

Update on the ongoing benefit-risk review of Avandia, Avandamet and Avaglim

- The CHMP is currently reviewing the rosiglitazone-containing antidiabetes medicines **Avandia** (rosiglitazone), **Avaglim** (rosiglitazone/glimepiride) and **Avandamet** (rosiglitazone/metformin hydrochloride), from SKB, to determine the impact of new data, from recent publications on the risk of cardiovascular problems, on the benefit-risk profile of these medicines. Prescribers in Europe are reminded to strictly follow the recommendations in the product information with respect to patients indicated for treatment, defined contraindications and warnings.

Update on the review of rotavirus vaccines

- The CHMP finalised a review of the oral vaccine **Rotarix** (rotavirus vaccine, live) from GlaxoSmithKline Biologicals S.A., following the detection of porcine circovirus 1 (PCV1) DNA in the vaccine. Conclusion: The vaccine continues to have a positive benefit-risk balance; the presence of a very small amount of viral particles does not present a risk to public health.
- The review of the rotavirus vaccine, **Rotateq**, from Sanofi Pasteur MSD, SNC, following the detection of porcine virus in this vaccine is still ongoing and will be considered in September. The CHMP is awaiting further information from the manufacturer on the root cause of the findings and on measures to manufacture the vaccine free of porcine virus. The CHMP confirmed its previous position that there is no need to restrict the use of Rotateq.

Review of topical formulations of ketoprofen concluded

- In this Art. 107 review the CHMP concluded that the benefits of these medicines continue to outweigh their risks. However, doctors should inform patients on how to use these medicines appropriately to prevent the occurrence of serious skin photosensitivity reactions.

Review of modafinil-containing medicines concluded

- In this Art. 31 review the CHMP recommended restricting the use of these medicines to the treatment of sleepiness associated with narcolepsy. Doctors and patients should no longer use these medicines for the treatment of idiopathic hypersomnia, excessive sleepiness associated with obstructive sleep apnoea or chronic shift work sleep disorder.

- The review had been initiated because of a number of safety concerns relating to neuropsychiatric disorders, skin and subcutaneous tissue reactions as well as significant off-label use and potential for abuse.

Review of modified-release oral opioids concluded

- The CHMP recommended the suspension of formulations using polymethacrylate-triethylcitrate controlled release systems because of their interaction with alcohol. Other formulations had a positive benefit-risk balance, but existing warnings regarding concomitant use of these medicines with alcohol should be harmonised.

Harmonisation referral on Daivobet concluded

- The CHMP recommended the EU wide harmonisation of the prescribing information for **Daivobet** (calcipotriol/betamethasone), from Leo Pharma for treatment of psoriasis.

Review of dexrazoxane-containing medicines started

- The CHMP has begun a review of the possible risk of acute myelogenous leukaemia (AML), myelodyspastic syndrome (MDS) and solid tumours in paediatric patients taking **dexrazoxane-containing medicines** for the prevention of anthracycline-induced cardiotoxicity. This follows the review of published literature, together with the results of randomised clinical trials, which suggests that these medicines may be linked with a three-fold increased risk of secondary malignancies, especially AML and MDS. At the same time, the available clinical studies show only limited efficacy of these medicines in the prevention of cardiotoxicity, and the alternative treatment options of heart failure have been markedly improved.
- The CHMP will review all available data thoroughly, including published data, non-clinical and clinical data (including data from clinical trials and epidemiological studies), to clarify the impact of the increased risk of secondary malignancies, coupled with limited data on efficacy, on the balance of risks and benefits of these medicines.

Date of the next CHMP meeting: 20 – 23 September 2010, since the August meeting is usually replaced by a written procedure.

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