News from the EMA

Activities of the CHMP

During its meeting from 20-22 September 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted:

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

- **Dificlir** (fidaxomicin) from FGK Representative, intended for the treatment of Clostridium difficile infections, also known as C. difficile-associated diarrhoea in adults.
- **Ipreziv** (azilsartan medoxomil), from Takeda, intended for the treatment of essential hypertension in adults.
- **Edurant** (rilpivirine hydrochloride), from Janssen-Cilag), intended for the treatment of human immunodeficiency virus-1f (HIV-1) infections in adults in combination with other antiretroviral medicinal products.
- **Eviplera** (emtricitabine/rilpivirine/tenofovir disoproxil), from Gilead, intended for the treatment of human immunodeficiency virus-1f (HIV-1) infections in adults.
- **Rasitrio** (aliskiren/amlodipine/hydrochlorothiazide), from Novartis, intended for the treatment of essential hypertension in adult patients whose blood pressure is adequately controlled on the combination of aliskiren, amlodipine and hydrochlorothiazide.
- **Onduarp** (telmisartan(amlodipine) from Boehringer Ingelheim intended for the treatment of essential hypertension in adult patients.
- **Komboglyze** (saxagliptin/metformin), from BMS/AstraZeneca, intended for the treatment of type 2 diabetes in adults.

- six positive opinions for extension of indications:

- **Avastin** (Bevacizumab), from Roche, to include the treatment in combination with carboplatin and paclitaxel for advanced (FIGO stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer
- **Levemir** (insulin detemir), from Novo Nordisk, to include children aged 2 years and above (up to now: children aged 6-17 years)
- **Prevenar 13** (13 valent pneumococcal polysaccharide conjugate vaccine), from Wyeth, to include active immunisation for the prevention of invasive disease caused by Streptococcus pneumoniae in adults aged 50 years and older
- **Soliris** (eculizmab), from Alexion, to include treatment of atypical hemolytic uremic syndrome (aHUS)
- **Xarelto** (rivaroxaban), from Bayer, to include for two new strengths the following two further indications: treatment of deep vein thrombosis (DVT), and prevention of recurrent DVT and pulmonary embolism (PE) following an acute DVT in adults and prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.
- **Alimta (pemetrexed),** from Lilly, to include monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology n patient whose disease has not progressed immediately following platinum-based chemotherapy.

- one negative vote on extension of the indication for:

- **Victoza (liraglutide)** from Novo Nordisk; combination therapy with basal insulin should not be approved as a new indication since the design of the study to support this extension was not satisfactory for the CHMP. Yet, the information on this study should be included in the product information.

- ten positive opinions for the following generics:

- Dasselta (desloratadine) from Krka and Desloratadine Krka and Desloratadine Teva
- Levetiracetam Actavis Group
- Pioglitazone Actavis, Pioglitazone Actavis Group, Pioglitazone Teva, Pioglitazone Teva Pharma, Pioglitazone Teva Generics and Spioglin (pioglitazone) from Vaia.

Pharmacovigilance:

Review of Revlimid (Lenalidomide): The CHMP concluded that the benefit risk balance otf this anticancer medicine remains positive but recommended that the prescribing information be updated with a warning and advice to doctors on the risk of new cancers.

Review of suppositories containing terpenic derivatives: The CHMP concluded that these anti-cough medicines should no longer recommended for use in children under 30 months, children with a history of febrile convulsion or epilepsy and children with a recent history of anorectal lesion. .

Review of Baxter`s dialysis solutions: The CHMP finalised new recommendations to ensure continued supply of these dialysis solutions in the EU while quality-improvement measures are being put in place at the manufacturing plant in Ireland to ensure the production of endotoxin-free solutions.

Review of Vimpat (lacosamide) syrup: The CHMP recommended discontinuation of Vimpat syrup because of quality defect; other Vimpat presentations remain available for patients with epilepsy.

Review of Multaq (dronedarone): The CHMP recommended restricting use of Multaq and a number of other risk minimisation measures to reduce the risk of injuries to liver, lung and cardiovascular system.

Review of orlistat-containing medicines started: The EMA has started a review of orlistat-containing anti-obesity medicines, to determine whether the very rare cases of hepatic injury have an impact on their benefit-risk profile and conditions of use. The review includes the centrally authorised prescription-only medicine Xenical (orlistat 120 mg) and the centrally authorised over-the-counter-medicine Alli (orlistat 60 mg), as well as a number of medicines containing orlistat that have either already or are in the process of being authorised at national level.

Shortage of Apidra (insulin glusiline) cartridges: The CHMP agreed several recommendations to manage the shortage of Apidra cartridges and patients continue to receive appropriate treatment during the temporary supply shortage.

Date of the next CHMP meeting: 17–20 October 2011.

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Guide to Drug Regulatory Affairs www.drugregulatoryaffairs.eu