23 March 2018
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Inspections, Human Medicines Pharmacovigilance and Committees Division

PDCO monthly report of opinions on paediatric investigation plans and other activities

20-23 March 2018

Opinions on paediatric investigation plans

The Paediatric Committee (PDCO) adopted opinions agreeing paediatric investigation plans (PIPs) for the following medicines:

- Fosnetupitant / palonosetron, EMEA-001198-PIP03-17, from Helsinn Birex Pharmaceuticals Limited, for the prevention of chemotherapy-induced nausea and vomiting;
- Emtricitabine / tenofovir alafenamide, EMEA-001577-PIP03-17, from Gilead Sciences International Ltd., for the prevention of human immunodeficiency virus (HIV-1) infection

A PIP sets out a programme for the development of a medicine in the paediatric population. The PIP aims to generate the necessary quality, safety and efficacy data through studies to support the authorisation of the medicine for use in children of all ages. These data have to be submitted to the European Medicines Agency, or national competent authorities, as part of an application for a marketing authorisation for a new medicine, or for one covered by a patent. In some cases, a PIP may include a waiver of the studies in one or more paediatric subsets, or a deferral.

Opinions on product-specific waivers

The PDCO adopted positive opinions for product-specific waivers, recommending that the obligation to submit data obtained through clinical studies with children be waived in all subsets of the paediatric population, for the following medicines:

- Amlodipine /iIrbesartan, EMEA-002192-PIP02-17, from WIN MEDICA S.A., for the treatment of hypertension;
- Clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins, EMEA-001039-PIP03-17, from Merz Pharmaceuticals GmbH, for the treatment of hemifacial spasm;
- Ibuprofen / paracetamol, EMEA-002002-PIP02-17, from Farmalíder, S.A., for the treatment of febrile disorders and treatment of pain;
- Eszopiclone, EMEA-002309-PIP01-17, from Alfred E. Tiefenbacher (GmbH & Co. KG), for the

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treatment of insomnia;

- (2R)-2-Amino-1-[3-({2-[p-(4-{3-[(3,5-diamino-6-chloro-2-pyrazinyl)carbonyl]guanidino}butyl)phenoxy]ethyl}{3-[(2R)-2-amino-6-guanidinohexanoylamino]propyl}amino)propylamino]-6-guanidino-1-hexanone hexahydrochloride, EMEA-002291-PIP01-17, from Shire Pharmaceuticals Ireland Limited, for the treatment of dry eye disease;
- Ranibizumab, EMEA-000527-PIP05-17, from Novartis Europharm Limited, for the treatment of diabetic retinopathy;

Waivers can be issued if there is evidence that the medicine concerned is likely to be ineffective or unsafe in the paediatric population, or that the disease or condition targeted occurs only in adult populations, or that the medicine, or the performance of trials, does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Opinions on modifications to an agreed PIP

The PDCO also adopts, every month, opinions on modifications to an agreed PIP, which can be requested by the applicant when the plan is no longer appropriate or when there are difficulties that render the plan unworkable. The PDCO adopted positive opinions, agreeing change(s), for the following products:

- Edoxaban (tosylate), EMEA-000788-PIP02-11-M07, from Daiichi Sankyo Europe GmbH, for the prevention of arterial thromboembolism, prevention of venous thromboembolism and treatment of venous thromboembolism;
- Inebilizumab, EMEA-001911-PIP01-15-M01, from MedImmune, LLC, for the treatment of neuromyelitis optica spectrum disorders;
- Guselkumab, EMEA-001523-PIP02-14-M02, from Janssen Cilag International NV, for the treatment of psoriasis;
- Peginterferon alfa-2a, EMEA-000298-PIP01-08-M06, from Roche Registration Ltd, for the treatment of chronic hepatitis B and treatment of chronic hepatitis C;
- Angiotensin II, EMEA-001912-PIP02-16-M01, from La Jolla Pharmaceutical II B.V., for the treatment of hypotension associated with distributive or vasodilatory shock;
- Sunitinib, EMEA-000342-PIP01-08-M07, from Pfizer Limited, for the treatment of gastro-intestinal stromal tumour;
- Testosterone, EMEA-001529-PIP02-14-M01, from Acerus Biopharma Inc., for the treatment of male hypogonadism;
- Liquid ethanolic extract 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus limon (L.) Burm. f. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L., EMEA-001835-PIP01-15-M03, from LEGACY HEALTHCARE, for the treatment of alopecia;
- Treprostinil, EMEA-000207-PIP01-08-M06, from Ferrer Internacional, S.A., for the treatment of pulmonary arterial hypertension;
- Naloxone (hydrochloride), EMEA-001567-PIP01-13-M03, from Develco Pharma GmbH, for the treatment of opioid-induced constipation;

- Galcanezumab, EMEA-001860-PIP03-16-M01, from Eli Lilly and Company Limited, for the prevention of migraine headaches;

Opinion on compliance check

The PDCO adopted positive opinions on (full) compliance check for:

- Drospirenone, EMEA-C-001495-PIP01-13-M01, from LABORATIORIOS LEÓN FARMA, S.A., for the prevention of pregnancy;
- Abatacept, EMEA-C-000118-PIP02-10-M03, from Bristol-Myers Squibb Pharma EEIG, for the treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis);

A compliance check is performed to verify that all the measures agreed in a PIP and reflected in the Agency's decision have been conducted in accordance with the decision, including the agreed timelines. Full compliance with all studies/measures contained in the PIP is one of several prerequisites for obtaining the rewards and incentives provided for in Articles 36 to 38 of the Paediatric Regulation.

Before the submission of a request for a compliance check, applicants are encouraged to consult the Agency's Procedural advice for validation of a new marketing authorisation application or extension/variation application and compliance check with an agreed PIP.

Withdrawals

The PDCO noted that 3 applications were withdrawn during the late stages of the evaluation (30 days or less before completion of the procedure).

The PDCO also noted that the application leading to the opinion adopted during the March 2018 PDCO meeting for Dusquetide, EMEA-002306-PIP01-17, from Soligenix UK Limited, for the treatment of oral mucositis, has been withdrawn before the decision was adopted by the Agency.

Other matters

The PDCO welcomed the new alternate from Denmark, Mrs Mona Ring Gatke.

The next meeting of the PDCO will be held on 24-27 April 2018.

– END –

Notes:

1. As of 26 January 2009, pharmaceutical companies that submit an application for a marketing authorisation for a medicinal product, or those that submit an application for an extension of indication, a new route of administration, or a new pharmaceutical form of a medicinal product already authorised in the European Union, have to provide either the results of studies in children conducted in accordance with an approved PIP, or an Agency's decision on a waiver or on a deferral.

2. PDCO opinions on PIPs and waivers are transformed into Agency's decisions within the timeframe laid down by the Paediatric Regulation (Regulation (EC) No 1901/2006, as amended). The decisions can be found on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/landing/pip_search.jsp&murl=menus/medicines/medicines.jsp&mid=WC0b01ac058001d129

3. More information about the PDCO and the Paediatric Regulation is available in the Regulatory section of the Agency's website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000023.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac05800240cd

4. This meeting report, together with other information on the work of the Agency's, can be found on the Agency's website: http://www.ema.europa.eu

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