21 September 2018
EMEA/PDCO/668248/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

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

18-21 September 2018

Opinions on paediatric investigation plans

Adoption of an opinion following re-examination

The PDCO adopted opinions for the following products:

- Following the re-examination of the positive opinion on a modification to an agreed PIP adopted on 27 July 2018 for Darunavir / cobicistat / emtricitabine / tenofovir alafenamide, EMEA-001825-PIP01-15-M02, from Janssen-Cilag International NV, for the treatment of human immunodeficiency virus type-1 (HIV-1) infection, the PDCO adopted a revised positive opinion and agreed to the changes regarding the measures in the scope set out in the Annex I of this opinion.
- Following the re-examination of the positive opinion on a PIP with deferral and waiver adopted on 29 June 2018 for Alicaforsen, EMEA-002060-PIP02-17, from Atlantic Pharmaceuticals (Holdings) Ltd, for the treatment of pouchitis, the PDCO adopted a revised positive opinion and agreed the paediatric investigation plan in accordance with Article 17(1); granted a deferral in accordance with Article 21; granted a waiver for one or more subsets of the paediatric population in accordance with Article 13 and concluded in accordance with Article 11(1)(b), on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

A re-examination of the opinion can be requested by the applicant within 30 days following receipt of the opinion of the PDCO. The grounds for the re-examination should be based only on the original information and scientific data provided in the application that were previously available to the PDCO and on which the initial opinion was based. This may include new analysis of the same data or minor protocol amendments to a previously proposed study. Significant changes to the previous plan cannot be part of the re-examination process.

Opinions on product-specific waivers

The PDCO adopted an opinion advocating the review of a granted waiver for the following product:

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- 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;

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:

- Peanut Allergen Extract, EMEA-001481-PIP01-13-M03, from DBV Technologies S.A, for the treatment of peanut allergy;

Opinion on compliance check

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

- Paclitaxel, EMEA-C-001308-PIP01-12-M02, from Celgene Europe Ltd, for the treatment of solid malignant tumours;
- Human normal immunoglobulin, EMEA-C-001797-PIP01-15-M01, from Octapharma Pharmazeutika Produktionsges.m.b.H, for the treatment of primary immunodeficiency;
- Glycerol Phenylbutyrate, EMEA-C-000297-PIP02-12-M02, from Horizon Pharma Ireland Limited, for the treatment of urea cycle disorders;

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.

Other matters

The PDCO welcomed the new alternate from Germany, Dr Yuansheng Sun.

The PDCO thanked Irena Meissner Wantuch for her work as she has resigned from the Committee.

The PDCO thanked Riccardo Riccardi for his work as he has resigned from the Committee.

The next meeting of the PDCO will be held on 16-19 October 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

Enquiries to: AskEMA
(http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=)