13 September 2018
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Inspections, Human Medicines Pharmacovigilance and Committees Division

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

Written procedure 21-24 August 2018

Opinions on paediatric investigation plans

No items

Adoption of an opinion following re-examination

No items

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:

- Autologous dendritic cells pulsed with allogeneic tumour cell lysate, EMEA-002381-PIP01-18, from Amphera BV, for the treatment of malignant mesothelioma;
- Pamiparib, EMEA-002389-PIP01-18, from BeiGene, Ltd., for treatment of gastric and gastroesophageal junction adenocarcinoma;
- Cell-free solution of lysed Escherichia coli culture, strain Laves, EMEA-002393-PIP01-18, from Laves-Arzneimittel GmbH, for the treatment of irritable bowel syndrome, treatment of colitis (excluding infective);
- Indapamide / Perindopril arginine / Atorvastatin calcium trihydrate, EMEA-002395-PIP01-18, from Les Laboratoires Servier, for the prevention of Cardiovascular diseases and treatment of Cardiovascular diseases;
- Brentuximab vedotin, EMEA-000980-PIP04-18, from Takeda Pharma A/S, for the treatment of Mature T and NK neoplasms (excluding anaplastic large-cell lymphoma and cutaneous T-cell lymphoma);
- Telisotuzumab vedotin, EMEA-002361-PIP01-18, from AbbVie Ltd., for lung carcinoma (small cell

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and non-small cell carcinoma);

- Diphtheria Toxin Interleukin-3 Fusion Protein, EMEA-002244-PIP02-18, from Stemline Therapeutics, Inc., for the treatment of blastic plasmacytoid dendritic cell neoplasm;
- 3-(3-(3,5-Dimethyl-1H-pyrazol-4-yl)propoxy)-4-fluorobenzoic acid, EMEA-002363-PIP01-18, from Eidos Therapeutics, Inc., for the treatment of transthyretin amyloidosis (ATTR amyloidosis);
- Ianalumab, EMEA-002338-PIP02-18, from Novartis Europharm Limited, for the primary Sjögren's Syndrome (pSS);
- Sarilumab, EMEA-001045-PIP02-18, from Sanofi-aventis recherche et développement, for the treatment of vasculitides;
- A synthetic ribonucleic acid oligonucleotide directed against superoxide dismutase 1 (SOD1) messenger ribonucleic acid, EMEA-002403-PIP01-18, from Biogen Idec Ltd, for the treatment of amyotrophic lateral sclerosis;

The PDCO adopted 1 opinion on the **refusal** of a request for waiver for:

- Eflapegrastim, EMEA-002385-PIP01-18, from Spectrum Pharmaceuticals, Inc., for the treatment of Chemotherapy- Induced Neutropenia;

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

No items

Opinion on compliance check

No items

Withdrawals

The PDCO noted that 1 application was withdrawn during the late stages of the evaluation (30 days or less before completion of the procedure).

Other matters

The next meeting of the PDCO will be held on 18-21 September 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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