EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2019
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Inspections, Human Medicines Pharmacovigilance and Committees Division

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

17-20 September 2019

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 negative Opinion on a modification to an agreed PIP adopted on 28 June 2019 for mirabegron, EMEA-000597-PIP02-10-M07, from Astellas Pharma Europe B.V., for the treatment of idiopathic overactive bladder, the PDCO adopted a revised positive Opinion and agree to the changes regarding the measures and the timelines of the paediatric investigation plan and the timelines of the deferral in the scope set out in the Annex I of this Opinion.
- Following the re-examination of the negative Opinion on a modification to an agreed PIP adopted on 28 June 2019 for reslizumab, EMEA-001202-PIP02-13-M03, from Teva Pharmaceuticals Europe, for the treatment of asthma, the PDCO recommended to maintain the Opinion and agreed to the changes regarding the measures and the timelines of the paediatric investigation plan in the scope set out in the Annex I of this Opinion.

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 a 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 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:

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

- Recombinant human arylsulfatase A (rhASA), EMEA-002050-PIP01-16, from Shire Pharmaceuticals Ireland Limited, for the treatment of metachromatic leukodystrophy (MLD)

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:

- *Neisseria meningitidis* serogroup Y polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup W-135 polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup C polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup A polysaccharide conjugated to tetanus toxoid, EMEA-001930-PIP01-16-M02, from Sanofi Pasteur, for the prevention of invasive meningococcal disease;
- Sitagliptin EMEA-000470-PIP01-08-M11, from Merck Sharp and Dohme (Europe), Inc., for the treatment of type 2 diabetes mellitus;

Opinion on compliance check

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

- Sildenafil citrate, EMEA-C-000671-PIP01-09-M10, from Pfizer Limited, for the treatment of pulmonary arterial hypertension (PAH);
- Tapentadol (hydrochloride), EMEA-C-000018-PIP01-07-M13, from Grünenthal GmbH, for the treatment of acute pain;
- Rivaroxaban, EMEA-C-000430-PIP01-08-M11, from Bayer AG, for the prevention/treatment of thromboembolic events;
- Sucroferric oxyhydroxide (mixture of polynuclear iron(III)-oxyhydroxide, sucrose, and starches), EMEA-C-001061-PIP01-10-M03, from Vifor Fresenius Medical Care Renal Pharma France, for the treatment of hyperphosphataemia;
- Atezolizumab, EMEA-C-001638-PIP01-14-M02, from Roche Registration GmbH, for the treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms);
- Tenofovir alafenamide / emtricitabine, EMEA-C-001577-PIP03-17, from Gilead Sciences International Ltd., for the prevention of human immunodeficiency virus (HIV-1) infection;
- Decitabine, EMEA-C-000555-PIP01-09-M06, from Janssen-Cilag International NV, for the treatment of acute myeloid leukaemia.

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 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 15-18 October 2019.

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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