EMADOC-1700519818-1840304

European Medicines Agency decision

EMA/PE/0000225073

of 28 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant parathyroid hormone (Natpar) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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on the acceptance of a modification of an agreed paediatric investigation plan for recombinant parathyroid hormone (Natpar) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0205/2014 issued on 8 August 2014, the decision P/0255/2015 issued on 30 October 2015, the decision P/0325/2017 issued on 31 October 2017, the decision P/0136/2019 issued on 17 April 2019, the decision P/0460/2020 issued on 4 December 2020 the decision P/0369/2021 issued on 8 September 2021, and the decision P/0276/2023 issued on 14 July 2023,

Having regard to the application submitted by Takeda Pharmaceuticals International AG on 5 September 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 13 December 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for recombinant parathyroid hormone (Natpar), including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

A waiver for recombinant parathyroid hormone (Natpar), the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Takeda Pharmaceuticals International AG, Block 2 Miesian Plaza, Dublin 2 – D02 HW68, Ireland.

EMADOC-1700519818-1698896
Amsterdam, 13 December 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMA/PE/0000225073

Scope of the application

Active substance(s):

Recombinant parathyroid hormone

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hypoparathyroidism

Pharmaceutical form(s):

Powder and solvent for solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Takeda Pharmaceuticals International AG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Takeda Pharmaceuticals International AG submitted to the European Medicines Agency on 5 September 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0205/2014 issued on 8 August 2014, the decision P/0255/2015 issued on 30 October 2015, the decision P/0325/2017 issued on 31 October 2017, the decision P/0136/2019 issued on 17 April 2019, the decision P/0460/2020 issued on 4 December 2020, the decision P/0369/2021 issued on 8 September 2021, and the decision P/0276/2023 issued on 14 July 2023.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver for all subsets of the paediatric population.

The procedure started on 14 October 2024.

Scope of the modification

All measures of the Paediatric Investigation Plan have been deleted and a waiver for all paediatric subsets has been granted.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion;
   - to grant a waiver for one or more subsets of the paediatric population concluded in accordance with Article 11(1)(c) of Regulation (EC) No 1901/2006 as amended, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   The Paediatric Committee members of Liechtenstein and Norway agree with the above-mentioned recommendation of the Paediatric Committee.

2. The subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Treatment of hypoparathyroidism

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- powder and solvent for solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

Not applicable.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of hypoparathyroidism

Authorised indication(s):

- as adjunctive treatment of adult patients with chronic hypoparathyroidism who cannot be adequately controlled with standard therapy alone.
  - Invented name(s): Natpar
  - Authorised pharmaceutical form(s): Powder and solvent for solution for injection
  - Authorised route(s) of administration: Subcutaneous use
  - Authorised via centralised procedure