EMADOC-1700519818-1810838

European Medicines Agency decision

EMA/PE/0000224273

of 3 January 2025

on the acceptance of a modification of an agreed paediatric investigation plan for whole-cell heat-inactivated bacterial strains of *Escherichia coli, Klebsiella pneumoniae, Proteus vulgaris and Enterococcus faecalis* 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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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/0211/2022 issued on 10 June 2022,

Having regard to the application submitted by Inmunotek S.L. on 31 July 2024 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 15 November 2024, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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.

(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.

[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 whole-cell heat-inactivated bacterial strains of *Escherichia coli, Klebsiella pneumoniae, Proteus vulgaris and Enterococcus faecalis*, 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

This decision is addressed to Inmunotek S.L., Calle Punto Mobi 5, 28805 - Alcala De Henares, Spain.

EMADOC-1700519818-1678180 Corr[1]
Amsterdam, 15 November 2024

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMA/PE/0000224273

Scope of the application

Active substance(s):

Whole-cell heat-inactivated bacterial strains of *Escherichia coli, Klebsiella pneumoniae, Proteus vulgaris and Enterococcus faecalis*

Invented name and authorisation status:

See Annex II

Condition(s):

Prevention of urinary tract infections

Pharmaceutical form(s):

Sublingual spray

Route(s) of administration:

Sublingual use

Name/corporate name of the PIP applicant:

Inmunotek S.L.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Inmunotek S.L. submitted to the European Medicines Agency on 31 July 2024 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0211/2022 issued on 10 June 2022.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 16 September 2024.

[1] 13 December 2024

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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.

   The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and 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:

Prevention of urinary tract infection

The waiver applies to:

- the paediatric population from birth to less than 4 years of age;
- sublingual spray, sublingual use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Prevention of urinary tract infection

2.1.1. Indication(s) targeted by the PIP

Prevention of recurrent uncomplicated lower urinary tract infections (R-UTIs)

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 4 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Sublingual spray

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable.
Non-clinical studies	Not applicable.
Clinical studies	**Study 1** (ITK-URO-2021-01) Double-blind, randomised, multicentre, placebo-controlled trial to evaluate safety and efficacy of whole-cell heat-inactivated bacterial strains of *Escherichia coli, Klebsiella pneumoniae, Proteus vulgaris* and *Enterococcus faecalis* (Uromune) in children from 4 years to less than 18 years of age with recurrent uncomplicated lower urinary tract infections (R-UTIs).
Extrapolation, modelling and simulation studies	Not applicable.

Other studies	Not applicable.
Other measures	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By March 2030
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.