EMA/365815/2022

European Medicines Agency decision

P/0210/2022

of 10 June 2022

on the agreement of a paediatric investigation plan and on the granting of a deferral for reparixin (EMEA-001693-PIP03-21) 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 application submitted by Dompé farmaceutici S.p.A. on 17 May 2021 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 April 2022, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

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

A paediatric investigation plan for reparixin, age appropriate oral formulation, tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for reparixin, age appropriate oral formulation, tablet, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision is addressed to Dompé farmaceutici S.p.A., Via Santa Lucia, 6, 20122 – Milano, Italy.

EMA/PDCO/38182/2022
Amsterdam, 22 April 2022

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-001693-PIP03-21

Scope of the application

Active substance(s):

Reparixin

Condition(s):

Treatment of coronavirus disease 2019 (COVID-19)

Pharmaceutical form(s):

Age appropriate oral formulation

Tablet

Route(s) of administration:

Oral use

Name/corporate name of the PIP applicant:

Dompé farmaceutici S.p.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Dompé farmaceutici S.p.A. submitted for agreement to the European Medicines Agency on 17 May 2021 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation.

The procedure started on 12 July 2021.

Supplementary information was provided by the applicant on 28 December 2021. The applicant proposed modifications to the paediatric investigation plan.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 17(1) of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

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

2. The measures and timelines of the agreed paediatric investigation plan 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 annex 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of coronavirus disease 2019 (COVID-19)

2.1.1. Indication(s) targeted by the PIP

Treatment of coronavirus disease 2019 (COVID-19)

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

From birth to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Age appropriate oral formulation

Tablet

2.1.4. Measures

Area	**Description**
Quality-related studies	**Study 1** Development of an age-appropriate oral dosage form (powder for syrup) **Study 2** Development of an age-appropriate oral solid dosage form (tablet)
Non-clinical studies	Not applicable
Clinical studies	**Study 3** Single arm, open label study of pharmacokinetic, activity and safety of reparixin in paediatric patients from birth to less than 18 years of age with COVID-19 at high risk of disease progression
Extrapolation, modelling and simulation studies	**Study 4** Population PK (PopPK) study to guide the dose to be used and guide sampling timepoints in patients below 18 years of age based on adult data

	Study 5 Physiologically Based Pharmacokinetic (PBPK) study of reparixin to predict the paediatric dose for patients below 18 years of age. **Study 6** Comparison of pharmacokinetic and pharmacodynamic (inflammatory status), efficacy and safety data from phase 3, placebo-controlled study (REP0321) in adults, to paediatric data generated in Study 3 to support extrapolation of efficacy
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 April 2025
Deferral for one or more measures contained in the paediatric investigation plan:	Yes