EMA/53064/2024

European Medicines Agency decision

P/0042/2024

of 9 February 2024

on the agreement of a paediatric investigation plan and on the granting of a deferral for clobetasol propionate, (EMEA-003458-PIP01-23) 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 Laboratorios Salvat, S.A. on 30 May 2023 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 19 January 2024, 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 clobetasol propionate, eye drops, emulsion, ocular 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 clobetasol propionate, eye drops, emulsion, ocular 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 Laboratorios Salvat, S.A., Gall, 30-36, 08950 - Esplugues de Llobregat, Spain.

EMA/PDCO/483204/2023 Corr[1]
Amsterdam, 19 January 2024

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

EMEA-003458-PIP01-23

Scope of the application

Active substance(s):

Clobetasol propionate

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of ocular inflammations and manifestations associated with ocular surgery

Pharmaceutical form(s):

Eye drops, emulsion

Route(s) of administration:

Ocular use

Name/corporate name of the PIP applicant:

Laboratorios Salvat, S.A.

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Laboratorios Salvat, S.A. submitted for agreement to the European Medicines Agency on 30 May 2023 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 10 July 2023.

Supplementary information was provided by the applicant on 11 October 2023. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

[1] 5 February 2024

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 Paediatric Committee member of Norway 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 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

Not applicable

2. Paediatric investigation plan

2.1. Condition:

Treatment of ocular inflammations and manifestations associated with ocular surgery

2.1.1. Indication(s) targeted by the PIP

Treatment of inflammation and pain associated with ocular surgery.

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)

Eye drops, emulsion

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 (CLOSE-3 - EudraCT Nr: 2022-000624-37). Randomised, parallel-group, assessor-blind, active-controlled, multicentre trial in children following cataract surgery to assess the safety the efficacy on ocular inflammation and pain of clobetasol propionate ophthalmic emulsion, 0.05% treatment after cataract surgery in children from birth to less than 4 years of age, compared to prednisolone acetate ophthalmic suspension, 1%.
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	Studies CLOSE-1 (in adults) and CLOSE-2 (in adults) and CLOSE-3 (PIP study 1) are part of the extrapolation plan of efficacy and safety data to the paediatric population from birth to less than 4 years of age and from 4 years to less than 18 years of age, as agreed by the PDCO.

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

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.