EMA/285269/2023

European Medicines Agency decision

P/0269/2023

of 14 July 2023

on the agreement of a paediatric investigation plan and on the granting of a waiver for clindamycin phosphate / benzoyl peroxide (hydrous) / adapalene (micronized) (EMEA-003263-PIP01-22) 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 Bausch Health Ireland Limited on 26 May 2022 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 May 2023, in accordance with Article 17 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 agreement of a paediatric investigation plan and on the granting of a waiver.

(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 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

A paediatric investigation plan for clindamycin phosphate / benzoyl peroxide (hydrous) / adapalene (micronized), gel, cutaneous 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 waiver for clindamycin phosphate / benzoyl peroxide (hydrous) / adapalene (micronized), gel, cutaneous 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 Bausch Health Ireland Limited, 3013 Lake Drive, Citywest Business Campus, D24PPT3 - Dublin Ireland.

EMA/PDCO/102918/2023 Corr[1]
Amsterdam, 26 May 2023

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

EMEA-003263-PIP01-22

Scope of the application

Active substance(s):

Clindamycin phosphate / benzoyl peroxide (hydrous) / adapalene (micronized)

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of acne vulgaris

Pharmaceutical form(s):

Gel

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

Bausch Health Ireland Limited

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Bausch Health Ireland Limited submitted for agreement to the European Medicines Agency on 26 May 2022 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 11 July 2022.

Supplementary information was provided by the applicant on 20 February 2023. The applicant proposed modifications to the paediatric investigation plan.

[1] 7 July 2023

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 waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

   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 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:

Treatment of acne vulgaris

The waiver applies to:

- the paediatric population from birth to less than 9 years of age;
- gel, cutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Treatment of acne vulgaris

2.1.1. Indication(s) targeted by the PIP

Treatment of acne vulgaris

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

From 9 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Gel

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (V01-126A-201)** Randomised, double-blind, placebo-controlled study to evaluate the safety, tolerability and efficacy of a fixed dose combination of clindamycin phosphate, benzoyl peroxide and adapalene (IDP-126 Gel) compared with each of its dual components (IDP-126 Component A Gel [benzoyl peroxide 3.1%/adapalene 0.15%], IDP-126 Component B Gel [clindamycin phosphate 1.2%/ benzoyl peroxide 3.1%], and IDP-126 Component C Gel [clindamycin phosphate 1.2%/adapalene 0.15%]) and vehicle (IDP-126 Vehicle Gel) in paediatric patients from 9 years to less than 18 years of age with moderate to severe acne vulgaris.

	Study 2 (V01-126A-501) Open label, uncontrolled study to evaluate pharmacokinetics and safety of clindamycin and adapalene in IDP-126 Gel (clindamycin phosphate 1.2%, benzoyl peroxide [BPO] 3.1%, and adapalene 0.15%) in comparison with EpiDuo Forte Gel (0.3% adapalene/2.5% BPO) in paediatric patients from 9 years to less than 18 years of age with moderate or severe acne vulgaris. **Study 3 (V01-126A-301)** Randomised, double blind, placebo-controlled study to evaluate safety and efficacy of a fixed dose combination of clindamycin phosphate, benzoyl peroxide and adapalene (IDP-126 Gel) in paediatric patients from 9 years to less than 18 years of age with moderate or severe acne vulgaris. **Study 4 (V01-126A-302)** Randomised, double-blind, placebo-controlled study to evaluate safety and efficacy of a fixed dose combination of clindamycin phosphate, benzoyl peroxide and adapalene (IDP-126 Gel) in paediatric patients from 9 years to less than 18 years of age with moderate or severe acne vulgaris. **Study 5 (V01-126A-202)** Randomised, double-blind, placebo- and active comparator-controlled study to evaluate safety and efficacy of a fixed dose combination of clindamycin phosphate, benzoyl peroxide and adapalene (IDP-126 Gel) in paediatric patients from 12 years to less than 18 years of age with moderate or severe acne vulgaris.
Modelling and simulation studies	Not applicable
Other studies	Not applicable
Extrapolation plan	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By November 2022
Deferral for one or more measures contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.