EMA/511007/2020

European Medicines Agency decision

P/0389/2020

of 1 October 2020

on the acceptance of a modification of an agreed paediatric investigation plan for peanut allergen extract (EMEA-001481-PIP01-13-M04) 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 peanut allergen extract (EMEA-001481-PIP01-13-M04) 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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0121/2015 issued on 5 June 2015 and the decision P/0286/2015 issued on 27 November 2015 and the decision P/0342/2018 issued on 9 November 2018,

Having regard to the application submitted by DBV Technologies S.A. on 5 June 2020 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 4 September 2020, 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.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for peanut allergen extract, cutaneous patch, cutaneous use, 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 DBV Technologies S.A., 177-181 avenue Pierre Brossolette, 92120 - Montrouge, France.

EMA/PDCO/327707/2020
Amsterdam, 4 September 2020

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

EMEA-001481-PIP01-13-M04

Scope of the application

Active substance(s):

Peanut allergen extract

Condition(s):

Treatment of peanut allergy

Pharmaceutical form(s):

Cutaneous patch

Route(s) of administration:

Cutaneous use

Name/corporate name of the PIP applicant:

DBV Technologies S.A.

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, DBV Technologies S.A. submitted to the European Medicines Agency on 5 June 2020 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/0121/2015 issued on 5 June 2015 and the decision P/0286/2015 issued on 27 November 2015 and the decision P/0342/2018 issued on 9 November 2018.

The procedure started on 6 July 2020.

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

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 Norwegian Paediatric Committee member 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 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

1.1. Condition

Treatment of peanut allergy

The waiver applies to:

- the paediatric population from birth to less than 1 year of age;
- cutaneous patch, cutaneous 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

Treatment of peanut allergy

2.1.1. Indication(s) targeted by the PIP

Treatment of peanut allergy

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

From 1 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Cutaneous patch

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	9	**Study 1** (V712-101 or PEP01.09) Double-blind, randomised, placebo-controlled trial to evaluate safety and tolerability of peanut allergen extract in children from 6 to less than 18 years of age (and adults) with peanut allergy **Study 2** (V712-202 or VIPES) Double-blind, randomised, placebo-controlled multiple-dose trial to evaluate efficacy and safety of peanut allergen extract in children from 6 to less than 18 years of age (and adults) with peanut allergy

		Study 3 (V712-203 or OLFUS-VIPES) Open-label, extension trial to assess long-term safety and efficacy of peanut allergen extract in children from 6 to less than 18 years of age (and adults) with peanut allergy **Study 4** (V712-301 or PEPITES) Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of peanut allergen extract in children from 4 to less than 12 years of age with peanut allergy **Study 5** (V712-306) Double-blind, randomised, placebo-controlled trial to evaluate the efficacy and safety of peanut allergen extract in children from 12 to less than 18 years of age (and adults) with peanut allergy **Study 6** (V712-303 or PEOPLE) Open-label, extension study to evaluate safety and efficacy of peanut allergen extract in children from 4 to less than 12 years of age with peanut allergy **Study 7** (V712-307) Open-label, extension study to assess safety and efficacy of peanut allergen extract in children from 12 to less than 18 years of age (and adults) with peanut allergy **Study 8** (V712-304 or EPITOPE) *Added during procedure EMEA-001481-PIP01-13-M01* Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of peanut allergen extract in children from 1 to less than 4 years of age with peanut allergy **Study 9** (V712-305 or EPOPEX) *Added during procedure EMEA-001481-PIP01-13-M01* Open-label, extension study to evaluate safety and efficacy of peanut allergen extract in children from 1 to less than 4 years of age with peanut allergy
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	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 March 2026
Deferral for one or more measures contained in the paediatric investigation plan:	Yes