MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-102201-PIP01-25-M01

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 the Decision

Pursuant to the Human Medicines Regulations 2012, DBV Technologies S.A. submitted to the licensing authority on 20/11/2025 21:47 GMT an application for a Modification

The procedure started on 09/12/2025 07:42 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-102201-PIP01-25-M01

Of 13/03/2026 07:41 GMT

On the adopted decision for Peanut Allergen Extract (MHRA-102201-PIP01-25-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Peanut Allergen Extract, Cutaneous patch , CUTANEOUS USE .

This decision is addressed to DBV Technologies S.A., 107 Avenue de la République, Châtillon, FRANCE, 92320

ANNEX I

1. Waiver

1.1 Condition:

1.1 Condition: Treatment of peanut allergy The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Cutaneous patch Route(s) of administration: Cutaneous use Reason for granting waiver: 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(s):

Treatment of peanut allergy

2.2 Indication(s) targeted by the PIP:

Allergen immunotherapy in patients with peanut allergy for the reduction of clinical reactivity to peanut exposure

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Cutaneous patch

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	12	Study 1 (V712-101 / PEP01.09) Double-blind, randomised, placebo-controlled trial to evaluate safety and tolerability of peanut allergen extract in children from 6 years to less than 18 years of age (and adults) with peanut allergy. Study 2 (V712-202 / VIPES) Double-blind, randomised, placebo-controlled, multiple-dose trial to evaluate efficacy and safety of peanut allergen extract in children from 6 years to less than 18 years of age (and adults) with peanut allergy. Study 3 (V712-203 / OLFUS-VIPES) Open-label extension trial to evaluate long-term safety and efficacy of peanut allergen extract in children from 6 years to less than 18 years of age (and adults) with peanut allergy. Study 4 (V712-301 / PEPITES) Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of peanut allergen extract in children from 4 years to less than 12 years of age with peanut allergy. Study 5 (Phase 3 8-17) Double-blind, randomised, placebo-controlled trial with optional open-label extension

		to evaluate the efficacy and safety of peanut allergen extract in children from 8 years to less than 18 years of age with peanut allergy. Study 6 (V712-303 / PEOPLE) Open-label extension trial to evaluate long-term safety and efficacy of peanut allergen extract in children from 4 years to less than 12 years of age with peanut allergy.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Study 8 (V712-304 / EPITOPE) Double-blind, randomised, placebo-controlled trial to evaluate efficacy and safety of peanut allergen extract in children from 1 year to less than 4 years of age with peanut allergy. Study 9 (V712-305 / EPOPEX) Open-label extension trial to evaluate long-term safety and efficacy of peanut allergen extract in children from 1 year to less than 4 years of age with peanut allergy. Study 10 (V712-205 / THRIVE) Open-label trial to evaluate efficacy and safety of peanut allergen extract in children from 6 months to less than 12 months of age with peanut allergy. Study 11 (V712-308 / COMFORT Toddlers) Double-blind, randomised, placebo-controlled trial with optional open-label extension to evaluate safety of peanut allergen extract in children from 1 year to less than 4 years of age with peanut allergy. Study 12 (Phase 3 1-3) Double-blind, randomised, placebo-controlled trial with optional open-label extension to evaluate safety of peanut allergen extract in children from 1 year to less than 4 years of age with peanut allergy. Study 13 (V712-306 / VITESSE) Double-blind, randomised, placebo-controlled trial with optional open-label extension to evaluate efficacy and safety of peanut allergen extract in children from 4 years to less than 8 years of age with peanut allergy.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/10/2031
Deferral of one or more studies contained in the paediatric investigation plan:	Yes