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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver.

MHRA-102287-PIP01-25

Scope of the Application

Active Substance(s)

Clostridium botulinum, neurotoxin serotype A/B

Condition(s)

Treatment of skin wrinkling

Pharmaceutical Form(s)

Powder for solution for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Ipsen Pharma

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Ipsen Pharma submitted to the licensing authority on 18/12/2025 10:17 GMT an application for a Paediatric Investigation Plan

The procedure started on 13/01/2026 08:35 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 grant a product specific waiver

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-102287-PIP01-25

Of 11/02/2026 14:39 GMT

On the adopted decision for Clostridium botulinum, neurotoxin serotype A/B (MHRA-102287-PIP01-25) in accordance with the Human Medicines Regulations 2012.

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

Granting a waiver in all age groups for the listed condition(s).

This decision applies to a Paediatric Investigation Plan for Clostridium botulinum, neurotoxin serotype A/B, All pharmaceutical forms , All routes of administration .

This decision is addressed to Ipsen Pharma, 70 Rue Balard, Paris, FRANCE, 75015

ANNEX I

1. Waiver

1.1 Condition:

Treatment of skin wrinkling The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): All pharmaceutical forms Route(s) of administration: All routes of administration Reason for granting waiver: On the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s)

2. Paediatric Investigation Plan:

2.1 Condition(s):

Not applicable.

2.2 Indication(s) targeted by the PIP:

Not applicable.

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

Not applicable.

2.4 Pharmaceutical Form(s):

Not applicable.

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
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:	
Date of completion of the paediatric investigation plan:	
Deferral of one or more studies contained in the paediatric investigation plan:	