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-100978-PIP01-23

Scope of the Application

Active Substance(s)

Genetically detoxified Pertussis Toxin (PTgen) and Pertussis Filamentous Haemagglutinin (FHA)

Condition(s)

Prevention of Pertussis disease

Pharmaceutical Form(s)

Suspension for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

BIONET EUROPE

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, BIONET EUROPE submitted to the licensing authority on 14/04/2023 11:52 BST an application for a Waiver

The procedure started on 18/09/2023 15:01 BST

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.

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

gov.uk/mhra

Final Decision Letter

MHRA-100978-PIP01-23

Of 27/11/2023 18:13 GMT

On the adopted decision for Genetically detoxified Pertussis Toxin (PTgen) and Pertussis Filamentous Haemagglutinin (FHA) (MHRA-100978-PIP01-23) 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 Waiver for Genetically detoxified Pertussis Toxin (PTgen) and Pertussis Filamentous Haemagglutinin (FHA) , Suspension for injection , INTRAMUSCULAR USE .

This decision is addressed to BIONET EUROPE, 41 quai Fulchiron, Lyon, FRANCE, 69005

ANNEX I

1. Waiver

1.1 Condition:

Prevention of Pertussis disease The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Suspension for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: 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(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		
Non-Clinical Studies		
Clinical Studies		
Extrapolation, Modeling & Simulation Studies		
Other Studies		
Other Measures		

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:	