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

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a deferral and grant a waiver

MHRA-100030-PIP01-21

Scope of the Application

Active Substance(s)

9-valent vaccine consisting of the O-antigen polysaccharides of the extraintestinal pathogenic Escherichia coli (ExPEC) serotypes O1A, O2, O4, O6A, O15, O16, O18A, O25B and O75 bioconjugated to the carrier exoprotein A (EPA), a genetically detoxified protein from Pseudomonas aeruginosa (ExPEC9V)

Condition(s)

Prevention of infections caused by extraintestinal pathogenic Escherichia coli (ExPEC)

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Intramuscular use

Name / Corporate name of the PIP applicant

Janssen-Cilag UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Janssen-Cilag UK Ltd submitted to the licensing authority on 18/02/2022 19:36 GMT an application for a Paediatric Investigation Plan

The procedure started on 03/10/2022 07:38 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 agree a paediatric investigation plan and grant a deferral and grant a 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-100030-PIP01-21

Of 19/10/2022 17:27 BST

On the adopted decision for 9-valent vaccine consisting of the O-antigen polysaccharides of the extraintestinal pathogenic Escherichia coli (ExPEC) serotypes O1A, O2, O4, O6A, O15, O16, O18A, O25B and O75 bioconjugated to the carrier exoprotein A (EPA), a genetically detoxified protein from Pseudomonas aeruginosa (ExPEC9V) (MHRA-100030-PIP01-21) 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 a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for 9-valent vaccine consisting of the O-antigen polysaccharides of the extraintestinal pathogenic Escherichia coli (ExPEC) serotypes O1A, O2, O4, O6A, O15, O16, O18A, O25B and O75 bioconjugated to the carrier exoprotein A (EPA), a genetically detoxified protein from Pseudomonas aeruginosa (ExPEC9V), Solution for injection , Intramuscular use .

This decision is addressed to Janssen-Cilag UK Ltd, 50-100 Holmers Farm way, High Wycombe, United Kingdom, HP12 4EG

ANNEX I

1. Waiver

1.1 Condition:

Prevention of infections caused by extraintestinal pathogenic Escherichia coli (ExPEC) The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 weeks of age Pharmaceutical form(s): Solution for injection Route(s) of administration: Intramuscular 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):

Prevention of infections caused by extraintestinal pathogenic Escherichia coli (ExPEC)

2.2 Indication(s) targeted by the PIP:

Active immunisation for the prevention of recurrent urinary tract infection (rUTI) caused by vaccine serotypes

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

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

2.4 Pharmaceutical Form(s):

Solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	1	Study 1 Toxicity and local tolerance study of ExPEC9V in New Zealand white rabbits administered intramuscularly (IM) in a 5-dose schedule.
Clinical Studies	2	Study 2 Double-blind, randomised, placebo-controlled trial to evaluate immunogenicity, safety and reactogenicity of ExPEC9V in children from 1 year to less than 18 years of age at risk for recurrent urinary tract infection (rUTI). Study 3 Double-blind, randomised, placebo-controlled trial to establish a dosing schedule and to evaluate immunogenicity, safety and reactogenicity of ExPEC9V in infants from 6 weeks to less than 1 year of age at risk for recurrent urinary tract infection (rUTI).
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:	No
Date of completion of the paediatric investigation plan:	31/07/2032
Deferral of one or more studies contained in the paediatric investigation plan:	Yes