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

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Decision Cover Letter

Decision of the licensing authority to:

a grant a product specific waiver

MHRA-101204-PIP01-23

Scope of the Application

Active Substance(s)

Ravulizumab (ALXN1210)

Condition(s)

Prevention of kidney injury in high-risk patients with chronic kidney disease undergoing cardiopulmonary bypass

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Alexion Europe SAS

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Alexion Europe SAS submitted to the licensing authority on 03/10/2023 17:28 BST an application for a Waiver

The procedure started on 16/05/2024 14:02 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.

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Final Decision Letter

MHRA-101204-PIP01-23

Of 01/08/2024 12:12 BST

On the adopted decision for Ravulizumab (ALXN1210) (MHRA-101204-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

This decision applies to a Waiver for Ravulizumab (ALXN1210) , Concentrate for solution for infusion , INTRAVENOUS .

This decision is addressed to Alexion Europe SAS, 103 - 105 rue Anatole France, , Levallois-Perret, FRANCE, 92300

ANNEX I

1. Waiver

1.1 Condition:

Prevention of kidney injury in high-risk patients with chronic kidney disease undergoing cardiopulmonary bypass

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:	