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

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Decision Cover Letter

Decision of the licensing authority to:

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

MHRA-101303-PIP01-23

Scope of the Application

Active Substance(s)

OBINUTUZUMAB

Condition(s)

Treatment of glomerulonephritis and nephrotic syndrome

Pharmaceutical Form(s)

Concentrate for solution for infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

Roche Products Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Roche Products Limited submitted to the licensing authority on 14/08/2024 09:48 BST an application for a Paediatric Investigation Plan

The procedure started on 25/10/2024 08:50 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.

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Final Decision Letter

MHRA-101303-PIP01-23

Of 21/01/2025 08:55 GMT

On the adopted decision for OBINUTUZUMAB (MHRA-101303-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:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for OBINUTUZUMAB, Concentrate for solution for infusion , INTRAVENOUS USE .

This decision is addressed to Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, UNITED KINGDOM, AL7 1TW

ANNEX I

1. Waiver

1.1 Condition:

Treatment of glomerulonephritis and nephrotic syndrome The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 2 years of age Pharmaceutical form(s): Concentrate for solution for infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of glomerulonephritis and nephrotic syndrome

2.2 Indication(s) targeted by the PIP:

Treatment of idiopathic nephrotic syndrome

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

The paediatric population from 2 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Concentrate for solution for infusion

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	1	Study 1 (WA43380) Open-label, randomised, active controlled trial to evaluate pharmacokinetics, safety and efficacy of obinutuzumab compared to mycophenolate mofetil (MMF) in children from 2 years to less than 18 years of age with childhood-onset idiopathic nephrotic syndrome (INS).
Extrapolation, Modeling & Simulation Studies	1	Study 2 Population PK (popPK) modelling study in participants with lupus nephritis (LN), primary membranous nephropathy (pMN), or childhood-onset idiopathic nephrotic syndrome (INS).
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:	Yes
Date of completion of the paediatric investigation plan:	31/07/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes