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-100118-PIP02-22

Scope of the Application

Active Substance(s)

OCRELIZUMAB

Condition(s)

Treatment of multiple sclerosis

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

SUBCUTANEOUS 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 19/12/2022 18:19 GMT an application for a Paediatric Investigation Plan

The procedure started on 23/05/2023 15:23 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-100118-PIP02-22

Of 16/06/2023 14:53 BST

On the adopted decision for OCRELIZUMAB (MHRA-100118-PIP02-22) 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 OCRELIZUMAB, Solution for injection , SUBCUTANEOUS 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 multiple sclerosis The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 10 years of age Pharmaceutical form(s): Solution for injection Route(s) of administration: SUBCUTANEOUS 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):

Treatment of multiple sclerosis

2.2 Indication(s) targeted by the PIP:

Treatment of relapsing remitting multiple sclerosis (RRMS)

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

The paediatric population from 10 years 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	0	Not applicable.
Clinical Studies	1	Study 1 Open-label study to evaluate pharmacokinetics of subcutaneous ocrelizumab administration in children and adolescents with relapsing remitting multiple sclerosis.
Extrapolation, Modeling & Simulation Studies	2	Study 2 Population pharmacokinetic (PPK) model to evaluate the use of ocrelizumab administered subcutaneously in children from 10 years to less than 18 years of age with relapsing remitting multiple sclerosis. Study 3 Extrapolation of efficacy from studies in paediatric patients receiving intravenous ocrelizumab and from studies in adult patients receiving subcutaneous (SC) ocrelizumab to paediatric patients from 10 years to less than 18 years age receiving SC ocrelizumab.
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:	31/08/2029
Deferral of one or more studies contained in the paediatric investigation plan:	Yes