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

MHRA-100120-PIP01-21

Scope of the Application

Active Substance(s)

TOCILIZUMAB

Condition(s)

Treatment of coronavirus disease 2019 (COVID-19)

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 13/08/2021 10:50 BST an application for a Paediatric Investigation Plan

The procedure started on 22/09/2021 08:51 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

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-100120-PIP01-21

Of 18/10/2021 15:57 BST

On the adopted decision for TOCILIZUMAB (MHRA-100120-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 TOCILIZUMAB, 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:

Not applicable

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of coronavirus disease 2019 (COVID-19)

2.2 Indication(s) targeted by the PIP:

Treatment of coronavirus disease 2019 (COVID-19) in hospitalized paediatric patients who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation

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

All subsets of the paediatric population from birth 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 Open-label, single arm study assessing the pharmacokinetics (PK), pharmacodynamics (PD), safety and exploratory efficacy of tocilizumab treatment in paediatric patients from birth to less than 18 years of age hospitalised with COVID-19.
Extrapolation, Modeling & Simulation Studies	1	Study 2 Extrapolation study of pharmacokinetics (PK) / pharmacodynamics (PD) of tocilizumab from adult to paediatric patients with COVID-19 pneumonia based on the analyses of data collected in adult and paediatric patients.
Other Studies	1	Study 3 Review of available data in the worldwide published literature or other sources on the use of tocilizumab in hospitalized paediatric patients with COVID-19.
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:	31/12/2023
Deferral of one or more studies contained in the paediatric investigation plan:	Yes