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

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Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-100699-PIP01-22-M01

Scope of the Application

Active Substance(s)

DIROXIMEL FUMARATE

Condition(s)

Treatment of multiple sclerosis

Pharmaceutical Form(s)

Gastro-resistant capsule, hard

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Biogen Netherlands B.V.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Biogen Netherlands B.V. submitted to the licensing authority on 29/09/2022 12:08 BST an application for a Modification

The procedure started on 29/03/2023 15:56 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-100699-PIP01-22-M01

Of 12/04/2023 09:47 BST

On the adopted decision for DIROXIMEL FUMARATE (MHRA-100699-PIP01-22-M01) 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(s)

This decision applies to a Modification for DIROXIMEL FUMARATE, Gastro-resistant capsule, hard , ORAL USE .

This decision is addressed to Biogen Netherlands B.V., Prins Mauritslaan 13, Badhoevedorp, NETHERLANDS, 1171-LP

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 18 years of age. Pharmaceutical form(s): Gastro-resistant capsule, hard Route(s) of administration: ORAL 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):

Studies 1, 2 and 3 were deleted during procedure MHRA-100699-PIP01-22-M01.

2.2 Indication(s) targeted by the PIP:

N/A

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

N/A

2.4 Pharmaceutical Form(s):

N/A

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	N/A
Non-Clinical Studies	0	N/A
Clinical Studies	0	N/A
Extrapolation, Modeling & Simulation Studies	0	N/A
Other Studies	0	N/A
Other Measures	0	N/A

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:	