

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-101243-PIP01-23

Scope of the Application

Active Substance(s)

3-[2-(Dimethylamino)ethyl]-1H-indol-4-yl dihydrogen phosphate

Condition(s)

Major depressive disorder

Pharmaceutical Form(s)

Capsule, hard

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

COMPASS Pathfinder Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, COMPASS Pathfinder Limited submitted to the licensing authority on 17/11/2023 14:39 GMT an application for a Waiver

The procedure started on 12/03/2024 14:27 GMT

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-101243-PIP01-23

Of 07/01/2025 14:57 GMT

On the adopted decision for 3-[2-(Dimethylamino)ethyl]-1H-indol-4-yl dihydrogen phosphate (MHRA-101243-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(s)

This decision applies to a Waiver for 3-[2-(Dimethylamino)ethyl]-1H-indol-4-yl dihydrogen phosphate, Capsule, hard , ORAL USE .

This decision is addressed to COMPASS Pathfinder Limited, 3rd Floor, 1 Ashley Road, Altrincham, UNITED KINGDOM, WA14 2DT

ANNEX I

1. Waiver

1.1 Condition:

Treatment of major depressive disorder The waiver applies to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Capsules, hard Route(s) of administration: ORAL Reason for granting waiver: For all subsets from birth to less than 7 years of age - on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s) For all subsets from 7 years to less than 18 years of age: - on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible

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:	

