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

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Decision Cover Letter

Decision of the licensing authority to:

confirm the applicability of the Class Waiver

MHRA-102203-PIP01-25

Scope of the Application

Active Substance(s)

Opevesostat tosilate

Condition(s)

Treatment of breast cancer

Pharmaceutical Form(s)

Tablet

Route(s) of Administration

ORAL USE

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Ltd.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Ltd. submitted to the licensing authority on 30/10/2025 17:01 GMT an application for a Waiver

The procedure started on 28/11/2025 13:49 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 confirm the applicability of the Class 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-102203-PIP01-25

Of 17/12/2025 16:42 GMT

On the adopted decision for Opevesostat tosilate (MHRA-102203-PIP01-25) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Confirmation of the applicability of the Class Waiver for the listed condition(s).

This decision applies to a Waiver for Opevesostat tosilate, Tablet , ORAL USE .

This decision is addressed to Merck Sharp & Dohme (UK) Ltd. , 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Treatment of breast cancer. The waiver applies / applied to: Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Tablet Route(s) of administration: ORAL USE Reason for granting waiver: the product belongs to the class of ‘Androgen receptor modulator, of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone-metabolism modulator medicinal products’ as stated in Annex II of the adopted Class Waiver Decision CW/0001/2025.

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:	