

**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-101881-PIP01-25

### **Scope of the Application**

#### **Active Substance(s)**

opevesostat

#### **Condition(s)**

Treatment of prostate malignant neoplasms

#### **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 28/03/2025 11:17 GMT an application for a Waiver

The procedure started on 01/05/2025 16:29 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 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-101881-PIP01-25

Of 12/05/2025 10:59 BST

On the adopted decision for opevesostat (MHRA-101881-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, 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 prostate malignant neoplasms. 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, oestrogen receptor modulator, growth and sex hormone as well as their releasing or inhibiting factors, sex hormone-metabolism modulator medicinal products for the treatment of breast malignant neoplasms, prostate malignant neoplasms and neuroendocrine malignant neoplasms' as stated in Annex II of the adopted Class Waiver Decision CW/0001/2015.

### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Not Applicable

**2.2 Indication(s) targeted by the PIP:**

Not Applicable
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**2.3 Subset(s) of the paediatric population concerned by the paediatric development:**

Not Applicable
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**2.4 Pharmaceutical Form(s):**

Not Applicable
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**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:	

