

**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-100125-PIP01-21

### **Scope of the Application**

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

PEMBROLIZUMAB; vibostolimab

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

Malignant neoplasms (except CNS, haematopoietic, lymphoid tissue melanoma), Malignant CNS neoplasms

#### **Pharmaceutical Form(s)**

Concentrate for solution for infusion;

#### **Route(s) of Administration**

Intravenous 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 12/07/2021 09:18 BST an application for a Waiver

The procedure started on 04/07/2022 11:18 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 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-100125-PIP01-21

Of 14/07/2022 07:25 BST

On the adopted decision for PEMBROLIZUMAB; vibostolimab (MHRA-100125-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:

Granting a waiver in all age groups for the listed condition(s)

This decision applies to a Waiver for PEMBROLIZUMAB; vibostolimab, Concentrate for solution for infusion; , Intravenous 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 all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue and melanoma) 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): Concentrate for solution for infusion  
Route(s) of administration: Intravenous use  
Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).  
1. Waiver 1.2 Condition: Treatment of malignant neoplasms of the central nervous system  
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): Concentrate for solution for infusion  
Route(s) of administration: Intravenous use  
Reason for granting waiver: on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

### 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:**

| <b>Study Type</b>                                       | <b>Number of Studies</b> | <b>Study Description</b> |
|---|--------------------------|--------------------------|
| <b>Quality Measures</b>                                 |                          |                          |
| <b>Non-Clinical Studies</b>                             |                          |                          |
| <b>Clinical Studies</b>                                 |                          |                          |
| <b>Extrapolation, Modeling &amp; Simulation Studies</b> |                          |                          |
| <b>Other Studies</b>                                    |                          |                          |
| <b>Other Measures</b>                                   |                          |                          |

**3. Follow-up, completion and deferral of a PIP:**

|  |  |
|--|--|
| <b>Concerns on potential long term safety and efficacy issues in relation to paediatric use:</b> |  |
| <b>Date of completion of the paediatric investigation plan:</b>                                  |  |
| <b>Deferral of one or more studies contained in the paediatric investigation plan:</b>           |  |

