

**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-100858-PIP01-23

### **Scope of the Application**

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

sabatolimab

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

Treatment of myelodysplastic syndromes

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

Concentrate for solution for infusion

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

INTRAVENOUS USE

#### **Name / Corporate name of the PIP applicant**

Novartis Pharmaceuticals UK Limited

#### **Basis for the Decision**

Pursuant to the Human Medicines Regulations 2012, Novartis Pharmaceuticals UK Limited submitted to the licensing authority on 04/04/2023 14:04 BST an application for a Waiver

The procedure started on 18/09/2023 14:55 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-100858-PIP01-23

Of 27/11/2023 17:45 GMT

On the adopted decision for sabatolimab (MHRA-100858-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 sabatolimab , Concentrate for solution for infusion ,  
INTRAVENOUS USE .

This decision is addressed to Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, UNITED KINGDOM, W12 2FQ

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of myelodysplastic syndromes 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
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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:**

<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>	