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

**gov.uk/mhra**

# Decision Cover Letter

## Decision of the licensing authority to:

grant a product specific waiver

MHRA-101349-PIP01-24

# Scope of the Application

## Active Substance(s)

SECUKINUMAB

## Condition(s)

Treatment of rotator cuff tendinopathy

## Pharmaceutical Form(s)

Solution for injection; Powder for solution for injection/infusion

## Route(s) of Administration

SUBCUTANEOUS 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 31/01/2024 13:07 GMT an application for a Waiver

The procedure started on 20/03/2024 14:10 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-101349-PIP01-24

Of 15/05/2024 17:36 BST

On the adopted decision for SECUKINUMAB (MHRA-101349-PIP01-24) 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 SECUKINUMAB, Solution for injection; Powder for solution for injection/infusion , SUBCUTANEOUS 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 7FQ

## ANNEX I

### 1. Waiver

### 1.1 Condition:

| |
|---|
| Treatment of rotator cuff tendinopathy 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): Solution for injection Powder for solution for injection/infusion Route(s) of administration: SUBCUTANEOUS USE Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments |

### 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:** | |