

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

[gov.uk/mhra](https://gov.uk/mhra)

## **Decision Cover Letter**

### **Decision of the licensing authority to:**

grant a product specific waiver.

MHRA-102425-PIP01-26

### **Scope of the Application**

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

PF-08634404

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

Treatment of all conditions included in the category of malignant neoplasms (except melanoma, central nervous system, haematopoietic and lymphoid tissue)

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

Concentrate for solution for infusion

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

INTRAVENOUS USE

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

Pfizer Limited

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

Pursuant to the Human Medicines Regulations 2012, Pfizer Limited submitted to the licensing authority on 19/03/2026 05:14 GMT an application for a Waiver

The procedure started on 13/04/2026 11:21 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-102425-PIP01-26

Of 09/06/2026 07:49 BST

On the adopted decision for PF-08634404 (MHRA-102425-PIP01-26) 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 PF-08634404, Concentrate for solution for infusion ,  
INTRAVENOUS USE .

This decision is addressed to Pfizer Limited, Ramsgate Road, Sandwich, Kent, UNITED KINGDOM,  
CT13 9NJ

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Treatment of all conditions included in the category of malignant neoplasms (except melanoma, central nervous system, haematopoietic and lymphoid tissue) The waiver applies / applied to: Paediatric Subset(s): 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 the specific medicinal product does not represent a significant therapeutic as clinical studies are not feasible.

### 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:           |  |