

**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-101355-PIP01-24

### Scope of the Application

#### Active Substance(s)

(3S,10S,14S)-1-[4-[[[(2S)-4-carboxy-2-[(2S)-4-carboxy-2-(6-[<sup>18</sup>F] fluoropyridin-3-amido)butanamido]butanamido]methyl]phenyl]-3-[(naphthalen-2-yl)methyl]-1,4,12-trioxo-2,5,11,13-tetraazahexadecane-10,14,16-tricarboxylic acid ([<sup>18</sup>F]PSMA-1007)

#### Condition(s)

Visualisation of prostate specific membrane antigen in prostate cancer

#### Pharmaceutical Form(s)

Solution for injection

#### Route(s) of Administration

INTRAVENOUS USE

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

ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH

#### Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH submitted to the licensing authority on 31/01/2024 15:36 GMT an application for a Waiver

The procedure started on 06/02/2024 10:41 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-101355-PIP01-24

Of 08/02/2024 07:03 GMT

On the adopted decision for (3S,10S,14S)-1-[4-[[[(2S)-4-carboxy-2-[(2S)-4-carboxy-2-(6-[18F] fluoropyridin-3-amido)butanamido]butanamido]methyl]phenyl]-3-[(naphthalen-2-yl)methyl]-1,4,12-trioxo-2,5,11,13-tetraazahexadecane-10,14,16-tricarboxylic acid ([18F]PSMA-1007) (MHRA-101355-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 (3S,10S,14S)-1-[4-[[[(2S)-4-carboxy-2-[(2S)-4-carboxy-2-(6-[18F] fluoropyridin-3-amido)butanamido]butanamido]methyl]phenyl]-3-[(naphthalen-2-yl)methyl]-1,4,12-trioxo-2,5,11,13-tetraazahexadecane-10,14,16-tricarboxylic acid ([18F]PSMA-1007) , Solution for injection , INTRAVENOUS USE .

This decision is addressed to ABX advanced biochemical compounds Biomedizinische Forschungsreagenzien GmbH, Heinrich-Glaeser-Str. 10-14, Radeberg, GERMANY, 01454

## ANNEX I

### 1. Waiver

#### 1.1 Condition:

Visualisation of prostate specific membrane antigen in prostate cancer 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 Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).
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### 2. Paediatric Investigation Plan:

#### 2.1 Condition(s):

Not Applicable
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**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>	

