MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

grant a product specific waiver

MHRA-101226-PIP01-23

Scope of the Application

Active Substance(s)

Volrustomig

Condition(s)

Treatment of cervical cancer, Treatment of renal cell carcinoma, Treatment of lung cancer, Treatment of mesothelioma

Pharmaceutical Form(s)

Concentrate for solution for injection/infusion

Route(s) of Administration

INTRAVENOUS USE

Name / Corporate name of the PIP applicant

AstraZeneca UK Limited

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, AstraZeneca UK Limited submitted to the licensing authority on 07/11/2023 13:27 GMT an application for a Waiver

The procedure started on 07/02/2024 07:51 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-101226-PIP01-23

Of 05/03/2024 07:56 GMT

On the adopted decision for Volrustomig (MHRA-101226-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 Volrustomig, Concentrate for solution for injection/infusion , INTRAVENOUS USE .

This decision is addressed to AstraZeneca UK Limited, 2 Pancras Square - 8th Floor, London, UNITED KINGDOM, N1C 4AG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of cervical 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): Concentrate for solution for injection/infusion Route(s) of administration: INTRAVENOUS USE Reason for granting waiver: For the paediatric population of male patients from birth to less than 18 years of age and female patients from birth to less than 14 years of age: - 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). For the paediatric population of female patients from 14 years of age to less than 18 years of age: - 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). Reason for Refusing Waiver: Not Applicable 1.2 Condition: Treatment of renal cell carcinoma 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 injection/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 benefit as clinical studies(s) are not feasible. Reason for Refusing Waiver: Not Applicable 1.3 Condition: Treatment of lung 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): Concentrate for solution for injection/infusion 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). Reason for Refusing Waiver: Not Applicable 1.4 Condition: Treatment of mesothelioma 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 injection/ infusion 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).

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:	