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-100383-PIP01-21

Scope of the Application

Active Substance(s)

TRASTUZUMAB DERUXTECAN

Condition(s)

Treatment of lung cancer

Pharmaceutical Form(s)

All pharmaceutical forms

Route(s) of Administration

All routes administration.

Name / Corporate name of the PIP applicant

DAIICHI SANKYO UK LIMITED

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, DAIICHI SANKYO UK LIMITED submitted to the licensing authority on 17/12/2021 10:29 GMT an application for a

The procedure started on 12/08/2022 15:00 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-100383-PIP01-21

Of 19/09/2022 07:59 BST

On the adopted decision for TRASTUZUMAB DERUXTECAN (MHRA-100383-PIP01-21) 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 for TRASTUZUMAB DERUXTECAN, All pharmaceutical forms , Intravenous use .

This decision is addressed to DAIICHI SANKYO UK LIMITED, Building 4, Uxbridge Business Park, Sanderson Road, Uxbridge, United Kingdom, UB8 1DH

ANNEX I

1. Waiver

1.1 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): All pharmaceutical forms Route(s) of administration: All routes of administration 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:	