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

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Decision Cover Letter

Decision of the licensing authority to:

confirm the applicability of the Class Waiver.

MHRA-101915-PIP01-25

Scope of the Application

Active Substance(s)

Patritumab deruxtecan

Condition(s)

Treatment of breast malignant neoplasms

Pharmaceutical Form(s)

Powder for concentrate for solution for infusion

Route(s) of Administration

PARENTERAL USE

Name / Corporate name of the PIP applicant

Daiichi Sankyo UK Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Daiichi Sankyo UK Ltd submitted to the licensing authority on 17/04/2025 18:37 BST an application for a Waiver

The procedure started on 07/05/2025 11:25 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 confirm the applicability of the Class 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-101915-PIP01-25

Of 28/05/2025 16:00 BST

On the adopted decision for Patritumab deruxtecan (MHRA-101915-PIP01-25) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Confirmation of the applicability of the Class Waiver for the listed condition(s)

This decision applies to a Waiver for Patritumab deruxtecan , Powder for concentrate for solution for infusion , PARENTERAL USE .

This decision is addressed to Daiichi Sankyo UK Ltd, Building 4, Uxbridge Business Park, Sanderson Road, Uxbridge, UNITED KINGDOM, UB8 1DH

ANNEX I

1. Waiver

1.1 Condition:

Treatment of breast cancer Paediatric Subset(s): All subsets of the paediatric population from birth to less than 18 years of age Pharmaceutical form(s): Powder for concentrate for solution for infusion Route(s) of administration: PARENTERAL USE Reason for granting waiver: the product belongs to “the class of Her-/ epidermal growth factor-receptor antibody medicinal products for treatment of breast malignant neoplasms, intestinal malignant neoplasms and head and neck epithelial malignant neoplasms”, as stated in Annex II of the adopted Class Waiver Decision CW/0001/2015.

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:	