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-101702-PIP01-24

Scope of the Application

Active Substance(s)

Modified messenger ribonucleic acid encoding individual patient-specific tumour neoantigens V940 (mRNA-4157)

Condition(s)

Treatment of melanoma

Pharmaceutical Form(s)

Dispersion for injection

Route(s) of Administration

INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Merck Sharp & Dohme (UK) Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Merck Sharp & Dohme (UK) Ltd submitted to the licensing authority on 22/11/2024 11:01 GMT an application for a Waiver

The procedure started on 02/12/2024 09:36 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-101702-PIP01-24

Of 19/02/2025 09:02 GMT

On the adopted decision for Modified messenger ribonucleic acid encoding individual patient-specific tumour neoantigens V940 (mRNA-4157) (MHRA-101702-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 Modified messenger ribonucleic acid encoding individual patient-specific tumour neoantigens V940 (mRNA-4157), Dispersion for injection , INTRAMUSCULAR USE .

This decision is addressed to Merck Sharp & Dohme (UK) Ltd, 120 Moorgate, London, UNITED KINGDOM, EC2M 6UR

ANNEX I

1. Waiver

1.1 Condition:

Treatment of melanoma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 18 years of age. Pharmaceutical form(s): Dispersion for injection Route(s) of administration: INTRAMUSCULAR USE Reason for granting waiver: For the paediatric population from birth to less than 12 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 from 12 years to less than 18 years of age: - on the grounds that the specific medicinal product does not represent a significant therapeutic benefit 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:	