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-102452-PIP01-26

Scope of the Application

Active Substance(s)

mRNA that encodes immunogenic peptides derived from IDO-1 and PD-L1

Condition(s)

Treatment of melanoma

Pharmaceutical Form(s)

Dispersion for injection

Route(s) of Administration

INTRAMUSCULAR

Name / Corporate name of the PIP applicant

Moderna Biotech Spain, S.L.

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Moderna Biotech Spain, S.L. submitted to the licensing authority on 13/04/2026 17:36 BST an application for a Paediatric Investigation Plan

The procedure started on 20/04/2026 07:26 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-102452-PIP01-26

Of 21/10/2026 16:50 BST

On the adopted decision for mRNA that encodes immunogenic peptides derived from IDO-1 and PD-L1 (MHRA-102452-PIP01-26) 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 Paediatric Investigation Plan for mRNA that encodes immunogenic peptides derived from IDO-1 and PD-L1, Dispersion for injection , INTRAMUSCULAR .

This decision is addressed to Moderna Biotech Spain, S.L., C/ Julián Camarillo n ° 31, Madrid, SPAIN, 28037

ANNEX I

1. Waiver

1.1 Condition:

Treatment of melanoma 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): Dispersion for injection Route(s) of administration: Intramuscular use Reason for granting waiver: For the paediatric subset 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 subset 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	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

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:	