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-101118-PIP01-23

Scope of the Application

Active Substance(s)

5’-capped mRNA encoding HPV16 oncoprotein E6 5’-capped mRNA encoding HPV16 oncoprotein E7

Condition(s)

Treatment of head and neck squamous cell carcinoma

Pharmaceutical Form(s)

All pharmaceutical forms

Route(s) of Administration

All roues of administration

Name / Corporate name of the PIP applicant

BioNTech SE

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, BioNTech SE submitted to the licensing authority on 15/09/2023 16:36 BST an application for a Paediatric Investigation Plan

The procedure started on 11/01/2024 09:14 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-101118-PIP01-23

Of 22/02/2024 17:22 GMT

On the adopted decision for 5'-capped mRNA encoding HPV16 oncoprotein E6 5'-capped mRNA encoding HPV16 oncoprotein E7 (MHRA-101118-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 Paediatric Investigation Plan for 5'-capped mRNA encoding HPV16 oncoprotein E6 5'-capped mRNA encoding HPV16 oncoprotein E7 , All pharmaceutical forms , All routes of administration .

This decision is addressed to BioNTech SE, An der Goldgrube 12, Mainz, GERMANY, 55131

ANNEX I

1. Waiver

1.1 Condition:

Treatment of head and neck squamous 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): 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	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:	