

MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the waiver

MHRA-100557-PIP01-22-M01

Scope of the Application

Active Substance(s)

Hepatitis B (rDNA) surface antigen adjuvanted

Condition(s)

Prevention of hepatitis B virus infection

Pharmaceutical Form(s)

Solution for injection

Route(s) of Administration

Intramuscular use.

Name / Corporate name of the PIP applicant

Dynavax GmbH

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Dynavax GmbH submitted to the licensing authority on 24/06/2022 15:58 BST an application for a Modification

The procedure started on 20/09/2022 17:47 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 accept change(s) to the agreed paediatric investigation plan and to the 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-100557-PIP01-22-M01

Of 03/10/2022 17:09 BST

On the adopted decision for Hepatitis B (rDNA) surface antigen adjuvanted (MHRA-100557-PIP01-22-M01) in accordance with the Human Medicines Regulations 2012.

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

Agreement on modification of a paediatric investigation plan including modification of a waiver included in that paediatric investigation plan

This decision applies to a Modification for Hepatitis B (rDNA) surface antigen adjuvanted, Solution for injection , Intramuscular use .

This decision is addressed to Dynavax GmbH, Eichsfelder strasse 11, Düsseldorf, GERMANY, D-40595

ANNEX I

1. Waiver

1.1 Condition:

Prevention of hepatitis B virus infection 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): Solution for injection Route(s) of administration: Intramuscular use. Reason for granting waiver: From birth to less than 2 years of age: on the grounds that the specific medicinal product is likely to be unsafe. From 2 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(s) 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	Study 1 and 2 deleted during procedure MHRA-100557-PIP01-22-M01
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:	