EMA/427608/2021

European Medicines Agency decision

P/0304/2021

of 11 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for hepatitis B (rDNA) surface antigen adjuvanted (HEPLISAV B), (EMEA-001127-PIP02-11-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

European Medicines Agency decision

P/0304/2021

of 11 August 2021

on the acceptance of a modification of an agreed paediatric investigation plan for hepatitis B (rDNA) surface antigen adjuvanted (HEPLISAV B), (EMEA-001127-PIP02-11-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0051/2012 issued on 2 March 2012,

Having regard to the application submitted by Dynavax GmBH on 19 March 2021 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 25 June 2021, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for hepatitis B (rDNA) surface antigen adjuvanted (HEPLISAV B), solution for injection, intramuscular use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Dynavax GmBH, Eichsfelder Strasse 11, D-40595 - Dusseldorf, Germany.

EMA/PDCO/210575/2021
Amsterdam, 25 June 2021

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-001127-PIP02-11-M01

Scope of the application

Active substance(s):

Hepatitis B (rDNA) surface antigen adjuvanted

Invented name:

HEPLISAV B

Condition(s):

Prevention of hepatitis B virus infection

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Dynavax GmbH

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Dynavax GmBH submitted to the European Medicines Agency on 19 March 2021 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0051/2012 issued on 2 March 2012.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral.

The procedure started on 27 April 2021.

Scope of the modification

Some timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed paediatric investigation plan (PIP)

1. Waiver

1.1. Condition:

Prevention of hepatitis B virus infection

The waiver applies to:

- the paediatric population from birth to less than 2 years of age;
- for solution for injection, for intramuscular use;
- on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan

2.1. Condition:

Prevention of hepatitis B virus infection

2.1.1. Indication(s) targeted by the PIP

Prevention of hepatitis B infection in children and adolescents 2 to less than 18 years of age with stage 4 and 5 chronic kidney disease

Prevention of hepatitis B infection in children and adolescesnts 2 to less than 18 years of age who are hyporesponsive/non-responsive to hepatitis B vaccination

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 2 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	**Study 1:** Randomized, active-controlled, non-inferiority, observer-blind efficacy, safety and immunogenicity study of hepatitis B (rDNA) surface antigen adjuvanted vaccine and hepatitis B vaccine comparator (Engerix-B) in children and adolescents from 2 to less than 18 years of age with stage 4 and 5 chronic kidney disease. (DV2-HBV-P2)

		Study 2: Randomized, active-controlled, non-inferiority, observer-blind efficacy, safety and immunogenicity study of hepatitis B (rDNA) surface antigen adjuvanted vaccine and Engerix-B in children and adolescents from 2 to less than 18 tears of age who are potentially hyporesponsive/non-responsive to hepatitis B vaccination. (DV2-HBV-P1)

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By March 2028
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Prevention of hepatitis B virus infection Authorised indication(s):

- HEPLISAV B is indicated for active immunisation against hepatitis B virus infection (HBV) caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.

The use of HEPLISAV B should be in accordance with official recommendations.

It can be expected that hepatitis D will also be prevented by immunisation with HEPLISAV B as hepatitis D (caused by the delta agent) does not occur in the absence of hepatitis B infection.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Intramuscular use