

EMA/108063/2012

European Medicines Agency decision P/0051/2012

of 2 March 2012

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for hepatitis B (rDNA) surface antigen adjuvanted (EMA-001127-PIP02-11) 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.

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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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Dynavax International BV on 11 July 2011 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 February 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 of said Regulation and Article 13 of said Regulation,

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 agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver.
- (2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.
- (3) It is therefore appropriate to adopt a decision granting a deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

A paediatric investigation plan for hepatitis B (rDNA) surface antigen adjuvanted, solution for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

Article 2

A deferral for hepatitis B (rDNA) surface antigen adjuvanted, solution for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

A waiver for hepatitis B (rDNA) surface antigen adjuvanted, solution for injection, intramuscular use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 4

This decision is addressed to Dynavax International BV, Prins Bernhardplein 200, 1097 J5 – Amsterdam, The Netherlands.

Done at London, 2 March 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/921349/2011

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral and a waiver

EMA-001127-PIP02-11

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 International BV

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Dynavax International BV submitted for agreement to the European Medicines Agency on 11 July 2011 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 16 August 2011.

Supplementary information was provided by the applicant on 21 November 2011.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

- to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
- to grant a deferral in accordance with Article 21 of said Regulation,
- to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed 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 annex(es) and appendix.

London, 10 February 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

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

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 adolescents 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

Area	Number of studies	Description
		vaccine and Engerix-B in children and adolescents from 2 to less than 18 years 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 June 2021
Deferral for one or more studies contained in the paediatric investigation plan:	Yes