EMA/439664/2021 corr

European Medicines Agency decision

P/0373/2021

of 8 September 2021

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for multivalent pneumococcal polysaccharide conjugate to carrier protein (SP0202) (EMEA-002780-PIP02-20) 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 726/2004[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 application submitted by Sanofi Pasteur on 10 July 2020 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 23 July 2021, in accordance with Article 17 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 multivalent pneumococcal polysaccharide conjugate to carrier protein (SP0202), suspension 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 multivalent pneumococcal polysaccharide conjugate to carrier protein (SP0202), suspension 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 multivalent pneumococcal polysaccharide conjugate to carrier protein (SP0202), suspension 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 Sanofi Pasteur, 14 Espace Henry Vallée, 69007 – Lyon, France.

EMA/PDCO/77037/2021 corr
Amsterdam, 23 July 2021

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

EMEA-002780-PIP02-20

Scope of the application

Active substance(s):

Multivalent pneumococcal polysaccharide conjugate to carrier protein (SP0202)

Condition(s):

Prevention of disease caused by *Streptococcus pneumoniae*

Pharmaceutical form(s):

Suspension for injection

Route(s) of administration:

Intramuscular use

Name/corporate name of the PIP applicant:

Sanofi Pasteur

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur submitted for agreement to the European Medicines Agency on 10 July 2020 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 18 August 2020.

Supplementary information was provided by the applicant on 15 April 2021. The applicant proposed modifications to the paediatric investigation plan.

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 17(1) 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)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees 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 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

Prevention of disease caused by *Streptococcus pneumoniae*

The waiver applies to:

- the paediatric population from birth to less than 42 days of age;
- Suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric investigation plan

2.1. Condition:

Prevention of disease caused by *Streptococcus pneumoniae*

2.1.1. Indication(s) targeted by the PIP

Active immunization for the prevention of invasive disease, pneumonia, and acute otitis media caused by *Streptococcus pneumoniae* (or pneumococcus), in infants, children, and adolescents from 42 days to less than 18 years of age

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

From 42 days to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Suspension for injection

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	0	Not applicable
Non-clinical studies	0	Not applicable
Clinical studies	6	**Study 1 (PSK00008)** Randomized, single (observer) blind, active-controlled study to evaluate immunogenicity and safety of three different SP0202 formulations in healthy toddlers and infants aged from 42 days to less than 16 months at the time of enrolment, in order to identify a lead formulation for the confirmatory safety and immunogenicity studies

		Study 2 (PSK03) Randomized, single (observer) blind, parallel-group, active-controlled, confirmatory study to evaluate the safety and immunogenicity of SP0202 versus the comparator vaccine (Prevenar 13) in healthy children from 42 days to less than 90 days of age at the time of enrolment **Study 3 (PSK04)** Randomized, single (observer) blind, parallel-group, active-controlled, confirmatory study to evaluate the safety and immunogenicity of SP0202 versus the comparator vaccine (Prevenar 13) in healthy children from 42 days to less than 90 days of age at the time of enrolment **Study 4 (PSK05)** Randomized, single (observer) blind, active-controlled study to evaluate the safety of SP0202 administered as a primary series and booster schedule to extend the overall safety database in healthy children from 42 days to less than 90 days of age at the time of enrolment **Study 5 (PSK00010)** Randomized, single (observer) blind, parallel-group, active-controlled study to evaluate the immune response and safety profile of SP0202 and the comparator vaccine (Prevenar 13) one month after vaccination in healthy toddlers aged from 12 months to less than 24 months and in healthy children/adolescents aged from 2 years to less than 18 years of age **Study 6** Randomized, single (observer) blind, active-controlled study to evaluate the immune response and the safety profile of SP0202 and the comparator in children at increased risk of pneumococcal disease, from 6 years to less than 18 years of age
Extrapolation, modelling and simulation studies	0	Not applicable
Other studies	0	Not applicable
Other measures	0	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long-term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2029
Deferral for one or more measures contained in the paediatric investigation plan:	Yes