EMA/364892/2024

European Medicines Agency decision

P/0288/2024

of 14 August 2024

on the acceptance of a modification of an agreed paediatric investigation plan for multivalent pneumococcal polysaccharide conjugate to carrier protein (PCV21) (EMEA-002780-PIP02-20-M02), 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0373/2021 issued on 8 September 2021 and the decision P/0113/2024 issued on 12 April 2024,

Having regard to the application submitted by Sanofi Pasteur on 25 April 2024 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 26 July 2024, 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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for multivalent pneumococcal polysaccharide conjugate to carrier protein (PCV21), suspension 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 Sanofi Pasteur, 14 Espace Henry Vallee, 69007 – Lyon, France.

EMA/PDCO/222584/2024
Amsterdam, 26 July 2024

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

EMEA-002780-PIP02-20-M02

Scope of the application

Active substance(s):

Multivalent pneumococcal polysaccharide conjugate to carrier protein (PCV21)

Invented name and authorisation status:

See Annex II

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 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur submitted to the European Medicines Agency on 25 April 2024 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/0373/2021 issued on 8 September 2021 and the decision P/0113/2024 issued on 12 April 2024.

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

The procedure started on 27 May 2024.

Scope of the modification

Some measures and 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 Paediatric Committee member of Norway 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

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	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1 (PSK00008)** Randomized, single (observer) blind, active-controlled study to evaluate immunogenicity and safety of three different SP0202 formulations in healthy children 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 PCV21 versus the comparator vaccine 20vPCV (20-valent PCV, Prevenar 20) 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 PCV21 versus the comparator vaccine 15vPCV (15-valent PCV, Vaxneuvance) in healthy children from 42 days to less than 113 days of age at the time of enrolment **Study 4 (PSK05)** Randomized, single (observer) blind, active-controlled study to evaluate the safety of PCV21 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 PCV21 and the comparator vaccine (20vPCV) one month after the last vaccination in healthy naïve children from 7 months to less than 12 months of age, in healthy children aged from 12 months to less than 24 months and in healthy naïve or with partial or full regimen with other PCVs children from 2 years to less than 18 years of age **Study 6 (PSK00026)** Randomized, single (observer) blind, active-controlled study to evaluate the immune response and the safety profile of PCV21 and the comparator in children at increased risk of pneumococcal disease from 2 years to less than 18 years of age
Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	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 May 2027
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.