EMA/287622/2023

European Medicines Agency decision

P/0246/2023

of 14 July 2023

on the acceptance of a modification of an agreed paediatric investigation plan for pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) (Apexxnar), (EMEA-002330-PIP01-18-M03) 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/0159/2020 issued on 17 April 2020, decision P/0380/2021 issued on 8 September 2021 and the decision P/0239/2022 issued on 8 July 2022,

Having regard to the application submitted by Pfizer Europe MA EEIG on 16 February 2023 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 May 2023, 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 pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) (Apexxnar), 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 Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 – Brussels, Belgium.

EMA/PDCO/103066/2023
Amsterdam, 26 May 2023

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

EMEA-002330-PIP01-18-M03

Scope of the application

Active substance(s):

Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)

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:

Pfizer Europe MA EEIG

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Pfizer Europe MA EEIG submitted to the European Medicines Agency on 16 February 2023 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/0159/2020 issued on 17 April 2020, decision P/0380/2021 issued on 8 September 2021 and the decision P/0239/2022 issued on 8 July 2022.

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

The procedure started on 27 March 2023.

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

1.1. Condition:

Prevention of disease caused by *Streptococcus pneumoniae*

The waiver applies to:

- the paediatric population from birth to less than 6 weeks of age;
- suspension for injection, intramuscular use;
- on the grounds that the specific medicinal product is likely to be ineffective.

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* in infants, children and adolescents from 6 weeks to less than 18 years of age

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

From 6 weeks 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 (B7471003)** Randomised, active-controlled trial to evaluate safety, tolerability and immunogenicity of a 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 42 to 98 days of age at enrolment

	Study 2 (B7471011) Randomised, double-blind active-controlled trial to evaluate safety, tolerability, and immunogenicity of a 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 42 to 98 days of age at enrolment **Study 3 (B7471012)** Randomised, double-blind active-controlled trial to evaluate safety, tolerability, and immunogenicity, of 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 42 to 112 days of age at enrolment **Study 4 (B7471013)** Randomised, double-blind active-controlled trial to evaluate safety of 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 42 to 98 days of age at enrolment **Study 5 (B7471014)** Single-arm trial to evaluate safety and immunogenicity of 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) in healthy children from 15 months to less than 18 years of age **Study 6 (B7471027)** Randomised, active-controlled trial to evaluate safety and immunogenicity of 20-valent pneumococcal polysaccharide conjugate vaccine (20vPnC) compared to 13-valent pneumococcal polysaccharide conjugate vaccine (13vPnC) in healthy infants from 12 months to less than 24 months of age *This study was added with procedure EMEA-002330-PIP01-18-M01*
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 June 2023

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Prevention of disease caused by Streptococcus pneumoniae

Authorised indication(s):

- Active immunisation for the prevention of invasive disease and pneumonia caused by Streptococcus pneumoniae in individuals 18 years of age and older.
  - Invented name(s): Apexxnar
  - Authorised pharmaceutical form(s): suspension for injection
  - Authorised route(s) of administration: intramuscular use
  - Authorised via centralised procedure.