EMA/595648/2022

European Medicines Agency decision

P/0222/2022

of 24 June 2022

on the acceptance of a modification of an agreed paediatric investigation plan for Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (MenACYW) (MenQuadfi) (EMEA-001930-PIP01-16-M04) 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/0359/2017 issued on 1 December 2017, the decision P/0164/2019 issued on 6 May 2019, the decision P/0169/2019 issued on 11 October 2019 and the decision P/0285/2021 issued on 29 July 2021,

Having regard to the application submitted by Sanofi Pasteur on 18 February 2022 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 20 May 2022, 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.

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

[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 Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (MenACYW) (MenQuadfi), solution for injection, intramuscular use, 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 Vallée, 69007 – Lyon, France.

EMA/PDCO/146548/2022
Amsterdam, 20 May 2022

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

EMEA-001930-PIP01-16-M04

Scope of the application

Active substance(s):

Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (MenACYW)

Invented name:

MenQuadfi

Condition(s):

Prevention of invasive meningococcal disease

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:

Sanofi Pasteur

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Sanofi Pasteur submitted to the European Medicines Agency on 18 February 2022 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/0359/2017 issued on 1 December 2017, the decision P/0164/2019 issued on 6 May 2019, the decision P/0169/2019 issued on 11 October 2019 and the decision P/0285/2021 issued on 29 July 2021.

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

The procedure started on 21 March 2022.

Scope of the modification

Some measures 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 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 invasive meningococcal disease

The waiver applies to:

- the paediatric population from birth to less than 6 weeks of age;
- solution 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 invasive meningococcal disease

2.1.1. Indication(s) targeted by the PIP

Active immunization to prevent invasive meningococcal disease caused by *N. meningitidis* serogroups A, C, Y, and W-135

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)

Solution for injection

2.1.4. Measures

Area	**Description**
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	**Study 1** An open-label, randomized, parallel-group, controlled, multi-centre study to evaluate the immunogenicity and safety profile of a single dose of MenACYW conjugate vaccine when given alone compared to that of the licensed Meningococcal (Groups A, C, Y and W-135) Diphtheria Conjugate Vaccine (Menveo), and when MenACYW conjugate vaccine is given concomitantly with diphtheria, pertussis, and tetanus (Tdap) vaccine and human papilloma virus (HPV) vaccine in paediatric subjects from 10 to less than 18 years of age; (study MET50).

	Study 2 A randomized, active-controlled, open-label study to evaluate the immunogenicity and safety profile of a single dose of MenACYW conjugate vaccine when given alone compared to that of a licensed meningococcal group A, C, W-135 and Y conjugate vaccine (Nimenrix) in 12 to 23 months old paediatric subjects; (study MET54). **Study 3** A modified double-blind, randomized, parallel-group, active-controlled, multi-centre trial to compare the immunogenicity and describe the safety of a single dose of MenACYW conjugate vaccine to a single dose of licensed quadrivalent meningococcal polysaccharide groups A, C, W-135, and Y conjugate vaccine (MenACWY-Tetanus Toxoid [TT], Nimenrix) in paediatric subjects from 12 to less than 24 months old in the European Union (EU) who were either meningococcal vaccine naïve or had received monovalent MenC vaccination during infancy (MET51). **Study 4** Open-label, randomized, parallel-group, active-controlled, multi-centre study to describe the immunogenicity and safety of a single dose of MenACYW conjugate vaccine when administered alone and when administered concomitantly with other paediatric vaccine(s) in paediatric subjects from 12 to less than 24 months old; (study MET57). **Study 5** A double-blind, randomized, parallel-group, active-controlled, trial to evaluate the immunogenicity and describe the safety of MenACYW conjugate vaccine compared to Meningococcal (Groups A, C, Y and W-135) Diphtheria Conjugate Vaccine (Menveo) in paediatric subjects 2 to 9 years of age in the United States; (study MET35). **Study 6** Open-label, randomized, parallel-group, active-controlled, multi-centre study to compare the immunogenicity and safety of MenACYW conjugate vaccine when administered concomitantly with Men B vaccine in the 2nd year of life to healthy paediatric subjects in Europe; (study MET52). **Study 7** Open-label, randomized, parallel-group, active-controlled, multi-centre study to compare the immunogenicity and safety of MenACYW conjugate vaccine to a licensed quadrivalent meningococcal olysaccharide groups A, C, W-135, and Y conjugate vaccine (Nimenrix) when administered concomitantly with routine paediatric vaccines to healthy paediatric subjects from 2 to 3 months old in EU; (study MET58). **Study 8** Open-label, randomized, parallel-group, active-controlled, multi-centre study to compare the immunogenicity and safety of MenACYW conjugate vaccine and Meningococcal (Groups A, C, Y and W-135) Diphtheria

	Conjugate Vaccine (Menveo) when administered concomitantly with routine paediatric vaccines to paediatric subjects 2 months old in the United States; (study MET42). **Study 9** Double-blind, randomized, parallel-group, active-controlled, study to describe the safety of MenACYW conjugate vaccine when administered concomitantly with routine paediatric vaccines given to healthy infants and toddlers in the United States; (study MET41). **Study 10** Open-label, randomized, parallel-group, active-controlled, multi-centre study to describe the immunogenicity and safety of a 3-dose immunization schedule of MenACYW conjugate vaccine or a 4-dose immunization schedule of a licensed quadrivalent meningococcal conjugate vaccine (Menveo) when administered concomitantly with routine paediatric vaccines in healthy infants and toddlers in the Philippines, the Russian Federation, and Mexico; (study MET33). **Study 11** Open-label, randomized, parallel-group, active-controlled, multi-centre study to compare the immunogenicity and safety of MenACYW conjugate vaccine and Menveo or Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (Menactra) when administered concomitantly with routine paediatric vaccines to paediatric subjects 6 to 19 months old, in the United States; (study MET61). **Study 12** Modified double-blind, randomized, parallel-group, active-controlled, multi-centre study to evaluate immune lot consistency of MenACYW conjugate vaccine, evaluate the immune non-inferiority versus Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (Menactra), and describe the safety and additional immunogenicity of study vaccines in paediatric patients 10 to less than 18 years old; (study MET43). **Study 13** Double-blind, randomized, parallel-group, active-controlled, multi-centre trial to compare the immunogenicity and describe the safety of a booster dose of MenACYW conjugate vaccine compared to Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine (Menactra) in paediatric subjects from 15 to less than 18 years old; (study MET56). **Study 14** Open-label, multi-centre study to describe the immune persistence of the priming dose and describe the immunogenicity and safety of a booster dose of MenACYW conjugate vaccine in children in Finland who

	had been vaccinated 3 years earlier as toddlers with either MenACYW conjugate vaccine or quadrivalent meningococcal olysaccharide groups A, C, W-135, and Y conjugate vaccine (Nimenrix) as part of the MET54 study (Study 2) in paediatric subjects 4 to 5 years old (MET62). **Study 15** Open-label, multi-centre study to evaluate the immune persistence of the priming dose and describe the immunogenicity and safety of a booster dose of MenACYW conjugate vaccine, when co-administered along with MenB vaccines in adolescents (and adults) in USA who had been vaccinated 5 years earlier as adolescents with either MenACYW conjugate vaccine or Meningococcal (Groups A, C, Y and W-135) Diphtheria Conjugate Vaccine (Menveo) as part of the MET50 study (Study 1); (study MET59).
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 September 2024
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Prevention of invasive meningococcal disease

Authorised indication(s):

- Indicated for active immunisation of individuals from the age of 12 months and older, against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y.

Authorised pharmaceutical form(s):

Solution for injection

Authorised route(s) of administration:

Intramuscular use