MHRA
10 South Colonnade
Canary Wharf
London
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United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

agree a paediatric investigation plan and grant a waiver

MHRA-100110-PIP02-22

Scope of the Application

Active Substance(s)

Yellow fever virus, strain vYF-247

Condition(s)

Prevention of yellow fever disease

Pharmaceutical Form(s)

Powder and solvent for solution for injection

Route(s) of Administration

SUBCUTANEOUS USE; INTRAMUSCULAR USE

Name / Corporate name of the PIP applicant

Sanofi Pasteur

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Sanofi Pasteur submitted to the licensing authority on 18/10/2022 15:38 BST an application for a Paediatric Investigation Plan

The procedure started on 20/03/2023 17:32 GMT

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to agree a paediatric investigation plan and grant a waiver

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-100110-PIP02-22

Of 12/04/2023 07:39 BST

On the adopted decision for Yellow fever virus, strain vYF-247 (MHRA-100110-PIP02-22) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on a paediatric investigation plan

This decision applies to a Paediatric Investigation Plan for Yellow fever virus, strain vYF-247, Powder and solvent for solution for injection , SUBCUTANEOUS USE; INTRAMUSCULAR USE .

This decision is addressed to Sanofi Pasteur, 14 Espace Henry Vallée, Lyon, FRANCE, 69007

ANNEX I

1. Waiver

1.1 Condition:

Prevention of yellow fever disease The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age Pharmaceutical form(s): Powder and solvent for solution for injection Route(s) of administration: SUBCUTANEOUS USE INTRAMUSCULAR USE Reason for granting waiver: on the grounds that the specific medicinal product is likely to be unsafe.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Prevention of yellow fever disease

2.2 Indication(s) targeted by the PIP:

Prevention of yellow fever disease

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 6 months to less than 18 years of age

2.4 Pharmaceutical Form(s):

Powder and solvent for solution for injection

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	0	Not applicable.
Extrapolation, Modeling & Simulation Studies	1	Study 1 (SLR-vYF-01) Systematic review of existing inhouse clinical and literature data on immunogenicity and safety profiles of 17D-204 yellow fever vaccines to support the extrapolation of immunogenicity and safety of vYF vaccine from adult to paediatric populations from 6 months to less than 18 years of age.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	31/12/2024
Deferral of one or more studies contained in the paediatric investigation plan:	No