MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Decision Cover Letter

Decision of the licensing authority to:

accept change(s) to the agreed paediatric investigation plan and to the deferral

MHRA-100237-PIP01-21-M01

Scope of the Application

Active Substance(s)

Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain; Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain; Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage); Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage)

Condition(s)

Prevention of influenza infection

Pharmaceutical Form(s)

Suspension for injection in pre-filled syringe

Route(s) of Administration

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 18/02/2022 12:19 GMT an application for a Modification

The procedure started on 09/05/2022 07:46 BST

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 accept change(s) to the agreed paediatric investigation plan and to the deferral

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.

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

Final Decision Letter

MHRA-100237-PIP01-21-M01

Of 19/05/2022 08:44 BST

On the adopted decision for Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain; Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain; Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage); Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage) (MHRA-100237-PIP01-21-M01) 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 modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan)

This decision applies to a Modification for Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain; Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain; Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage); Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage), Suspension for injection in pre-filled syringe , 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 influenza infection The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 6 months of age; The immunocompetent paediatric population from 9 years to less than 18 years of age Pharmaceutical form(s): Suspension for injection in pre-filled syringe Route(s) of administration: Intramuscular use Reason for granting waiver: 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(s):

Prevention of influenza infection

2.2 Indication(s) targeted by the PIP:

Prevention of influenza infection

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

The paediatric population from 6 months to less than 9 years of age; The immunocompromised paediatric population from 9 years to less than 18 years of age

2.4 Pharmaceutical Form(s):

Suspension for injection in pre-filled syringe

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable
Non-Clinical Studies	0	Not applicable
Clinical Studies	4	Study 1 (QHD04) Dose-finding, randomised, modified double-blind, active-controlled trial to evaluate safety and immunogenicity of 3 different doses of Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain, A/H3N2-like strain, B-like strain (Victoria lineage) and B-like strain (Yamagata lineage) (from here defined as : Quadrivalent influenza vaccine- high dose: QIV-HD) versus an unadjuvanted QIV-standard dose (QIV-SD) in healthy children from 6 months to less than 9 years of age and an adjuvanted TIV-SD in a subset of healthy children from 6 to less than 24 months. Study 2 (QHD00014) Randomised, modified double blind, active-controlled trial to demonstrate the superior clinical efficacy and immunogenicity of 1 or 2 doses of QIV-HD compared to standard-dose QIV (QIV-SD), and to describe the safety profile of QIV-HD in healthy

		children from 6 months to less than 3 years of age Study 3 (QHD00015) Deleted during procedure MHRA-100237-PIP01-21-M01. Study 4 (QHD00020) Deleted during procedure MHRA-100237-PIP01-21-M01. Study 5 (QHD00022) Randomised, blinding to be determined, active-controlled trial to evaluate immunogenicity and safety of QIV-HD versus QIV-SD in immunocompromised children and adolescents from 6 months to less than 18 years of age. Study 6 (QHD00026) Added during procedure MHRA-100237-PIP01-21-M01. Open-label, uncontrolled trial to demonstrate the non-inferior immunogenicity for each of the 4 influenza strains contained in QIV-HD in children from 3 years to less than 9 years of age previously unvaccinated against influenza, compared to children 6 months through less than 3 years of age previously unvaccinated against influenza.
Extrapolation, Modeling & Simulation Studies	0	Not applicable
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:	31/12/2027
Deferral of one or more studies contained in the paediatric investigation plan:	Yes