RISK MANAGEMENT PLAN - PART VI

SUMMARY OF THE RISK MANAGEMENT PLAN

Active substance(s) (INN or common name)	**High-Dose, Quadrivalent Influenza Vaccine (split virus, inactivated)** Active Substance(s): Influenza virus (split, inactivated) of the following strains as recommended by WHO and Europe Hemagglutinin-strain A (H1N1) Hemagglutinin-strain A (H3N2) Hemagglutinin-strain B (Victoria Lineage) Hemagglutinin-strain B (Yamagata Lineage) **Referred in this document as QIV-HD**
Product's concerned (Brand name(s))	**Tradename not yet known**
Name of Marketing Authorization Holder or Applicant	Sanofi Pasteur 14 ESPACE HENRY VALLEE 69007 LYON FRANCE
Data lock point (DLP) for this module	**15-SEP-2018**
Version number of Risk Management Plan (RMP) when this module was last updated	**Version 0.2**

TABLE OF CONTENTS

ABBREVIATIONS

ATM:	Acute Transverse myelitis
DLP:	Data Lock Point
EEA:	European Economic Area
EMA:	European Medicines Agency
EPAR:	European Public Assessment Report
IM:	Intramuscular
PBRER:	Periodic Benefit-Risk Evaluation Report
QIV-HD:	Quadrivalent influenza vaccine (split virion, inactivated), High-Dose
RMP:	Risk Management Plan
SmPC:	Summary of Product Characteristics
TIV-HD:	High-Dose Trivalent Influenza Vaccine
WHO:	World Health Organization

Summary of risk management plan for Quadrivalent influenza vaccine (split virion, inactivated) High-Dose, suspension for injection in pre-filled syringe.

(INN: High-Dose, Quadrivalent Influenza Vaccine (split virus, inactivated))

This is a summary of the risk management plan (RMP) for 'Quadrivalent influenza vaccine (split virion, inactivated), High-Dose, suspension for injection in pre-filled syringe (referred hereafter as QIV-HD). The RMP details important risks of QIV-HD, how these risks can be minimized, and how additional information will be obtained about the risks and uncertainties (missing information).

QIV-HD summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how it should be used.

This summary of the RMP for QIV-HD should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new safety concerns or changes to the current ones will be included in updates to the RMP of QIV-HD.

VI.1. THE MEDICINE AND WHAT IT IS USED FOR

Quadrivalent influenza vaccine High-Dose is not currently licensed or marketed in European Economic Area (EEA) or around the world. QIV-HD is indicated for active immunization in individuals 65 years of age and older for the prevention of influenza. (See SmPC for full indication). It contains Influenza virus (inactivated, split virion), as recommended by World Health Organization (WHO)/Europe each season, Hemagglutinin-strain A (H1N1), Hemagglutinin-strain A (H3N2), Hemagglutinin-strain B (Victoria lineage) and Hemagglutinin-strain B (Yamagata lineage), as the active substances and it is given by intramuscular (IM) route of administration.

Further information about the evaluation of QIV-HD vaccine's benefits can be found in QIV-HD's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

VI.2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;

- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;

- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimize its risks. Together, these measures constitute routine risk minimization measures. In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (PSUR) assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities. If important information that may affect the safe use of QIV-HD vaccine is not yet available, it is listed under 'missing information' outlined in the next section.

VI.2.1. List of important risks and missing information

There are no important risks or missing information with QIV-HD for the inclusion as safety concerns that require specific risk minimization measures.

VI.2.2. Summary of important risks

Not applicable.

VI.2.3. Post-authorization development plan

VI.2.3.1.Studies which are conditions of the marketing authorization

Not applicable. There are no studies which are required as a condition of the marketing authorization.

VI.2.3.2.Other studies in post-authorization development plan

Not applicable. There are no other studies planned in post-authorization development plan.

REFERENCES

None