Summary of the risk management plan for Fluad Tetra influenza vaccine (surface antigen, inactivated, adjuvanted)

This is a summary of the risk management plan (RMP) for Fluad Tetra (adjuvanted quadrivalent influenza vaccine [aQIV]), suspension for injection in pre-filled syringe. The RMP details important risks of Fluad Tetra and how these risks can be minimised and how more information will be obtained about Fluad Tetra risks and uncertainties (missing information).

Fluad Tetra summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Fluad Tetra should be used.

This summary of the RMP for Fluad Tetra 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 concerns or changes to the current ones will be included in updates of the aQIV RMP.

I. The medicine and what it is used for

Fluad Tetra (aQIV) is a purified, inactivated, surface antigen quadrivalent influenza vaccine, adjuvanted with MF59C.1 with proposed indications for use in elderly persons ≥ 65 years.

It is to be administered as a single 0.5 mL dose by IM injection into the deltoid muscle.

Influenza is a highly infectious respiratory disease that can cause epidemics. It can cause people to feel severely unwell and sometimes cause death, either through influenza illness itself or pneumonia (chest infection) or by making a medical condition worse, (e.g. if the patient has heart disease or chronic chest disease). Although the risk of complications is higher in elderly patients or persons that already have medical illnesses, the influenza virus can cause severe illness or death in young persons and persons who were previously healthy.

https://www.ema.europa.eu/en/medicines/human/EPAR/fluad-tetra

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of aQIV, together with measures to minimise such risks, are outlined below.

- 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 minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of aQIV are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of aQIV. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Summary of safety concerns

Important identified risks	Nil
Important potential risks	Nil
Missing information	Nil
Other safety concerns	Nil

II.B Summary of important risks

Not applicable

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation.

II.C.2 Other studies in post-authorisation development plan

Not applicable