Swiss Summary of the Risk Management Plan (RMP)

for

FLUARIX TETRA
Quadrivalent influenza vaccine (split virion, inactivated)

(Hemagglutinin of four strains, two A strains and two B strains.
The strains selected each year depend on the annual
WHO recommendation.)

RMP Summary: Version 1, May 2023
Marketing Authorisation Holder: GlaxoSmithKline AG

Based on EU RMP version 13.0

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.

The RMP summary of Fluarix Tetra is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the “Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Fluarix Tetra in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic. GlaxoSmithKline AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Fluarix Tetra.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Fluarix Tetra

This is a summary of the risk management plan (RMP) for Fluarix Tetra. The RMP details important risks of Fluarix Tetra, how these risks can be minimised, and how more information will be obtained about Fluarix Tetra's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Fluarix Tetra is authorised for active immunisation of adults and children from 6 months of age for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine (see SmPC for the full indication). It contains hemagglutinin of four strains, two A strains and two B strains, one each from Victoria and Yamagata lineages as the active substance and it is given by intramuscular route of administration

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

Important risks of Fluarix Tetra, together with measures to minimise such risks and the proposed studies for learning more about Fluarix Tetra's risks, are outlined below.

Measures to minimise 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 minimise its risks.

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Fluarix Tetra 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 Fluarix Tetra. 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);

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 or specific obligation of Fluarix Tetra.

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

Study Short Name: EPI-FLU-039 US PR (201476)

A prospective, exploratory, cohort to detect and describe abnormal pregnancy outcomes in women intentionally or unintentionally vaccinated with Fluarix™ or Fluarix™ Quadrivalent or FluLaval™ or FluLaval™ Quadrivalent during pregnancy or within 28 days preceding conception.

Purpose of the Study: The purpose of this pregnancy registry is to detect and describe abnormal pregnancy outcomes in women intentionally or unintentionally vaccinated with GSK sIIVs. The combination of the large number of women who are of reproductive capacity in the indicated age range for vaccination with GSK sIIVs and the lack of data concerning vaccination during pregnancy makes such a Registry an important component of the ongoing program to assess the safety of these vaccines.

Study Short Name: EPI-FLU-057 VS EU (207749)

Enhanced safety surveillance of GSK's quadrivalent seasonal influenza vaccines

Purpose of the Study: To comply with European Medicines Agency (EMA) guidance, an enhanced safety study was conducted to rapidly collect and assess adverse events (AEs) within seven days following vaccination with GSK's inactivated quadrivalent seasonal influenza vaccine (IIV4) in 2019/20.

The aim was to assess safety events occurring after vaccination and thus to contribute to better detecting potential safety signals in near real-time using customised adverse event reporting cards (AERCs) and electronic reporting system. Predefined AEIs (defined by EMA to identify common events associated with influenza vaccines) were listed on the AERC as well as the possibility to report if any other AE or no AE occurred.