Summary of risk management plan for Influvac Tetra (Influenza Vaccine (Surface Antigen, Inactivated))

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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 minimise them.

The RMP summary of "Influvac 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 Influvac Tetra in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. "Mylan Pharma GmbH, Steinhausen" is fully responsible for the accuracy and correctness of the content of the published summary RMP of Influvac Tetra.

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PART VI. SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for the Trivalent and Quadrivalent Influenza Vaccine (Surface Antigen, Inactivated)

This summary of the risk management plan (RMP) comprises but are not limited to the following trade names for the trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) as approved in the EU/EEA: Influvac; Batrevac; Vacciflu; Influvac sub-unit; Influvac Junior; Influvac S; Serinflu; Influvac Tetra; Batrevac Tetra; Xanaflu Tetra; Influenza vaccine Tetra MYL; Influvac sub-unit Tetra; FluVaccinol Subunit Tetra, Influvactetra. In the following sections these medicinal products generic names, i.e., trivalent influenza vaccine (surface antigen, inactivated) and quadrivalent influenza vaccine (surface antigen, inactivated), are used instead of the associated trade names.

The summary of product characteristics (SmPC) and package leaflet of the trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) give essential information to healthcare professionals and patients on how the medicinal products should be used.

I. The medicine and what it is used for

In the EU/EEA, the trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) are intended to be used for the prophylaxis of seasonal influenza in adults and infants/children from 6 months of age, especially in those who run an increased risk of associated complications. Details on age groups for which influenza vaccine is approved in children is provided with the national product information.

The medicinal products contain either the trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) as active substances and are administered by intramuscular or deep subcutaneous injection. Use of either the trivalent or quadrivalent influenza vaccine should be based on official recommendations.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

For Abbott’s trivalent and quadrivalent influenza vaccine (surface antigen, inactivated), important risks to be presented in the RMP together with routine measures to minimize such risks are outlined below, if applicable (see section II.A).

Measures to minimize risks related to a medicinal product could be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC/product information addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorized 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, information about adverse reactions is collected continuously and regularly analyzed so that immediate action can be taken as necessary. These measures constitute routine Pharmacovigilance activities.

Furthermore, if important information that may affect the safe use of Abbott's trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) is not yet available, it is listed under 'missing information' below, if applicable (see section II.A).

II.A List of important risks and missing information

Important risks of trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) would be risks that need special risk management activities to further investigate or minimize 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 the trivalent and quadrivalent influenza vaccine (surface antigen, inactivated). 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).

Neither for the trivalent nor for the quadrivalent influenza vaccine (surface antigen, inactivated) there are such important risks or missing defined that needs to be included in this RMP version.

II.B Summary of important risks

As outlined in the preceding sections, there is no important identified or potential risk and no missing information for the trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) that qualifies for inclusion in this RMP version.

II.C Post-authorization development plan

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

There are no studies with the trivalent or quadrivalent influenza vaccine (surface antigen, inactivated) which are conditions of the marketing authorization or a specific obligation in the context of a conditional marketing authorization or a marketing authorization under exceptional circumstances.

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

There are no required additional pharmacovigilance activities for the trivalent and quadrivalent influenza vaccine (surface antigen, inactivated).