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 the following trade names for the trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) in the EU/EEA: Influvac; Batrevac; Vacciflu; Xanaflu; Influvac sub-unit; Influvac Junior; Serinflu; Influvac Tetra and Batrevac Tetra. 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

The trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) are authorized for the prophylaxis of seasonal influenza in adults, especially in those who run an increased risk of associated complications. The trivalent vaccine is also indicated for seasonal influenza prophylaxis in children from six months of age; whereas the quadrivalent influenza vaccine is also authorized for prophylaxis in children and adolescents from 9 to 17 years and in children from 3 to 8 years of age who have previously been vaccinated with a seasonal influenza vaccine. 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.

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

Important risks of trivalent and quadrivalent influenza vaccine (surface antigen, inactivated) are 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).

The safety profile of the trivalent and quadrivalent influenza vaccine is generally well known with proven effects in its approved indication (see section I). Products with the trivalent influenza vaccine has been marketed for more than 30 years. Thus, its safety has been well established during this period and can also be extrapolated to the quadrivalent vaccine. Over the years, there was no evidence from published studies or from postmarketing data suggesting that this known safety profile is different for special patient groups for which only limited clinical information is available (such as for pregnant women), compared to that of the general population. As the risks associated with both vaccines are, overall, well known, no further characterization via additional measures is deemed necessary. The safety of the trivalent and quadrivalent influenza vaccine is regularly followed up via the company's routine surveillance activities. Additionally, the company's reference safety information is considered to adequately inform on any risks associated with both vaccines and gives recommendations to reduce or avoid known risks. There are also no risk-related precautionary measures included in this reference safety information which are not already considered part of standard clinical practice. All data from the company's reference safety information serves as template for national SmPCs and package leaflets. In conclusion, there is currently no risk or missing information for the trivalent or quadrivalent influenza vaccine (surface antigen, inactivated) identified which have an impact on the overall well-known risk-benefit profile of both products. Consequently, there is currently no important identified or potential risk and no missing information for the trivalent or quadrivalent influenza vaccine that qualifies for inclusion in this RMP version and no safety concerns are listed. This company assessment was done in accordance with current European guidance documents.

II.A List of important risks and missing information

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

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).