EU-RISK MANAGEMENT PLAN FOR TRIVALENT AND QUADRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)

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RISK MANAGEMENT PLAN – PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Vaxigrip (Trivalent Influenza Vaccine [Split Virion, Inactivated])

This is a summary of the RMP for Vaxigrip. The RMP details important risks of Vaxigrip, how these risks can be minimized, and how more information will be obtained about the risks and uncertainties (missing information).

Vaxigrip's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Vaxigrip should be used.

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

I. THE MEDICINE AND WHAT IT IS USED FOR

Vaxigrip is not currently licensed or marketed in EEA. It is under review for registration in the EU. It contains influenza virus (inactivated, split) as recommended by WHO/EMA each season: Haemagglutinin-strain A (H1N1), Haemagglutinin-strain A (H3N2), Haemagglutinin-strain B as the active substance and it is given by IM or SC route of administration. Vaxigrip is available under one presentation: pre-filled syringe (thiomersal-free vaccine). Vaxigrip pre-filled syringe presentation (thiomersal-free vaccine) is indicated for the prevention of influenza disease caused by influenza virus types A and B contained in the vaccine for:

- Active immunization of adults, including pregnant women, and children from 6 months of age and older,
- Passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Vaxigrip, together with measures to minimize such risks and the proposed studies for learning more about Vaxigrip’s risks, are outlined in the next sections.

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 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

The information about adverse reactions is collected continuously and regularly analyzed, including PBRER 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

Table 29 - List of important risks and missing information

	Vaxigrip pre-filled syringe presentation (thiomersal-free vaccine)
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Vaxigrip pre-filled syringe presentation (thiomersal-free vaccine)

There are no important risks or missing information with Vaxigrip pre-filled syringe presentation for the inclusion as safety concerns in the EU-RMP.

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligation of Vaxigrip.

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

Table 30 - Other studies in post-authorization development plan

Development of Robust Innovative Vaccine Effectiveness (DRIVE) (Cat. 3)
Purpose of the study: Objectives is to measure season IVE against medically attended laboratory-confirmed influenza, by vaccine brand, then by vaccine type (eg, by antigen preparation strategy, number of virus strains, adjuvant,) then by overall influenza vaccination. To comply with the Guideline on Influenza vaccines - Non-clinical and Clinical Module (EMA/CHMP/VWP/457259/2014) of Jul-2016, a supporting IMI program called on DRIVE. Development of Robust Innovative Vaccine Effectiveness aims to assess the feasibility of building a sustainable platform in Europe able to generate brand specific IVE data in Europe.

DRIVE: Development of Robust Innovative Vaccine Effectiveness; IVE: Influenza Vaccine Effectiveness; IMI: Innovative Medicines Initiative; VE: Vaccine Effectiveness.

Summary of risk management plan for Vaxigrip Tetra (Quadrivalent Influenza Vaccine [Split Virion, Inactivated]))

This is a summary of the RMP for Vaxigrip Tetra. The RMP details important risks of Vaxigrip Tetra, how these risks can be minimized, and how more information will be obtained about the risks and uncertainties (missing information).

Vaxigrip Tetra's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Vaxigrip Tetra should be used.

Important new safety concerns or changes to the current ones will be included in updates to the RMP of Vaxigrip Tetra.

III. THE MEDICINE AND WHAT IT IS USED FOR

Vaxigrip Tetra contains influenza virus (inactivated, split) as recommended by WHO/EMA each season: Haemagglutinin-strain A (H1N1), Haemagglutinin-strain A (H3N2) and two Haemagglutinin-strain B as the active substance and it is given by intramuscular (IM) or SC route of administration. Vaxigrip Tetra is available under two presentations: pre-filled syringe (thiomersal-free vaccine) and MDV (thiomersal-containing vaccine). Vaxigrip Tetra pre-filled syringe presentation (thiomersal-free vaccine) is indicated for the prevention of influenza disease caused by influenza virus types A and B contained in the vaccine for:

- Active immunization of adults, including pregnant women, and children from 6 months of age and older,
- Passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women

Vaxigrip Tetra MDV presentation (thiomersal-containing vaccine) is indicated for active immunization of adults and children from 6 months of age and older 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.

IV. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of Vaxigrip Tetra, together with measures to minimize such risks and the proposed studies for learning more about Vaxigrip Tetra's risks, are outlined in the next sections.

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 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

The information about adverse reactions is collected continuously and regularly analyzed, including PBRER assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

IV.A List of important risks and missing information

Table 31 - List of important risks and missing information

	Vaxigrip Tetra pre-filled syringe presentation (thiomersal-free vaccine)	Vaxigrip Tetra MDV presentation (thiomersal-containing vaccine)
Important identified risks	None	None
Important potential risks	None	None
Missing information	None	Use in pregnant or lactating women

MDV: Mulitidose Vial.

IV.B Summary of important risks

Vaxigrip Tetra pre-filled syringe presentation (thiomersal-free vaccine)

There are no important risks or missing information with Vaxigrip Tetra pre-filled syringe presentation for the inclusion as safety concerns in the EU-RMP.

Vaxigrip Tetra MDV presentation (thiomersal-containing vaccine)

There are no important risks with Vaxigrip Tetra MDV presentation for the inclusion as safety concerns. The following missing information has been included as safety concern in the EU-RMP:

Table 32 - Missing information with corresponding risk minimization activities and additional pharmacovigilance activities, if any: Use in pregnant or lactating women

Missing information – Use in pregnant or lactating women	
Risk minimization measures	**Routine risk minimization measures:** • Section 4.6 of SmPC. **Additional risk minimization measures:** None
Additional pharmacovigilance activities	None

SmPC: Summary of Product Characteristics.

IV.C Post-authorization development plan

IV.C.I Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Vaxigrip Tetra.

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

Table 33 - Other studies in post-authorization development plan

Development of Robust Innovative Vaccine Effectiveness (DRIVE) (Cat. 3)
Purpose of the study: Objectives is to measure season IVE against medically attended laboratory-confirmed influenza, by vaccine brand, then by vaccine type (eg, by antigen preparation strategy, number of virus strains, adjuvant,) then by overall influenza vaccination. To comply with the Guideline on Influenza vaccines - Non-clinical and Clinical Module (EMA/CHMP/VWP/457259/2014) of Jul-2016, a supporting IMI program called on DRIVE. Development of Robust Innovative Vaccine Effectiveness aims to assess the feasibility of building a sustainable platform in Europe able to generate brand specific IVE data in Europe.

DRIVE: Development of Robust Innovative Vaccine Effectiveness; IVE: Influenza Vaccine Effectiveness; IMI: Innovative Medicines Initiative; VE: Vaccine Effectiveness.