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

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

Summary of risk management plan for EFLUELDA (Trivalent Influenza Vaccine [Split Virion, Inactivated] High Dose) (TIV-HD)

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

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

I. THE MEDICINE AND WHAT IT IS USED FOR

EFLUELDA is not currently licensed or marketed in EEA. It is under review for registration in the EU with a proposed indication for active immunization in adults 60 years of age and older for the prevention of influenza disease. It contains Influenza virus (inactivated, split) as recommended by WHO/Europe each season; Haemagglutinin-strain A (H1N1), Haemagglutinin-strain A (H3N2), Haemagglutinin-strain B as the active substance and it is given by IM route of administration.

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

Important risks of EFLUELDA, together with measures to minimize such risks and the proposed studies for learning more about EFLUELDA'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.

II.A List of important risks and missing information

There are no important identified and potential risks or missing information with EFLUELDA for inclusion as safety concerns that require specific risk minimization measures.

Table 21 - List of important risks and missing information

Important identified risk	None
Important potential risk	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-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 EFLUELDA.

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

Table 22 - 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.

CHMP: Committee for Medicinal Products for Human Use; DRIVE: Development of Robust Innovative Vaccine Effectiveness; EMA: European Medicines Agency; IVE: Influenza Vaccine Effectiveness; IMI: Innovative Medicines Initiative; VE: Vaccine Effectiveness; VWP: Vaccine Working Party.

Summary of risk management plan for EFLUELDA TETRA (Quadrivalent Influenza Vaccine [Split Virion, Inactivated] High Dose) (QIV-HD)

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

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

III. THE MEDICINE AND WHAT IT IS USED FOR

EFLUELDA TETRA is indicated for active immunization in adults 60 years of age and older for the prevention of influenza disease (See SmPC for full indication). It contains Influenza virus (inactivated, split virion), as recommended by WHO/Europe each season, Haemagglutinin-strain A (H1N1), Haemagglutinin-strain A (H3N2), Haemagglutinin-strain B (Victoria lineage) and Haemagglutinin-strain B (Yamagata lineage), as the active substances and it is given by intramuscular (IM) route of administration.

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

Important risks of EFLUELDA TETRA, together with measures to minimize such risks and the proposed studies for learning more about EFLUELDA 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.

IV.A List of important risks and missing information

There are no important identified and potential risks or missing information with EFLUELDA TETRA for inclusion as safety concerns that require specific risk minimization measures.

Table 23 List of important risks and missing information

Important identified risk	None
Important potential risk	None
Missing information	None

IV.B Summary of important risks

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

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 EFLUELDA TETRA.

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

Table 24 - 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.

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