Summary of risk management plan for Zoonotic Influenza Vaccine Seqirus (aH5N1)

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

Zoonotic Influenza Vaccine Seqirus summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals and patients on how Zoonotic Influenza Vaccine Seqirus should be used.

This summary of the RMP for Zoonotic Influenza Vaccine Seqirus should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR), available on the EMA website, under the medicine's webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/zoonotic-influenza-vaccine-seqirus

Important new concerns or changes to the current ones will be included in updates of Zoonotic Influenza Vaccine Seqirus RMP.

I. The medicine and what it is used for

Zoonotic Influenza Vaccine Seqirus is a zoonotic influenza vaccine authorised for an active immunisation against H5N1 subtype of Influenza A virus in adults (18 years of age and older). It contains an inactivated, surface antigen monovalent, influenza vaccine adjuvanted with MF59C.1. It is to be administered as two doses of 0.5 mL by intramuscular injection into the deltoid muscle. One dose of 0.5 mL should be given at an elected date and a second dose of 0.5 mL after an interval of at least 3 weeks.

Further information about the evaluation of Zoonotic Influenza Vaccine Seqirus benefits will be available in Zoonotic Influenza Vaccine Seqirus EPAR, upon the application approval, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of Zoonotic Influenza Vaccine Seqirus, together with measures to minimise such risks and the proposed studies for learning more about Zoonotic Influenza Vaccine Seqirus 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 PL 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.

II.A List of important risks and missing information

Important risks of Zoonotic Influenza Vaccine Seqirus 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 Zoonotic Influenza Vaccine Seqirus. 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).

Table Part VI. 1: Summary of safety concerns for Zoonotic Influenza Vaccine Seqirus

Important identified risk	None
Important potential risk	Neuritis Convulsions Encephalitis (*encephalomyelitis*) Vasculitis Guillain-Barré Syndrome Demyelination Bell's palsy Immune thrombocytopenia
Missing information	Use in pregnancy and lactation

II.B Summary of important risks

Table Part VI. 2: Summary of important risks for Zoonotic Influenza Vaccine Seqirus

Neuritis	
Risk minimisation measures	Routine risk minimisation measures: Neuritis is described in: *Zoonotic Influenza Vaccine Seqirus SmPC: Section 4.8* *Zoonotic Influenza Vaccine Seqirus PL: Section 4* Additional risk minimisation measures: None
Additional Pharmacovigilance activities	Not applicable
Convulsions	
Risk minimisation measures	Routine risk minimisation measures: Convulsions are described in: *Zoonotic Influenza Vaccine Seqirus SmPC: Section 4.8* *Zoonotic Influenza Vaccine Seqirus PL: Section 2 and 4* Additional risk minimisation measures: None
Additional Pharmacovigilance activities	Not applicable
Encephalitis (*encephalomyelitis*)	
Risk minimisation measures	Routine risk minimisation measures: Neurological disorders, such as encephalomyelitis, are described in: *Zoonotic Influenza Vaccine Seqirus SmPC: Section 4.8* *Zoonotic Influenza Vaccine Seqirus PL: Section 4* Additional risk minimisation measures: None
Additional Pharmacovigilance activities	Not applicable
Vasculitis	
Risk minimisation measures	Routine risk minimisation measures: Vasculitis is described in: *Zoonotic Influenza Vaccine Seqirus SmPC: Section 4.8* *Zoonotic Influenza Vaccine Seqirus PL: Section 4* Additional risk minimisation measures: None
Additional Pharmacovigilance activities	Not applicable
Guillain-Barré Syndrome	
Risk minimisation measures	Routine risk minimisation measures: Guillain-Barré syndrome is described in:

	Zoonotic Influenza Vaccine Seqirus SmPC: Section 4.8 *Zoonotic Influenza Vaccine Seqirus PL: Section 4* <u>Additional risk minimisation measures:</u> None
Additional Pharmacovigilance activities	Not applicable
Demyelination	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> None; included as a potential safety concern based on pharmacological class effects <u>Additional risk minimisation measures:</u> None
Additional Pharmacovigilance activities	Not applicable
Bell's palsy	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> None; included as a potential safety concern based on pharmacological class effects <u>Additional risk minimisation measures:</u> None
Additional Pharmacovigilance activities	Not applicable
Immune thrombocytopenia	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> None; included as a potential safety concern based on pharmacological class effects <u>Additional risk minimisation measures:</u> None
Additional Pharmacovigilance activities	Not applicable
Use in pregnancy and lactation	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Pregnancy and breast-feeding are described in: *Zoonotic Influenza Vaccine Seqirus SmPC: Section 4.6* *Zoonotic Influenza Vaccine Seqirus PL: Section 2* <u>Additional risk minimisation measures:</u> None
Additional Pharmacovigilance activities	Not applicable

II.C Post-authorisation development plan

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

Not applicable. There are no safety studies imposed as condition of the marketing authorisation (category 1), or as a specific obligation in the context of a conditional marketing authorisation or a marketing authorisation under exceptional circumstances (category 2) or required by the competent authority (category 3).

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

Not applicable.