Summary of risk management plan for Foclivia (aH5N1)

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

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

This summary of the RMP for Foclivia 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).

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

I. The medicine and what it is used for

Foclivia is a pandemic influenza vaccine authorised for the prophylaxis of influenza in an officially declared pandemic situation.. 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 or anterolateral thigh (depending on the muscle mass). One dose of 0.5 mL at an elected date. And a second dose of 0.5 mL should be given after an interval of at least 3 weeks.

Further information about the evaluation of Foclivia benefits can be found in Foclivia EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/foclivia

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

Important risks of Foclivia, together with measures to minimise such risks and the proposed studies for learning more about Foclivia 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 Foclivia 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 Foclivia. 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 Foclivia

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 Foclivia

Neuritis	
Risk minimisation measures	Routine risk minimisation measures: Neuritis is described in: *Foclivia SmPC: Section 4.8* *Foclivia PL: Section 4* Additional risk minimisation measures: *No additional measures*

Additional Pharmacovigilance activities	<u>Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection:</u> *S-PSUR (in situation of pandemic)* *Neuritis targeted follow-up questionnaire*
Convulsions	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Convulsions are described in: *Foclivia SmPC: Section 4.4 and 4.8* *Foclivia PL: Section 2 and 4* <u>Additional risk minimisation measures:</u> *No additional measures*
Additional Pharmacovigilance activities	<u>Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection:</u> *S-PSUR (in situation of pandemic)* *Convulsions targeted follow-up questionnaire*
Encephalitis (*encephalomyelitis*)	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Neurological disorders, such as Encephalomyelitis, are described in: *Foclivia SmPC: Section 4.8* *Foclivia PL: Section 4* <u>Additional risk minimisation measures:</u> *No additional measures*
Additional Pharmacovigilance activities	<u>Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection:</u> *S-PSUR (in situation of pandemic)* *Encephalitis (encephalomyelitis) targeted follow-up questionnaire*
Vasculitis	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Vasculitis is described in: *Foclivia SmPC: Section 4.8* *Foclivia PL: Section 4* <u>Additional risk minimisation measures:</u> *No additional measures*
Additional Pharmacovigilance activities	<u>Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection:</u> *S-PSUR (in situation of pandemic)* *Vasculitis targeted follow-up questionnaire*
Guillain-Barré Syndrome	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> Guillain-Barré syndrome is described in: *Foclivia SmPC: Section 4.8* *Foclivia PL: Section 4* <u>Additional risk minimisation measures:</u> *No additional measures*

Additional Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *Guillain-Barré Syndrome targeted follow-up questionnaire*
Demyelination	
Risk minimisation measures	Routine risk minimisation measures: None; included as a potential safety concern based on pharmacological class effects Additional risk minimisation measures: *No additional measures*
Additional Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *Demyelination targeted follow-up questionnaire*
Bell's palsy	
Risk minimisation measures	Routine risk minimisation measures: None; included as a potential safety concern based on pharmacological class effects Additional risk minimisation measures: *No additional measures*
Additional Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *Bell's Palsy targeted follow-up questionnaire*
Immune thrombocytopenia	
Risk minimisation measures	Routine risk minimisation measures: None; included as a potential safety concern based on pharmacological class effects Additional risk minimisation measures: *No additional measures*
Additional Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)* *Immune thrombocytopenia targeted follow-up questionnaire*
Use in pregnancy and lactation	
Risk minimisation measures	Routine risk minimisation measures: Pregnancy and breast-feeding are described in *Foclivia SmPC: Section 4.6* *Foclivia PL: Section 2* Additional risk minimisation measures: *No additional measures*
Additional Pharmacovigilance activities	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: *S-PSUR (in situation of pandemic)*

	Pregnancy Reporting/Outcome form <u>Additional pharmacovigilance activities:</u> *V87_27OB (pregnancy registry)*

II.C Post-authorisation development plan

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

As a specific post-authorisation pharmacovigilance requirement, in accordance with EMA/CHMP/VWP/457259/2014 Guidance on Influenza Vaccines, the following studies are planned:

- The Enhanced Safety Surveillance will be performed during the pandemic period aiming rapidly collect the data within a month from the start of vaccination.
- A non-interventional study of vaccine effectiveness of pandemic influenza vaccine (Foclivia®), an analysis of vaccine effectiveness for pandemic influenza vaccination versus no vaccination.

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

- It is considered that for the majority of safety concerns, routine pharmacovigilance activities alone will be sufficient. However, in the situation of a pandemic, required Category 3 Study V87_27OB study is planned to address the missing information *Use in pregnancy and lactation*: V87_27OB is a postmarketing, observational cohort study to evaluate the safety of pandemic A/H5N1* vaccine (Foclivia®) in pregnant women (pregnancy registry). This study is planned in case of pandemic and will follow from enrolment to pregnancy outcome and in live-born infants until 3 months of age.

** The strain is subject to change to be matched with the next pandemic strain*