Part VI: Summary of the risk management plan

This is a summary of the risk management plan (RMP) for QIVc. The RMP details important risks of QIVc, how those risks can be minimized, and how more information will be obtained about QIVc's risks and uncertainties (missing information).

QIVc's summary of product characteristics (SmPC) and its package insert give essential information to healthcare professionals and patients on how QIVc should be used.

It 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 QIVc's RMP.

I. The medicine and what it is used for

QIVc is authorised for prophylaxis of influenza for adults and children of 2 years of age and older. It contains Quadrivalent Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) as the active substance and it is a suspension for injection in pre-filled syringe. It is given by intra-muscular injection.

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

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

Important risks of QIVc together with measures to minimise such risks and the proposed studies for learning more about QIVc's 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 package leaflet 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.

If important information that may affect the safe use of QIVc is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of QIVc 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 QIVc. 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	Safety in immunocompromised patients
	Safety in subjects with underlying diseases
	Use in pregnant/breastfeeding women

II.B Summary of important risks

Important potential risk: None	
Important potential risk: None	
Missing information	
Safety in immunocompromised patients	
Risk minimisation measures	Routine risk communication: *SmPC Section 4.4*

	PL Section 2 Additional risk minimisation measures *None*
Safety in subjects with underlying diseases	
Risk minimisation measures	Routine risk communication: *SmPC Section 4.4* *PL Section 2* Additional risk minimisation measures *None*
Use in pregnant/breastfeeding women	
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.6* *PL Section 2* Additional risk minimisation measures: *None*
Additional pharmacovigilance activities	A Pregnancy Registry (V130_110B) to evaluate pregnancy outcomes as well as events of interest of major congenital malformations, preterm birth and low birth weight among women immunized as part of routine care with the seasonal cell culture quadrivalent (QIVc) vaccine during pregnancy is ongoing.

II.C Post-authorisation development plan

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

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

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

Not applicable.