Part VI: Summary of the risk management plan

Summary of risk management plan for IPV-AI AJV (Poliovirus type 1, 2 and 3 vaccine (adsorbed, reduced antigens content))

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

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

I. The medicine and what it is used for

Picovax is authorised for active immunisation against poliomyelitis (see SmPC for the full indication). It contains inactivated poliovirus type 1, 2 and 3 (adsorbed, reduced antigens content) as the active substances and it is given by intramuscular route of administration.

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

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

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

II.A List of important risks and missing information

Important risks of Picovax 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 Picovax. 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	Underdose
Missing information	Use in pregnant and lactating women

II.B Summary of important risks

Underdose	
Evidence for linking the risk to the medicine	Medication errors are always a risk when administering a medicinal product in a real-life setting. No cases of underdosing were reported in the clinical trials. Underdose caused by fractional dose of vaccine: In the context of IPV shortage, WHO recommends a 2-dose fractional dose schedule of IPV vaccines administered intradermally. However, as IPV-Al AJV has reduced antigen content compared to other IPV vaccines, this could lead to vaccination failure. Indeed, IPV-CU demonstrated that fractional doses of IPV Vaccine AJV (which contain a higher antigen content than IPV-Al AJV) administered intradermally were significantly less immunogenic than full doses of IPV Vaccine AJV administered intramuscularly. Underdose caused by insufficient shaking of IPV-Al AJV before administration: Contrary to other IPV vaccines, IPV-Al AJV is adsorbed to aluminium hydroxide and must therefore be shaken before administration as with other aluminium adsorbed vaccines. Aluminium adsorbed vaccines are suspensions and must therefore be shaken before administration to ensure correct dosage.
Risk factors and risk groups	There are no specific risk factors or risk groups that apply to underdose of Picovax.
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 2,3, 4.2, 4.4, 6.5, 6.6* *PL section 3, 6* Other routine risk minimisation measures beyond the Product Information: Picovax is only available on prescription and is administered by health care personnel. Additional risk minimisation measures: None
Additional pharmacovigilance activities	None

Use in pregnant and lactating women	
Evidence for linking the risk to the medicine	There is no information on the use of Picovax in pregnant women and the effect on the foetus. Administration of Picovax to the mothers has not been studied. No animal data with respect to effects on pregnancy, foetal development, parturition and post-natal development is available.
Risk factors and risk groups	Women of childbearing potential, pregnant and lactating women
Risk minimisation measures	Routine risk minimisation measures: *SmPC section 4.6* *PL section 2* Other routine risk minimisation measures beyond the Product Information: Picovax is only available on prescription and is administered by health care personnel. Also, A specific adverse reaction follow-up questionnaire for exposure during pregnancy is submitted to the reporter at the time of expected delivery. Additional risk minimisation measures: None
Additional pharmacovigilance activities	None

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Picovax.

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

There are no studies required for Picovax.