Summary of risk management plan for Galli Ad (Gallium (^{68}Ga) chloride)

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

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

Important new concerns or changes to the current ones will be included in updates of Galli Ad's RMP.

I. The medicine and what it is used for

Galli Ad is authorised for in vitro radiolabelling of various kits for radiopharmaceutical preparation developed and approved for radiolabelling with such solution to be used for positron emission tomography (PET) imaging (see SmPC for the full indication). It contains Gallium (^{68}Ga) chloride as the active substance and it is given by the route of administration approved for the final medicinal product.

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

Important risks of Galli Ad, together with measures to minimise such risks and the proposed studies for learning more about Galli Ad'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, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of Galli Ad 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 Galli Ad. 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	Not applicable
Important potential risks	Accidental direct use in patients ^{68}Ge breakthrough Carcinogenicity and hereditary effects Occupational and inadvertent exposure to radiation
Missing information	Not applicable

II.B Summary of important risks

Accidental direct use in patients	
Evidence for linking the risk to the medicine	No case reported so far
Risk factors and risk groups	No risk groups or risk factors have been identified based on the available data's.
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.1 SmPC section 4.2 SmPC section 4.4 SmPC section 4.9 SmPC section 5.2

^{68}Ge breakthrough	
Evidence for linking the risk to the medicine	No case reported so far
Risk factors and risk groups	No risk groups or risk factors have been identified based on the available data's.
Risk minimisation measures	Routine risk minimisation measures: SmPC section 1.2

Carcinogenicity and hereditary effects	
Evidence for linking the risk to the medicine	No case reported so far
Risk factors and risk groups	No risk groups or risk factors have been identified based on the available data's.
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4

Occupational and inadvertent exposure to radiation	
Evidence for linking the risk to the medicine	No case reported so far
Risk factors and risk groups	No risk groups or risk factors have been identified based on the available data's.
Risk minimisation measures	Routine risk minimisation measures: SmPC section 6.4 SmPC section 6.6 SmPC section 1.1

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 Galli Ad.

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

There are no studies required for Galli Ad.