Part VI: Summary of activities in the risk management plan

Summary of risk management plan for Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation (technetium (^{99m}Tc)-albumin macroaggregates)

This is a summary of the risk management plan (RMP) for Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation. The RMP details important risks of MEDI-MAA 2.5 mg Kit for radiopharmaceutical preparation, how these risks can be minimised, and how more information will be obtained about Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation risks and uncertainties (missing information).
Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation summary of product characteristics (SmPC) and patient leaflet give essential information to healthcare professionals and patients on how Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation should be used.
Important new concerns or changes to the current ones will be included in updates of Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation RMP.

I. The medicine and what it is used for

Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation is intended for pulmonary perfusion scintigraphy and for radionuclide venography. It contains technetium (^{99m}Tc) - albumin macroaggregates or (^{99m}Tc)-MAA as the active substance and it is given by intravenous route.

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

Important risks of Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation together with measures to minimise such risks and the proposed studies for learning more about Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation risks, are outlined below.
The main safety concern for (^{99m}Tc)-MAA is suspected transmission of an infectious agent via product.

Measures to minimise the risks identified for medicinal products include specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals.
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, 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 Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation 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 Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation. 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	Suspected transmission of an infectious agent via product
Missing information	None

II.B Summary of important risks

Important potential risk 1: Suspected transmission of an infectious agent via product	
Evidence for linking the risk to the medicine	Suspected transmission of an infectious agent is considered as Important Potential Risk as it may result in clinically significant infectious consequences for a patient. This evaluation is based on published literature, post-marketing data, safety database and SmPC as well as Guidelines on the warning on transmissible agents in summary of product characteristics (SmPC) and package leaflets for plasma derived medicinal products. (EMA/CHMP/BWP/360642/2010 rev1).
Risk factors and risk groups	All patients and particularly immunocompromised patients are at higher risk
Risk minimisation measures	Routine risk minimisation measures Warnings are implemented regarding keeping the record of the name and batch number of the product at every administration in order to maintain a link between the patient and the batch of the product. This medicinal product is for use in hospitals or in designated nuclear medicine facilities only. Additional risk minimisation measures 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 Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation.

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

There are no studies required for Medi-MAA 2.5 mg Kit for radiopharmaceutical preparation.