PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Pentamidine Tillomed 300 mg powder for solution for injection/infusion or powder for nebuliser solution (herein referred as Pentamidine Powder):

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

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

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

I. The medicine and what it is used for

Pentamidine Tillomed 300 mg powder for solution for injection/infusion or powder for nebuliser solution is authorised in adults and children for

- Prophylaxis and therapy of Pneumocystis jirovecii (formerly known as Pneumocystis carinii) pneumonia.
- Treatment of visceral and cutaneous Leishmaniasis.
- Treatment of first-stage of human African trypanosomiasis due to Trypanosoma brucei gambiense

See SmPC for the full indication.

Pentamidine Powder contains pentamidine diisetionate as the active substance and it is administered by intravenous (IV), intramuscular (IM) or inhalational route.

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

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

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*.

II.A List of important risks and missing information

Important risks of Pentamidine Powder 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 Pentamidine Powder. 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	• None

II. B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 Pentamidine Powder.

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

There are no studies required for Pentamidine Powder.