PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Aviptadil/ phentolamine mesylate, solution for injection

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

Aviptadil/Phentolamine summary of product characteristics (SmPC) and their package leaflets give essential information to healthcare professionals and patients on how Aviptadil/Phentolamine should be used.

I. The medicine and what it is used for

Aviptadil/Phentolamine is indicated for the symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology.

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

Important risks of Aviptadil/Phentolamine, together with measures to minimise such risks and the proposed studies for learning more about Aviptadil/Phentolamine'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 Aviptadil/Phentolamine 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 Aviptadil/Phentolamine. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected.

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 Aviptadil/Phentolamine.

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

There are no studies required for Aviptadil/Phentolamine.