Part VI: Summary of the Risk Management Plan

As the safety concerns and their management are identical for all products covered by this RMP, the information in Part VI is presented only once together for all products.

Summary of risk management plan for Iloprost Zentiva (Iloprost Zentiva k.s.) (Iloprost)
This is a summary of the risk management plan (RMP) for Iloprost Zentiva (Iloprost Zentiva k.s.). The RMP details important risks of Iloprost Zentiva (Iloprost Zentiva k.s.) and how more information will be obtained about Iloprost Zentiva (Iloprost Zentiva k.s.)'s risks and uncertainties (missing information). Iloprost Zentiva (Iloprost Zentiva k.s.)'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Iloprost Zentiva (Iloprost Zentiva k.s.) should be used.

Important new concerns or changes to the current ones will be included in updates of Iloprost Zentiva (Iloprost Zentiva k.s.)'s RMP.

I. The medicine and what it is used for

Iloprost Zentiva (Iloprost Zentiva k.s.) is authorised for treatment of adult patients with primary pulmonary hypertension, classified as NYHA functional class III, to improve exercise capacity and symptoms. (see SmPC for the full indication). It contains Iloprost as the active substance and it is inhaled 2.5 or 5 micrograms.

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

Important risks of Iloprost Zentiva (Iloprost Zentiva k.s.), together with measures to minimise such risks and the proposed studies for learning more about Iloprost Zentiva (Iloprost Zentiva k.s.)'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 Iloprost Zentiva (Iloprost Zentiva k.s.) are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Iloprost Zentiva (Iloprost Zentiva k.s.). Potential risks are 18/27concerns 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).

Summary of safety concerns	
Important identified risks	• *Medication error*
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 Iloprost Zentiva (Iloprost Zentiva k.s.).

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

There are no studies required for Iloprost Zentiva (Iloprost Zentiva k.s.).