PART V: RISK MINIMISATION MEASURES (INCLUDING EVALUATION OF THE EFFECTIVENESS OF RISK MINIMISATION ACTIVITIES)

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

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Meropenem for injection:

Meropenem is a carbapenem antibacterial, that exerts its bactericidal activity by inhibiting bacterial cell wall synthesis in Gram-positive and Gram-negative bacteria through binding to penicillin-binding proteins (PBPs).

This is a summary of the risk management plan (RMP) for meropenem powder for solution for injection/infusion 500 mg/vial and 1000 mg/vial. The RMP details important risks of meropenem, how these risks can be minimized and how more information will be obtained about meropenem's risks and uncertainties (missing information). Meropenem's summary of product characteristics (SmPC) and its

package leaflet give essential information to healthcare professionals and patients on how meropenem should be used.

This summary of the RMP for meropenem should be read in the context of all this information including

I. The medicine and what it is used for:

Meropenem is authorised for the treatment of severe pneumonia, including hospital and ventilator-associated pneumonia, Broncho-pulmonary infections in cystic fibrosis, complicated urinary tract infections, complicated intra-abdominal infections, Intra- and post-partum infections, complicated skin and soft tissue infections, acute bacterial meningitis and treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. Meropenem may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection. It is given by the intravenous route.

II. Risks associated with the medicine and activities to minimize or further characterize the risks:

Important risks of meropenem, together with measures to minimize such risks and the proposed studies for learning more about meropenem's risks, are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and summary of product characteristics (SmPC) addressed to patients and healthcare professionals.
- Important advice on the medicine's packaging.
- The medicine's legal status - the way a medicine is supplied to the patient (e.g. with or without Prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization 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 meropenem are risks that need special risk management activities to further investigate or minimize 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 enough proof of a link with the use of meropenem. 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).

Table 2: Summary of safety concerns

This is not applicable as there are no important identified risks, important potential risks and missing information identified for meropenem powder for solution for injection/infusion 500 mg/vial and 1000 mg/vial.

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 meropenem.

II.C.2 Other Studies in Post Authorisation Development Plan

There are no studies required for meropenem.