PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Meropenem Qilu 500 mg and 1000 mg Powder for solution for injection / infusion's

This is a summary of the risk management plan (RMP) for Meropenem Qilu 500 mg and 1000 mg Powder for solution for injection / infusion. The RMP details important risks of Meropenem Qilu 500 mg and 1000 mg Powder for solution for injection / infusion, how these risks can be minimised, and how more information will be obtained about Meropenem Qilu 500 mg and 1000 mg Powder for solution for injection / infusion's risks and uncertainties (missing information).

Meropenem Qilu 500 mg and 1000 mg Powder for solution for injection / infusion's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

Important new concerns or changes to the current ones will be included in updates of Meropenem Qilu 500 mg and 1000 mg Powder for solution for injection / infusion's RMP.

I. The medicine and what it is used for

Meropenem is indicated for the treatment of the following infections in adults and children aged 3 months and older:

- Severe pneumonia, including hospital-acquired 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

Meropenem may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection. It is also use for treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. The medicinal product contains meropenem trihydrate as the active substance and it is given as intravenous infusion.

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

Important risks of Meropenem Qilu 500 mg and 1000 mg Powder for solution for injection / infusion, together with measures to minimise such 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 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 Qilu 500 mg and 1000 mg Powder for solution for injection / infusion 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 Meropenem Qilu 500 mg and 1000 mg Powder for solution for injection / infusion. 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.

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 with the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

Not applicable.

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

Not applicable.