Part VI:
Summary of the risk management plan for Bevione

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

I. The medicine and what it is used for

Bevione is authorised for prevention and treatment of symptomatic thiamine deficiency (incl. beriberi and Wernicke-Korsakoff syndrome) due to malabsorption/malnutrition.

It contains thiamine as the active substance and it is administered by injection for either intramuscular or intravenous use.

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

Important risks of Bevione, together with measures to minimise such risks and the proposed studies for learning more about Bevione'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 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 Bevione 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 Bevione. 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
List of important risks and missing information	
Missing information	None

II.B Summary of important risks

No important risks have been identified as all risks have not been considered important. The risks are listed in SmPC and routine risk minimizing measures should apply.

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 Bevione.

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

There are no studies required for Bevione.