PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Sacubitril/Valsartan Vale and SACAZARTI (sacubitril/valsartan)

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

Sacubitril/Valsartan Vale and SACAZARTI'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 Sacubitril/Valsartan Vale and SACAZARTI's RMP.

I. The Medicine and What it is Used For

Sacubitril/Valsartan Vale and SACAZARTI are authorised in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction and in children and adolescents aged one year or older for treatment of symptomatic chronic heart failure with left ventricular systolic dysfunction (see SmPC for the full indication).

They contain sacubitril and valsartan as the active substances and are given by oral route of administration.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Sacubitril/Valsartan Vale and SACAZARTI, 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Sacubitril/Valsartan Vale and SACAZARTI is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Sacubitril/Valsartan Vale and SACAZARTI are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Sacubitril/Valsartan Vale and SACAZARTI. 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/use in special patient populations etc.);

Table 1: Part VI.1- Summary of safety concerns

List of Important Risks and Missing Information	
Important Identified Risks	• Embryo-fetal toxicity/lethality
Important Potential Risks	• Neonatal/infantile toxicity through exposure from breast milk • Cognitive impairment
Missing Information	• Long term use of sacubitril/valsartan in HF patients

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 Sacubitril/Valsartan Vale and SACAZARTI.

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

There are no studies required for Sacubitril/Valsartan Vale and SACAZARTI.