PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Neomercazole(Carbimazole) (herein referred as Carbimazole).

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

Important new concerns or changes to the current ones will be included in updates of Carbimazole's RMP.

I. The medicine and what it is used for

Carbimazole is authorised in all conditions where reduction of thyroid function is required like hyperthyroidism, in preparation for thyroidectomy in hyperthyroidism and as a therapy prior to and post radio-iodine treatment (see SmPC for the full indication). It contains carbimazole as the active substance and are given by oral route.

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

Important risks of Carbimazole, together with measures to minimise such risks and the proposed studies for learning more about Carbimazole'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 Carbimazole 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 Carbimazole. 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).

Summary of safety concerns	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

Not Applicable as no safety concerns have been proposed.

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 for Carbimazole

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

There are no studies required for Carbimazole.