PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR SPIRIVA (TIOTROPIUM BROMIDE)

This is a summary of the Risk Management Plan (RMP) for Spiriva. The RMP details important risks of Spiriva, how these risks can be minimised, and how more information will be obtained about Spiriva's risks and uncertainties (missing information).

Spiriva's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Spiriva should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

Spiriva is authorised for maintenance treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD). Spiriva Respimat is authorised for add-on maintenance treatment in patients aged 6 years and older with severe asthma who experienced 1 or more severe asthma exacerbations in the preceding year (see SmPCs for the full indication). They contain tiotropium bromide as the active substance and they are given by inhalation.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

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

If important information that may affect the safe use of Spiriva is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Spiriva 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 Spiriva. 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).

PVI.Table 1 List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risks
None

Important potential risks
None

Missing information
None

II.C Post-authorisation development plan

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

There are no studies which are conditions for the marketing authorisation or specific obligation for Spiriva.

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

There are no studies that are required for Spiriva.

ABBREVIATIONS

COPD	Chronic obstructive pulmonary disease
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics