PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR STRIVERDI (OLODATEROL HYDROCHLORIDE)

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

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

This summary of the RMP for Striverdi should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all of which are part of the European Public Assessment Report (EPAR).

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

I. THE MEDICINE AND WHAT IT IS USED FOR

Striverdi is authorised for once daily maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease (COPD). It contains olodaterol hydrochloride as the active substance and it is given by oral inhalation via a propellant-free metered dose inhaler called the Respimat Soft Mist Inhaler.

Further information about the evaluation of Striverdi's benefits can be found in Striverdi's EPAR, including in its plain-language summary, available on the European Medicines Agency website, under the medicine's webpage.

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

Important risks of Striverdi, together with measures to minimise such risks and the proposed studies for learning more about Striverdi'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 as 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 Striverdi is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Striverdi 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 Striverdi. 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 yet been established 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
Important 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 that are conditions for the marketing authorisation or specific obligation for Striverdi.

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

No studies are required for Striverdi.

ABBREVIATIONS

COPD	Chronic obstructive pulmonary disease
EPAR	European Public Assessment Report

RMP	Risk Management Plan
SmPC	Summary of Product Characteristics