Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for Tiotropium 10 microgram per delivered dose inhalation powder, hard capsule

This is a summary of the risk management plan (RMP) for Tiotropium 10 microgram per delivered dose inhalation powder, hard capsule (herein after also referred to as Tiotropium). The RMP details important risks of Tiotropium, how these risks can be minimised, and how more information will be obtained about Tiotropium's risks and uncertainties (missing information).

Tiotropium's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tiotropium should be used.

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

I. The Medicine and What It is used for

Tiotropium is authorised as a maintenance bronchodilator treatment to relieve symptoms of patients with chronic obstructive pulmonary disease (COPD) (see SmPC for the full indication). It contains Tiotropium as the active substance and it is given by inhalation.

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

Important risks of Tiotropium, together with measures to minimise such risks and the proposed studies for learning more about Tiotropium’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 the case of Tiotropium, these measures are supplemented with *additional risk minimisation measure* mentioned under relevant important potential risk of medication errors, below.

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*.

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

II.A List of Important Risks and Missing Information

Important risks of Tiotropium 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 Tiotropium. 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).

Table 9: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• Cardiac mortality • Blood and lymphatic system disorders • Blood glucose increased • Psychiatric disorders • Syncope • Cardiac disorders (ischaemic heart disease, myocardial infarction, cardiac arrhythmia, cardiac failure, angina pectoris) • Vascular disorders (aneurysm, hypertension) • Renal failure • Overdose • Medication error
Missing information	• Pregnant and breast-feeding women • Patients with a recent history of myocardial infarction, unstable or life-threatening cardiac arrhythmia, paroxysmal tachycardia and decompensated heart failure • Treatment of paediatric patients • Long term safety in asthma

II.B Summary of Important Risks

Table 10: Summary of Risk Minimisation Activities by Safety Concern

Important potential risk: Medication error	
Evidence for linking the risk to the medicine	There is potential risk of prescribing and administration errors and the healthcare professionals are advised to inform the patients being transferred from the Spiriva® HandiHaler® to Tiotropium Teva and/or the carer that the dosing schedule is one capsule, once daily. The pre-metered dose of Tiotropium Teva (13 mcg) is lower than the pre-metered dose of Spiriva® (18 mcg), however the 'delivered doses' (i.e. dose delivered to the patient) of both products are the same (10 mcg).
Risk factors and risk groups	Unintended prescribing errors, patients who previously used reference product containing tiotropium 18 microgram (inhalation powder, hard capsules); medication errors related to drug use, elderly
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.2. Described in PIL sections 1, 2 and 3. Prescription only medicine. Additional risk minimisation measures: Educational material for HCPs

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 Tiotropium.

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

There are no studies required for Tiotropium.