Part VI: Summary of the risk management plan

Summary of risk management plan for Tupakair (beclometasone dipropionate /formoterol fumarate)

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

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

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

I. The medicine and what it is used for

Tupakair 100/6 mcg and 200/6 mcg per actuation pressurised inhalation solution is authorised for the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled rapid-acting beta2-agonist or
- patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists.

Tupakair 200/6 mcg per actuation pressurised inhalation solution is indicated in adults.

In addition, Tupakair 100/6 mcg per actuation pressurised inhalation solution is authorised for the symptomatic treatment of patients with severe COPD (FEV1 < 50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.

It contains beclometasone and formoterol as the active substances and it is given by inhalation.

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

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

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

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 Tupakair.

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

There are no studies required for Tupakair.