Summary of risk management plan for Asmanex (Mometasone furoate Dry Powder Inhaler)

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

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

Important new concerns or changes to the current ones will be included in updates of the RMP for Asmanex.

I. The Medicine and What it is Used for

Asmanex is authorized for adults and adolescents 12 years of age and older for regular treatment to control persistent asthma (see SmPC for the full indication). It contains 200 mcg and 400 mcg of mometasone furoate as the active substance and it is for inhalation use only.

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

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

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

II.A List of Important Risks and Missing Information

Important risks of Asmanex are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely as an Inhaler. 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 Asmanex. 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).

The important identified or potential risks included in prior versions of the RMP have been removed based on the review of accumulating clinical data and the guidance in GVP module 5 (Rev 2), as per routine updates of the RMP during the life cycle of the product.

II.B Summary of Important Risks

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 of the marketing authorisation or specific obligation of MF DPI

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

There are no post-authorization studies required for MF DPI.