Part VI: Summary of the risk management plan

Summary of risk management plan for Indacaterol / Glycopyrronium Viatris (Indacaterol maleate, Glycopyrronium bromide)

This is a summary of the risk management plan (RMP) for Indacaterol / Glycopyrronium Viatris. The RMP details important risks of Indacaterol / Glycopyronium Viatris, and how more information will be obtained about Indacaterol / Glycopyrronium Viatris's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Indacaterol / Glycopyrronium Viatris's RMP.

I. The medicine and what it is used for

Indacaterol / Glycopyrronium Viatris is authorised for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD) (see SmPC for the full indication) (see SmPC for the full indication).

It contains indacaterol maleate and glycopyrronium bromide as the active substances and it is given by inhalation use as inhalation powder hard capsules.

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

Important risks of Indacaterol / Glycopyrronium Viatris, together with measures to minimise such risks and the proposed studies for learning more about Indacaterol / Glycopyrronium Viatris'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*.

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

II.A List of important risks and missing information

Important risks of Indacaterol / Glycopyrronium Viatris 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 Indacaterol / Glycopyrronium Viatris. 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 Indacaterol / Glycopyrronium Viatris.

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

There are no studies required for Indacaterol / Glycopyrronium Viatris.