VI. PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR SYMBICORT

This is a summary of the risk management plan (RMP) for Symbicort Turbuhaler and Symbicort pressurised inhalation, suspension.

Symbicort Turbuhaler and Symbicort pressurised inhalation, suspension respective Summary of Product Characteristics (SmPC) and corresponding package leaflets give essential information to healthcare professionals and patients on how Symbicort Turbuhaler and Symbicort pressurised inhalation, suspension should be used.

VI.1 THE MEDICINE AND WHAT IT IS USED FOR

Symbicort is available as Symbicort Turbuhaler and Symbicort pressurised inhalation, suspension. Both products contain budesonide and formoterol as the active substances given by inhalation. Symbicort is authorised for COPD and asthma (see respective SmPC for the full indication).

VI.2 RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

In compliance with present EU RMP guidelines, there are no important identified risks, important potential risks or missing information included in the Symbicort EU RMP.

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.

Information about adverse reactions is collected continuously and regularly analysed, including Periodic Safety Update Report (PSUR) assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

VI.2.1 List of important risks and missing information

Important risks 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 the medicinal product. 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 VI-1 List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing Information	None

VI.2.2 Summary of important risks

There are no important risks or missing information for Symbicort Turbuhaler or Symbicort pressurised inhalation, suspension.

VI.2.3 Post-authorisation development plan

Not applicable.