PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN FOR TRIXEO / RILTRAVA AEROSPHERE (FORMOTEROL, GLYCOPYRRONIUM AND BUDESONIDE)

This is a summary of the EU RMP for TRIXEO / RILTRAVA AEROSPHERE. The EU RMP details important risks of TRIXEO / RILTRAVA AEROSPHERE, how these risks can be minimised, and how more information will be obtained about TRIXEO / RILTRAVA AEROSPHERE's risks and uncertainties (missing information).

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

THE MEDICINE AND WHAT IT IS USED FOR

TRIXEO / RILTRAVA AEROSPHERE is intended for a maintenance treatment for adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) (see respective SmPC for the full indication). It contains budesonide, glycopyrronium bromide, and formoterol fumarate dehydrate as the active substances and it is given by pressurised inhalation suspension.

TRIXEO AEROSPHERE

https://www.ema.europa.eu/en/medicines/human/EPAR/trixeo-aerosphere

RILTRAVA AEROSPHERE

https://www.ema.europa.eu/en/medicines/human/EPAR/riltrava-aerosphere

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

In compliance with present EMA RMP guidelines, there are no important identified risks, important potential risks or missing information included in the TRIXEO / RILTRAVA AEROSPHERE 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 local label 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 (eg, with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

AstraZeneca does not plan to perform any risk minimisation activities in relation to the use of TRIXEO / RILTRAVA AEROSPHERE other than routine 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.

AstraZeneca does not plan to perform any pharmacovigilance activities outside of routine activities and measures in relation to TRIXEO / RILTRAVA AEROSPHERE nor has AstraZeneca received any request to perform any such activity.

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 TRIXEO / RILTRAVA AEROSPHERE. 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 (eg, on the long-term use of the medicine).

There are no important risks or missing information for TRIXEO / RILTRAVA AEROSPHERE.

Summary of important risks

Not applicable.

Post-authorisation development plan

Not applicable.

Studies which are conditions of the marketing authorisation

Not applicable.

Other studies in post-authorisation development plan

Not applicable