This is a summary of the Risk Management Plan (RMP) for BEVESPI AEROPSHERE. The RMP details important risks of BEVESPI AEROSPHERE, how these risks can be minimised, and how more information will be obtained about BEVESPI AEROSPHERE's risks.

BEVESPI AEROSPHERE's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how BEVESPI AEROSPHERE should be used. This summary of the RMP for BEVESPI AEROSPHERE should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of BEVESPI AEROSPHERE's EU-RMP.

I: THE MEDICINE AND WHAT IT IS USED FOR

BEVESPI AEROSPHERE is authorised for maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD) (see SmPC for the full indication). It contains glycopyrronium and formoterol as the active substances, and it is given by oral inhalation.

Clinical studies have shown BEVESPI AEROSPHERE to be effective for treating patients with COPD. Further information about the evaluation of BEVESPI AEROSPHERE's benefits can be found in BEVESPI AEROSPHERE's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage: https://www.ema.europa.eu/en/medicines/human/EPAR/bevespi-aerosphere

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

Important risks of BEVESPI AEROSPHERE, together with measures to minimise such risks and the proposed studies for learning more about BEVESPI AEROSPHERE'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 (eg, 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 Periodic Safety Updata Report assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

1.1 LIST OF IMPORTANT RISKS AND MISSING INFORMATION

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 BEVESPI 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.

List of important risks and missing information

Important identified risks	None
Important potential risks	Serious cardiovascular and cerebrovascular events
Missing information	None

1.2 Summary of important risks

Important potential risk: Serious cardiovascular and cerebrovascular events

Evidence for linking the risk to the medicine	There is no overt signal for serious cardiovascular or cerebrovascular events from the clinical programme. The use of LAMA has been suggested to be associated with an increased risk of cardiovascular and cerebrovascular events, but the data are conflicting.
Risk factors and risk groups	Age, smoking, hypertension, hyperlipidaemia, obesity, diabetes, atrial fibrillation, arterial stenosis, family history of heart disease, poor diet, BMI $\geq$30 kg/m^2, and physical inactivity.
Risk minimisation measures	Routine risk minimisation measures: SmPC Section 4.4 and Patient Information Leaflet Section 2
Additional pharmacovigilance activities	Additional pharmacovigilance activities: None.

1.3 Summary of missing information

None.

1.4 Post-authorisation development plan

1.3.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of BEVESPI AEROSPHERE.

1.4.1 Other studies in post-authorisation development plan

There are no studies required for BEVESPI AEROPSHERE.