VERTEX PHARMACEUTICALS INCORPORATED

Swiss Summary of the Risk Management Plan for Symdeko® (tezacaftor/ivacaftor)

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Based on EU RMP Version 4.0

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Symdeko® is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary may differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g., by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document, which is valid and relevant for the effective and safe use of Symdeko® in Switzerland, is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch), approved and authorised by Swissmedic. Vertex Pharmaceuticals (CH) GmbH is fully responsible for the accuracy and correctness of the content of the published RMP summary of Symdeko®.

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SUMMARY OF THE RISK MANAGEMENT PLAN FOR SYMDEKO (TEZACAFTOR/IVACAFTOR)

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

Symdeko's Product Information and its package information leaflet give essential information to healthcare professionals and patients on how Symdeko should be used.

Important new safety concerns or changes to the current safety concerns will be included in updates of the Symdeko RMP.

I. The medicine and what it is used for

Symdeko is authorised for the treatment of patients with cystic fibrosis (CF) aged 6 years and older who are homozygous for the *F508del* mutation or are heterozygous for the *F508del* mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (*CFTR*) gene: *P67L, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G,* or *3849+10kbC→T*. Symdeko contains tezacaftor in combination with ivacaftor as the active substances in the morning dose and ivacaftor as the active substance in the evening dose. Symdeko is given orally.

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

Important risks of Symdeko, together with measures to minimise such risks and the proposed studies for learning more about Symdeko'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 product information 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.

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

II.A List of important risks and missing information

Important risks of Symdeko 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 Symdeko. 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

There are no important identified risks, important potential risks, or missing information for Symdeko.

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 Symdeko.

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

There are no ongoing or planned studies in the post-authorisation development plan.