Part VI: Summary of the risk management plan

Summary of risk management plan for Ezetimib/Simvastatin Sandoz; Ezetimib/Simvastatin Hexal 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg, Tablets (Ezetimib/Simvastatin)

This is a summary of the RMP for Ezetimib/Simvastatin Sandoz and Ezetimib/Simvastatin, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg, tablets (Sandoz's products containing ezetimibe/simvastatin). The RMP details important risks of Sandoz's products containing ezetimibe/simvastatin, tablets, how these risks can be minimized, and how more information will be obtained about Sandoz's products containing ezetimibe/simvastatin, tablets' risks and uncertainties (missing information).

Sandoz's products containing ezetimibe/simvastatin, tablets' summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how Sandoz's products containing ezetimibe/simvastatin, tablets should be used.

Important new concerns or changes to the current ones will be included in updates of the Sandoz's products containing ezetimibe/simvastatin, tablet's RMP.

I. The medicine and what it is used for

Sandoz's products containing ezetimibe/simvastatin are authorized for:

Prevention of cardiovascular events

Ezetimibe/Simvastatin is indicated to reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), either previously treated with a statin or not.

Hypercholesterolemia

Ezetimibe/Simvastatin is indicated as adjunctive therapy to diet for use in patients with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia where use of a combination product is appropriate:

- patients not appropriately controlled with a statin alone
- patients already treated with a statin and ezetimibe

Homozygous familial hypercholesterolemia (HoFH)

Ezetimibe/Simvastatin is indicated as adjunctive therapy to diet for use in patients with HoFH. Patients may also receive adjunctive treatments (e.g., low-density lipoprotein (LDL) apheresis).

It contains ezetimibe/simvastatin as an active substance and is taken orally as tablets (10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg).

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

Important risks of Sandoz's products containing ezetimibe/simvastatin, tablets, together with measures to minimize such risks are outlined below.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and HCPs;
- Important advice on the medicine's packaging;
- The authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report (PSUR) assessment (if applicable) so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Sandoz's products containing ezetimibe/simvastatin, tablets are risks that need special risk management activities to further investigate or minimize 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 Sandoz's products containing ezetimibe/simvastatin, tablets. 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	Rhabdomyolysis/Myopathy
	Abnormal liver function
Important potential risks	New onset diabetes mellitus/impaired glucose metabolism
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 authorization or specific obligation of Sandoz's products containing ezetimibe/simvastatin, tablets.

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

There are no studies required for Sandoz's products containing ezetimibe/simvastatin, tablets.