Part VI: Summary of the Risk Management Plan

Summary of risk management plan for Lenalidomide Glenmark (Lenalidomide)

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

Lenalidomide Glenmark summary of product characteristics (SmPC) and its package leaflet (PL) give essential information to healthcare professionals (HCPs) and patients on how Lenalidomide Glenmark should be used.

I. The medicine and what it is used for

Lenalidomide Glenmark is authorised for treatment of multiple myeloma as:

- monotherapy for the maintenance treatment of adult patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation.
- combination therapy for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for transplant.
- in combination with dexamethasone for the treatment of multiple myeloma in adult patients who have received at least one prior therapy

It contains lenalidomide as the active substance and it is given orally.

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

Important risks of Lenalidomide Glenmark, together with measures to minimise such risks and the proposed studies for learning more about Lenalidomide Glenmark 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 PL and SmPC addressed to patients and HCPs;
- 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment if PSUR is required by Health Authority, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

In the case of Lenalidomide Glenmark, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

II.A. List of important risks and missing information

Important risks of Lenalidomide Glenmark 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 Lenalidomide Glenmark. 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 risk(s)	• Teratogenicity • Serious infection due to neutropenia • Second primary malignancies
Important potential risk(s)	• Cardiac failure • Cardiac arrhythmias • Ischaemic heart disease (including myocardial infarction) • Off-label use
Missing information	• None

II.B. Summary of important risk

Important Identified Risk – Teratogenicity	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> The information regarding this safety concern is mentioned in the following section(s): **SmPC** • Section 4.3: Contraindications • Section 4.4: Special warnings and precautions for use • Section 4.6: Fertility, pregnancy and lactation • Section 4.8: Undesirable effects • Section 5.3: Preclinical safety data **PL:** • Section 2: What you need to know before you take [Product name] <u>Additional risk minimisation measures:</u> Pregnancy Prevention Programme: • Educational HCP's kit • Educational brochures for Patients

Important Identified Risk – Teratogenicity	
	• Patient Cards
Additional pharmacovigilance activities.	Monitoring of Pregnancy Prevention Programme: The objective is monitoring of implementation of Pregnancy Prevention Programme. The requirement will be agreed on a country specific basis in accordance with local legal framework and with agreement of the relevant national competent authorities

Important Identified Risk – Second primary malignancy	
Risk minimisation measures	Routine risk minimisation measures: The information regarding this safety concern is mentioned in the following section(s): **SmPC** • Section 4.4: Special warnings and precautions for use • Section 4.8: Undesirable effects **PL:** • Section 4: Possible side effects Additional risk minimisation measures: Educational HCP's kit

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 Lenalidomide Glenmark.

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

There are no studies required for Lenalidomide Glenmark. However, monitoring of implementation of Pregnancy Prevention Programme will be agreed on a country specific basis in accordance with local legal framework and with agreement of the relevant national competent authorities.