Summary of risk management plan for lenalidomide

This is a summary of the risk management plan (RMP) for lenalidomide (Lenalidomide Stada Nordic 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg capsule hard, Ferulinor 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg capsule hard, Lenalidomide Cooper 5 mg, 10 mg, 15 mg, 20 mg, 25 mg capsule hard, Lenalidomide Ariti 5 mg, 10 mg, 15 mg, 20 mg, 25 mg capsule hard), Lenalidomide Newbury 2.5 mg, 7.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg capsule hard. The RMP details important risks of lenalidomide, how these risks can be minimised, and how more information will be obtained about lenalidomide's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Lenalidomide is authorised for multiple myeloma, myelodysplastic syndromes, mantle cell lymphoma and follicular lymphoma (see SmPC for the full indication). 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, together with measures to minimise such risks and the proposed studies for learning more about lenalidomide'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 (e.g. with or without prescription) can help to minimise its risks.

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

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

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, 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 Lenalidomide 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. 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	• Teratogenicity • Serious infection due to neutropenia • SPM (Second primary malignancies) <u>Important Identified Risk Related to Indication/Target Population</u>

List of important risks and missing information	
	• For MCL (mantle cell lymphoma) and FL (follicular lymphoma): TFR (Tumor Flare Reaction)
Important potential risks	• Cardiac failure • Cardiac arrhythmias • Ischaemic heart disease (including myocardial infarction) • Off-label use
Missing information	• None

II.B Summary of important risks

Important identified risk: Teratogenicity	
Risk minimisation measures	Routine risk minimisation measures Covered under the following section of SmPC: Section 4.3 of SmPC: contraindicated in pregnant women and in women of childbearing potential unless all the conditions of the lenalidomide PPP are met Section 4.4 of SmPC: warnings and precautions for use - Criteria for women of non-childbearing potential - Counselling - Contraception - Pregnancy testing - Precautions for men - Additional precautions - Reference to educational materials, prescribing and dispensing restrictions. Section 4.6 of SmPC: fertility, pregnancy and lactation. Sections 4.8 and 5.3 of SmPC: the potential teratogenic effects oflenalidomide are highlighted. Advice to patients in PL.

Important identified risk: Teratogenicity	
	Other routine risk minimisation measures Prescription only medicine **Additional risk minimisation measure(s)** Main Additional Risk Minimisation Measures: • Educational Programme for HCPs (physicians and pharmacists) and patients • Therapy management • Prescribing controls • Dispensing controls • Assessment PPP (Pregnancy Prevention Programme) Educational Programme: (HCP kit, Treatment algorithm, pregnancy reporting form, patient card, patient brochure and checklists) ➢ Brochure for male patients **Therapy management** (Criteria for determining women of childbearing potential, Contraceptive measures and pregnancy testing for women of childbearing potential, Advice in SmPC & Package Leaflet, and educational materials) **Patient Card** (to document childbearing status, counselling and pregnancy testing)
Additional pharmacovigilance activities	Additional pharmacovigilance activities: In respect to pregnancy, a **specific pregnancy report form** is provided with each HCP Kit to optimise data collection and reporting of pregnancies.

Important Identified risk SPM (Second primary malignancies)	
Risk minimisation measures	**Routine risk minimisation measures** **<u>Covered under the following section of SmPC and PIL</u>:** - Section 4.4 of SmPC: warning of haematological SPM and advice for cancer screening. - SPM listed as ADRs in Section 4.8 of SmPC. - Advice to patients provided in PL. **Other routine risk minimisation measures** Prescription only medicine Specific adverse reaction follow-up questionnaires **Additional risk minimisation measure(s)** HCP Kit (HCP Brochure)

Important Identified risk	
For MCL and FL: TFR	Routine Pharmacovigilance **<u>Covered under the following section of SmPC and PIL</u>:** − Section 4.2 of SmPC: dose interruption advice for TFR. − Section 4.4 of SmPC warning. − Listed as an ADR in Section 4.8 of SmPC. **Other routine risk minimisation measures** Prescription only medicine **Additional risk minimisation measure(s)** HCP Kit: HCP Guide

II.C Post-authorisation development plan

Not applicable.