Summary of risk management plan for Lenalidomide Orion (lenalidomide) Orion Corporation

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

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

Important new concerns or changes to the current ones will be included in updates of Lenalidomide Orion's RMP.

I. The medicine and what it is used for

Lenalidomide Orion is authorised for treatment of multiple myeloma and follicular lymphoma (see SmPC for the full indication). It contains lenalidomide as the active substance and it is taken by mouth.

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

Important risks of Lenalidomide Orion, together with measures to minimise such risks and the proposed studies for learning more about Lenalidomide Orion'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 Orion, 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 Orion 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 • Second Primary Malignancy (SPM) • Tumour Flare Reaction (TFR) (risk related to Indications/Target Population Follicular lymphoma (FL))
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

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Important identified risk: Teratogenicity	
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC sections 4.3, 4.4, 4.6, 5.3 and 6.6. PL sections 2 and 3. Lenalidomide is contraindicated during pregnancy. The conditions of the Pregnancy Prevention Programme must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule Warning in the outer package:

Important identified risk: Teratogenicity	
	"WARNING: Risk of severe birth defects. Do not use while pregnant or breastfeeding. You must follow the Pregnancy Prevention Programme." *Legal status:* Restricted medical prescription and distribution concerning patients with child-bearing potential. <u>Additional risk minimisation measures:</u> • Educational material for healthcare professionals including DHPC • Patient educational material • Patient card

Important identified risk: Second Primary Malignancy (SPM)	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC sections 4.4 and 4.8. PL sections 2 and 4. Physicians should carefully evaluate patients before and during treatment using standard cancer screening for occurrence of SPM and institute treatment as indicated. <u>Additional risk minimisation measures:</u> • Educational material for healthcare professionals including DHPC

Important identified risk: Tumour Flare Reaction (TFR) (risk related to Indications/Target Population Follicular lymphoma (FL))	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC sections 4.2, 4.4 and 4.8. PL sections 2 and 4. <u>Additional risk minimisation measures:</u> • Educational material for healthcare professionals including DHPC

II.C Post-authorisation development plan

There are no studies required for Lenalidomide Orion.