Part VI: Summary of the risk management plan

Summary of risk management plan for Pomalidomide

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

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

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

I. The medicine and what it is used for

The Applicant's Pomalidomide is a medicine used for the following indications:

- Pomalidomide in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.
- Pomalidomide in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

The Applicant's Pomalidomide contains pomalidomide as the active substance and it is taken orally.

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

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

List of important risks and missing information	
Important identified risks	Cardiac failure
	Non-melanoma skin cancer
	Severe infection due to neutropenia and pancytopenia
	Teratogenicity
	Thrombocytopenia and bleeding
Important potential risks	Cardiac arrhythmia
	Other second primary malignancies
Missing information	None

I.A Summary of important risks

Important identified risks	
Cardiac failure	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4 and 4.8. A warning regarding heart failure is included in the PL. Pomalidomide is a prescription only medicine. Additional risk minimisation measures: Educational HCP brochure.
Additional pharmacovigilance activities	Not applicable.
Non-melanoma skin cancer	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4 and 4.8. A warning regarding BCC and SCC is included in the PL. Pomalidomide is a prescription only medicine. Additional risk minimisation measures: None.

Additional pharmacovigilance activities	Not applicable.
Severe infection due to neutropenia and pancytopenia	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC sections 4.2, 4.4 and 4.8. PL section 2. Pomalidomide is a prescription only medicine. <u>Additional risk minimisation measures:</u> None.
Additional pharmacovigilance activities	Not applicable.
Teratogenicity	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC sections 4.3, 4.4, 4.6, 4.8 and 5.3. The PL warns of the potential teratogenic effects of pomalidomide and the need to avoid pregnancy. Pomalidomide is a prescription only medicine. <u>Additional risk minimisation measures:</u> PPP Educational Programme • Educational HCP kit to include educational HCP brochure, educational brochures for patients, patient card, risk awareness forms, and information on where to find latest SmPC. Therapy management • Criteria for determining women of childbearing potential, contraceptive measures and pregnancy testing for women of childbearing potential. • Advice in SmPC and educational materials. System to ensure appropriate measures have been completed • Patient Card to document childbearing status, counselling and pregnancy testing.
Additional pharmacovigilance activities	Monitor implementation and compliance of the Applicant's PPP on a country basis in agreement with the relevant NCA.

Thrombocytopenia and bleeding	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.2, 4.4 and 4.8. The PL warns that pomalidomide may cause bleeding or bruising without a cause, and lists bleeding within the skull, nosebleeds and bleeding from the bowels or stomach as possible side effects. Pomalidomide is a prescription only medicine. Additional risk minimisation measures: • Educational HCP brochure. • Educational brochure for patients.
Additional pharmacovigilance activities	Not applicable.
Important potential risks	
Cardiac arrhythmia	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.8. Atrial fibrillation listed in PL. Pomalidomide is a prescription only medicine. Additional risk minimisation measures: None.
Additional pharmacovigilance activities	Not applicable
Other second primary malignancies	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4 and 5.3. A warning regarding BCC and SCC is included in the PL. Pomalidomide is a prescription only medicine. Additional risk minimisation measures: None.
Additional pharmacovigilance activities	Not applicable.
Missing information	

None

I.A Post-authorisation development plan

I.A.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of the Applicant's Pomalidomide.

II.A.1 Other studies in post-authorisation development plan

There are no studies required for the Applicant's Pomalidomide.