## Part VI: Summary of the risk management plan

### Summary of risk management plan for Pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, Hard capsules

This is a summary of the risk management plan (RMP) for pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules. The RMP details important risks of pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules, how these risks can be minimized, and how more information will be obtained about pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules' risks and uncertainties (missing information).

Pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules' RMP.

### I. The medicine and what it is used for

Pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules is authorized for:

- 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.

It contains pomalidomide as active substance and is given orally as hard capsules (1 mg, 2 mg, 3 mg and 4 mg).

### II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules, together with measures to minimize such risks and the proposed studies for learning more about pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules' 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 package leaflet and SmPC addressed to patients and healthcare professionals;
- 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 the case of pomalidomide, 1 mg, 2 mg, 3 mg and 4 mg, hard capsules, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 pomalidomide 1 mg, 2 mg, 3 mg and 4 mg, hard capsules are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered or 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 1 mg, 2 mg, 3 mg and 4 mg, hard capsules. 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);

**Table 7 - Part VI II.A: List of important risks and missing information**

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

### *II.B Summary of important risks*

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

## Table 8 - Part VI II.B: Summary of important risks

| **Important identified risk: Teratogenicity** | |
|---|---|
| Risk minimization measures | Routine risk minimization measures:<br>• SmPC<br>– Sections 4.3, 4.4, 4.6, 4.8 and 5.3.<br>• PL<br>– The PL warns of the potential teratogenic effects of pomalidomide and the need to avoid pregnancy.<br>• Pomalidomide is a prescription only medicine.<br>**Additional risk minimization measures:**<br>1. PPP<br>• Controlled access is designed to minimize the risk of exposure to pediatric patients or non-target populations and provide education on the risk and the necessary steps to prevent fetal exposure.<br>2. Educational Programme.<br>• Educational HCP's kit to include educational healthcare professional brochure, educational brochures for patients, patient card, risk awareness forms, and information on where to find latest SmPC.<br>3. Therapy management:<br>• Criteria for determining women of childbearing potential, contraceptive measures and pregnancy testing for women of childbearing potential.<br>• Advice in SmPC and educational materials.<br><br>Controlled access system (in agreement with relevant NCA) to ensure appropriate measures have been completed.<br>Patient Card to document childbearing status, counselling and pregnancy testing. |
| Additional pharmacovigilance activities | Monitoring of the implementation of the pregnancy prevention programme (PPP) on a country basis in agreement with the relevant NCA. |

| **Important identified risk: Thrombocytopenia and bleeding** | |
|---|---|
| Risk minimization measures | Routine risk minimization measures:<br>• SmPC<br>– Sections 4.2, 4.4 and 4.8.<br>• PL<br>– 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.<br>• Pomalidomide is a prescription only medicine.<br>**Additional risk minimization measures:**<br>• HCP additional educational materials.<br>• Patient brochure. |

| **Important identified risk: Cardiac failure** | |
|---|---|
| Risk minimization measures | **Routine risk minimization measures:**<br>Routine risk minimisation measures:<br>• SmPC<br>– Sections 4.4 and 4.8.<br>• PL<br>– A warning regarding heart failure is included in the PL.<br>• Pomalidomide is a prescription only medicine.<br>**Additional risk minimization measures:**<br>• HCP additional educational material. |

## *II.C Post-authorization development plan*

### II.C.1 Studies which are conditions of the marketing authorization.

There are no studies which are conditions of the marketing authorization or specific obligation of pomalidomide.

### II.C.2 Other studies in post-authorization development plan

There are no studies required for pomalidomide.