EU Risk Management Plan
for
Pomalidomide Accord 1 mg hard capsules
Pomalidomide Accord 2 mg hard capsules
Pomalidomide Accord 3 mg hard capsules
Pomalidomide Accord 4 mg hard capsules
(Pomalidomide)

RMP version to be assessed as part of this application:

RMP Version number	2.0
Data lock point for this RMP	09-Feb-2026
Date of final sign off	04-May-2026

Rationale for submitting an updated RMP: This Risk Management Plan (RMP) has been updated in line with European Public Assessment Report (EPAR) - RMP of reference product Imnovid® (Pomalidomide) (version 18.0, dated 11-Mar-2025) published by EMA on 20-Jan-2026.

Summary of significant changes in this RMP: Part I, Part III.1, Part VI (II.C) and Part VII (Annex 6, 7 and 8) have been updated.

Other RMP versions under evaluation: Not applicable

Details of the currently approved RMP:

RMP Version	Procedure	Approval date
1.2	Centralised Procedure (EMEA/H/C/006273)	30-May-2024

QPPV name: Agata Gesiewicz

QPPV signature: 

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Part I: Product(s) Overview

Table 1: Product(s) Overview

Active substance(s) (INN or common name)	Pomalidomide
Pharmacotherapeutic group(s) (ATC Code)	**Pharmacotherapeutic group(s):** Immunosuppressants, Other immunosuppressants, **ATC code:** L04AX06
Marketing Authorisation Applicant	Accord Healthcare S.L.U, Spain
Medicinal products to which this RMP refers	04
Invented name(s) in the European Economic Area (EEA)	Pomalidomide Accord 1 mg hard capsules Pomalidomide Accord 2 mg hard capsules Pomalidomide Accord 3 mg hard capsules Pomalidomide Accord 4 mg hard capsules
Marketing authorisation procedure	Centralised Procedure (EMEA/H/C/006273)
Brief description of the product	**Chemical class**: It is a dicarboximide, a member of isoindoles, a member of piperidones and an aromatic amine. Pomalidomide, an analogue of thalidomide, is an immunomodulatory antineoplastic agent.
	Summary of mode of action: Pomalidomide has direct anti-myeloma tumoricidal activity, immunomodulatory activities and inhibits stromal cell support for multiple myeloma tumour cell growth.

	Specifically, pomalidomide inhibits proliferation and induces apoptosis of haematopoietic tumour cells. Additionally, pomalidomide inhibits the proliferation of lenalidomide-resistant multiple myeloma cell lines and synergises with dexamethasone in both lenalidomide-sensitive and lenalidomide-resistant cell lines to induce tumour cell apoptosis. Pomalidomide enhances T cell- and natural killer (NK) cell-mediated immunity and inhibits production of pro-inflammatory cytokines (e.g., TNF-α and IL-6) by monocytes. Pomalidomide also inhibits angiogenesis by blocking the migration and adhesion of endothelial cells. Pomalidomide binds directly to the protein cereblon (CRBN), which is part of an E3 ligase complex that includes deoxyribonucleic acid (DNA) damage-binding protein 1(DDB1), cullin 4 (CUL4), and regulator of cullins-1 (Roc1), and can inhibit the auto-ubiquitination of CRBN within the complex. E3 ubiquitin ligases are responsible for the poly-ubiquitination of a variety of substrate proteins, and may partially explain the pleiotropic cellular effects observed with pomalidomide treatment. In the presence of pomalidomide in vitro, substrate proteins Aiolos and Ikaros are targeted for ubiquitination and subsequent degradation leading to direct cytotoxic and immunomodulatory effects. In vivo, pomalidomide therapy led to reduction in the levels of Ikaros in patients with relapsed lenalidomide-refractory multiple myeloma.
	Important information about its composition: *Pomalidomide Accord 1 mg hard capsules* Each hard capsule contains 1 mg of pomalidomide. *Pomalidomide Accord 2 mg hard capsules* Each hard capsule contains 2 mg of pomalidomide.

	Pomalidomide Accord 3 mg hard capsules Each hard capsule contains 3 mg of pomalidomide. *Pomalidomide Accord 4 mg hard capsules* Each hard capsule contains 4 mg of pomalidomide.
Hyperlink to the Product Information	Refer to Module 1.3.1 for SmPC and PIL.
Indication(s) in the EEA	***Current*** Pomalidomide Accord 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 Accord 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.
Dosage in the EEA	***Current*** **Posology:** *Pomalidomide in combination with bortezomib and dexamethasone* The recommended starting dose of pomalidomide is 4 mg taken orally once daily on Days 1 to 14 of repeated 21- day cycles. Pomalidomide is administered in combination with bortezomib and dexamethasone. The recommended starting dose of bortezomib is 1.3 mg/m^2 intravenous or subcutaneous once daily: • For cycles 1-8: on day 1, 4, 8 and 11 of 21-Day cycle.

	• For cycle 9 onwards: on day 1 and 8 of 21-Day cycle. The recommended dose of dexamethasone is 20 mg taken orally once daily • For cycles 1-8: on day 1, 2, 4, 5, 8, 9, 11 and 12 of 21-Day cycle • For cycle 9 onwards: on day 1, 2, 8 and 9 of 21-Day cycle Treatment with pomalidomide combined with bortezomib and dexamethasone should be given until disease progression or until unacceptable toxicity occurs. *Pomalidomide in combination with dexamethasone* The recommended starting dose of pomalidomide is 4 mg taken orally once daily on Days 1 to 21 of each 28-day cycle. The recommended dose of dexamethasone is 40 mg taken orally once daily on Days 1, 8, 15 and 22 of each 28-day cycle. Treatment with pomalidomide combined with dexamethasone should be given until disease progression or until unacceptable toxicity occurs. **Method of administration:** Oral use. Pomalidomide hard capsules should be taken orally at the same time each day. The capsules should not be opened, broken or chewed. The capsules should be swallowed whole, preferably with water, with or without food.
Pharmaceutical form(s) and strengths	***Current*** **Pharmaceutical form(s):** Hard capsules **Strengths:** 1 mg, 2 mg, 3 mg and 4 mg

Is the product subject to additional monitoring in the EU?	No

Part II: Safety specification

Module SI - Epidemiology of the indication(s) and target population(s)

Not applicable

Module SII - Non-clinical part of the safety specification

Not applicable

Module SIII - Clinical trial exposure

Not applicable

Module SIV - Populations not studied in clinical trials

SIV.1 Exclusion criteria in pivotal clinical studies within the development programme

Not applicable

SIV.2 Limitations to detect adverse reactions in clinical trial development programmes

Not applicable

SIV.3 Limitations in respect to populations typically under-represented in clinical trial development programmes

Not applicable

Module SV - Post-authorisation experience

SV.1 Post-authorisation exposure

Not applicable

Module SVI - Additional EU requirements for the safety specification

Potential for misuse for illegal purposes

Not applicable

Module SVII - Identified and potential risks

The safety concerns for this RMP have been updated in line with EPAR - RMP of the reference product Imnovid® (Pomalidomide) (version 18, dated 11-Mar-2025) published by EMA on 20-Jan-2026. There is no change proposed by MAH in these safety concerns mentioned in Module SVIII.

Hence, this section remains "Not applicable".

SVII.1 Identification of safety concerns in the initial RMP submission

SVII.1.1. Risks not considered important for inclusion in the list of safety concerns in the RMP

Not applicable

SVII.1.2. Risks considered important for inclusion in the list of safety concerns in the RMP

Not applicable

SVII.2 New safety concerns and reclassification with a submission of an updated RMP

Not applicable

SVII.3 Details of important identified risks, important potential risks, and missing information

SVII.3.1. Presentation of important identified risks and important potential risks

Not applicable

SVII.3.2 Presentation of the missing information

Not Applicable

Module SVIII - Summary of the safety concerns

Table 2: Summary of safety concerns

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

Part III: Pharmacovigilance Plan (including post-authorisation safety studies)

III.1 Routine pharmacovigilance activities

Routine pharmacovigilance activities including collection and reporting of adverse reactions and signal detection as stated in pharmacovigilance system master file are sufficient for the safety concerns mentioned in module SVIII.

In addition to expedited reporting, Accord vigilantly undertakes follow-up on all ADRs, including serious ADRs that are provided to health authorities to ensure that all details of the case are captured for optimal clinical evaluation. This includes efforts to obtain all relevant information and to establish the final outcome of the ADRs.

Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:

Specific adverse reaction follow-up questionnaire for safety concerns listed below:

- **Pregnancy follow-up forms (Teratogenicity)**
    - Event-Specific Questionnaire for HCP - Pregnancy Background (Patient or Partner of Patient)
    - Event-Specific Questionnaire for HCP - Pregnancy Follow-up (Patient or Partner of Patient)
    - Event-Specific Questionnaire for HCP - Pregnancy Outcome (Patient or Partner of Patient)
    - Event-Specific Questionnaire for Primary Care Physician or Pediatrician- Infant Follow-up
- **Neutropenia**
- **Thrombocytopenia/Bleeding**
- **Cardiac Failure**
- **Second Primary Malignancies**
- **Cardiac Arrhythmia and ECG Changes**

Purpose: For collection and reporting of safety information concerning the safety concerns for Pomalidomide.

Targeted follow-up questionnaires and data collection forms are appended in Annex 4 of this RMP.

Other forms of routine pharmacovigilance activities for Teratogenicity:

An Analysis of Adverse Drug Reactions of Special Interest within the Required PSURs

Emerging potential safety signals can be detected by periodic and if appropriate, cumulative evaluation of the ADRs. The results are compiled in the PSUR with summaries and conclusions submitted to the health authorities. PSURs are submitted in accordance with "Guidelines on Good Pharmacovigilance Practices in the EU". The requirement of periodicity of the PSUR submissions shall be determined as per the most current EURD list.

In addition, data regarding pregnancy exposure to pomalidomide are targeted for review and specifically discussed in the PSUR document. These data include all pregnancy case reports collected during the specified period together with cumulative data. Non-medically confirmed case reports of suspected foetal exposure are also provided, whenever applicable. Non-patient exposure in pregnant females (eg, a nurse opening the capsules, laboratory technician, or carer) is also provided with the corresponding outcome in each PSUR.

Expedited Reporting and Follow-up of Pregnancy

The pregnancy capture and follow-up procedure is detailed below.

The PPP aims to minimise the risks of teratogenicity by ensuring HCPs and patients are fully informed of and understand the risks of teratogenicity prior to starting their pomalidomide treatment. Like thalidomide and lenalidomide, pomalidomide is an immunomodulatory agent with expected teratogenic effects in humans. Therefore, the core PPP for pomalidomide shall be based on the EU and EEA approved core PPP for lenalidomide and thalidomide. It reflects advice, guidance and direction obtained from the Member States during the implementation process for lenalidomide and thalidomide. Where possible and with the agreement of the National Competent Authority (NCA), In order to ensure there is a consistent approach with the ability to capture all information across EU member states, the same principles on obtaining follow-up data on pregnancies are implemented in relevant member states where pomalidomide is marketed.

The objectives of the system are:

• To obtain information on all reported pregnancies of females exposed to pomalidomide.

• To obtain information on all reported pregnancies of female partners of male patients exposed to pomalidomide.

• To determine the root cause of all pregnancies and hence failures of the PPP.

In the EU, Accord uses the following methods to enhance the capture of reports of pregnancy over and above reliance upon spontaneous reporting:

• The Educational Materials in the HCP Kit make reference to the requirement to report all suspected pregnancies to the local Accord/affiliate/partners office and where applicable to the NCA. The Patient Brochure also advises the patient to immediately seek medical advice if there is any risk or suspicion of possible pregnancy. Similar advice shall also be provided with reference to female partners of male patients.

Database of Pregnancy Reports

All reports of pregnancies received by Accord shall be entered into Accord's Global Safety Database. This includes all Consumer reports in addition to HCP reports. Any abnormal pregnancy test result (eg, β-hCG elevated and positive urine pregnancy test) shall be managed as per Accord procedures and reported to EU Health Authorities as per Accord procedures.

Follow-up

All reports of pregnancies shall be followed up. Follow-up shall be via the physician/obstetrician/neonatologist/paediatrician as appropriate. Any report of pregnancy shall be followed up by the Drug Safety staff and shall be handled as per Accord procedures.

All reports of abnormal pregnancy test results shall be followed up with the prescriber and follow-up information shall be reported to Health Authorities as required based on Accord procedures.

Frequency/Duration of Follow-up

Upon receipt of a notification of pregnancy, the pregnancy specific follow-up questionnaire is sent to the reporter. Upon receipt of this information by Accord, dates for further follow-up actions shall be tracked.

The HCP/Obstetrician shall also sent a Follow-Up and Outcome Form to be completed at the outcome of the Pregnancy.

An Infant follow-up form is available for use in the event that a birth defect is detected as an outcome.

Corresponding standard forms are available on request.

Root Cause of Failure of Pregnancy Prevention Programme

The Pregnancy Background Form includes questions to determine why the PPP was unsuccessful for the case in question.

Regulatory Reporting of Pregnancies

All initial pregnancy reports and follow-up information shall be reported on an expedited basis within 15 days.

Should any suspected teratogenic effect be reported following treatment with pomalidomide, this is expedited immediately.

Compliance with the PPP shall be monitored for each member state. Examples of methods to monitor compliance include keeping a record of counselling patients prior to prescription, a record of a negative pregnancy test within 3 days of prescription and a record of dispensing within 7 days of the prescription date, etc. The maximum interval of consecutive PPP compliance studies is agreed on between Accord and individual NCAs.

III.2 Additional pharmacovigilance activities

Pregnancy Prevention Programme Implementation

The pregnancy capture and follow-up procedure is detailed above.

Physicians are encouraged or required as by local legislation to report pregnancies to Accord or in accordance to local legislation to the NCA.

Additional monitoring of the implementation of the Accord PPP is carried out on a country basis in agreement with relevant NCA (Table III.3).

III.3 Summary Table of additional Pharmacovigilance activities

Study; **Status**	**Summary of objectives**	**Safety concerns addressed**	**Milestones** (required by regulators)	**Due dates**
Category 3: Monitoring of implementation of the PPP				
Short title: Pregnancy prevention programme for Pomalidomide (Category 3 study) Status: Planned	To monitor the implementation of the PPP on a country-specific basis	Teratogenicity	Data will be collected on a regular basis after product launch and to report results in PSURs, in accordance with the PSUR schedule, in-line with DLP of latest EURD list	Data will be reviewed on an on-going basis as a part of signal detection and reported within PSURs in-line with EURD list

Part IV: Plans for post-authorisation efficacy studies

Not applicable

Part V: Risk minimisation measures (including evaluation of the effectiveness of risk minimisation activities)

Risk Minimisation Plan

V.1. Routine Risk Minimisation Measures

Table 3: Description of routine risk minimisation measures by safety concern

Safety Concern	Routine risk minimisation activities
Important Identified Risks	
Teratogenicity	*Routine risk communication*: - SmPC section 4.8 - PIL section 02 *Routine risk minimisation activities recommending specific clinical measures to address the risk*: - SmPC sections 4.3, 4.4, 4.6, 5.3 & PIL section 02 *Other routine risk minimisation measures beyond the Product Information*: - The prescription only status of the product
Severe infection due to neutropenia and pancytopenia	*Routine risk communication*: - SmPC section 4.8 - PIL sections 02 and 04 *Routine risk minimisation activities recommending specific clinical measures to address the risk*: - SmPC sections 4.2 and 4.4 *Other routine risk minimisation measures beyond the Product Information*: - The prescription only status of the product

Safety Concern	**Routine risk minimisation activities**
Thrombocytopenia and bleeding	*Routine risk communication:* - SmPC section 4.8 - PIL sections 02 and 04 *Routine risk minimisation activities recommending specific clinical measures to address the risk:* - SmPC sections 4.2 and 4.4 *Other routine risk minimisation measures beyond the Product Information:* - The prescription only status of the product
Cardiac failure	*Routine risk communication:* - SmPC sections 4.8 - PIL sections 02 and 04 *Routine risk minimisation activities recommending specific clinical measures to address the risk:* SmPC section 4.4 *Other routine risk minimisation measures beyond the Product Information:* - The prescription only status of the product
Non-Melanoma Skin Cancer	*Routine risk communication:* - SmPC section 4.8 - PIL sections 02 and 04 *Routine risk minimisation activities recommending specific clinical measures to address the risk:* - SmPC section 4.4 & PIL section 04

Safety Concern	**Routine risk minimisation activities**
	Other routine risk minimisation measures beyond the Product Information: - The prescription only status of the product
Important Potential Risks	
Other second Primary Malignancies	*Routine risk communication*: - SmPC section 4.4 - PIL section 02 *Routine risk minimisation activities recommending specific clinical measures to address the risk*: SmPC section 4.4 & PIL section 02 *Other routine risk minimisation measures beyond the Product Information*: - The prescription only status of the product
Cardiac Arrhythmia	*Routine risk communication*: - SmPC section 4.8 - PIL section 04 *Routine risk minimisation activities recommending specific clinical measures to address the risk*: - SmPC section 4.4 *Other routine risk minimisation measures beyond the Product Information*: - The prescription only status of the product
Missing Information	
None	

V.2. Additional Risk Minimisation Measures

In line with reference medicinal product, Additional Risk Minimisation Measures (aRMMs) have been proposed for following risks:

- Teratogenicity
- Thrombocytopenia and bleeding
- Cardiac failure

The Marketing Authorisation Holder (MAH) has developed Education Material for Healthcare Professional to ensure that physicians who intend to prescribe Pomalidomide and Patient Guide to patients who take Pomalidomide are aware about the precautions and important risks.

Proposed additional risk minimisation measures are listed below and are detailed summarised in Annex 6.

1. Additional risk minimisation: Pregnancy Prevention Programme

Objectives:

The Accord PPP is designed to minimise the risk of teratogenicity by:

- Ensuring that exposure of an unborn child to pomalidomide does not occur
- Ensuring early alert to the physician of any pregnancies
- Educating patients and HCPs on the safe use of pomalidomide
- Pregnancy testing and contraceptive requirements
- A system to ensure that all appropriate measures have been performed prior to the drug being dispensed
- Managing and monitoring the distribution of pomalidomide
- Follow-up on the effectiveness of the PPP
- Compliance monitoring and assessment (examples include record of counselling patients prior to prescription, record of negative pregnancy test within 3 days of prescription and record of dispensing within 7 days of prescription date).

This controlled access is designed to minimise the risk of exposure to paediatric patients or non-target populations and provide education on the risk and the necessary steps to prevent foetal exposure.

Rationale for the additional risk minimisation activity:

To minimise the risk of teratogenicity and provide education on the risk and necessary steps to prevent foetal exposure to pomalidomide.

Target Audience and Planned Distribution Path:

The target audience is HCPs who will prescribe pomalidomide and patients.

Proposed Actions

The key elements of the Accord PPP are:

- Educational Programme:
    - 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.
- Therapy management
- Prescribing controls
- Dispensing controls
- Assessment

The Patient Card and/or an equivalent tool is used to manage the controlled access within the national territory as agreed with the NCA.

Plans to Evaluate the Effectiveness of the Interventions and Criteria for Success:

Pregnancy prevention programme shall be implemented as a Category 3 study; details are summarised in Part III.3 of this RMP. MAH shall agree with the national competent authority in each member state prior to marketing of pomalidomide for set-up of national measures to assess for the effectiveness of and compliance with the Pregnancy Prevention Programme. (eg, record of counselling patients prior to prescription, record of a negative pregnancy test within 3 days of prescription and a record of dispensing within 7 days of the prescription date, etc).

Routine pharmacovigilance activities involving analysis of ADR reports to assess compliance with SmPC recommendations will allow assessing and judging the success of the risk minimisation measures. Effectiveness of this measure will be analysed by MAH as per the requirements for submission of periodic safety update reports (PSUR) for this medicinal product are set out in the list of European Union Reference Dates (EURD list) provided as per Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European Medicines Agency's web-portal and also will be evaluated in details in periodic signal management activity.

Criteria for Success

Outcome indicator: pregnancy exposures

2. Additional risk minimisation: Additional HCP Educational Materials

Objectives:

Provision of information to HCPs for the risks of:

- Thrombocytopenia and bleeding
- Cardiac failure

Rationale for the Additional Risk Minimisation Activity:

HCPs to understand the risks specified above and the appropriate management of these risks.

Target Audience and Planned Distribution Path:

Pomalidomide HCP additional educational materials to be provided to prescribing physicians and pharmacists

Plans to Evaluate the Effectiveness of the Interventions and Criteria for Success:

Routine pharmacovigilance activities involving analysis of ADR reports to assess compliance with SmPC recommendations will allow assessing and judging the success of the risk minimisation measures. Effectiveness of this measure will be analysed by MAH as per the requirements for submission of periodic safety update reports (PSUR) for this medicinal product are set out in the list of European Union Reference Dates (EURD list) provided as per Article 107c (7) of Directive 2001/83/EC and any subsequent updates published on the European Medicines Agency's web-portal and also will be evaluated in details in periodic signal management activity.

Criteria for Success

No significant increase in frequency of reports in the postmarketing setting as presented in the SmPC.

Planned Dates for Assessment

Next PSUR update with next data-lock point covered.

3. Additional risk minimisation: Additional Patient Educational Materials

Objectives:

Provision of a Pomalidomide Patient brochure to patients for the risk of Thrombocytopenia and bleeding.

Rationale for the Additional Risk Minimisation Activity:

A Pomalidomide Patient brochure is provided as additional educational material to advise that pomalidomide may cause thrombocytopenia and the need for regular blood tests.

Target Audience and Planned Distribution Path:

The target audience is patients who are prescribed pomalidomide.

Plans to Evaluate the Effectiveness of the Interventions and Criteria for Success:

Routine pharmacovigilance activities involving analysis of ADR reports to assess compliance with SmPC recommendations will allow assessing and judging the success of the risk minimisation measures. Effectiveness of this measure will be analysed by MAH as per the requirements for submission of periodic safety update reports (PSUR) for this medicinal product are set out in the list of European Union Reference Dates (EURD list) provided as per Article 107c (7) of Directive 2001/83/EC and any subsequent updates published on the European Medicines Agency's web-portal and also will be evaluated in details in periodic signal management activity

Criteria for Success

No significant increase in frequency of reports in the post marketing setting as presented in the SmPC.

Planned Dates for Assessment

Next PSUR update with next data-lock point covered.

V.3. Summary of risk minimisation measures

Table 4: Summary table of pharmacovigilance activities and risk minimisation activities by safety concern

Safety concern	Risk minimisation measures	Pharmacovigilance activities
Important Identified Risks		
Teratogenicity	Routine risk minimisation measures: • SmPC sections 4.3, 4.4, 4.6, 4.8 and 5.3 • PIL section 02 • The prescription only status of the product Additional risk minimisation measures: • Pregnancy Prevention Programme (PPP)	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Specific pregnancy follow-up questionnaires have been proposed. • Expedited reporting of all pregnancy cases Additional pharmacovigilance activity: Pregnancy prevention programme for Pomalidomide shall be implemented as Category 3 study.
Severe infection due to neutropenia and pancytopenia	Routine risk minimisation measures: • SmPC sections 4.2, 4.4 and 4.8 • PIL sections 02 and 04	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection:

Safety concern	**Risk minimisation measures**	**Pharmacovigilance activities**
	• The prescription only status of the product Additional risk minimisation measures: None	• Specific follow-up questionnaires have been proposed for severe infection due to neutropenia and pancytopenia Additional pharmacovigilance activity: None
Thrombocytopenia and bleeding	Routine risk communication: • SmPC section 4.2, 4.4 and 4.8 • PIL sections 02 and 04 • The prescription only status of the product. Additional risk minimisation measures: • Additional HCP Educational Materials • Additional Patient Educational Material	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Specific follow-up questionnaires have been proposed for tthrombocytopenia and bleeding Additional pharmacovigilance activities: None
Cardiac failure	Routine risk communication: • SmPC section 4.4 and 4.8. • PIL sections 02 and 04 • The prescription only status of the product	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Specific follow-up questionnaires have

Safety concern	Risk minimisation measures	Pharmacovigilance activities
	Additional risk minimisation measures: • Additional HCP Educational Materials	been proposed for Cardiac failure Additional pharmacovigilance activities: None
Non-Melanoma Skin Cancer	Routine risk communication: • SmPC section 4.4 and 4.8 • PIL sections 02 and 04 • The prescription only status of the product Additional risk minimisation measures: None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Specific follow-up questionnaires have been proposed for non-melanoma skin cancer Additional pharmacovigilance activities: None
Important Potential Risks		
Other second Primary Malignancies	Routine risk communication: • SmPC section 4.4 • PIL sections 02 • The prescription only status of the product Additional risk minimisation measures: None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Specific follow-up questionnaires have been proposed for other second primary malignancies

Safety concern	**Risk minimisation measures**	**Pharmacovigilance activities**
		Additional pharmacovigilance activities: None
Cardiac Arrhythmia	Routine risk communication: • SmPC section 4.4 and 4.8 • PIL section 04 • The prescription only status of the product Additional risk minimisation measures: None	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: • Specific follow-up questionnaires have been proposed for cardiac arrhythmia Additional pharmacovigilance activities: None

Part VI: Summary of the risk management plan

Summary of risk management plan for Pomalidomide Accord 1 mg, 2 mg, 3 mg and 4 mg hard capsules (Pomalidomide)

This is a summary of the risk management plan (RMP) for Pomalidomide Accord 1 mg, 2 mg, 3 mg and 4 mg hard capsules. Throughout this summary all products have been referred to as Pomalidomide hard capsules. The RMP details important risks of Pomalidomide hard capsules, how these risks can be minimised, and how more information will be obtained for Pomalidomide hard capsules' risks and uncertainties (missing information).

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

This summary of the RMP for Pomalidomide hard capsules should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Pomalidomide Accord 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 Accord 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 the active substance and it is given by oral route.

Further information about the evaluation of Pomalidomide hard capsules' benefits can be found in Pomalidomide hard capsules' EPAR, including in its plain-language summary, available on the

EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/pomalidomide-accord.

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

Important risks of Pomalidomide hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Pomalidomide hard capsules' risk, 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 hard capsules, 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 Pomalidomide hard capsules 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 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):

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

Important Identified Risks: Teratogenicity	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.3, 4.4, 4.6, 4.8 and 5.3 • PIL section 02 • The prescription only status of the product. Additional risk minimisation measures: • Pregnancy Prevention Programme (PPP)
Important Identified Risks: Thrombocytopenia and bleeding	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.2, 4.4 and 4.8 • PIL sections 02 and 04 • The prescription only status of the product

	Additional risk minimisation measures: • Additional HCP Educational Materials • Additional Patient Educational Material
Important Identified Risks: Cardiac failure	
Risk minimisation measures	Routine risk minimisation measures: • SmPC sections 4.4 and 4.8. • PIL sections 02 and 04 • The prescription only status of the product Additional risk minimisation measures: Additional HCP Educational Materials

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 Pomalidomide Accord 1 mg, 2 mg, 3 mg and 4 mg hard capsules.

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

A Category 3 study to monitor the implementation and the effectiveness of the PPP for Pomalidomide Accord 1 mg, 2 mg, 3 mg and 4 mg hard capsules.

Annex 4 - Specific adverse drug reaction follow-up form

MAH has developed following targeted follow-up questionnaires;

- **Pregnancy follow-up forms (Teratogenicity)**
    - Event-Specific Questionnaire for HCP - Pregnancy Background (Patient or Partner of Patient)
    - Event-Specific Questionnaire for HCP - Pregnancy Follow-up (Patient or Partner of Patient)
    - Event-Specific Questionnaire for HCP - Pregnancy Outcome (Patient or Partner of Patient)
    - Event-Specific Questionnaire for Primary Care Physician or Paediatrician- Infant Follow-up
- **Neutropenia**
- **Thrombocytopenia/Bleeding**
- **Cardiac Failure**
- **Second Primary Malignancies**
- **Cardiac Arrhythmia and ECG Changes**

Event-Specific Questionnaire for HCP - Pregnancy Background (Patient or Partner of Patient)

Reporter Information			
Reporter name:			
Address:		City, state, zip, country:	
Phone no.:		Fax no.:	
Obstetrician Information (Please provide)			
Obstetrician name:			
Address:		City, state, zip, country:	
Phone no.:		Fax no.:	
Patient Information:			
Patient Id:	Date of birth:	Ethnicity: ☐ White ☐ Black ☐ Asian ☐ Other, specify_____	
Partner of Patient information ☐ Not applicable			
Date of birth:	**Ethnicity:** ☐ White ☐ African-American ☐ Asian ☐ Other, specify_____		
Patient Treatment information: Pomalidomide			
Lot No:	Expiry Date:	Dose:	Frequency:
Route:	Start Date:	Stop Date:	
Indication for use:			
Cytogenic abnormalities: ☐ No ☐ Yes If Yes, Specify_____			

Current Pregnancy			
Date of last menstrual period:		Estimated delivery date:	
Pregnancy test	Date	Reference Range	Result
Urine Qualitative			
Serum Quantitative			

Prenatal tests		
	Date	Result
Ultrasound		

Ultrasound		
Ultrasound		
Amniocentesis		
Maternal serum AFP		

Pregnancy History		
No of previous pregnancy: Date of last pregnancy:	No of full-term deliveries:	No of pre-term birth:
No of fetal death:	No of living children:	No of abortion: Elective_____Spontaneous:_____
Type of Delivery: ☐ Vaginal ☐ C-section		
Did birth defect occur in any previous pregnancy? ☐ No ☐ Yes ☐ Unknown If Yes, specify_____		
Did a stillbirth or spontaneous abortion occur in any previous pregnancy? ☐ No ☐ Yes ☐ Unknown 1) If Yes, in what week of pregnancy did the stillbirth or spontaneous abortion occur? _____ 2) Was there any birth defect noted? ☐ No ☐ Yes, if Yes Specify: _____		

Relevant medical history

☐ No ☐ Yes, if Yes Specify: _____

Medical History	Date of Diagnosis	Medical History	Date of Diagnosis

Social history

Alcohol ☐ No ☐ Yes, If yes, amount/unit consumed per day:

Tobacco ☐ No ☐ Yes	IV OR recreational drug use: ☐ No ☐ Yes, specify:

Family history

Congenital Abnormalities ☐ No ☐ Yes, if Yes, Specify:_____

If there is a family history of congenital abnormalities, was there a consultation with a Geneticist?
☐ No ☐ Yes, if Yes, Specify:_____

Environmental Exposure (e.g. radiation, chemical exposure) ☐ No ☐ Yes, If Yes, specify:

Medications/Treatments (including herbal, alternative and over-the-counter medicines and dietary supplements) During Pregnancy

Medication/Treatment	Start date	Stop date/ ongoing	Indication

Adverse Event(s) During Pregnancy

Event(s)	**Onset date**	**Stop date/ Ongoing**	**Serious**		**Causal relationship to pomalidomde**	
			Y/N	**Serious Criteria***	**Y/N**	**If no, what medications, disease state, etc played a role in the event?**

*Serious criteria: 1) death, 2) life-threatening, 3) required inpatient hospitalization or prolongation of existing hospitalisation, 4) a persistent or significant disability/incapacity, 5) a congenital anomaly/birth defect, 6) medically significant

Root cause of pregnancy:

1.What forms of birth control was your patient using while on Pomalidomide before you/ your partner got pregnant? Please check all that apply.

Tubal ligation	☐ Yes	☐ No
IUD	☐ Yes	☐ No
Hormonal birth control	☐ Yes	☐ No
Partner's vasectomy	☐ Yes	☐ No
Male latex or synthetic condom	☐ Yes	☐ No
Diaphragm	☐ Yes	☐ No
Cervical cap or shield	☐ Yes	☐ No
Spermicide or sponge	☐ Yes	☐ No
Withdrawal	☐ Yes	☐ No
Abstinence	☐ Yes	☐ No

2. Was your patient or their partner without contraception for even one day at any time during use of Pomalidomide?

☐ No, please proceed to Question 5

☐ Yes, please answer Question 3, Question 4, Question 5, and Question 6

3. If applicable per Question 2, how often did your patient have unprotected sexual intercourse?

☐ Multiple times	☐ Once a month
☐ Once a week	☐ Not at all
☐ Once every 2 weeks	☐ Other, specify_____

4. If applicable per Question 2, why did your patient and/or their partner interrupt or stop using contraception?

☐ Wanted a child	☐ Health concerns
☐ Partner disapproved	☐ Inconvenient to use
☐ Side effects	☐ Other, specify_____

5. Please ask your patient, if they received the pomalidomide Patient Information (e.g., Medication Guide or Patient leaflet)

☐ No, please proceed to Question 5.3

☐ Yes, please answer the question 5.1

5.1 Please ask your patient, if they read the pomalidomide Patient Information (e.g., Medication Guide or Patient leaflet)

☐ No, please proceed to Question 5.3

☐ Yes, please answer the question 5.2

5.2 Please ask your patient, if they understood the information in the pomalidomide Patient Information (e.g., Medication Guide or Patient leaflet)

☐ No, please proceed to Question 5.3

☐ Yes, please proceed to Question 5.3

5.3. Please ask your patient, where most of their knowledge about. contraception during pomalidomide use came from?

☐ Physician who prescribed Pomalidomide

☐ Pomalidomide Patient Information (e.g., Medication Guide or Patient leaflet)

☐ Other, specify: _____

6. Please ask your patient if they felt that they and their partner had a good understanding of the risk of pregnancy during pomalidomide use.

☐ Yes

☐ No

☐ Don't know

Signature of person completing this form:_____ **Date: __/__/____**

Event-Specific Questionnaire for HCP - Pregnancy Follow-up (Patient or Partner of Patient)

Date: ___/___/_____	**Period covered: _____ to _____** **(Date) (Date)**
Reporter Information	
Reporter name:	
Address:	City, State, Zip, Country:
Phone no.:	Fax no.:
Name of Patient or Pregnant Partner of Male Patient:_____	
Current pregnancy	
Prenatal Tests (If any additional medical records relating to these prenatal tests are available, please attach along with this form)	

Test	Date	Result
Ultrasound		
Ultrasound		
Ultrasound		
Amniocentesis		
Maternal Serum AFP		
Other Tests, Specify:		

Pregnancy Type ☐ Singleton ☐ Twin ☐ Triplet ☐ Other, Specify_____

Medication/Treatments (including herbal, alternative and over-the-counter medicines and dietary supplements) during pregnancy:

Medication/Treatments	Start Date	Stop Date/ Continuing	Indication

Adverse Event(s) during pregnancy

Event(s)	Onset Date	Stop Date/ Ongoing	Serious		Causal relationship to Pomalidomide product	
			Y/N	Serious criteria*	Y/N	If No, what medication, disease states, etc played a role in the event?

* Serious criteria: 1) Death, 2) life threatening, 3) required inpatient hospitalisation or prolongation of existing hospitalisation, 4) a persistent or significant disability/incapacity, 5) congenital anomaly/birth defect, 6) medically significant

Signature of person completing this form:_____ **Date: ___/___/_____**

[redacted]

Event-Specific Questionnaire for HCP - Pregnancy Outcomes (Patient or Partner of Patient)

Reporter Information		
Reporter name:		
Address:		City, State, Zip, Country:
Phone no.:		Fax no.:
Patient Information		
Patient id:	Date of birth:	Ethnicity: ☐ White ☐ Black ☐ Asian ☐ Other, specify_____
Partner of Patient Information: ☐ Not applicable		
Date of Birth:	**Ethnicity:** ☐ White ☐ African- American ☐ Asian ☐ Other, Specify_____	
Pregnancy Type ☐ Singleton ☐ Twin ☐ Triplet ☐ Other, Specify_____		

PREGNANCY OUTCOME:

DATE OF DELIVERY:			**GESTATION AGE AT DELIVERY:**
DELIVERY DETAILS	NO	YES	ADDITIONAL COMMENTS
Normal	☐	☐	
C-Section	☐	☐	
Induced	☐	☐	
Assisted (e.g., forceps)	☐	☐	
Elective termination	☐	☐	Date:
Spontaneous abortion (≤20 weeks)	☐	☐	Weeks from LMP:
Fetal death/Still birth (> 20 weeks)	☐	☐	
Were the products of conception examined?	☐	☐	If yes, was the fetus normal? ☐ Yes ☐ No ☐ Unknown

			If no, describe: _____ _____

Obstetrics Information			
	NO	YES	
Complications During Pregnancy	☐	☐	If Yes Specify: _____ _____
Complications During labor/Delivery	☐	☐	If Yes Specify: _____ _____
Post-partum Maternal Complications	☐	☐	If Yes Specify: _____ _____

Fetal and Neonatal Status			
	NO	YES	
Live Normal Infant	☐	☐	
Fetal Distress	☐	☐	If Yes, please specify: _____ _____
Intra-uterine Growth Retardation	☐	☐	If Yes, please specify: _____ _____
Neonatal Complications*	☐	☐	If Yes, please specify: _____ _____
Birth Defect Noted?	☐	☐	If Yes, please specify: _____ _____

Sex: ☐ Male ☐ Female **Birth Weight**: ____lbs____ oz__ ***or***_____ Kg **Length:** _____ inches ***or*** _____cm

Apgar Score:	Unknown	1 min:	5 Min:	10 min:

*Please provide a brief summary of the management of the complications

Signature of person completing this form:_____ **Date: ___/___/_____**

Event-Specific Questionnaire for Primary Care Physician or Pediatrician - Infant Follow-up

Date of Assessment: _____

Age in months: _____

Weight (at the time of this assessment): _____lbs _____oz or _____kg

Length (at the time of this assessment): _____inches or _____cm

Name of Patient on _____

Name of Infant (if known): _____

Please provide information for the period from (Date) to (Date): _____ to _____

Birth Defects/Anomalies:

New birth defects or anomalies noted since previous report**?** ☐ Yes ☐ No

If **yes**, please list the birth defects/anomalies below:

Birth Defect/ Anomaly	**Was the defect/ Anomaly Attributed to Pomalidomide therapy?** (Y/N/Unknown)	**Factors that may have contributed to this outcome:** (e.g. Family history, Maternal age, obesity, Alcohol consumption during Pregnancy, etc.)	**Defect/ Anomaly noted prior to Birth?** (Y/N)	**Infant age when Defect/ Anomaly was noted** (specify weeks or months)

Developmental Assessment:

Is the child developing normally for his/her age?

If no, please define your concerns regarding any developmental issues or abnormalities:

_____

_____

_____

Diagnosis date of any developmental issues: ___/___/_____

Infant illnesses, Hospitalisations, Drug therapies:

Infant Illnesses	**Hospitalised?**	**Drug Therapies**
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	

Signature of person completing this form:_____ **Date: ___/___/_____**

Targeted follow up questionnaire for Neutropenia

INFORMATION PREVIOUSLY PROVIDED DOES NOT NEED TO BE REPEATED ON THIS FORM:

Patient Demographics:

Patient's date of birth (DD-MMM-YYYY):___-____-_____ **Gender:** ☐ Male ☐ Female

Age: _____

Race/Ethnicity: ☐ Aborignal ☐ African-American ☐ Asian ☐ American Indian or Alaskan native ☐ Native Hawaiian or Pacific islander ☐ Toress Strat Islander ☐ White ☐ Black ☐ Non Hispanic

Age group: _____

Note: Please provide Age Group if Patient's Date of Birth or Age is not available.

[Age Group Definition: Neonate: 0 - 27 days, Infant: 28 days to 23 months, Child: 2 years to 11years, Adolescent: 12 years to 18 years, Adult: More than 18 years and less than or equal to 65 years and Elderly: equal or greater than 66 years.]

Suspect Products: Please provide suspect product(s) information [those product(s) that are suspected to be associated with one or more adverse events]:

	Suspect Product #1	Suspect Product #2	Suspect Product #3
Product name			
Daily dose and regimen			
Route of administration			
Indication			
Start date or treatment duration			
Stop date (DD-MMM-YYYY)			
Lot/Batch number(s)			
Expiration date(s)			
Action Taken with the suspect product			

(Choose from one of the following for action Taken with Suspect Product: Drug withdrawn, Dose reduced, Dose increased, Dose not changed, Unknown)

Adverse Event (AE) Description: Please provide diagnosis or symptoms/signs if diagnosis is unavailable.

	Adverse Event #1	Adverse Event #2	Adverse Event #3	Adverse Event #4
Add Diagnosis Here				
Start Date (DD/MMM/YYYY)				
Stop Date (DD/MMM/YYYY)				
Time lag if AE occurred after cessation of treatment with the suspect product(s):				
Required Hospitalisation (Yes/No)				
Life-Threatening (Yes/No)				
Persistent or significant disability (Yes/No)				
Congenital abnormality (Yes/No)				
Cause of Death (Yes/No)				
Treatment of Adverse Event				
Outcome (recovery and sequelae, if any)				
Did the event(s) abate after suspect Product was stopped or dose reduced? (Yes/No)				
Did the event recur after reintroducing (Yes/No) Did the event recur after				

reintroducing (Yes/No)				

Please summarise course of reported events including signs and symptoms in chronological order:

_____

_____

- Diagnostic tests (use additional pages if needed): Please indicate test unit where applicable

Date	Test name	Pre-treatment value	AE onset value	AE resolution value	Normal low	Normal high
	WBC					
	ANC					

Please provide causal relationship assessment between the suspect product(s) and adverse event(s)

_____

_____

Concomitant Medications (use additional pages if needed):

Did the Patient take any concomitant medication?

☐ Yes (please complete below) ☐ No Unknown

Medication Name	Daily dose and regimen	Route of administration	Indication	Start date DD-MMM-YYYY	Stop date DD-MMM-YYYY

Other Etiological Factors: ☐ Yes (Please complete below) ☐ None ☐ Unknown

☐ Relevant medical and/or drug history (please specify), including start date or duration:

_____

_____

_____

☐ Family history (please specify):_____

☐ Drug/alcohol/tobacco abuse: _____

☐ Other (please specify): _____

Additional questions:

1. What treatments were given for the neutropenia? Please include dates. Did the patient receive G-CSF? GM-CSF? Please provide details.

_____

_____

2. Did your patient experience an infection in association with the neutropenia?
   ☐ No ☐ Yes

   If yes, please explain.

_____

_____

3. Does the patient have a history of recurrent infection? ☐ Yes ☐ No
   If yes, please explain.

_____

_____

4. Please provide the stage/classification of patient's disease at the time of infection.

_____

_____

5. Does your patient have a medical history of autoimmune disease, abnormal disease of spleen, bone marrow disease, etc.?

_____

_____

6. Has your patient received prior radiation therapy? If so, please provide treatment details including dates.

_____

_____

7. Does your patient have a medical history of cancer effecting bone marrow?

_____

_____

8. Please include the culture/serology/bone marrow studies/X-ray results for the event of infection.

_____

_____

_____
Health Practitioner Name (Print)

_____
Health Practitioner Name (Signature)

Additional information regarding this Adverse Event Report:

Description of event: [narrative]

Targeted follow up questionnaire for Thrombocytopenia/Bleeding

INFORMATION PREVIOUSLY PROVIDED DOES NOT NEED TO BE REPEATED ON THIS FORM:

Patient Demographics:

Patient's date of birth (DD-MMM-YYYY):___-____-_____ **Gender:** ☐ Male ☐ Female

Age: _____

Race/Ethnicity: ☐ Aborignal ☐ African-American ☐ Asian ☐ American Indian or Alaskan native ☐ Native Hawaiian or Pacific islander ☐ Toress Strat Islander ☐ White ☐ Black ☐ Non Hispanic

Age group: _____

Note: Please provide Age Group if Patient's Date of Birth or Age is not available.

[Age Group Definition: Neonate: 0 - 27 days, Infant: 28 days to 23 months, Child: 2 years to 11years, Adolescent: 12 years to 18 years, Adult: More than 18 years and less than or equal to 65 years and Elderly: equal or greater than 66 years.]

Suspect Products: Please provide suspect product(s) information [those product(s) that are suspected to be associated with one or more adverse events]:

	Suspect Product #1	Suspect Product #2	Suspect Product #3
Product name			
Daily dose and regimen			
Route of administration			
Indication			
Start date or treatment duration			
Stop date (DD-MMM-YYYY)			
Lot/Batch number(s)			
Expiration date(s)			
Action Taken with the suspect product			

(Choose from one of the following for action Taken with Suspect Product: Drug withdrawn, Dose reduced, Dose increased, Dose not changed, Unknown)

Adverse Event (AE) Description: Please provide diagnosis or symptoms/signs if diagnosis is unavailable.

	Adverse Event #1	Adverse Event #2	Adverse Event #3	Adverse Event #4
Add Diagnosis Here				
Start Date (DD/MMM/YYYY)				
Stop Date (DD/MMM/YYYY)				
Time lag if AE occurred after cessation of treatment with the suspect product(s):				
Required Hospitalisation (Yes/No)				
Life-Threatening (Yes/No)				
Persistent or significant disability (Yes/No)				
Congenital abnormality (Yes/No)				
Cause of Death (Yes/No)				
Treatment of Adverse Event				
Outcome (recovery and sequelae, if any)				
Did the event(s) abate after suspect Product was stopped or dose reduced? (Yes/No)				
Did the event recur after reintroducing (Yes/No) Did the event recur after				

reintroducing (Yes/No)				

Please summarise course of reported events including signs and symptoms in chronological order:

_____

_____

- Diagnostic tests (use additional pages if needed): Please indicate test unit where applicable

Date	Test name	Pre-treatment value	AE onset value	AE resolution value	Normal low	Normal high
	Platelets					
	PT					
	aPTT					
	INR					
	ESR					
	LFTs					
	Factor VIII					
	Factor IX					

Please provide causal relationship assessment between the suspect product(s) and adverse event(s)

_____

_____

Concomitant Medications (use additional pages if needed):

Did the Patient take any concomitant medication?

☐ Yes [Please complete below. Please provide relevant concomitant medications, including thromboprophylaxis (type/dose/dates as well as corresponding lab monitoring values if applicable), and possible platelet transfusion need to prevent hemorrhagic event])

☐ No Unknown

Medication Name	Daily dose and regimen	Route of administration	Indication	Start date DD-MMM-YYYY	Stop date DD-MMM-YYYY

Other Etiological Factors: ☐ Yes (Please complete below) ☐ None ☐ Unknown

☐ Relevant medical and/or drug history (please specify), including start date or duration:

_____

_____

☐ Family history (please specify):_____

☐ Drug/alcohol/tobacco abuse: _____

☐ Other (please specify): _____

Additional questions:

1. Please provide location of bleeding/haemorrhage.

_____

_____

2. Relevant medical history: Does the patient have
   a. History of anemia? Was patient transfusion dependent? If yes, since when and how frequent?

_____

_____

b. Episodes of hypotension? Hypertension? Gingivorrhagia or epistaxis? Headache? Pallor? Dyspnoea? Weakness? Please describe

_____

_____

c. Please describe history of bleeding/haemorrhage? Coagulation disorder? Please describe.

_____

_____

3. Please provide date of diagnosis of underlying disease, stage at the time of diagnosis and stage of patient's disease at the time of event.

_____

_____

4. Please include bone marrow studies/X-ray/CT scan results for the event of thrombocytopenia/ Bleedings/Hemorrhage.

_____

_____

5. What treatment were given for thrombocytopenia/Bleedings/ Haemorrhage? Please include dates/dose.

_____

_____

_____
Health Practitioner Name (Print)

_____
Health Practitioner Name (Signature)

Additional information regarding this Adverse Event Report:

Description of event: [narrative]

Targeted follow up questionnaire for Cardiac Failure

INFORMATION PREVIOUSLY PROVIDED DOES NOT NEED TO BE REPEATED ON THIS FORM:

Patient Demographics:

Patient's date of birth (DD-MMM-YYYY):___-____-_____ **Gender:** ☐ Male ☐ Female

Age: _____

Race/Ethnicity: ☐ Aborignal ☐ African-American ☐ Asian ☐ American Indian or Alaskan native ☐ Native Hawaiian or Pacific islander ☐ Toress Strat Islander ☐ White ☐ Black ☐ Non Hispanic

Age group: _____

Note: Please provide Age Group if Patient's Date of Birth or Age is not available.

[Age Group Definition: Neonate: 0 - 27 days, Infant: 28 days to 23 months, Child: 2 years to 11years, Adolescent: 12 years to 18 years, Adult: More than 18 years and less than or equal to 65 years and Elderly: equal or greater than 66 years.]

Suspect Products: Please provide suspect product(s) information [those product(s) that are suspected to be associated with one or more adverse events]:

	Suspect Product #1	Suspect Product #2	Suspect Product #3
Product name			
Daily dose and regimen			
Route of administration			
Indication			
Start date or treatment duration			
Stop date (DD-MMM-YYYY)			
Lot/Batch number(s)			
Expiration date(s)			
Action Taken with the suspect product			

(Choose from one of the following for action Taken with Suspect Product: Drug withdrawn, Dose reduced, Dose increased, Dose not changed, Unknown)

Adverse Event (AE) Description: Please provide diagnosis or symptoms/signs if diagnosis is unavailable.

	Adverse Event #1	Adverse Event #2	Adverse Event #3	Adverse Event #4
Add Diagnosis Here				
Start Date (DD/MMM/YYYY)				
Stop Date (DD/MMM/YYYY)				
Time lag if AE occurred after cessation of treatment with the suspect product(s):				
Required Hospitalisation (Yes/No)				
Life-Threatening (Yes/No)				
Persistent or significant disability (Yes/No)				
Congenital abnormality (Yes/No)				
Cause of Death (Yes/No)				
Treatment of Adverse Event				
Outcome (recovery and sequelae, if any)				
Did the event(s) abate after suspect Product was stopped or dose reduced? (Yes/No)				
Did the event recur after reintroducing (Yes/No) Did the event recur after				

reintroducing (Yes/No)				

Please summarise course of reported events including signs and symptoms in chronological order:

_____

_____

_____

Diagnostic tests (use additional pages if needed): Please indicate test unit where applicable

Date	Test name	Pre-treatment value	AE onset value	AE resolution value	Normal low	Normal high
	Calcium					
	Magnesium					
	Total CPK					
	CK-MB					
	Troponins					
	BNP					
	WBC					
	RBC					
	Platelets					
	Hemoglobin					
	Hematocrit					

Please provide causal relationship assessment between the suspect product(s) and adverse event(s)

_____

_____

Concomitant Medications (use additional pages if needed):

Did the Patient take any concomitant medication?

☐ Yes (please complete below) ☐ No Unknown

Medication Name	Daily dose and regimen	Route of administration	Indication	Start date DD-MMM-YYYY	Stop date DD-MMM-YYYY

Other Etiological Factors: ☐ Yes (Please complete below) ☐ None ☐ Unknown

☐ Relevant medical and/or drug history (please specify), including start date or duration:

_____

_____

_____

☐ Family history (please specify):_____

☐ Drug/alcohol/tobacco abuse: _____

☐ Other (please specify): _____

Additional questions:

1. Did the cardiac failure occur prior to therapy? ☐ Yes ☐ No

a. If the cardiac failure occurred prior to therapy, would you consider it an exacerbation? ☐ Yes ☐ No

b. Please provide the exacerbation of was diagnosed _____

2. Please circle classification of cardiac failure:

a. Class I (mild) Patients with cardiac disease but without limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or angina pain

b. Class II (mild) Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or angina pain.

c. Class III (moderate) Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea, or angina pain.

d. Class IV (severe) Patients with cardiac disease resulting in the inability to carry on any physical activity without discomfort. Symptoms of heart failure or the angina syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased

3. Please provide result of EKG, echocardiogram and ejection fraction including the baseline data and dates.

_____

_____

4. Did the patient receive any recent blood transfusion or IV infusion? ☐ Yes ☐ No

If yes, please specify what was transfused and provide the amount of transfused with dates.

_____

_____

5. Does the patient have other cardiac history including coronary artery disease, cardiac stents, myocardial infarction, vascular heart diseases, cardiomyopathy, other chemotherapy, endocarditis or myocarditis?

_____

_____

6. Please provide any associated risk factor including history of hyperlipidaemia, obesity, hypertension, COPD, renal disease, diabetes, sepsis, substance abuse and family history of heart disease.

_____

_____

7. Any exposure to other chemotherapeutic agents (previous and/or ongoing)? Please specify.

_____

_____

8. Are there any concurrent events that contributed or led up to the cardiac failure? Please specify.

_____

_____

9. What treatment/interventions were provided to the patient for the cardiac failure? Please specify.

_____

_____

_____
Health Practitioner Name (Print)

_____
Health Practitioner Name (Signature)

Additional information regarding this Adverse Event Report:

Description of event: [narrative]

Targeted Follow Up Questionnaire for Second Primary Malignancies

INFORMATION PREVIOUSLY PROVIDED DOES NOT NEED TO BE REPEATED ON THIS FORM:

Patient Demographics:

Patient's date of birth (DD-MMM-YYYY):___-____-_____ **Gender:** ☐ Male ☐ Female

Age: _____

Race/Ethnicity: ☐ Aborignal ☐ African-American ☐ Asian ☐ American Indian or Alaskan native ☐ Native Hawaiian or Pacific islander ☐ Toress Strat Islander ☐ White ☐ Black ☐ Non Hispanic

Age group: _____

Note: Please provide Age Group if Patient's Date of Birth or Age is not available.

[Age Group Definition: Neonate: 0 - 27 days, Infant: 28 days to 23 months, Child: 2 years to 11years, Adolescent: 12 years to 18 years, Adult: More than 18 years and less than or equal to 65 years and Elderly: equal or greater than 66 years.]

Suspect Products: Please provide suspect product(s) information [those product(s) that are suspected to be associated with one or more adverse events]:

	Suspect Product #1	Suspect Product #2	Suspect Product #3
Product name			
Daily dose and regimen			
Route of administration			
Indication			
Start date or treatment duration			
Stop date (DD-MMM-YYYY)			
Lot/Batch number(s)			
Expiration date(s)			
Action Taken with the suspect product			

(Choose from one of the following for action Taken with Suspect Product: Drug withdrawn, Dose reduced, Dose increased, Dose not changed, Unknown)

Adverse Event (AE) Description: Please provide diagnosis or symptoms/signs if diagnosis is unavailable.

	Adverse Event #1	Adverse Event #2	Adverse Event #3	Adverse Event #4
Add Diagnosis Here				
Start Date (DD/MMM/YYYY)				
Stop Date (DD/MMM/YYYY)				
Time lag if AE occurred after cessation of treatment with the suspect product(s):				
Required Hospitalisation (Yes/No)				
Life-Threatening (Yes/No)				
Persistent or significant disability (Yes/No)				
Congenital abnormality (Yes/No)				
Cause of Death (Yes/No)				
Treatment of Adverse Event				
Outcome (recovery and sequelae, if any)				
Did the event(s) abate after suspect Product was stopped or dose reduced? (Yes/No)				
Did the event recur after reintroducing (Yes/No) Did the event recur after reintroducing (Yes/No)				

Please summarise course of reported events including signs and symptoms in chronological order:

- Diagnostic tests (use additional pages if needed): Please indicate test unit where applicable

Date	Test name	Pre-treatment value	AE onset value	AE resolution value	Normal low	Normal high
	Calcium					
	Phosphate					
	Uric Acid					
	Creatinine					
	Potassium					
	LDH					
	Albumin					
	Protein					

Please provide causal relationship assessment between the suspect product(s) and adverse event(s)

_____

_____

Concomitant Medications (use additional pages if needed):

Did the Patient take any concomitant medication?

☐ Yes [Please complete below.) ☐ No Unknown

Please include drugs that are potentially nephrotoxic (NSAIDS, antibiotics) including over the counter drugs.

Medication Name	Daily dose and regimen	Route of administration	Indication	Start date DD-MMM-YYYY	Stop date DD-MMM-YYYY

Other Etiological Factors: ☐ Yes (Please complete below) ☐ None ☐ Unknown

☐ Relevant medical history (including history of malignancies) and/or drug history (please specify), including start date or duration:

_____

_____

☐ Family history (please specify), including history of malignancies with estimated dates: _____

☐ Drug/alcohol/tobacco abuse: _____

☐ Other (please specify): _____

Additional questions:

When querying about SPMs, specify the malignancy or diagnosis. Do not use the term SPM when diagnosis is known.

Core questions for follow-up of SPMs:

1. Dates of the underlying disease's diagnosis

   _____

2. Date of first clinical symptoms of SPM
3. Stage of the underlying disease treated with Pomalidomide at baseline, the end of treatment if applicable, and at the time of the event with supportive documentation if available.

   _____

   _____

   Medical history of bone marrow transplant including dates, type, donor details, source, and conditioning regimens such as treatment with alkylating agents (i.e. Cyclophosphamide, Melphalan,etc.).

   _____

   _____

4. Environmental exposure e.g. atmospheric pollutants/toxic chemicals (pesticides, herbicides, benzene, solvents); occupation/hobbies.

   _____

   _____

5. Full SPM (*specify malignancy or diagnosis if known*) biopsy reports with exact stage. If not available please provide the detailed results.

_____

_____

In addition to the Core Questions specific information should be requested based on the risk factors for individual types of cancer, including:

Hematologic Malignancies (including Lymphoma and B-cell malignancy):

- Previous chemotherapy rounds (dates, type) and /or radiotherapy (zone, duration, cumulative dose) or subsequent ones if SPM (specify malignancy or diagnosis) detected after product discontinuation
- Medical conditions that compromise the immune system – HIV/AIDS, autoimmune diseases, diseases requiring immune suppressive therapy-organ transplant
- For lymphoma: Infection with HIV, Epstein-Barr virus+++, Helicobacter pylori, hepatitis B or C, human T-lymphotrophic virus type I, Burkitt's lymphoma
- Concurrent or medical/family history of inherited syndromes with genetic changes that raise the risk of acute lymphocytic leukaemia (ALL) including: Down syndrome, Klinefelter syndrome, Fanconi anaemia, Bloom syndrome, Ataxia-telangiectasia, Neurofibromatosis.
- Exposure to benzene (solvent used in the rubber industry, oil refineries, chemical plants, shoe manufacturing, and gasoline-related industries, and is also present in cigarette smoke, as well as some glues, cleaning products, detergents, art supplies, and paint strippers).
- Smoking history – Product smoked (i.e. cigars, cigarettes, etc.) and depth of inhalation, length of time, number of cigarettes/days or pack-years, age at starting
- Exposure to high levels of radiation
- Medical history of treated hematologic malignancies or concurrent leukaemias or lymphomas including: Chronic Lymphocytic Leukaemia (CLL), Richter transformation, and Diffuse Large B-cell lymphoma (DLBCL) such as Hodgkin's disease and plasmablastic lymphoma.
- Relevant diagnostic test results (if available), including: biopsy, immunohistochemistry, flow cytometry, cytogenetics, reverse transcriptase polymerase chain reaction, Fluorescence in situ hybridisation (FISH), and next generation sequencing

Lung Cancer:

- Smoking history –
  Length of time_____ Number of cigarettes/days _____ Age at starting_____
  Gender_____ Product smoked (i.e. cigars, cigarettes, etc.)_____
  Depth of inhalation_____ length of time _____
- Pre-existing pulmonary disease ☐

- Family history of lung cancer ☐

Thyroid Cancer:

- Personal or family history of thyroid and/or autoimmune diseases
  ☐ Hypo or hyperthyroidism ☐ Goiter ☐ Benign thyroid nodules
  ☐ Hashimoto's disease ☐ Graves disease
- Family history of
  ☐ Familial medullary thyroid cancer ☐ Multiple endocrine neoplasia
  ☐ Familial adenomatous polyposis
- Living in iodine deficient area ☐
- History of radiation exposure ☐

Breast Cancer:

- Receptor status of the tumor
  ☐ ER ☐ PR ☐ Her2/neu
- Age at onset of menses _____ and age of menopause_____
- Number of pregnancies _____ and age at first birth _____
- History of breastfeeding children _____
- Use of oral contraceptives or hormone replacement therapy _____
- Obesity ☐
- Economic status _____
- Dietary iodine deficiency _____

Ovarian Cancer:

- Number of pregnancies _____ and childbearing status _____
- History of hormone replacement therapy _____
- History of breast cancer _____

Uterine Cancer:

- Age at onset of menses _____ and age of menopause _____
- Number of pregnancies _____
- Use of oral contraceptives _____
- Obesity ☐

Colon Cancer:

- Family or personal history of adenomatous polyposis (FAP) ☐
- Family or personal history of Lynch syndrome (Hereditary nonpolyposis colorectal cancer) ☐
- Diet
  ☐ High in red meat and animal fat ☐ Refined carbohydrates

☐ Low-fiber diet ☐ Low overall intake of fruits and vegetables

- Obesity and sedentary habits ☐
- Any history of inflammatory conditions of digestive tract

  ☐ Chronic ulcerative colitis ☐ Crohn's disease longer duration, greater extent of colon involvement

Anorectal Cancer:

- History of infection with

  ☐ Human papillomavirus ☐ Chronic fistulas ☐ Irradiated anal skin

  ☐ Leukoplakia ☐ Lymphogranulomatoma venereum ☐ Condyloma acuminatum
- HIV status _____

Gastric Cancer:

- Diet

  ☐ Rich in pickled vegetables ☐ Salted fish ☐ Salt ☐ Smoked meats
- Helicobacter pylori infection ☐
- Obesity ☐
- Previous gastric surgery
- ☐ Pernicious anemia ☐ Adenomatous polyps ☐ Gastric ulcer
- Chronic atrophic gastritis ☐
- Radiation exposure _____
- History of alcohol use/smoking ☐

Oesophageal Cancer:

- Genetic causes - tylosis (hyperkeratosis palmaris et plantaris)
- History of alcohol use/smoking _____
- History of

  ☐ Chronic or acute inflammation (e.g. GERD, Barrett's esophagus, caustic ingestion)

  ☐ Achalasia (esophageal motility disorder)
- Human papilloma virus ☐
- Sclerotherapy ☐
- Plummer-Vinson syndrome (dysphagia, associated with iron deficiency anemia) ☐

Liver cancer:

- History of cirrhosis (including alcoholic, biliary cirrhosis), other chronic liver dysfunction ☐
- History of alcohol use/smoking _____
- Hepatitis B, C _____
- Hemochromatosis ☐
- Indigestion of food contaminated with fungal aflatoxins (in subtropical regions) ☐

Pancreatic Cancer:

- History of alcohol use/smoking ☐
- Obesity ☐
- Diet (red meat) ☐
- History of chronic pancreatitis or long-standing diabetes mellitus (Primarily in women) ☐
- Inherited predisposition hereditary pancreatitis, familial adenomatous polyposis)☐

Renal Cancer (renal cell carcinoma):

- Smoking history –
  Length of time_____ Number of cigarettes/days _____ Age at starting_____
  Gender_____ Product smoked (i.e. cigars, cigarettes, etc.)_____
  Depth of inhalation_____ length of time _____
- Obesity ☐
- Hypertension ☐
- Phenacetin-containing analgesics taken in large amounts ☐
- History of renal transplantation ☐
- Exposure to radiopaque dyes, asbestos, cadmium, and leather tanning and petroleum products ☐
- Inherited von Hippel-Lindau disease (VHL), Adult polycystic kidney disease, Tuberous sclerosis ☐

Bladder Cancer:

- Smoking history –
  Length of time_____ Number of cigarettes/days _____ Age at starting_____
  Gender_____ Product smoked (i.e. cigars, cigarettes, etc.)_____
  Depth of inhalation_____ length of time _____
- Industrial exposure to aromatic amines in dyes, paints, solvents, leather dust, inks, combustion products, rubber, and textiles ☐
- Occupation - painting, driving trucks, and working with metal ☐
- Prior spinal cord injuries with long-term indwelling catheters ☐

Prostate Cancer:

- Smoking history –
  Length of time_____ Number of cigarettes/days _____ Age at starting_____
  Gender_____ Product smoked (i.e. cigars, cigarettes, etc.)_____
  Depth of inhalation_____ length of time _____
- History of high-grade prostatic intraepithelial neoplasia (PIN) ☐
- Genome changes-deletion of chromosome 3 and fusion of TMPRSS2 and ERG genes ☐
- Testosterone level _____
- History of sexually transmitted diseases ☐
- History of vasectomy ☐
- History of exposure to cadmium ☐
- History of genitor-urinary infections ☐

Head and Neck Cancer:

- History of smoking and alcohol use ☐
- Exposure to Human papilloma virus (HPV) or Epstein-Barr virus (EBV) ☐
- History of poor oral hygiene and/or poor nutrition ☐
- Exposure to asbestos, wood dust, paint fumes or chemicals ☐
- History of Gastroesophageal reflux disease (GERD) or laryngopharyngeal reflux disease (LPRD) ☐

Brain tumors (gliomas and menigiomas):

- Exposure to radiation ☐
- Exposure to vinyl chloride, Pesticides ☐
- Immune system disorders ☐
- Hormone replacement therapy ☐

Larynx Cancer:

- History of smoking/ alcohol use ☐
- Asbestos exposure ☐
- Any activity requiring loud speech, exposure to sudden and frequent temperature changes ☐
- Frequent hoarseness and persistent cough ☐
- Persistently swollen neck glands ☐
- Tonsillectomy and laryngeal surgery ☐

Nasal and Paranasal Sinus Cancer:

- Woodworking, any dust/flour chronic exposure ☐
- History of Infection with human papillomavirus (HPV) ☐
- Smoking history –
  Length of time_____ Number of cigarettes/days _____ Age at starting_____
  Gender_____ Product smoked (i.e. cigars, cigarettes, etc.)_____
  Depth of inhalation_____ length of time _____

Mouth and Oropharyngeal Cancer:

- History of smoking/ alcohol use ☐
- History of poor oral hygiene ☐
- Chronic mucosal /gum irritation /ill-fitting dentures ☐
- Betel-Nut chewing (Indian Population) ☐
- History of syphilis or viral infection ☐
- Impaired immunity -AIDS, transplant with anti-rejection drug ☐
- Precancerous mouth plaques -Leukoplakia or erythroplasia ☐
- History of cancer of the aero digestive tract ☐

Melanoma

- History of prolonged sun exposure (UV radiation)-severe blistering sunburns, frequent tanning, use of sunlamps and tanning booths ☐
- History of living close to equator or at high elevation ☐
- History of skin condition- Dysplastic nevus, Xeroderma pigmentosum, nevoid basal cell carcinoma syndromes ☐
- Skin type-fair (pale) skin -burns easily, freckles ☐
- Eye colour-blue, green or gray, Hair color -Blond or red
- Use of medication causing sensitivity to sun -antibiotics, hormones, antidepressants ☐
- Immune system depression –AIDS, Leukemias, etc ☐
- Exposure to arsenic, coal tar or creosote ☐
- For eye localisation: History of oculodermal melanocytosis or Dysplastic nevus syndrome ☐

_____
Health Practitioner Name (Print)

_____
Health Practitioner Name (Signature)

Additional information regarding this Adverse Event Report:

Description of event: [narrative]

Targeted Follow Up Questionnaire for Cardiac Arrhythmia and ECG Changes

INFORMATION PREVIOUSLY PROVIDED DOES NOT NEED TO BE REPEATED ON THIS FORM:

Patient Demographics:

Patient's date of birth (DD-MMM-YYYY):___-____-_____ **Gender:** ☐ Male ☐ Female

Age: _____

Race/Ethnicity: ☐ Aborignal ☐ African-American ☐ Asian ☐ American Indian or Alaskan native ☐ Native Hawaiian or Pacific islander ☐ Toress Strat Islander ☐ White ☐ Black ☐ Non Hispanic

Age group: _____

Note: Please provide Age Group if Patient's Date of Birth or Age is not available.

[Age Group Definition: Neonate: 0 - 27 days, Infant: 28 days to 23 months, Child: 2 years to 11years, Adolescent: 12 years to 18 years, Adult: More than 18 years and less than or equal to 65 years and Elderly: equal or greater than 66 years.]

Suspect Products: Please provide suspect product(s) information [those product(s) that are suspected to be associated with one or more adverse events]:

	Suspect Product #1	Suspect Product #2	Suspect Product #3
Product name			
Daily dose and regimen			
Route of administration			
Indication			
Start date or treatment duration			
Stop date (DD-MMM-YYYY)			
Lot/Batch number(s)			
Expiration date(s)			
Action Taken with the suspect product			

(Choose from one of the following for action Taken with Suspect Product: Drug withdrawn, Dose reduced, Dose increased, Dose not changed, Unknown)

Adverse Event (AE) Description: Please provide diagnosis or symptoms/signs if diagnosis is unavailable.

	Adverse Event #1	Adverse Event #2	Adverse Event #3	Adverse Event #4
Add Diagnosis Here				
Start Date (DD/MMM/YYYY)				
Stop Date (DD/MMM/YYYY)				
Time lag if AE occurred after cessation of treatment with the suspect product(s):				
Required Hospitalization (Yes/No)				
Life-Threatening (Yes/No)				
Persistent or significant disability (Yes/No)				
Congenital abnormality (Yes/No)				
Cause of Death (Yes/No)				
Treatment of Adverse Event				
Outcome (recovery and sequelae, if any)				
Did the event(s) abate after suspect Product was stopped or dose reduced? (Yes/No)				
Did the event recur after reintroducing (Yes/No) Did the event recur after				

reintroducing (Yes/No)				

Please summarise course of reported events including signs and symptoms in chronological order:

_____

_____

- Diagnostic tests (use additional pages if needed): Please indicate test unit where applicable

Date	Test name	Pre-treatment value	AE onset value	AE resolution value	Normal low	Normal high
	CPK					
	CPK-MB					
	Troponin					
	RBC					
	Hemoglobin					
	Metabolic Panel (Specify)					
	Serum Potassium					
	Serum magnesium					
	Phosphorus					
	Calcium					
	Uric acid					
	Creatinine					
	BUN					

Please provide causal relationship assessment between the suspect product(s) and adverse event(s)

_____

_____

Concomitant Medications (use additional pages if needed):

Did the Patient take any concomitant medication?

☐ Yes (please complete below) ☐ No Unknown

Please include any antiemetics

Medication Name	Daily dose and regimen	Route of administration	Indication	Start date DD-MMM-YYYY	Stop date DD-MMM-YYYY

Other Etiological Factors: ☐ Yes (Please complete below) ☐ None ☐ Unknown

☐ Relevant medical and/or drug history (please specify), including start date or duration:

_____

_____

☐ Family history (please specify):_____

☐ Drug/alcohol/tobacco abuse: _____

☐ Other (please specify): _____

Additional questions:

Please provide brief description of cardiac arrhythmia or ECG changes including the type and clinical sign/symptoms observe and including start date and stop date.

Please specify Types of arrhythmia /ECG change:

_____

_____

Clinical sign/symptoms if present (if none please state): _____

[redacted]

Start date _____ Stop date _____

Does the patient have a relevant cardiac history? If yes, please specify. If no please state.

_____

_____

Does the patient have a history of cardiac risk factor (e.g. hypertension, hyperlipidemia, hypercholesteremia, diabetes, sepsis, obesity, smoking, renal disease, cardio respiratory problems)? If yes please specify in the box below. If no, please state.

_____

_____

Please provide the available results of the diagnostic workup (include dates of baseline, event onset, and resolution results)..

Test	Pre-treatment results	AE onset results	AE resolution results
EKG findings			
Echocardiogram			
Chest X-ray			
Holter stress test			

Please describe specific treatments and interventions of the arrhythmia

_____

_____

_____
Health Practitioner Name (Print)

_____
Health Practitioner Name (Signature)

Additional information regarding this Adverse Event Report:

Description of event: [narrative]

Annex 6 - Details of proposed additional risk minimisation activities

1. The MAH shall agree the details of a controlled access programme with the National Competent Authorities and must implement such programme nationally to ensure that:

- Prior to prescribing (where appropriate, and in agreement with the National Competent Authority, dispensing) all healthcare professionals who intend to prescribe (and dispense) Pomalidomide Accord are provided with an Educational Healthcare Professional's Kit containing the following:

    i. Educational Healthcare Professional brochure

    ii. Educational brochures for patients

    iii. Patient card

    iv. Risk awareness forms

    v. Information on where to find latest Summary of Product Characteristics (SmPC)

2. The MAH shall implement a pregnancy prevention programme (PPP) in each Member State. Details of the PPP should be agreed with the National Competent Authorities in each Member State and put in place prior to the launch of the medicinal product.
3. The MAH should agree on the implementation of the controlled access programme in each Member State.
4. The MAH should agree the contents of the Educational Healthcare Professional's Kit with the National Competent Authority in each Member State prior to launch of the medicinal product and ensure that the materials contain the key elements as described below.

Key elements to be included

The Educational Healthcare Professional's Kit

The Educational Health Care Professional's Kit shall contain the following elements:

Educational Healthcare Professional brochure

- Brief background on pomalidomide
- Maximum duration of treatment prescribed
    - 4 weeks for women with childbearing potential

        - 12 weeks for men and women without childbearing potential
    - The need to avoid foetal exposure due to teratogenicity of pomalidomide in animals and the expected teratogenic effect of pomalidomide in humans
    - Guidance on handling the blister or capsule of Pomalidomide for healthcare professionals and caregivers
    - Obligations of the health care professional in relation to the prescribing of pomalidomide
        - Need to provide comprehensive advice and counselling to patients
        - That patients should be capable of complying with the requirements for the safe use of pomalidomide
        - Need to provide patients with appropriate patient educational brochure and patient card and/or equivalent tool
- Safety advice relevant to all patients
    - Description and management of thrombocytopenia including incidence rates from clinical studies
    - Description and management of cardiac failure
    - Disposal of unwanted medicine
    - Local country specific arrangements for a prescription for pomalidomide to be dispensed
    - That any unused capsules should be returned to the pharmacist at the end of the treatment
    - That the patient should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide.
- Description of the PPP and categorisation of patients based on sex and childbearing potential
    - Algorithm for implementation of PPP
    - Definition of women of childbearing potential (WCBP) and actions the physician should take if unsure
- Safety advice for women of childbearing potential
    - The need to avoid foetal exposure
    - Description of the PPP
    - Need for effective contraception (even if woman has amenorrhoea) and definition of effective contraception
    - That if she needs to change or stop using her method of contraception she should inform:

        - The physician prescribing her contraception that she is on pomalidomide
        - The physician prescribing pomalidomide that she has stopped or changed her method of contraception
    - Pregnancy test regime
        - Advice on suitable tests
        - Before commencing treatment
        - During treatment based on method of contraception
        - After finishing treatment
    - Need to stop pomalidomide immediately upon suspicion of pregnancy
    - Need to tell treating doctor immediately upon suspicion of pregnancy
- Safety advice for men
    - The need to avoid foetal exposure
    - The need to use condoms if sexual partner is pregnant or a WCBP and has no contraception (even if man has had a vasectomy)
        - During pomalidomide treatment
        - For at least 7 days following final dose
    - That he should not donate semen or sperm during therapy (including during dose interruptions) and for at least 7 days after discontinuation of pomalidomide treatment
    - That if his partner becomes pregnant whilst he is taking pomalidomide or shortly after he has stopped taking pomalidomide he should inform his treating doctor immediately
- Requirements in the event of pregnancy
    - Instructions to stop pomalidomide immediately upon suspicion of pregnancy if female patients
    - Need to refer to physician specialised or experienced in dealing with teratology and its diagnosis for evaluation and advice
    - Local contact details for reporting of any suspected pregnancy
- Local contact details for reporting adverse reaction

Educational Brochures for patients

The Educational brochures for patients should be of 3 types:

- Brochure for women patients of childbearing potential and their partners
- Brochure for women patients who are not of childbearing potential
- Brochure for male patients

All patient brochures should contain the following elements:

- That pomalidomide is teratogenic in animals and is expected to be teratogenic in humans
- That pomalidomide may cause thrombocytopenia and the need for regular blood tests
- Description of the patient card and its necessity
- Guidance on handling pomalidomide for patients, caregivers and family members
- National or other applicable specific arrangements for a prescription for pomalidomide to be dispensed
- That the patient should not give pomalidomide to any other person
- That the patient should not donate blood during treatment (including during dose interruptions) and for at least 7 days after discontinuation of pomalidomide treatment
- That the patient should tell their doctor about any adverse events
- That any unused capsules should be returned to the pharmacist at the end of the treatment

The following information should also be provided in the appropriate brochure:

Brochure for women patients with childbearing potential

- The need to avoid foetal exposure
- Description of the PPP
- The need for effective contraception and definition of effective contraception
- That if she needs to change or stop using her method of contraception she should inform:
    - The physician prescribing her contraception that she is on pomalidomide
    - The physician prescribing pomalidomide that she has stopped or changed her method of contraception
- Pregnancy test regime
    - Before commencing treatment
    - During treatment (including dose interruptions), at least every 4 weeks except in case of confirmed tubal sterilisation
    - After finishing treatment

- The need to stop pomalidomide immediately upon suspicion of pregnancy
- The need to contact their doctor immediately upon suspicion of pregnancy

Brochure for male patients

- The need to avoid fetal exposure
- The need to use condoms if sexual partner is pregnant or a WCBP and has no contraception (even if man has had vasectomy)
    - During pomalidomide treatment (including dose interruptions)
    - For at least 7 days following final dose
- That if his partner becomes pregnant he should inform his treating doctor immediately
- That he should not donate semen or sperm during therapy (including during dose interruptions) and for at least 7 days after discontinuation of pomalidomide treatment

Patient Card or equivalent tool

The patient card shall contain the following elements:

- Verification that appropriate counselling has taken place
- Documentation of childbearing potential status
- Check box (or similar) which physician ticks to confirm that patient is using effective contraception (if woman of childbearing potential)
- Pregnancy test dates and results

Risk Awareness Forms

There should be 3 types of risk awareness forms:

- Women of childbearing potential
- Women of non-childbearing potential
- Male patient

All risk awareness forms should contain the following elements:

- teratogenicity warning
- patients receive the appropriate counselling prior to treatment initiation
- affirmation of patient understanding regarding the risk of pomalidomide and the PPP measures
- date of counselling
- patient details, signature and date

- prescriber name, signature and date
- aim of this document i.e. as stated in the PPP: "The aim of the risk awareness form is to protect patients and any possible foetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse reactions associated with the use of pomalidomide. It is not a contract and does not absolve anybody from his/her responsibilities with regard to the safe use of the product and prevention of foetal exposure."

Risk awareness forms for women of childbearing potential should also include:

- Confirmation that the physician has discussed the following:
  - the need to avoid foetal exposure
  - that if she is pregnant or plans to be, she must not take pomalidomide
  - that she understands the need to avoid pomalidomide during pregnancy and to apply effective contraceptive measures without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment
  - that if she needs to change or stop using her method of contraception she should inform:
    - the physician prescribing her contraception that she is taking pomalidomide
    - the physician prescribing pomalidomide that she has stopped or changed her method of contraception
  - of the need for pregnancy tests i.e. before treatment, at least every 4 weeks during treatment and after treatment
  - of the need to stop pomalidomide immediately upon suspicion of pregnancy
  - of the need to contact their doctor immediately upon suspicion of pregnancy
  - that she should not share the medicinal product with any other person
  - that she should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide
  - that she should return the unused capsules to the pharmacist at the end of treatment

Risk awareness forms for women with no childbearing potential should also include:

- Confirmation that the physician has discussed the following:
  - that she should not share the medicinal product with any other person
  - that she should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide

- that she should return the unused capsules to the pharmacist at the end of treatment

Risk awareness forms for male patients should also include:

- Confirmation that the physician has discussed the following:
  - the need to avoid foetal exposure
  - that pomalidomide is found in semen and the need to use condoms if sexual partner is pregnant or is a WCBP not on effective contraception (even if the man has had a vasectomy)
  - that if his partner becomes pregnant, he should inform his treating doctor immediately and always use a condom
  - that he should not share the medicinal product with any other person
  - that he should not donate blood or semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide
  - that he should return the unused capsules to the pharmacist at the end of treatment