

# **Pomalidomide Rowex Content HCP Kit**

**Approved by the Malta Medicines Authority on the 23<sup>rd</sup> September 2026**

## **REPORTING OF ADVERSE REACTIONS**

Suspected adverse reactions and medication errors should be reported either to:

**ADR Reporting, The Medicines Authority, Post-Licensing Directorate,**  
Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta  
Website:  
[www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)  
e-mail: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

OR

### **Marketing Authorisation Holder:**

Rowex Limited  
Tel: 0877941968  
Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net)

\*HCP kit includes HCP brochure, patient brochure and risk awareness forms.  
Please refer to associated files (risk awareness forms, patient brochure) separately.

## Pomalidomide

1 mg, 2 mg, 3 mg, and 4 mg, hard gelatin capsules

|                                           |                                                                         |
|-------------------------------------------|-------------------------------------------------------------------------|
| Active substance(s) (INN or common name): | Pomalidomide                                                            |
| Product(s) concerned (brand name(s)):     | Pomalidomide Rowex 1 mg, 2 mg, 3 mg,<br>and 4 mg, hard gelatin capsules |
| Document status:                          | Final                                                                   |
| Applicable RMP version number:            | 2.0                                                                     |

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## **Pomalidomide HCPs' Information Pack**

### **Important Safety Information:**

HCPs involved in the prescribing or dispensing of pomalidomide must read and understand the information contained within this pack.

For complete safety information, please refer to the Summary of Product Characteristics (SmPC) for pomalidomide available at the regulatory authority website.

HCPs are asked to report any suspected adverse reactions via the regulatory authority website. Adverse reactions should also be reported to:

#### **ADR Reporting, The Medicines Authority, Post-Licensing Directorate**

Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta

Website:

[www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)

e-mail: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

### **Pomalidomide**

#### **HCPs' Information Pack**

This pack contains the information and materials needed for the prescribing and dispensing of pomalidomide, including information about the Pregnancy Prevention Program (PPP).

It is a requirement of the PPP that all HCPs ensure that they have read and understood this pack before prescribing or dispensing pomalidomide for ANY patient.

An easy reference guide is included at the back of your pack. This summarizes the information for ongoing patient safety and the main steps in the pomalidomide PPP process.

When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis.

If pomalidomide is taken during pregnancy, a teratogenic effect of pomalidomide in humans is expected. Pomalidomide is therefore contraindicated in pregnancy and in women of childbearing potential (WCBP) unless the conditions of the PPP in this pack are met.

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**Contents of the HCPs' Information Pack**

**Information for HCPs**

This section contains information for prescribers and pharmacists, providing an overview of the pomalidomide PPP.

**Pharmacy Registration Form**

You will need to complete the relevant registration form in order to obtain pomalidomide.

**Information for Patients**

This section contains information for your patients to take home and read, to reinforce the safety information you will provide to them during consultations.

**Risk Awareness Forms**

There are three versions of this form, depending on whether your patient is a WCBP, woman of non-childbearing potential (WNCBP), or male. Complete the relevant form before prescribing pomalidomide to your patients.

**Prescription Authorization Forms**

You will need to complete a Prescription Authorization Form with every prescription for pomalidomide (completed forms must be sent to Rowex Limited).

**Algorithm**

**Frequently Asked Questions**

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**Pregnancy Prevention Program**

**Information for HCPs**

Prescribing or Dispensing Pomalidomide

**This brochure contains the information needed for prescribing and dispensing pomalidomide, including information about the PPP. Please also refer to the pomalidomide SmPC, which can be found at [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt) for further information.**

**Pomalidomide PPP:**

If pomalidomide is taken during pregnancy, it is to expected cause severe birth defects or death to an unborn baby. This program is designed to make sure that unborn babies are not exposed to pomalidomide. It will provide you with information about how to follow the program and explain your responsibilities.

**Other side effects of pomalidomide:**

A full list of all side effects, further information, and recommended precautions can be found in the [Nationally completed name] SmPC.

Important information about the safe disposal of unwanted capsules and restrictions on donating blood during treatment is also included in this brochure.

This brochure will help you understand these problems and make sure you know what to do before prescribing and dispensing pomalidomide.

**For your patients' health and safety, please read this brochure carefully. You must ensure that your patients fully understand what you have told them about pomalidomide and that they have provided written confirmation on the Risk Awareness Form, before starting treatment.**

**Table of Contents**

|       |                                                                                        |    |
|-------|----------------------------------------------------------------------------------------|----|
| 1     | Introduction .....                                                                     | 7  |
| 1.1   | Summary of the Pomalidomide PPP .....                                                  | 7  |
| 1.2   | Overview of the HCPs' Information Pack .....                                           | 8  |
| 1.3   | Teratogenicity: Potential or Actual Fetal Exposure to Pomalidomide .....               | 8  |
| 1.4   | Safety Advice Relevant to all Patients .....                                           | 9  |
| 2     | Therapeutic Management Advice to Avoid Fetal Exposure .....                            | 9  |
| 2.1   | WNCBP .....                                                                            | 9  |
| 2.2   | WCBP .....                                                                             | 10 |
| 2.3   | Men .....                                                                              | 11 |
| 2.4   | Advice for All Patients .....                                                          | 12 |
| 3     | HCP Obligations.....                                                                   | 12 |
| 3.1   | Information for Prescribers.....                                                       | 13 |
| 3.2   | Information for Pharmacists .....                                                      | 14 |
| 3.2.1 | Dispensing pomalidomide.....                                                           | 14 |
| 3.2.2 | Dispensing advice.....                                                                 | 14 |
| 4     | Follow-up Assessment of the Effectiveness of the Program.....                          | 14 |
| 5     | Safety Advice Relevant to all Parties .....                                            | 15 |
| 5.1   | Risk of Thrombocytopenia and Cardiac Failure with Pomalidomide .....                   | 15 |
| 5.1.1 | Thrombocytopenia .....                                                                 | 15 |
| 5.1.2 | Cardiac failure .....                                                                  | 15 |
| 5.2   | Safety and Off-Label Use.....                                                          | 16 |
| 5.3   | Points to Consider for Handling the Medical Product: For HCPs and Caregivers .....     | 16 |
| 5.4   | Blood Donation .....                                                                   | 18 |
| 6     | Reporting Adverse Events, Suspected and Confirmed Pregnancy, and Fetal Exposures ..... | 18 |
| 7     | Description of the PPP and Patient Categorisation Algorithm.....                       | 20 |
| 8     | Contact Details .....                                                                  | 21 |

## 1 Introduction

This brochure contains the information needed for prescribing and dispensing pomalidomide, including information about the PPP.

Please also refer to the pomalidomide SmPC, which can be found at [www.medicinesauthority.com.mt](http://www.medicinesauthority.com.mt) for further information.

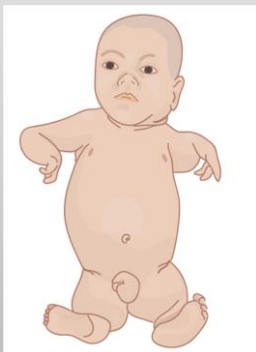
When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

### 1.1 Summary of the Pomalidomide PPP

This brochure contains the information needed for prescribing and dispensing pomalidomide, including information about the PPP.

**Pomalidomide is structurally related to thalidomide, a known human teratogenic substance that causes severe life-threatening birth defects. Pomalidomide induced, in rats and rabbits, malformations similar to those described with thalidomide.**

**If pomalidomide is taken during pregnancy, a teratogenic effect of pomalidomide in humans is expected. Pomalidomide is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the PPP are met (please refer to sections 4.4 and 4.6 of the SmPC for further details).**



- All men and all WCBP should undergo, at treatment initiation, counselling on the need to avoid pregnancy (this must be documented via a Risk Awareness Form).
- Patients should be capable of complying with the requirements of the safe use and handling of pomalidomide.
- Patients must be provided with a copy of the Patient Brochure and Patient Card.

In order to obtain pomalidomide, it is a requirement of the PPP that all HCPs ensure that they have read and understood the additional risk minimization materials before prescribing or dispensing pomalidomide for any patient.

- Prescribers must complete the appropriate Risk Awareness Form with every patient before the first prescription is issued.

All patients should be given a Patient Brochure and Patient Card to take home—these materials remind patients of the key educational information and risks of treatment, and can be found in the Information for Patients section of this pack.

For WCBP, prescriptions of pomalidomide should be limited to a maximum duration of 4 weeks of treatment, and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription, and dispensing should occur on the same day. Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription, and the date of the last negative pregnancy test must be within 3 days prior to the date of the prescription.

For all other patients, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks, and continuation of treatment requires a new prescription.

The following are core requirements of the PPP:

- All HCPs dispensing or prescribing pomalidomide must read the pomalidomide HCPs' Information Pack.

## **1.2 Overview of the HCPs' Information Pack**

All of the pomalidomide PPP materials are contained within this pack, and the additional risk minimization materials (ARMMs) are also available as individual materials. Additional hard copies can be obtained by contacting Rowex Limited using the contact details displayed on the front of this brochure.

You must ensure that your patients fully understand what you have told them about pomalidomide before starting treatment.

This brochure contains key information for HCPs and contains the following:

- Educational information
- Therapy management advice to avoid fetal exposure to pomalidomide
- A distribution control system
- Safety advice of relevance to all patients
- Process for follow-up of effectiveness of the measures described in this pack
- Process for reporting adverse events and pregnancy in patients treated with pomalidomide.

This HCPs' Information Pack also contains Adverse Event Reporting Forms, Treatment Checklists, Algorithms, and Treatment Initiation Forms for obtaining consent.

The description of the PPP and the categorization of patients based on sex and childbearing potential are set out in the attached Algorithm.

## **1.3 Teratogenicity: Potential or Actual Fetal Exposure to Pomalidomide**

Pomalidomide must never be used by women who are able to become pregnant unless they follow the pomalidomide PPP described in this pack.

Since pomalidomide may be present in the semen of male patients, all male and female patients must both follow effective contraceptive measures.

If a female patient or female partner of a male patient misses, or is suspected to have missed her period, or has any abnormality in menstrual bleeding, or suspects she is pregnant, then:

- Pomalidomide must be discontinued immediately, if the patient is female
- The woman must have a pregnancy test

- If the pregnancy test is positive, the woman should be referred to a physician experienced in teratology for further evaluation and counselling.

Any positive pregnancy test or suspected fetal exposure to pomalidomide must be reported immediately to the Malta Medicines Authority and to the MAH- Rowex Limited. In this instance, you must:

- Stop treatment immediately, if the patient is female
- Refer the patient/partner to a physician specialized or experienced in dealing with teratology for advice and evaluation
- Notify Rowex Limited immediately by contacting [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net).

#### 1.4 Safety Advice Relevant to all Patients

In addition to information about the PPP, this brochure contains important advice for HCPs about how to minimize the risk of adverse events during treatment with pomalidomide.

For further information about the appropriate use and safety profile of pomalidomide, please refer to the SmPC, which can be found on the Malta Medicines Authority website.

You must complete via website or send a copy of every completed PAF and submit immediately to Rowex Limited, for ALL patients, regardless of indication or risk category. This is an absolute requirement so that Rowex Limited can fulfil regulatory obligations to monitor PPP adherence and off-label usage.

Rowex Limited is obliged to provide anonymized reports on these data to the Malta Medicines Authority, to assess the effectiveness of risk minimization activities, and will not be able to comply if pharmacies do not complete their PAFs or provide them to Rowex Limited immediately. If sending paper PAFs, use the following contact details:

Rowex Limited

Tel: 0877941968

Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net)

Electronic copies of the PAF can also be found on the Malta Medicines Authority website.

Please keep a copy of the PAFs for your records.

## 2 Therapeutic Management Advice to Avoid Fetal Exposure

### 2.1 WNCBP

Women in the following groups are considered not to have childbearing potential and do not need to undergo pregnancy testing or receive contraceptive advice:

- Age  $\geq$  50 years and naturally amenorrheic for  $\geq$ 1 year. Please note, amenorrhea following cancer therapy or during breastfeeding does not rule out childbearing potential
- Premature ovarian failure confirmed by specialist gynecologist
- Previous bilateral salpingo-oophorectomy or hysterectomy
- XY genotype, Turner syndrome, or uterine agenesis

A female patient is considered to have childbearing potential unless she meets at least one of the above criteria. Prescribers are advised to refer their patient for a gynecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

If a patient does not meet at least one of above criteria, but the prescriber considers the patient to be of non-childbearing potential, then prior approval of any deviation from these stipulated criteria should be sought from Rowex Limited. The following information is required to assess whether a patient, who does not meet at least one of the above criteria, can be treated as a WNCBP:

- Date of birth and initials of the patient
- Details of why the prescriber considers the patient to be of non-childbearing potential
- Background to why a deviation has been requested.

## 2.2 WCBP

WCBP must never take pomalidomide if they are:

- Pregnant
- Able to become pregnant, even if not planning to become pregnant, unless all of the conditions of the PPP are met.

In view of the teratogenic risk of pomalidomide, fetal exposure should be avoided.

WCBP must understand the need to avoid pregnancy, and these patients must be adequately informed regarding the use of pregnancy prevention measures every time a prescription is issued.

WCBP (even if they have amenorrhea) must use at least one effective method of contraception for at least 4 weeks before therapy, during therapy, and until at least 4 weeks after pomalidomide therapy has finished, and even in case of dose interruption. This must be followed unless the patient commits to absolute and continuous abstinence confirmed with her physician on a monthly basis.

If your patient is not established on effective contraception, she must be referred to an appropriately trained HCP for contraceptive advice in order that contraception can be initiated.

The following can be considered to be examples of suitable methods of contraception:

- Implant
- Levonorgestrel-releasing intrauterine system
- Medroxyprogesterone acetate depot
- Tubal sterilization
- Sexual intercourse with a vasectomized male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (ie, desogestrel).

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking pomalidomide and dexamethasone, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception, the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4 to 6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone.

Implants and levonorgestrel-releasing intrauterine systems are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding. Prophylactic antibiotics should be considered particularly in patients with neutropenia.

Insertion of copper-releasing intrauterine devices is not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss, which may compromise patients with severe neutropenia or severe thrombocytopenia.

Your patient should be advised that if a pregnancy does occur while she is receiving pomalidomide, she must stop treatment immediately and inform her prescriber.

If your patient needs to change or stop her contraceptive method during her pomalidomide therapy, she must understand the need to discuss this first with:

- The physician prescribing her contraceptive method
- The physician prescribing her pomalidomide.

If a WCBP has sexual contact without using an effective contraceptive method while taking pomalidomide, or believes for any reason that she may be pregnant, she must stop treatment and immediately consult her doctor.

#### *Pregnancy testing*

For WCBP, a pregnancy test must be performed prior to issuing a prescription. This may be embarrassing for some patients and may need to be handled sensitively. A pregnancy test is required even if the patient has not had heterosexual intercourse since her last pregnancy test.

WCBP (even if they have amenorrhea) must have a medically supervised negative pregnancy test prior to issuing a prescription (with a minimum sensitivity of 25 mIU/ml) once she has been established on contraception for at least 4 weeks, at least every 4 weeks during therapy (this includes dose interruptions), and at least 4 weeks after the end of therapy (unless tubal sterilization is confirmed). This includes those WCBP who confirm absolute and continued abstinence.

Patients who are being prescribed the appropriate contraceptive method by their physician should inform their physician about pomalidomide treatment. Patients should be advised to inform you if a change in or termination of a method of contraception is needed.

A pregnancy test must be performed immediately if a patient misses her period, if there is any abnormality in menstrual bleeding, if she has heterosexual intercourse without using an effective contraceptive method, or if she suspects she is pregnant.

#### **If a female patient has a positive pregnancy test, then:**

- Stop treatment immediately
- Refer the patient to a physician specialized or experienced in dealing with teratology for advice and evaluation
- Notify Rowex Limited immediately by contacting the Rowex Limited Drug Safety Department (Rowex Limited, Tel: 0877941968, Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net)).
- Rowex Limited will wish to follow-up with you the outcome of all pregnancies
- You can report the suspected pregnancy to the Malta Medicines Authority.

### **2.3 Men**

In view of the expected teratogenic risk of pomalidomide, fetal exposure should be avoided. Therefore, your male patients must be counselled at treatment initiation on the risks and benefits of pomalidomide therapy, including the risk of birth defects, other side effects, and important precautions associated with pomalidomide therapy. Inform your patient which are the effective contraceptive methods that his female partner can use.

Pomalidomide is present in human semen during treatment. As a precaution, and taking into account special populations with potentially prolonged elimination time such as renal impairment, all male patients taking pomalidomide, including those who have had a vasectomy, as seminal fluid may still contain pomalidomide in the absence of spermatozoa, should use condoms throughout treatment duration, during dose interruption, and

for at least 7 days after cessation of treatment if their partner is pregnant or of childbearing potential and is not using contraception.

Patients should be instructed that if their partner does become pregnant while he is taking pomalidomide or within 7 days after he has stopped taking pomalidomide, he should inform his prescriber immediately. The partner should inform her physician immediately. It is recommended that she be referred to a physician specialized in teratology for evaluation and advice.

Male patients should not donate semen or sperm during treatment, including during dose interruptions and for at least 7 days following discontinuation of pomalidomide.

You can report suspected side effects using the contact details below:

- Rowex Limited contact details
- Malta Medicines Authority contact details.

## 2.4 Advice for All Patients

Your patient must be informed not to donate blood during or within 7 days after stopping treatment. If your patient discontinues therapy, they must return any unused pomalidomide to the pharmacy.

HCPs and caregivers should wear disposable gloves when handling the blister or capsule. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

They must also understand that their pomalidomide is only for them, and it:

- Must not be shared with anyone else, even if they have similar symptoms
- Must be stored away safely so no one else could take the capsules by accident
- Must be kept out of reach and sight of children.

## 3 HCP Obligations

HCPs have specific obligations that must be followed when prescribing or dispensing pomalidomide, which are:

### Prescriber: You must ensure that

- Your patient is fully educated on the risks of pomalidomide.
- You complete the appropriate Risk Awareness Form with your patient before the first prescription is issued.
- You provide the patient with a Patient Pocket Information Card, Patient Brochure, and a copy of the Risk Awareness Form.
- If relevant, your patient is using the appropriate method of contraception.
- Female patients of childbearing potential undergo a pregnancy test, which must be negative, before every prescription that you issue.
- You prescribe pomalidomide in accordance with the measures described in this brochure and the SmPC, which can be found on [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt).

### **3.1 Information for Prescribers**

#### **3.1.1 Patient and HCP Education**

As the prescriber, you play a central role in ensuring that pomalidomide is used safely and correctly.

Most importantly, you will be helping to ensure that your patients understand the risks involved in taking pomalidomide and that they are aware of their responsibilities in preventing fetal exposure to the drug. In addition, you may need to help your patients understand the processes involved in the pomalidomide PPP. This will help to prevent any delays in your patients receiving their treatment.

If you refer your patient to a fertility expert (eg, obstetrician or gynecologist) for further contraceptive advice or pregnancy testing counselling, it is your responsibility to ensure that the fertility expert is aware of the pomalidomide PPP.

#### **3.1.2 Patient Counselling and Education**

Because of the different levels of risk, you will need to communicate different information to men, women, and children. You must ensure that your patient understands the information before they complete their section of the Risk Awareness Form.

Please make use of the Patient Brochure and Patient Card to help explain the relevant information. Copies of the Patient Brochure and Patient Card are contained in your HCPs' Information Pack, and your patient should take these materials home to read in their own time or with a relative. Further copies can be obtained by using the contact details displayed on the front of this brochure.

#### **3.1.3 Prescribing Pomalidomide**

##### **3.1.3.1 Maximum Prescription Lengths**

- For WCBP, prescriptions of pomalidomide should be limited to a maximum duration of 4 weeks of treatment according to the approved indications and dosing regimens; prescriptions for all other patients can be for a maximum duration of 12 weeks. Do not dispense pomalidomide to WCBP unless the pregnancy test is negative and was performed within 3 days prior to the prescription.
- For all other patients, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks, and continuation of treatment requires a new prescription.

##### **3.1.3.2 Initial Prescription**

Before issuing the initial prescription, you must:

- Counsel the patient on the safe use of pomalidomide in accordance with the measures described in this brochure and the SmPC.
- Obtain their written confirmation (using the correct Risk Awareness Form) that they have received and understood this information, and provide the patient with a copy
- Provide the patient with a Patient Brochure and Patient Card

##### **3.1.3.3 Repeat of subsequent prescriptions**

The patient must return to the prescriber for every repeat prescription of pomalidomide.

### 3.2 Information for Pharmacists

As a pharmacist, you play an important role in ensuring that pomalidomide is used safely and correctly. Pomalidomide will only be supplied to pharmacies that have completed a Pomalidomide PPP—Pharmacy Registration Form and returned it to Rowex Limited.

Pharmacies that only complete and approve PAFs and do not order or dispense Pomalidomide will still need to complete the Pharmacy Registration Form.

#### 3.2.1 Dispensing pomalidomide

It is a requirement of the PPP that pharmacies wishing to purchase and dispense pomalidomide are registered with Rowex Limited.

**Dispensing of pomalidomide will only be allowed from pharmacies registered with Rowex Limited. Rowex Limited will not authorize purchase and supply of pomalidomide to pharmacies not registered with Rowex Limited.**

**Pomalidomide is supplied to pharmacies registered with the Rowex Limited Risk Minimization Program known as the PPP only for the purpose of dispensing the product by the PPP registered pharmacy to the patient.**

For WCBP, prescriptions for pomalidomide should be limited to a maximum duration of 4 weeks, and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription, and dispensing should occur on the same day. Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription, and the date of the last negative pregnancy test must be within the 3 days prior to the date of the prescription.

#### 3.2.2 Dispensing advice

- Please ensure that you dispense pomalidomide blisters intact; capsules must not be removed from blisters and packaged into bottles.
- For each prescription, dispense a maximum of a 4-week supply for WCBP or a 12-week supply for all other patients.
- Please educate all pharmacists within your pharmacy about the dispensing procedures for pomalidomide.
- Instruct patients to return any unused pomalidomide to the pharmacy. Pharmacies must accept any unused pomalidomide returned by patients for destruction, and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.

### 4 Follow-up Assessment of the Effectiveness of the Program

The terms of the pomalidomide Marketing Authorization require Rowex Limited to assess the effectiveness of the PPP in order to ensure that all reasonable steps are being taken to reduce the risk of pregnancy exposure in patients treated with pomalidomide.

Rowex Limited is, therefore, obliged to perform audits at regular intervals and to report appropriately anonymized and aggregated results to the Malta Medicines Authority. Rowex Limited conduct the audit from all of the completed PAFs received.

## 5 **Safety Advice Relevant to all Parties**

The following section contains advice for HCPs about how to minimize the risk of thrombocytopenia and cardiac failure associated with the use of pomalidomide. Please also refer to SmPC (Sections 4.2 Posology and method of administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use, and 4.8 Undesirable effects) for complete information on all the risks associated with pomalidomide.

In general, most adverse reactions occurred more frequently during the first 2 to 3 months of treatment. Please note that the posology, adverse event profile, and recommendations outlined herein, particularly in respect of thrombocytopenia, relate to the use of pomalidomide within its licensed indication. There is currently insufficient evidence regarding safety and efficacy in any other indication.

**When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.**

### 5.1 **Risk of Thrombocytopenia and Cardiac Failure with Pomalidomide**

#### 5.1.1 **Thrombocytopenia**

Thrombocytopenia is one of the major dose-limiting toxicities of treatment with pomalidomide. HCPs are, therefore, encouraged to monitor complete blood counts (CBC)—including platelet count—weekly for the first 8 weeks and monthly thereafter. A dose modification or interruption may be required. Patients may require use of blood product support and/or growth factors. Thrombocytopenia can be managed with dose modifications and/or interruptions. Recommended dose modifications during treatment and restart of treatment with pomalidomide are outlined in the table below.

#### *Dose Modification or Interruption Instructions*

| Toxicity                                                                                                                                                                                     | Dose Modification                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| Thrombocytopenia <ul style="list-style-type: none"> <li>• Platelet count <math>&lt;25 \times 10^9/L</math></li> <li>• Platelet count return to <math>\geq 50 \times 10^9/L</math></li> </ul> | Interrupt pomalidomide treatment, followed by weekly CBC tests<br><br>Resume pomalidomide treatment at one dose lower than previous dose |
| <ul style="list-style-type: none"> <li>• For each subsequent drop <math>&lt;25 \times 10^9/L</math></li> <li>• Platelet count return to <math>\geq 50 \times 10^9/L</math></li> </ul>        | Interrupt pomalidomide treatment<br><br>Resume pomalidomide treatment at one dose lower than the previous dose                           |

CBC: complete blood count.

To initiate a new cycle of pomalidomide, the platelet count must be  $\geq 50 \times 10^9/L$ .

#### 5.1.2 **Cardiac failure**

Cardiac events, including congestive cardiac failure, pulmonary edema, and atrial fibrillation (see Section 4.8 of the SmPC), have been reported, mainly in patients with pre-existing cardiac disease or cardiac risk factors. Appropriate caution should be exercised when considering the treatment of such patients with pomalidomide, including periodic monitoring for signs or symptoms of cardiac events (see Section 4.4 of the SmPC).

## 5.2 Safety and Off-Label Use

Please note that the posology, adverse event profile, and recommendations outlined above relate to the use of pomalidomide within its licensed indication. Pomalidomide must always be used according to the PPP described in this pack—these precautions must be followed, irrespective of the treatment setting, including the indication for treatment.

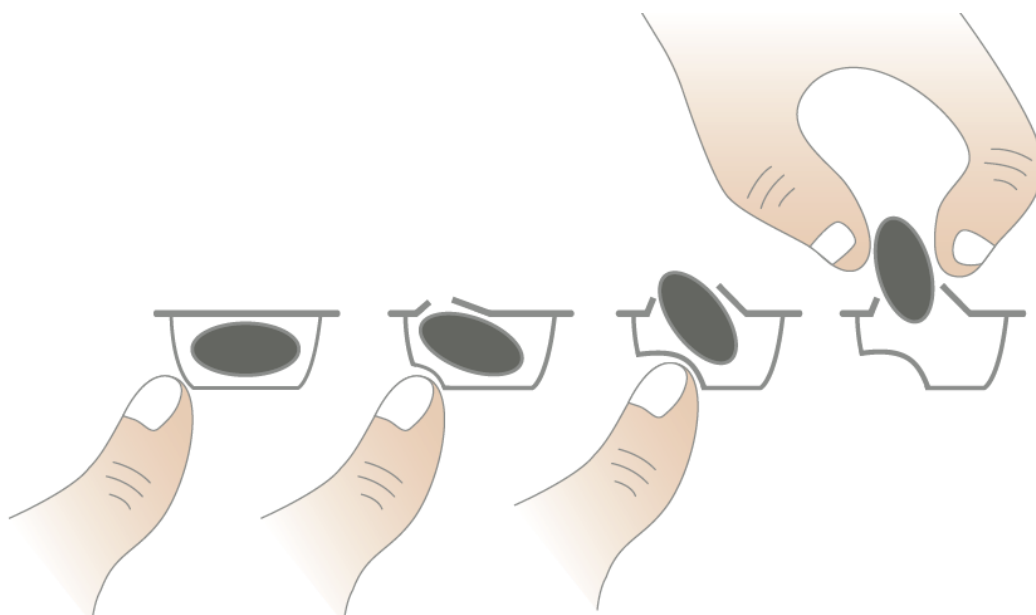
## 5.3 Points to Consider for Handling the Medical Product: For HCPs and Caregivers

Do not share the medicinal product with anyone else, even if they have similar symptoms. Store them safely so that no one else can take them by accident, and keep them out of the reach of children.

Keep the blisters with the capsules in the original pack.

Capsules can occasionally become damaged when pressing them out of the blister, especially when pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle. The pressure should be located at one site only, which reduces the risk of the capsule deforming or breaking (see figure below).

HCPs and caregivers should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag, and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.



**When handling the medicinal product, use the following precautions to prevent potential exposure if you are a HCP or caregiver.**

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule.
- Wear disposable gloves when handling product and/or packaging (ie, blister or capsule).

- Use proper technique when removing gloves to prevent potential skin exposure (see overleaf).
- Place gloves in sealable plastic polyethylene bag and dispose according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves.
- Patients should be advised never to give pomalidomide to another person.

**If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure:**

- If outer carton is visibly damaged, **DO NOT OPEN**.
- If blister strips are damaged or leaking or capsules are noted to be damaged or leaking, **close outer carton immediately**.
- Place the product inside a sealable plastic polyethylene bag.
- Return unused pack to the pharmacist for safe disposal as soon as possible.

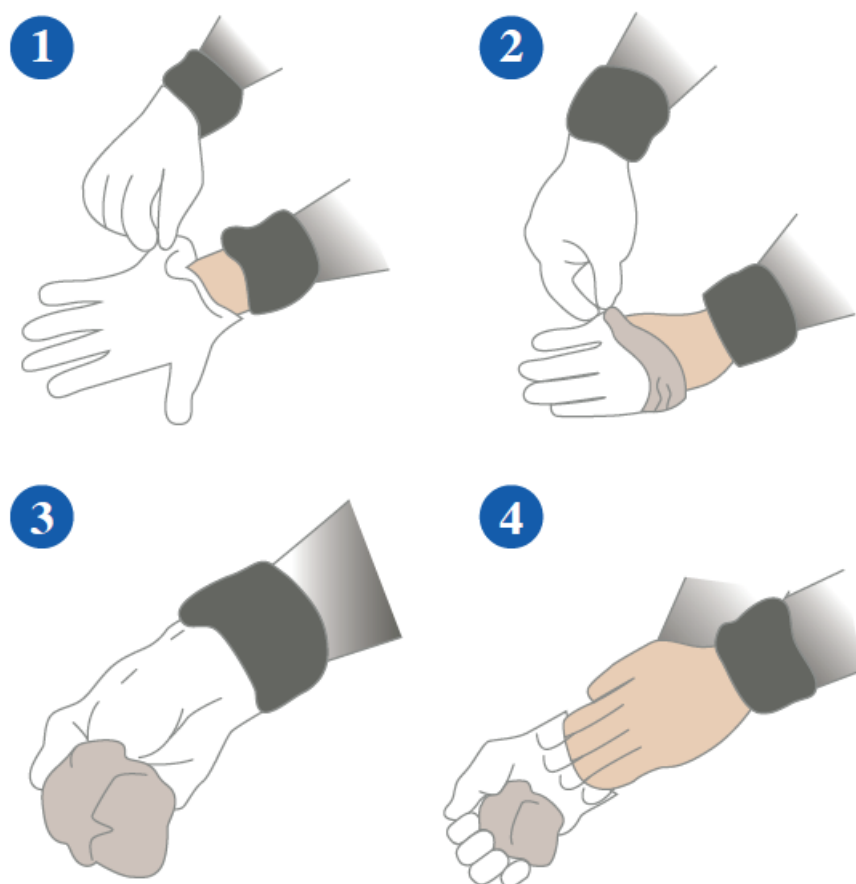
**If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protection.**

- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water and dry it.
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag. Dispose of it according to local requirements for medicinal products.
- Wash your hands thoroughly with soap and water after removing the gloves.
- Please report to Rowex Limited (Rowex Limited, Tel: 0877941968, Email: adverse.event.ireland@sandoz.net).

**If the contents of the capsule are attached to the skin or mucous membranes:**

- If you touch the drug powder, please wash exposed area thoroughly with running water and soap.
- If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush your eyes with copious quantities of water for at least 15 minutes. If irritation occurs, please contact an ophthalmologist.

**Proper Technique for Removing Gloves**



- Grasp outside edge near wrist (1).
- Peel away from hand, turning glove inside out (2).
- Hold in opposite gloved hand (3).
- Slide ungloved finger under the wrist of the remaining glove, being careful not to touch the outside of the glove (4).
- Peel off from inside, creating a bag for both gloves.
- Discard in appropriate container.
- Wash your hands with soap and water thoroughly.

#### 5.4 Blood Donation

No patient should donate blood during treatment (including dose interruptions) and for at least 7 days after cessation of treatment with pomalidomide.

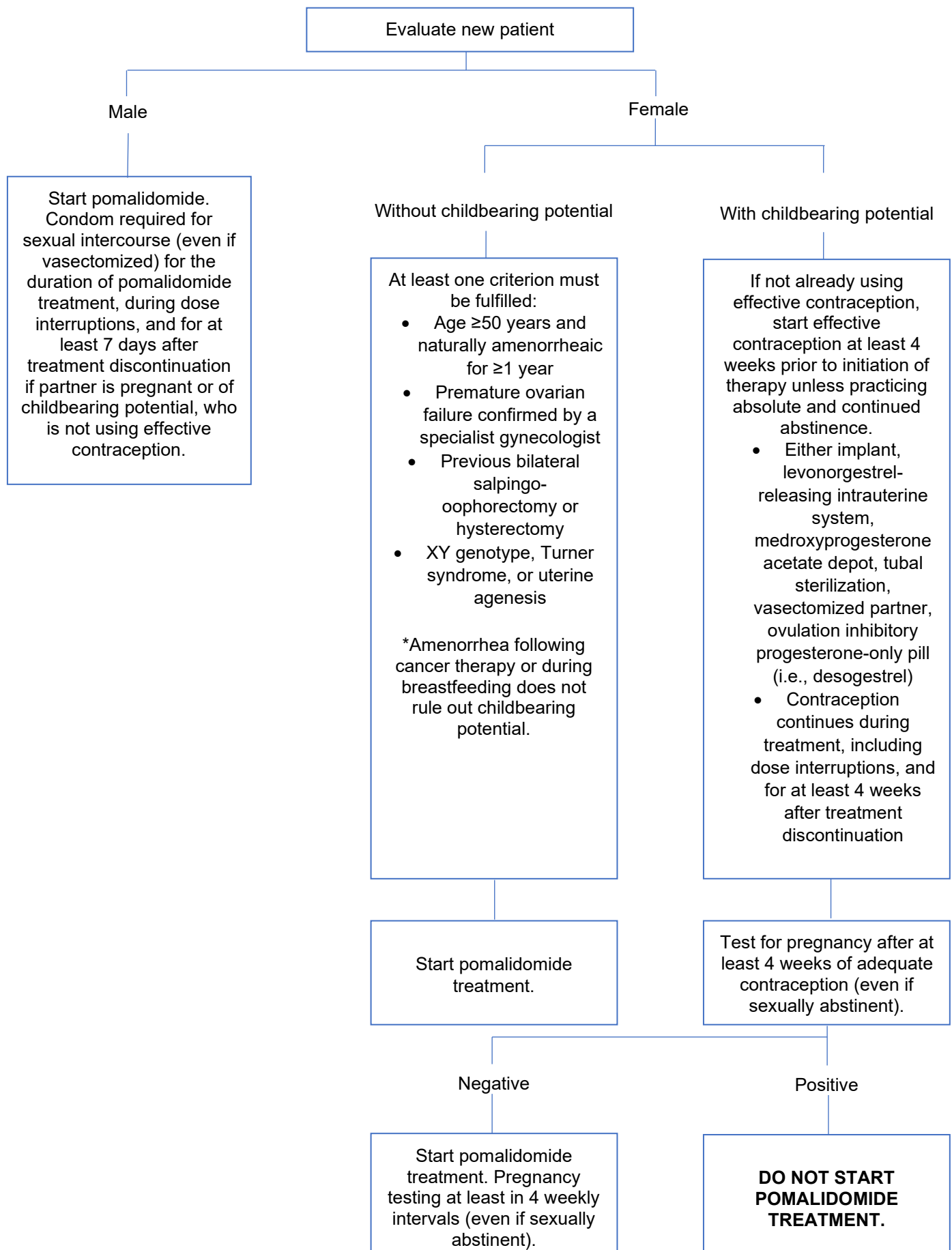
#### 6 Reporting Adverse Events, Suspected and Confirmed Pregnancy, and Fetal Exposures

The safe use of pomalidomide is of paramount importance.

Adverse events (and cases of suspected or confirmed pregnancy or fetal exposure) should be reported. Adverse Event Report forms should be forwarded to **Rowex Limited** (Rowex Limited, Tel: 0877941968, Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net)).

You can also report suspected pregnancies and adverse events online via [Malta Medicines Authority](#).

**7 Description of the PPP and Patient Categorisation Algorithm**



**8    Contact Details**

Rowex Limited

Tel: 0877941968

Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net)

**Pomalidomide Pharmacy Registration Form**  
**(Optional for Countries that require Pharmacy Registration Form implementation)**

To be completed by the Chief Pharmacist or appointed deputy

Please fill in all requested information completely. \*Fields are mandatory; incomplete information will result in a delay.

All Pharmacies completing and approving Rowex Limited Prescription Authorization forms (PAFs) and/or ordering and dispensing pomalidomide are required to complete this form.

|                                                                                                                                                                                                                                                                              |             |                                                                                      |                                     |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|--------------------------------------------------------------------------------------|-------------------------------------|
| *This form is being completed by (select as appropriate)                                                                                                                                                                                                                     |             | Chief Pharmacist <input type="checkbox"/> Deputy Pharmacist <input type="checkbox"/> |                                     |
| *Name of Pharmacist                                                                                                                                                                                                                                                          | First Name: | Surname:                                                                             |                                     |
| Pharmacist Registration Number:                                                                                                                                                                                                                                              |             |                                                                                      |                                     |
| Pharmacist Contact Details                                                                                                                                                                                                                                                   | Telephone:  | Email:                                                                               |                                     |
| <b>PHARMACY ADDRESS</b>                                                                                                                                                                                                                                                      |             |                                                                                      |                                     |
| Trust Name/Private Group/Other (enter full name):                                                                                                                                                                                                                            |             |                                                                                      |                                     |
| *Pharmacy Name:                                                                                                                                                                                                                                                              |             |                                                                                      |                                     |
| Pharmacy Registration Number (if applicable):                                                                                                                                                                                                                                |             |                                                                                      |                                     |
| *Address line 1:                                                                                                                                                                                                                                                             |             |                                                                                      |                                     |
| Address line 2:                                                                                                                                                                                                                                                              |             |                                                                                      |                                     |
| *Town/City:                                                                                                                                                                                                                                                                  | County:     | *Postcode:                                                                           |                                     |
| *Pharmacy Contact Details                                                                                                                                                                                                                                                    | Telephone:  | Email:                                                                               |                                     |
| <b>DELIVERY ADDRESS (IF DIFFERENT)</b>                                                                                                                                                                                                                                       |             |                                                                                      |                                     |
| *Address line 1:                                                                                                                                                                                                                                                             |             |                                                                                      |                                     |
| Address line 2:                                                                                                                                                                                                                                                              |             |                                                                                      |                                     |
| *Town/City:                                                                                                                                                                                                                                                                  | County:     | *Postcode:                                                                           |                                     |
| <b>*PHARMACY AGREEMENT</b>                                                                                                                                                                                                                                                   |             |                                                                                      |                                     |
| By registering the above-named pharmacy to order and dispense pomalidomide, I agree to implement and ensure compliance with the risk minimization measures associated with the Pregnancy Prevention Program (PPP) for pomalidomide and adhere to the following requirements: |             |                                                                                      | Select Box to Acknowledge Agreement |
| 1. Acknowledge receipt of the pomalidomide Healthcare Professionals' Information Pack (HCPIP) (the additional risk minimization materials (ARMMs)) provided.                                                                                                                 |             |                                                                                      | <input type="checkbox"/>            |
| 2. Confirm that all pharmacists who dispense pomalidomide will have read and understood the pomalidomide HCPIP and will ensure that pregnancy prevention measures have been implemented before dispensing pomalidomide.                                                      |             |                                                                                      | <input type="checkbox"/>            |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 3. Check that each pomalidomide prescription is provided with an associated pomalidomide Prescription Authorization Form (PAF), completed electronically via the [National electronic system] or by using the paper PAF.                                                                                                                                                                                                                                                                                                                                | ? |
| 4. Check the PAF for completeness and/or request any missing information from the prescriber and/or patient and complete the Dispensing Pharmacist section of the PAF, prior to dispensing pomalidomide.                                                                                                                                                                                                                                                                                                                                                | ? |
| 5. For <b>women of childbearing potential (WCBP)</b> , check that the PAF confirms: <ul style="list-style-type: none"> <li>a. the WCBP has been counselled/reminded about the teratogenic risk and has been on at least one effective method of contraception for at least 4 weeks</li> <li>b. the WCBP has had a negative pregnancy test within the 3 days prior to the prescription date</li> <li>c. the dispensing of pomalidomide is within 7 days of the prescription date</li> <li>d. the supply of treatment is no more than 4 weeks.</li> </ul> | ? |
| 6. For <b>male</b> patients, check that the PAF confirms: <ul style="list-style-type: none"> <li>a. the patient has been counselled/reminded about the teratogenic risk and the requirement to use a condom if sexually active with a pregnant woman or a WCBP not using effective contraception</li> <li>b. the supply of treatment is no more than 12 weeks.</li> </ul>                                                                                                                                                                               | ? |
| 7. For <b>women not of childbearing potential (WNCBP)</b> , check the supply of treatment is no more than 12 weeks.                                                                                                                                                                                                                                                                                                                                                                                                                                     | ? |
| 8. For pharmacies not completing PAFs via the [National electronic system], a copy of each completed paper PAF must be sent to Rowex Limited immediately after each pomalidomide prescription is dispensed. Pharmacies should retain the original paper PAF at the pharmacy premises for a minimum of 2 years.                                                                                                                                                                                                                                          | ? |
| 9. Should an institution utilize its own electronic systems (or paper PAF) to implement the risk minimization measures associated with the PPP, ensure that all data fields at a minimum, correspond to those that are included in the Rowex Limited PAF. Justification for use together with the proposed PAF should be provided to Rowex Limited for review and subsequent approval by the Malta Medicines Authority. <b>A copy of each completed PAF must be sent immediately to Rowex Limited.</b>                                                  | ? |
| 10. Ensure on receipt of pomalidomide, it is only dispensed to the patient by the pharmacy registered with Rowex Limited, to fulfil the requirements of the PPP for pomalidomide. <b>Wholesaling is strictly prohibited.</b>                                                                                                                                                                                                                                                                                                                            | ? |
| 11. Notify Rowex Limited immediately of changes in Chief Pharmacist or appointed Deputy Pharmacist, including their corresponding contact details in order to ensure appropriate registration of the pharmacy to order and dispense pomalidomide.                                                                                                                                                                                                                                                                                                       | ? |

**\*PHARMACIST DECLARATION**

|                                                                                                                                                                                                                                                                                                                               |   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|
| 1. I acknowledge this registration to order and dispense pomalidomide is valid for 2 years only, after which I am required to re-register the above-named pharmacy should I wish to continue to order and dispense pomalidomide.                                                                                              | ? |
| 2. I understand during the period of registration, if I am unable to fulfil requirements 1–11, the above-named pharmacy will be de-registered by Rowex Limited, and I will be unable to order any further pomalidomide and required to go through the registration process again, following any necessary remedial action(s). | ? |
| 3. I understand that my personal data will be processed by Rowex Limited for the purpose of administering the PPP for pomalidomide.                                                                                                                                                                                           | ? |

4. I understand the information supplied to Rowex Limited on PAFs will be used to provide anonymized aggregate reports to the Malta Medicines Authority to assess the implementation of the PPP.



**\*Pharmacist Signature:**

**\*Signature Date:**

Email the completed Pharmacy Registration Form to Rowex Limited, Tel: 0877941968, Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net).

[Placeholder for Information for Patient brochure]

### Risk Awareness Forms

There are three versions of this form, depending on whether your patient is a woman of childbearing potential, woman of non-childbearing potential, or male. Complete the relevant form before prescribing pomalidomide to your patients.

### Male Risk Awareness Form

#### RISK AWARENESS FORM FOR COUNSELLING THE PATIENT TO ENSURE THE PATIENT IS FULLY INFORMED ABOUT THE SAFE USE OF POMALIDOMIDE

This Risk Awareness Form is to assist you with counselling a patient before they commence pomalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each male patient prior to the initiation of their pomalidomide treatment. This form must be completed by a physician experienced in managing immunomodulatory drugs.

The purpose of the Risk Awareness Form is to protect patients and any possible fetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse drug 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 fetal exposure. It is mandatory that male patients receive counselling and education to be made aware of the risks of pomalidomide.

The form should be retained with their medical records and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding the safe use of the product and prevention of fetal exposure.

**Warning:** Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the PPP must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential. If pomalidomide is taken during pregnancy, it may cause severe birth defects or death to an unborn baby.

#### Patient Details

|                    |    |    |      |                  |    |    |      |  |  |  |  |  |
|--------------------|----|----|------|------------------|----|----|------|--|--|--|--|--|
| Patient First Name |    |    |      |                  |    |    |      |  |  |  |  |  |
| Patient Last Name  |    |    |      |                  |    |    |      |  |  |  |  |  |
| Date of Birth      | DD | MM | YYYY | Counselling date | DD | MM | YYYY |  |  |  |  |  |

#### Did you inform your patient:

|                                                                                                                                                               |      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| 1. Of the need to avoid fetal exposure                                                                                                                        | Tick |
| 2. To not share the medicinal product with any other person                                                                                                   | Tick |
| 3. That they should not donate blood during treatment) including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide | Tick |

|                                                                                                                                                                                                                             |             |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 4. That they should return the unused capsules to the pharmacist at the end of treatment                                                                                                                                    | <i>Tick</i> |
| 5. That pomalidomide is found in semen, so there is a need to use condoms if the sexual partner is pregnant or is a woman of childbearing potential not using effective contraception (even if the man has had a vasectomy) | <i>Tick</i> |
| 6. That if his partner becomes pregnant, he should inform his treating doctor immediately and always use a condom                                                                                                           | <i>Tick</i> |
| 7. That he should not donate semen during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide                                                                 | <i>Tick</i> |

#### Pregnancy Prevention

|                                                                                  |             |
|----------------------------------------------------------------------------------|-------------|
| The patient confirms that:                                                       |             |
| They will use a condom during intercourse with a woman of childbearing potential | <i>Tick</i> |
| Their female partner is using an effective method of contraception               | <i>Tick</i> |
| Their female partner is of non-childbearing potential                            | <i>Tick</i> |
| They are committed to complete and absolute abstinence                           | <i>Tick</i> |

#### Prescriber Confirmation

I have fully explained to the patient named above the nature, purpose, and risks of treatment associated with pomalidomide, especially the risks to women of childbearing potential.

I will comply with all my obligations and responsibilities as the prescribing physician of pomalidomide.

|                       |  |  |  |  |  |      |  |    |    |      |  |  |
|-----------------------|--|--|--|--|--|------|--|----|----|------|--|--|
| Prescriber First Name |  |  |  |  |  |      |  |    |    |      |  |  |
| Prescriber Last Name  |  |  |  |  |  |      |  |    |    |      |  |  |
| Prescriber Signature  |  |  |  |  |  | Date |  | DD | MM | YYYY |  |  |

#### Patient: Please read thoroughly and initial the adjacent box if you agree with the statement

|                                                                                                                                                                                                                                                                                                                                      |                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| I understand that pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects; therefore, pomalidomide is expected to be harmful to the unborn child.                                                                                                                         | <i>Patient Initials</i> |
| I understand that severe birth defects may occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide.                                                                    | <i>Patient Initials</i> |
| I understand that pomalidomide passes into human semen. If my partner is pregnant or able to become pregnant, and she does not use effective contraception, I must use condoms throughout the duration of my treatment, during dose interruptions, and for at least 7 days after I stop pomalidomide even if I have had a vasectomy. | <i>Patient Initials</i> |
| I know that I must inform my prescriber immediately if I think that my partner may be pregnant while I am taking pomalidomide or within 7 days after I have stopped taking pomalidomide, and my partner should be referred to a physician specialized or experienced in teratology for evaluation and advice.                        | <i>Patient Initials</i> |

|                                                                                                                                                                                                             |                  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.                                                                                                             | Patient Initials |
| I have read the pomalidomide Patient Brochure and understand the contents, including the information about other possible important health problems (side effects) associated with the use of pomalidomide. | Patient Initials |
| I know that I cannot donate blood while taking pomalidomide (including dose interruptions) or for at least 7 days after stopping treatment.                                                                 | Patient Initials |
| I know that I cannot donate semen or sperm while taking pomalidomide, during dose interruptions, and for at least 7 days after discontinuation of pomalidomide.                                             | Patient Initials |
| I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.                                                                                                 | Patient Initials |
| I have been informed about effective contraceptive methods that my female partner can use.                                                                                                                  | Patient Initials |
| I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.                                                                  | Patient Initials |

#### Patient Confirmation

I confirm that I understand and will comply with the requirements of the pomalidomide PPP, and I agree that my prescriber can initiate my treatment with pomalidomide.

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorization Form or PAF) will be processed by Rowex Limited, as the MAH of the pomalidomide for the purpose(s) of managing the PPP.

Your data will be kept for as long as necessary for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data, please contact your doctor or Rowex Limited. If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

|                   |  |      |    |    |      |
|-------------------|--|------|----|----|------|
| Patient Signature |  | Date | DD | MM | YYYY |
|-------------------|--|------|----|----|------|

#### Statement of the interpreter (where appropriate)

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

|                       |  |      |           |           |             |
|-----------------------|--|------|-----------|-----------|-------------|
| Interpreter Signature |  | Date | <i>DD</i> | <i>MM</i> | <i>YYYY</i> |
|-----------------------|--|------|-----------|-----------|-------------|

**Woman of Childbearing Potential Risk Awareness Form**

**RISK AWARENESS FORM FOR COUNSELLING THE PATIENT TO ENSURE THE PATIENT IS FULLY INFORMED ABOUT THE SAFE USE OF POMALIDOMIDE**

This Risk Awareness Form is to assist you with counselling a patient before they commence pomalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each female patient of childbearing potential prior to the initiation of their pomalidomide treatment. This form must be completed by a physician experienced in managing immunomodulatory drugs.

The purpose of the Risk Awareness Form is to protect patients and any possible fetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse drug 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 fetal exposure. It is mandatory that women of childbearing potential receive counselling and education to be made aware of the risks of pomalidomide, as it is contraindicated in women of childbearing potential unless all terms of counselling are met.

The form should be retained with their medical records and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding the safe use of the product and prevention of fetal exposure.

**Warning:** Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the PPP must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential. If pomalidomide is taken during pregnancy, it may cause severe birth defects or death to an unborn baby.

**Patient Details**

|                    |    |    |      |                  |  |  |  |    |    |      |  |  |
|--------------------|----|----|------|------------------|--|--|--|----|----|------|--|--|
| Patient First Name |    |    |      |                  |  |  |  |    |    |      |  |  |
| Patient Last Name  |    |    |      |                  |  |  |  |    |    |      |  |  |
| Date of Birth      | DD | MM | YYYY | Counselling date |  |  |  | DD | MM | YYYY |  |  |

**Did you inform your patient:**

|                                                                                                                                                                                                                                                                                      |      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| 1. Of the need to avoid fetal exposure                                                                                                                                                                                                                                               | Tick |
| 2. That if she is pregnant or plans to be, she must not take pomalidomide                                                                                                                                                                                                            | Tick |
| 3. 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 | Tick |
| 4. That if she needs to change or stop using her method of contraception, she should inform:<br>a) the physician prescribing her contraception that she is taking pomalidomide                                                                                                       | Tick |

|                                                                                                                                                               |             |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| b) the physician prescribing pomalidomide that she has stopped or changed her method of contraception                                                         |             |
| 5. Of the need for pregnancy tests (ie, before treatment) at least every 4 weeks during treatment and after treatment                                         | <i>Tick</i> |
| 6. Of the need to stop pomalidomide immediately upon suspicion of pregnancy                                                                                   |             |
| 7. Of the need to contact their doctor immediately upon suspicion of pregnancy                                                                                |             |
| 8. To not share the medicinal product with any other person                                                                                                   |             |
| 9. That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide |             |
| 10. That they should return the unused capsules to the pharmacist at the end of treatment                                                                     |             |

**Can you confirm your patient:**

|                                                                                                                      |            |           |
|----------------------------------------------------------------------------------------------------------------------|------------|-----------|
| 1. Was referred to a contraceptive consultant, if required?                                                          | <i>YES</i> | <i>NO</i> |
| 2. Is capable of complying with contraceptive measures?                                                              | <i>YES</i> | <i>NO</i> |
| 3. Agreed to undergo pregnancy testing at least in 4-weekly intervals unless tubal sterilization has been confirmed? | <i>YES</i> | <i>NO</i> |
| 4. Has had a negative pregnancy test before starting treatment even if practicing absolute and continued abstinence? | <i>YES</i> | <i>NO</i> |

**Contraceptive Referral**

|                                         |           |            |             |
|-----------------------------------------|-----------|------------|-------------|
| Contraceptive referral required         |           | <i>YES</i> | <i>NO</i>   |
| Contraceptive referral made             | <i>DD</i> | <i>MM</i>  | <i>YYYY</i> |
| Contraceptive consultation conducted on | <i>DD</i> | <i>MM</i>  | <i>YYYY</i> |

**Pregnancy Prevention**

|                                                                                                                      |             |
|----------------------------------------------------------------------------------------------------------------------|-------------|
| The patient has been established on one of the following for at least 4 weeks                                        |             |
| Implant                                                                                                              | <i>Tick</i> |
| Levonorgestrel-releasing intrauterine system                                                                         | <i>Tick</i> |
| Medroxyprogesterone acetate depot                                                                                    | <i>Tick</i> |
| Tubal sterilization                                                                                                  | <i>Tick</i> |
| Sexual intercourse with a vasectomized male partner only; vasectomy must be confirmed by two negative semen analyses | <i>Tick</i> |
| Ovulation inhibitory progesterone-only pills (ie, desogestrel)                                                       | <i>Tick</i> |
| Committed to complete and absolute abstinence                                                                        | <i>Tick</i> |

**Pregnancy test**

|                                      |           |           |             |
|--------------------------------------|-----------|-----------|-------------|
| Date of last negative pregnancy test | <i>DD</i> | <i>MM</i> | <i>YYYY</i> |
|--------------------------------------|-----------|-----------|-------------|

**TREATMENT FOR A WOMEN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO**

**INITIATION OF THERAPY OR COMMITS TO COMPLETE AND CONTINUED ABSTINENCE AND THE PREGNANCY TEST IS NEGATIVE!**

**Prescriber Confirmation**

I have fully explained to the patient named above the nature, purpose, and risks of treatment associated with pomalidomide, especially the risks to women of childbearing potential.

I will comply with all my obligations and responsibilities as the prescribing physician of pomalidomide.

|                       |  |  |  |  |  |      |    |    |      |  |  |  |
|-----------------------|--|--|--|--|--|------|----|----|------|--|--|--|
| Prescriber First Name |  |  |  |  |  |      |    |    |      |  |  |  |
| Prescriber Last Name  |  |  |  |  |  |      |    |    |      |  |  |  |
| Prescriber Signature  |  |  |  |  |  | Date | DD | MM | YYYY |  |  |  |

**Patient: Please read thoroughly and initial the adjacent box if you agree with the statement**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| I understand that pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects; therefore, pomalidomide is expected to be harmful to the unborn child.                                                                                                                                                                                                                                                                            | <i>Patient Initials</i> |
| I understand that severe birth defects may occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide.                                                                                                                                                                                                                       | <i>Patient Initials</i> |
| I understand that I must not take pomalidomide if I am pregnant or plan to become pregnant.                                                                                                                                                                                                                                                                                                                                                                                             | <i>Patient Initials</i> |
| I understand that I must use at least one effective method of contraception without interruption, for at least 4 weeks before starting treatment, throughout the entire duration of treatment even in case of dose interruptions, and for at least 4 weeks after the end of treatment, or commit to absolute and continuous sexual abstinence confirmed on a monthly basis. An effective method of contraception must be initiated by an appropriately trained healthcare professional. | <i>Patient Initials</i> |
| I understand that if I need to change or stop my method of contraception, I will discuss this first with the physician prescribing my contraception and the physician prescribing my pomalidomide.                                                                                                                                                                                                                                                                                      | <i>Patient Initials</i> |
| I understand that before starting pomalidomide treatment, I must have a medically supervised pregnancy test. Unless it is confirmed I have had a tubal sterilization, I will then have a pregnancy test every 4 weeks during treatment and a test at least 4 weeks after the end of treatment.                                                                                                                                                                                          | <i>Patient Initials</i> |

|                                                                                                                                                                                                                                                                   |                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| I understand that I must immediately stop taking pomalidomide and inform my prescriber if I become pregnant while taking this drug, if I miss my menstrual period or experience any unusual menstrual bleeding, if I think FOR ANY REASON that I may be pregnant. | <i>Patient<br/>Initials</i> |
| I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.                                                                                                                                                                   | <i>Patient<br/>Initials</i> |
| I have read the pomalidomide Patient Brochure and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.                                                                 | <i>Patient<br/>Initials</i> |
| I know that I cannot donate blood while taking pomalidomide (including dose interruptions) or for at least 7 days after stopping treatment.                                                                                                                       | <i>Patient<br/>Initials</i> |
| I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.                                                                                                                                                       | <i>Patient<br/>Initials</i> |
| I understand that even if I have amenorrhea, I must comply with advice on contraception.                                                                                                                                                                          | <i>Patient<br/>Initials</i> |
| I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.                                                                                                                        | <i>Patient<br/>Initials</i> |

#### Patient Confirmation

I confirm that I understand and will comply with the requirements of the pomalidomide PPP, and I agree that my prescriber can initiate my treatment with pomalidomide.

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorization Form or PAF) will be processed by Rowex Limited, as the MAH of pomalidomide for the purpose(s) of managing the PPP. Your data will be kept for as long as necessary for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data, please contact your doctor or Rowex Limited, at Rowex Limited, Tel: 0877941968, Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net). If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

|                   |  |      |           |           |             |
|-------------------|--|------|-----------|-----------|-------------|
| Patient Signature |  | Date | <i>DD</i> | <i>MM</i> | <i>YYYY</i> |
|-------------------|--|------|-----------|-----------|-------------|

**Statement of the interpreter (where appropriate)**

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

|                       |  |      |           |           |             |
|-----------------------|--|------|-----------|-----------|-------------|
| Interpreter Signature |  | Date | <i>DD</i> | <i>MM</i> | <i>YYYY</i> |
|-----------------------|--|------|-----------|-----------|-------------|

**Woman of Non-Childbearing Potential Treatment Initiation Form**

**RISK AWARENESS FORM FOR COUNSELLING THE PATIENT TO ENSURE THE PATIENT IS FULLY INFORMED ABOUT THE SAFE USE OF POMALIDOMIDE**

This Risk Awareness Form is to assist you with counselling a patient before they commence pomalidomide treatment in order to ensure it is used safely and correctly. It must be completed for each woman of non-childbearing potential prior to the initiation of their pomalidomide treatment. This form must be completed by a physician experienced in managing immunomodulatory drugs.

The purpose of the Risk Awareness Form is to protect patients and any possible fetuses by ensuring that patients are fully informed of and understand the risk of teratogenicity and other adverse drug 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 fetal exposure. It is mandatory that women of non-childbearing potential receive counselling and education to be made aware of the risks of pomalidomide.

The form should be retained with their medical records and a photocopy provided to the patient. It is not a contract and does not absolve anybody from his/her responsibilities regarding the safe use of the product and prevention of fetal exposure.

**Warning:** Pomalidomide must not be taken during pregnancy, since a teratogenic effect in humans is expected. Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. The conditions of the PPP must be fulfilled for all patients unless there is reliable evidence that the patient does not have childbearing potential.

If pomalidomide is taken during pregnancy, it may cause severe birth defects or death to an unborn baby.

**Patient Details**

|                    |    |    |      |                  |  |  |  |    |    |      |  |  |
|--------------------|----|----|------|------------------|--|--|--|----|----|------|--|--|
| Patient First Name |    |    |      |                  |  |  |  |    |    |      |  |  |
| Patient Last Name  |    |    |      |                  |  |  |  |    |    |      |  |  |
| Date of Birth      | DD | MM | YYYY | Counselling date |  |  |  | DD | MM | YYYY |  |  |

**Did you inform your patient:**

|                                                                                                                                                               |      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| 1. To not share the medicinal product with any other person                                                                                                   | Tick |
| 2. That they should not donate blood during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide | Tick |
| 3. That they should return the unused capsules to the pharmacist at the end of treatment                                                                      | Tick |

**Prescriber Confirmation**

I have fully explained to the patient named above the nature, purpose, and risks of treatment associated with pomalidomide, especially the risks to women of childbearing potential.

I will comply with all my obligations and responsibilities as the prescribing physician of pomalidomide.

|                       |  |  |  |  |  |      |    |    |      |  |  |  |
|-----------------------|--|--|--|--|--|------|----|----|------|--|--|--|
| Prescriber First Name |  |  |  |  |  |      |    |    |      |  |  |  |
| Prescriber Last Name  |  |  |  |  |  |      |    |    |      |  |  |  |
| Prescriber Signature  |  |  |  |  |  | Date | DD | MM | YYYY |  |  |  |

**Patient: Please read thoroughly and initial the adjacent box if you agree with the statement**

|                                                                                                                                                                                                                                                                   |                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| I understand that pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects; therefore, pomalidomide is expected to be harmful to the unborn child.                                                      | <i>Patient<br/>Initials</i> |
| I understand that severe birth defects can occur with the use of pomalidomide. I have been warned by my prescriber that any unborn baby has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking pomalidomide. | <i>Patient<br/>Initials</i> |
| I have read the pomalidomide Patient Brochure and understand the contents, including the information about other possible health problems (side effects) associated with the use of pomalidomide.                                                                 | <i>Patient<br/>Initials</i> |
| I understand that pomalidomide will be prescribed ONLY for me. I must not share it with ANYONE.                                                                                                                                                                   | <i>Patient<br/>Initials</i> |
| I know that I cannot donate blood while taking pomalidomide (including dose interruptions) or for at least 7 days after stopping treatment.                                                                                                                       | <i>Patient<br/>Initials</i> |
| I understand that I must return any unused pomalidomide capsules to my pharmacy at the end of my treatment.                                                                                                                                                       | <i>Patient<br/>Initials</i> |
| I have been informed about the thromboembolic risk and possible requirement to take thromboprophylaxis during treatment with pomalidomide.                                                                                                                        | <i>Patient<br/>Initials</i> |

**Patient Confirmation**

I confirm that I understand and will comply with the requirements of the pomalidomide PPP, and I agree that my prescriber can initiate my treatment with pomalidomide.

This form will be kept by your doctor. Your personal data (collected on the Prescription Authorization form or PAF) will be processed by Rowex Limited, as the MAH of pomalidomide for the purpose(s) of managing the PPP.

Your data will be kept for as long as necessary for the purposes of compliance with the Risk Management Plan legal obligations and for storage purposes.

Should you have any queries in relation to the use of your personal data, please contact your doctor or Rowex Limited, at Rowex Limited, Tel: 0877941968, Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net). If you are unhappy about how your personal data is being processed, you have the right to lodge a complaint with the supervisory authority.

|                   |  |      |           |           |             |
|-------------------|--|------|-----------|-----------|-------------|
| Patient Signature |  | Date | <i>DD</i> | <i>MM</i> | <i>YYYY</i> |
|-------------------|--|------|-----------|-----------|-------------|

**Statement of the interpreter (where appropriate)**

I have interpreted the information above to the patient/parent to the best of my ability and in a way in which I believe she/he/they can understand. She/he/they agree to follow the necessary precautions to prevent an unborn child being exposed to pomalidomide.

|                       |  |      |           |           |             |
|-----------------------|--|------|-----------|-----------|-------------|
| Interpreter Signature |  | Date | <i>DD</i> | <i>MM</i> | <i>YYYY</i> |
|-----------------------|--|------|-----------|-----------|-------------|

### A Guide to Completing the Prescription Authorization Form (PAF)

This guide will help you to complete the pomalidomide PAF. For prescribers and pharmacists not utilizing the [National electronic system], this form is available here.

| TO BE COMPLETED BY PRESCRIBING HEALTHCARE PROFESSIONAL                                                                                                                                                                                                                                                                                                                                                                     |             |          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|----------|
| <b>1. Prescriber Contact Details</b>                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| Full Name of Prescriber                                                                                                                                                                                                                                                                                                                                                                                                    | First Name: | Surname: |
| Supervising Physician                                                                                                                                                                                                                                                                                                                                                                                                      | First Name: | Surname: |
| Full Name of Prescribing Institution                                                                                                                                                                                                                                                                                                                                                                                       | Postcode:   |          |
| Prescriber Telephone/Pager Number:                                                                                                                                                                                                                                                                                                                                                                                         |             |          |
| <b>2. Please verify if this PAF is for an initial or subsequent prescription of pomalidomide—only tick one box</b>                                                                                                                                                                                                                                                                                                         |             |          |
| <input type="checkbox"/> Initial prescription (full teratogenic risk counselling)                                                                                                                                                                                                                                                                                                                                          |             |          |
| <input type="checkbox"/> Subsequent prescription (reminder teratogenic risk)                                                                                                                                                                                                                                                                                                                                               |             |          |
| <b>3. Patient Initials (First/Middle/Last):</b>                                                                                                                                                                                                                                                                                                                                                                            |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <b>4. Patient Date of Birth (DD/MM/YYYY):</b>                                                                                                                                                                                                                                                                                                                                                                              |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <b>5. Prescription Date (DD/MM/YYYY):</b>                                                                                                                                                                                                                                                                                                                                                                                  |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <b>6. Total Supply Prescribed:</b>                                                                                                                                                                                                                                                                                                                                                                                         |             |          |
| <input type="checkbox"/> 4 weeks <input type="checkbox"/> 8 weeks <input type="checkbox"/> 12 weeks                                                                                                                                                                                                                                                                                                                        |             |          |
| Other—please enter number of weeks: <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                   |             |          |
| <b>7. Indication:</b>                                                                                                                                                                                                                                                                                                                                                                                                      |             |          |
| <input type="checkbox"/> Licensed                                                                                                                                                                                                                                                                                                                                                                                          |             |          |
| <input type="checkbox"/> Unlicensed—specify indication below:                                                                                                                                                                                                                                                                                                                                                              |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <b>8. Patient Risk Category:</b>                                                                                                                                                                                                                                                                                                                                                                                           |             |          |
| <input type="checkbox"/> Woman of Childbearing Potential (WCBP)                                                                                                                                                                                                                                                                                                                                                            |             |          |
| <input type="checkbox"/> Male (Please proceed to section 9, 10a, & 11)                                                                                                                                                                                                                                                                                                                                                     |             |          |
| <input type="checkbox"/> Woman of Non-Childbearing Potential (WNCBP)                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <input type="checkbox"/> (Please proceed to section 11)                                                                                                                                                                                                                                                                                                                                                                    |             |          |
| <b>9. WCBP Pregnancy Test Date*</b>                                                                                                                                                                                                                                                                                                                                                                                        |             |          |
| (DD/MM/YYYY):                                                                                                                                                                                                                                                                                                                                                                                                              |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <b>Pregnancy Test Result:</b>                                                                                                                                                                                                                                                                                                                                                                                              |             |          |
| <input type="checkbox"/> Negative <input type="checkbox"/> Positive*                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <input type="checkbox"/> Inconclusive*                                                                                                                                                                                                                                                                                                                                                                                     |             |          |
| <input type="checkbox"/> Test not done*—Please provide reason                                                                                                                                                                                                                                                                                                                                                              |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| *DO NOT prescribe if positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilization) or pregnancy test date is more than 3 days before prescription date.                                                                                                                                                                                                              |             |          |
| <b>10. Patient Counselling: Only tick box(es) for applicable patient risk category</b>                                                                                                                                                                                                                                                                                                                                     |             |          |
| <b>10a. WCBP:</b>                                                                                                                                                                                                                                                                                                                                                                                                          |             |          |
| <input type="checkbox"/> The WCBP has been initially counselled and reminded about the expected teratogenic risk of pomalidomide and the need to avoid pregnancy.                                                                                                                                                                                                                                                          |             |          |
| <input type="checkbox"/> The WCBP has been on at least one effective method of contraception for at                                                                                                                                                                                                                                                                                                                        |             |          |
| least 4 weeks (includes male partners who have had a vasectomy, which must be confirmed by two negative semen tests, as well as absolute and continuous abstinence from heterosexual intercourse confirmed on a monthly basis).                                                                                                                                                                                            |             |          |
| <b>10b. Male:</b>                                                                                                                                                                                                                                                                                                                                                                                                          |             |          |
| <input type="checkbox"/> The male patient has been initially counselled and reminded about the expected teratogenic risk of pomalidomide and understands the need to use a condom, if involved in sexual activity with a pregnant woman or a WCBP not using effective contraception (even if the male patient has had a vasectomy).                                                                                        |             |          |
| <b>11. Prescriber's Declaration:</b> As the Prescriber, I have read and understood the Healthcare Professionals' Information Pack. I confirm the information provided on this PAF is accurate, complete, and in accordance with the requirements of the PPP for pomalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs. |             |          |
| <b>11a. Prescriber Signature:</b>                                                                                                                                                                                                                                                                                                                                                                                          |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <b>11b. Signature Date (DD/MM/YYYY):</b>                                                                                                                                                                                                                                                                                                                                                                                   |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| APPROVAL TO BE COMPLETED BY PHARMACIST                                                                                                                                                                                                                                                                                                                                                                                     |             |          |
| <b>12. Pharmacy Contact Details</b>                                                                                                                                                                                                                                                                                                                                                                                        |             |          |
| Full Name of Pharmacist                                                                                                                                                                                                                                                                                                                                                                                                    | First Name: | Surname: |
| Full Name of Pharmacy:                                                                                                                                                                                                                                                                                                                                                                                                     | Postcode:   |          |
| <b>13. Name and postcode of Third-Party Dispensing Pharmacy/Home Delivery (Please complete only if applicable)</b>                                                                                                                                                                                                                                                                                                         |             |          |
| Name:                                                                                                                                                                                                                                                                                                                                                                                                                      | Postcode:   |          |
| <b>14. Dispensing Date (DD/MM/YYYY):</b>                                                                                                                                                                                                                                                                                                                                                                                   |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| DO NOT dispense if pregnancy test is positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilization), or as follows:                                                                                                                                                                                                                                                   |             |          |
| For WCBP, do not dispense pomalidomide unless negative pregnancy test was conducted within 3 days of the prescription date and dispensing is taking place within 7 days of the prescription date. No more than a 4-week supply to a WCBP and a 12-week supply to a male patient or a WNCBP should be dispensed.                                                                                                            |             |          |
| <b>15. Pharmacist Confirmation</b>                                                                                                                                                                                                                                                                                                                                                                                         |             |          |
| Information that was not completed by the Prescriber and is required to fulfil the PPP for pomalidomide has been received by the Pharmacist via other routes, or verbally confirmed by the Prescriber and/or patient and documented in this form.                                                                                                                                                                          |             |          |
| Note: To indicate any changes/corrections made in the PAF, please add your initials and date against the changes and tick "Yes."                                                                                                                                                                                                                                                                                           |             |          |
| <input type="checkbox"/> Yes <input type="checkbox"/> Not Applicable                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <b>16. Pharmacist's Declaration:</b> As the Pharmacist, I have read and understood the Healthcare Professionals' Information Pack. I confirm the information provided on this PAF is accurate, complete, and in accordance with the requirements of the PPP for pomalidomide.                                                                                                                                              |             |          |
| <b>16a. Pharmacist Signature:</b>                                                                                                                                                                                                                                                                                                                                                                                          |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |
| <b>16b. Signature Date (DD/MM/YYYY):</b>                                                                                                                                                                                                                                                                                                                                                                                   |             |          |
| <input type="text"/>                                                                                                                                                                                                                                                                                                                                                                                                       |             |          |

#### Instructions for prescribers

1. Print your name clearly.  
Print the name of the Supervising Physician (if you are a non-physician prescriber), ie, the physician experienced in managing immunomodulatory drugs and supervising treatment.
2. Tick the appropriate box specifying whether this is an initial or subsequent prescription.
3. Enter the patient's initials.
4. Enter the patient's date of birth.
5. This refers to the date the prescription is authorized by the prescriber and not the date the patient is due to start treatment.
6. Please specify the total supply prescribed for this prescription. Four weeks would equate to a 4-week cycle.
7. Please specify whether pomalidomide is being used to treat a licensed or an unlicensed indication. If unlicensed, please specify the indication in the form.
8. Please specify whether the patient is a woman of childbearing potential (WCBP), male, or woman of non-childbearing potential (WNCBP).
9. For WCBP, you must provide a valid negative pregnancy test date (within 3 days prior to the

prescription date). If this is not the case, pomalidomide must not be dispensed.

10. Complete this section appropriately to indicate that counselling and appropriate use of contraception has occurred. This is a requirement of the Pregnancy Prevention Program (PPP).
11. You must sign, date, and print your name to declare that the information provided on the form is accurate, complete, and in accordance with the requirements of the PPP.

#### Instructions for pharmacists

12. Enter your full name and the full name and postcode of the pharmacy.

13. If applicable, complete the Third-Party Dispensing Pharmacy/Home Delivery information.
14. Please specify the date pomalidomide was dispensed. Prior to dispensing, please check that all relevant sections of the form have been fully completed by the prescriber.
  - Counselling and contraception measures must be in place.
  - Prescription must be accompanied by an accurately completed PAF.
  - For WCBP, pomalidomide can only be dispensed within 7 days of the prescription date.
  - Only a maximum of a 4-week supply for WCBP, or a maximum of a 12-week supply for all other patients, of pomalidomide can be dispensed at any one time.
15. Please specify whether there were any changes made to the PAF. To indicate any changes/corrections made in the PAF, please add your initials and date against the changes and indicate "Yes" in the pharmacist confirmation section.
16. You must sign, date, and print your name to declare that the information provided on this form is accurate, complete, and in accordance with the PPP. Email all completed PAFs to Rowex Limited, Tel: 0877941968, Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net) immediately after dispensing.

**Further information and materials are available from [Rowex Limited](#)**

**Pomalidomide Prescription Authorization Form (PAF)**  
**(optional for countries that require PAF implementation)**

A newly completed copy of this form **MUST** accompany **EVERY** pomalidomide prescription for **ALL** patients in accordance with the pomalidomide Pregnancy Prevention Program (PPP), mandated by <regulatory agency>. Email all completed PAFs to Rowex Limited, Tel: 0877941968, Email: adverse.event.ireland@sandoz.net immediately after dispensing.

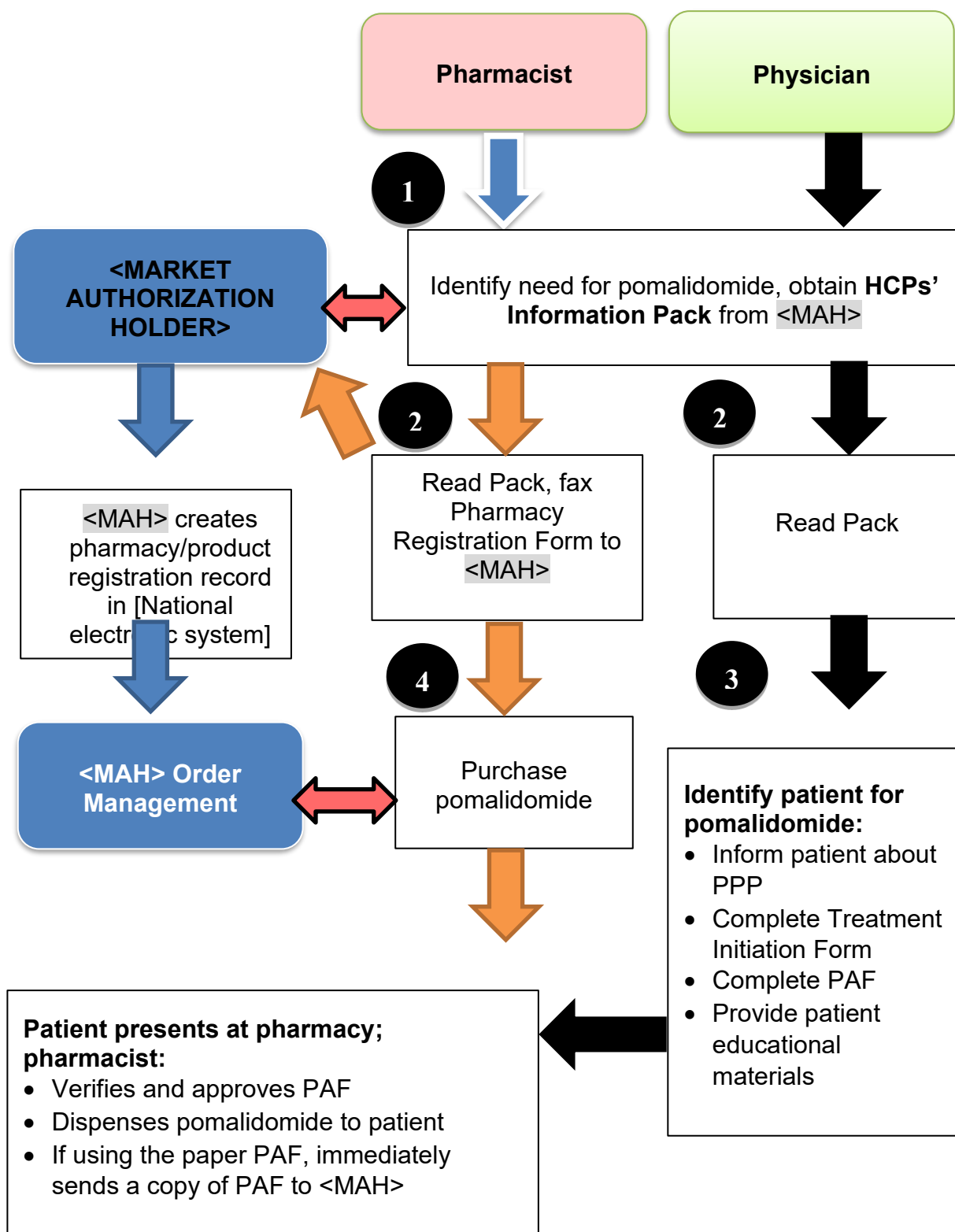
| TO BE COMPLETED BY PRESCRIBING HEALTHCARE PROFESSIONAL                                                                                                                                                                                                                                                                                                                                                         |             |                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Prescriber Contact Details</b>                                                                                                                                                                                                                                                                                                                                                                           |             |                                                                                                                                                                                                                                                                                                                           |
| Full Name of Prescriber                                                                                                                                                                                                                                                                                                                                                                                        | First Name: | Surname:                                                                                                                                                                                                                                                                                                                  |
| Supervising Physician                                                                                                                                                                                                                                                                                                                                                                                          | First Name: | Surname:                                                                                                                                                                                                                                                                                                                  |
| Full Name of Prescribing Institution                                                                                                                                                                                                                                                                                                                                                                           | Postcode:   |                                                                                                                                                                                                                                                                                                                           |
| Prescriber Telephone/Pager Number:                                                                                                                                                                                                                                                                                                                                                                             |             |                                                                                                                                                                                                                                                                                                                           |
| <b>2. Please verify if this PAF is for an initial or subsequent prescription of pomalidomide—only tick one box</b><br><input type="checkbox"/> Initial prescription (full teratogenic risk counselling)<br><input type="checkbox"/> Subsequent prescription (reminder teratogenic risk)                                                                                                                        |             |                                                                                                                                                                                                                                                                                                                           |
| <b>3. Patient Initials</b> (First/Middle/Last):<br><div> <div></div> <div></div> <div></div> <div></div> <div></div> </div>                                                                                                                                                                                                                                                                                    |             | <b>4. Patient Date of Birth</b> (DD/MMM/YYYY):<br><div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div>                                                                                                                                    |
| <b>5. Prescription Date</b> (DD/MMM/YYYY):<br><div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div>                                                                                                                                                                                                                             |             | <b>6. Total Supply Prescribed:</b><br><input type="checkbox"/> 4 weeks <input checked="" type="checkbox"/> 8 weeks <input type="checkbox"/> 12 weeks<br>Other—please enter number of weeks: <div></div>                                                                                                                   |
| <b>7. Indication:</b><br><input type="checkbox"/> Licensed<br><input type="checkbox"/> Unlicensed—specify indication below:<br><div></div>                                                                                                                                                                                                                                                                     |             | <b>8. Patient Risk Category:</b><br><input type="checkbox"/> Woman of Childbearing Potential (WCBP) (Please proceed to section 9, 10a, & 11)<br><input type="checkbox"/> Male (Please proceed to section 10b & 11)<br><input type="checkbox"/> Woman of Non-Childbearing Potential (WNCBP) (Please proceed to section 11) |
| <b>9. WCBP Pregnancy Test Date*</b><br>(DD/MMM/YYYY):<br><div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> <div></div> </div><br>*DO NOT prescribe if positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilization) or pregnancy test date is more than 3 days before prescription date. |             | <b>Pregnancy Test Result:*</b><br><input type="checkbox"/> Negative <input checked="" type="checkbox"/> Positive*<br><input type="checkbox"/> Inconclusive*<br><input type="checkbox"/> Test not done*—Please provide reason<br><div></div>                                                                               |
| <b>10. Patient Counselling: Only tick box(es) for applicable patient risk category</b>                                                                                                                                                                                                                                                                                                                         |             |                                                                                                                                                                                                                                                                                                                           |
| <b>10a. WCBP:</b><br><input type="checkbox"/> The WCBP has been initially counselled and reminded about the expected teratogenic risk of pomalidomide and the need to avoid pregnancy.                                                                                                                                                                                                                         |             | <b>10b. Male:</b><br><input type="checkbox"/> The male patient has been initially counselled and reminded about the expected teratogenic risk of pomalidomide and understands the need to use a condom, if involved in sexual activity with a pregnant                                                                    |

|                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> The WCBP has been on at least one effective method of contraception for at least 4 weeks (includes male partners who have had a vasectomy, which must be confirmed by two negative semen tests; as well as absolute and continuous abstinence from heterosexual intercourse confirmed on a monthly basis).                                                                                        | woman or a WCBP not using effective contraception (even if the male patient has had a vasectomy).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>11. Prescriber's Declaration:</b> As the Prescriber, I have read and understood the Healthcare Professionals' Information Pack. I confirm the information provided on this PAF is accurate, complete, and in accordance with the requirements of the PPP for pomalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>11a. Prescriber Signature:</b><br><div style="border: 1px solid black; height: 20px; width: 100%;"></div>                                                                                                                                                                                                                                                                                                               | <b>11b. Signature Date (DD/MMM/YYYY):</b><br><div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 2px;">D</div> <div style="border: 1px solid black; padding: 2px;">D</div> <div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div> </div> |

| APPROVAL TO BE COMPLETED BY PHARMACIST                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| <b>12. Pharmacy Contact Details</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |           |
| Full Name of Pharmacist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | First Name:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Surname:  |
| Full Name of Pharmacy:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Postcode:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |           |
| <b>13. Name and postcode of Third-Party Dispensing Pharmacy/Home Delivery</b> (Please complete only if applicable)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |           |
| Name:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Postcode: |
| <b>14. Dispensing Date (DD/MMM/YYYY):</b><br><div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 2px;">D</div> <div style="border: 1px solid black; padding: 2px;">D</div> <div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div> </div> <p>DO NOT dispense if pregnancy test is positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilization), or as follows:<br/>         For WCBP, do not dispense pomalidomide unless negative pregnancy test was conducted within 3 days of the prescription date and dispensing is taking place within 7 days of the prescription date. No more than a 4-week supply to a WCBP and a 12-week supply to a male patient or a WNCBP should be dispensed.</p> | <b>15. Pharmacist Confirmation</b><br>Information that was not completed by the Prescriber and is required to fulfil the PPP for pomalidomide has been received by the Pharmacist via other routes, or verbally confirmed by the Prescriber and/or patient and documented in this form.<br>Note: To indicate any changes/corrections made in the PAF, please add your initials and date against the changes and tick "Yes."<br><br><input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable                                                                                                                                                          |           |
| <b>16. Pharmacist's Declaration:</b> As the Pharmacist, I have read and understood the Healthcare Professionals' Information Pack. I confirm the information provided on this PAF is accurate, complete, and in accordance with the requirements of the PPP for pomalidomide.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |           |
| <b>16a. Pharmacist Signature:</b><br><div style="border: 1px solid black; height: 20px; width: 100%;"></div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>16b. Signature Date (DD/MMM/YYYY):</b><br><div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 2px;">D</div> <div style="border: 1px solid black; padding: 2px;">D</div> <div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">M</div> <div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div> <div style="border: 1px solid black; padding: 2px;">Y</div> </div> |           |



## Pharmacy Registration and Dispensing of Pomalidomide



\*HCP kit includes HCP brochure, patient brochure and risk awareness forms.

Please refer to associated files (risk awareness forms, patient brochure) separately.

HCPs are asked to report any suspected adverse drug reactions via the [www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt).

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### Frequently Asked Questions (FAQs)

#### **Where can I get further copies of the pomalidomide HCPs' Information Pack or the patient materials?**

If you would like further copies of the pomalidomide HCPs' Information Pack or any other materials for HCPs or patients, please telephone or email Rowex Limited using the contact details below, or speak to any Rowex Limited representative.

Rowex Limited

Tel: 0877941968

Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net)

#### **How should I report an adverse event or a suspected pregnancy?**

Adverse events and suspected pregnancies should be reported to Rowex Limited. Completed form should be forwarded to the Rowex Limited and the Malta Medicines Authority using the contact details below:

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,  
Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta

Website:

[www.medicinesauthority.gov.mt](http://www.medicinesauthority.gov.mt)

e-mail: [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

OR

Marketing Authorisation Holder:

Rowex Limited

Tel: 0877941968

Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net)

Suspected adverse reactions can be reported to the Malta Medicines Authority using the online system.

To contact Rowex Limited, please telephone or email the Medical Information department using the contact details below:

Tel: 0877941968

Email: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net)

#### **What are the maximum prescription durations for each different patient category?**

The maximum prescription duration for a WCBP is 4 weeks. The maximum prescription duration for a male patient and a WNCBP is 12 weeks.