▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Pomalidomide Adverse Event Form

This form must be returned to the MAH who provided the product. Please see contact details below:

NOTE: Please use the first three letters of the month (e.g.: JAN)

○ New ○ Follow-up

Case No:

For MAH use only

Date of receipt: DD MM YYYY

Received by: (Name and organization – eg CRO, or company representative)

Source: ○ Spontaneous ○ Comp. Use ○ Lit. ○ Other, specify

Suspect Drug

Drug, Dosage-form, Strength, Route (Drug, Dosage-form, Strength, Route) (eg. Tab 5mg, oral)	Dose & frequency	Lot/ Batch no.	Therapy start date: DD/ MM / YYYY	Therapy stop date: DD/ MM / YYYY	Drug-Event Causal relationship Other, Specify (Causal relationship 1 = Not related, 2 = Related)	Indication for use of drug
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		
			/ /	/ /		

Action Taken

○ None ○ Unknown ○ Not Applicable
○ Dose decreased, specify ○ Permanently discontinued
○ Dose increased, specify ○ Temporarily interrupted

Patient Data

Initials: Date of Birth: DD MM YYYY

Weight: kg Height: cm Gender ○ Male ○ Female

Adverse Event

Description of Adverse Event (provide diagnosis if available) - symptoms and treatment:

Event onset date: DD MM YYYY

Event stop date: DD MM YYYY

Outcome of Adverse Event

○ Recovered
○ Recovered with sequelae
○ Not recovered
○ Unknown
○ Death

Date of death: DD MM YYYY

Cause(s) of death:

Did the event result in hospitalization or prolonged hospitalization? ○ Yes ○ No

If autopsy is performed please forward report.
Please attach relevant clinical laboratory assessments to confirm the event.

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Case No:	

Medical History

◯ Yes (if yes, please specify)
◯ None
◯ Unknown

Other Medication (Medication taken during the last 3 months prior to the event)

Drug, Dosage-form, Strength, Route (Drug, Dosage-form, Strength, Route) (eg. Tab 5mg, oral)	Dose & frequency	Therapy Start date: *DD / MM /YYYY*	Therapy Stop date: *DD / MM /YYYY*	Indication for use of drug
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Has the patient discussed this event with their healthcare professional? ◯ Yes (if yes, would you please provide their healthcare professional's contact information below) ◯ No ◯ Unknown

Healthcare professional's contact information

Name:		Country:	
Address:		Fax:	
		Phone:	
		Email:	

Reporter

◯ Physician ◯ Nurse ◯ Pharmacist ◯ Patient ◯ Relative ◯ Other, please specify

Name:		Country:	
Address:		Fax:	
		Phone:	
		Email:	

Pharmacy Name (if applicable)

Name:		Email:	

Signature

Sign:		Date of AE awareness:	*DD*	*MM*	*YYYY*

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NOTE: Please use the first three letters of the month (e.g.: JAN)

Case No:	

Drug Safety Data Privacy notice

Your personal data will be processed by the relevant marketing authorisation holder, and its worldwide affiliates, to the extent and for as long as necessary, for the purposes of the compliance with drug safety legal obligations and for storage purposes. If you have any questions related to data privacy, want to contact a Data Protection Officer, or wish to exercise your rights of access, rectification, erasure, and/or restriction (as applicable), please contact the relevant marketing authorisation holder listed below. Learn more about how your personal data is processed, shared, stored, transferred, and retained by accessing the applicable privacy policy on the websites below.

This section applies only if the reporter is the patient or anyone but the prescriber/physician/HCP. Please chose one, as applicable:

◯ I grant the MAH permission to contact the prescriber/physician/HCP who treated me/the affected patient when the side effect(s) occurred and authorise him/her to provide data from my medical record related to the event(s) occurred.

◯ No, I do not grant the MAH permission to contact the prescriber/physician/HCP who treated me/the patient.

If you grant the MAH permission, please provide the information of the prescriber/physician/HCP

Contact information

Name:		Country:	
Address:		Fax:	
		Phone:	
		Email:	