Lenalidomide (Omdegzi)
Event-Specific Questionnaire for HCP - Pregnancy Outcome Form
(Patient or Partner of Patient)

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)

Reporter information

Reporter Name:	
Address:	
City, County, Country:	
Phone No.:	
Fax No.:	

Patient information

Patient ID:		Date of delivery:	D D M O N Y Y Y Y

Ethnicity:

Partner of patient information

◯ Not applicable

Ethnicity:

Pregnancy outcome

Date of delivery:	D D M O N Y Y Y Y	Gestation age at delivery:	

Normal No ◯ Yes ◯

C-section No ◯ Yes ◯

Induced No ◯ Yes ◯

Ectopic pregnancy No ◯ Yes ◯

Elective termination No ◯ Yes ◯

Date:	D D M O N Y Y Y Y
Weeks from LMP:	

Spontaneous abortion (≤20 weeks) No ◯ Yes ◯

Foetal death/stillbirth (>20 weeks) No ◯ Yes ◯

Were the products of conception Examined? No ◯ Yes ◯ If yes, was the foetus normal? ◯ No ◯ Yes ◯ Unknown If no, describe below:

This document has been reviewed and approved by The Saudi Food and Drug Authority

November,2025

Ver. no. 0001

Obstetrics information

Complications during pregnancy	No ◯ Yes ◯	If yes, please specify
Complication during labor/delivery	No ◯ Yes ◯	If yes, please specify
Post-partum maternal complications	No ◯ Yes ◯	If yes, please specify

Foetal Outcome

Live normal infant	No ◯ Yes ◯	
Foetal distress	No ◯ Yes ◯	
Intra-uterine growth retardation.	No ◯ Yes ◯	
Neonatal compilation	No ◯ Yes ◯	If yes, please specify
Birth Defect Noted ?	No ◯ Yes ◯	If yes, please specify

Sex: ◯ Male ◯ Female Birth Weight :____lbs____oz or ____Kg Length:____inch or ____cm

Apgar Score: 1 min:____ 5min:____ 10min:____ ◯ Unknown

Signature of Person completing this form

Signature :		Date:	D	D	M	O	N	Y	Y	Y	Y

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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. Should you have any queries in relation to the use of your personal data please contact the relevant marketing authorisation holder.

Reporter's Signature (required):

Signature:	Date signed:	D	D	M	O	N	Y	Y	Y	Y

Thank you for providing information that will assist us in our commitment to patient safety.

Alpha Pharma Drug Safety at the number/address below:

Tell: +966 11 293 1773 Ext: 111
Mobile: +966 53 040 8553 (24/7)
Alpha Pharma Industries, Al-Akaria 2nd, 4th floor, office No. 422, Olaya steet,Al-Olaya district, Riyadh, Saudi Arabia.
Email: pv@alphapharma.com.sa
Website: https://alphapharma.com.sa/
Or
The National Pharmacovigilance Centre (NPC)
Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Online: https://ade.sfda.gov.sa

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