

# Pomalidomide Krka (pomalidomide) Event-Specific Questionnaire for HCP - Pregnancy Outcome Form

This form must be returned to KRKA, d.d., Novo mesto; Telephone: +353 1 413 3710; Email: pharmacovigilance.IE@krka.biz

Reporter's Information			
Reporter's Name:			Email:
Reporter's Profession:			Telephone number:
Address:			Fax number:
Patients Information			
Patient's ID:	Date of birth: DD MM YYYY	Ethnicity:	
		<input type="checkbox"/> White	<input type="checkbox"/> African-Caribbean <input type="checkbox"/> Other, specify:
Partners of patients Information			
<input type="checkbox"/> Not applicable	Ethnicity:	<input type="checkbox"/> White	<input type="checkbox"/> African-Caribbean <input type="checkbox"/> Other, specify:
Pregnancy Outcome			
Date of delivery:	DD MM YYYY	Gestation age of delivery:	DD MM YYYY
Normal	<input type="checkbox"/> No <input type="checkbox"/> Yes		
C-section	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Induced	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Ectopic pregnancy	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Elective termination	<input type="checkbox"/> No <input type="checkbox"/> Yes	Date: DD MM YYYY	
Spontaneous abortion (≤20 weeks)	<input type="checkbox"/> No <input type="checkbox"/> Yes	Weeks from LMP:	
Foetal death/stillbirth (>20 weeks)	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Were the products of conception examined?	<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, was the foetus normal? If no describe below/Unknown	
Obstetrics Information			
Complications during pregnancy	<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, please specify:	
Complications during labour/delivery	<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, please specify:	
Post-partum maternal complications	<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, please specify:	
Foetal Outcome			
Live normal infant	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Foetal distress	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Intra-uterine growth retardation	<input type="checkbox"/> No <input type="checkbox"/> Yes		
Neonatal complication	<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, please specify:	
Birth defect noted?	<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, please specify:	
Sex	<input type="checkbox"/> Male <input type="checkbox"/> Female	Birth weight:.....lbs.....oz or.....Kg	
		Length.....inchs or .....cm	
Apgar score	1 min:..... 5 min:..... 10 min:.....	<input type="checkbox"/> Unknown	

Signature of the person completing this form (required)	Date DD MM YYYY
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## Data Privacy Notice

Your personal data (aggregated anonymised patient limited data e.g., patient initials, date of birth) will be processed by KRKA d.d. Novo mesto, as Marketing Authorisation Holder (MAH) of pharmaceutical products 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.

To conduct risk management program activities, we may use third party service providers, who will handle directly any reporting relating to pregnancy, acting on our behalf, and upon our prior instructions.

KRKA may disclose your personal information to regulatory authorities, affiliates of the KRKA Group, service providers or other collaborators. Some of these entities may be located outside of the EU. KRKA will take appropriate measures, such as implementing standard data protection clauses adopted by the European Commission, to ensure that your personal information will be kept secure in accordance with applicable data protection law. KRKA will only retain your personal data for the length of time required by law.

Under applicable law, you may have the right to access and verify your personal information held by KRKA, receive a copy of it, obtain its correction and deletion if it is inaccurate and object to certain processing. If you wish to exercise those rights, you can contact our data protection officer at Info.IE@krka.biz

Reporter's Signature (required)	Date DD MM YYYY
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On behalf of KRKA, thank you for providing information that will assist us in our commitment to patient safety.