Lenalidomide Krka (lenalidomide) Pregnancy Reporting Form

This Pregnancy Reporting Form must be completed for each female patient or female partner of a male patient who experienced pregnancy during therapy with lenalidomide.
Pregnancy Reporting Form must be sent to KRKA, d.d., Novo mesto IMMEDIATELY. Please see contact details below.
Krka, d.d., Novo mesto may contact you in order to gather additional information regarding foetal exposure to lenalidomide.

KRKA, d.d., Novo mesto
Telephone✆: +353 1 413 3710
Email✉: pharmacovigilance.IE@krka.biz

Reporter's Information			
Reporter's Name:		Reporter's Profession:	
Telephone number:		Email:	
Address:		Date of awareness: DD MM YYYY	
Patient and therapy Information			
Pregnant Woman's Initials (patient or female partner of a male patient receiving lenalidomide):		Date of Birth: DD MM YYYY	Age:
Please select one of the options below:			
☐ Pregnancy of Patient	☐ Pregnancy of Patient's Partner	☐ Exposure of a Pregnant Female	
Drug Name:			
Batch Number:	Shelf life:	Daily dosage:	Frequency:
Date of First Dose: DD MM YYYY		Date of Last Dose: DD MM YYYY	
Indication:			

Pregnancy test	**Reference Range:**	**Date** DD MM YYYY
☐ Urine Qualitative		
☐ Serum Quantitative		

Date of Last Menstrual Period:		
Female is Currently: ……. weeks pregnant	No Longer Pregnant	Unknown
Female has elected to	Carry Pregnancy to Term	Estimated Delivery Date: DD MM YYYY
	Terminate Pregnancy	Date Performed or Pending: DD MM YYYY

Patient's Prescriber's Information:	
Prescriber Name:	Date: DD MM YYYY
Address:	Email:
Phone number:	Fax:

Name of the person completing this form	**Signature**	**Date** DD MM YYYY

Background Information on Reason for Pregnancy		
Was patient erroneously considered not to be of childbearing potential?	☐ YES	☐ NO
If yes, state reason for considering not to be of childbearing potential		
• Age ≥ 50 years and naturally amenorrhoeic* for ≥ 1 year *amenorrhoea following cancer therapy or during breast-feeding does not rule out childbearing potential	☐ YES	☐ NO
• Premature ovarian failure confirmed by a specialist gynaecologist	☐ YES	☐ NO
• Previous bilateral salpingo-oophorectomy, or hysterectomy	☐ YES	☐ NO
• XY genoty pe, Turner syndrome, uterine agenesis	☐ YES	☐ NO
Indicate from the list below what contraception was used		
• Implant	☐ YES	☐ NO
• Levonorgestrel-releasing intrauterine system (IUS)	☐ YES	☐ NO
• Medroxyprogesterone acetate depot	☐ YES	☐ NO
• Tubal sterilisation (specify below)	☐ YES	☐ NO
○ Tubal ligation	☐ YES	☐ NO
○ Tubal diathermy	☐ YES	☐ NO
○ Tubal chips	☐ YES	☐ NO
• Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses	☐ YES	☐ NO
• Ovulation inhibitory progesterone-only pills (i.e. desogestrel)	☐ YES	☐ NO
• Other progesterone-only pills	☐ YES	☐ NO
• Combined oral contraceptive pill	☐ YES	☐ NO
• Other intra-uterine devices	☐ YES	☐ NO
• Condoms	☐ YES	☐ NO
• Cervical cap	☐ YES	☐ NO
• Sponge	☐ YES	☐ NO
• Withdrawal	☐ YES	☐ NO
• Other	☐ YES	☐ NO
• None	☐ YES	☐ NO
Indicate from the list below the reason for contraceptive failure		
• Missed oral contraception	☐ YES	☐ NO
• Other medication or intercurrent illness interacting with oral contraception	☐ YES	☐ NO
• Identified mishap with barrier method	☐ YES	☐ NO
• Unknown	☐ YES	☐ NO
• Had the patient committed to complete and continuous abstinence	☐ YES	☐ NO
• Was the drug started despite patient already being pregnant	☐ YES	☐ NO
• Did patient receive educational materials on the potential risk of teratogenicity	☐ YES	☐ NO
• Did patient receive instructions on need to avoid pregnancy	☐ YES	☐ NO

Prenatal Information	
Date of Last Menstrual Period: DD MM YYYY	Estimated Delivery Date: DD MM YYYY

Pregnancy test		
☐ Urine Qualitative	Reference Range:	Date: DD MM YYYY
☐ Serum Quantitative	Reference Range:	Date: DD MM YYYY

Past Obstetric History						
Year of Pregnancy	**Outcome**				**Gestational Age**	**Type of Delivery**
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
Y Y Y Y	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		

Birth defects			
Was there any birth defect from any pregnancy?	☐ YES	☐ NO	☐ UNKNOWN
Is there any family history of any congenital abnormality abstinence?	☐ YES	☐ NO	☐ UNKNOWN
If yes to either of these questions, please provide details below:			

Maternal Past Medical History				
Condition	**From Date**	**To Date**	**Treatment**	**Outcome**
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		
	DD MM YYYY	DD MM YYYY		

Background Information on Reason for Pregnancy			
Maternal Current Medical Conditions			
Condition	**From Date**		**Treatment**
	DD MM YYYY		
	DD MM YYYY		
	DD MM YYYY		
	DD MM YYYY		
	DD MM YYYY		
	DD MM YYYY		
	DD MM YYYY		
	DD MM YYYY		
Maternal Social History			
Alcohol	☐ YES	☐ NO	If yes, amount/units per day:
Tobacco	☐ YES	☐ NO	If yes, amount per day:
IV or recreational drug use	☐ YES	☐ NO	If yes, provide details:
Maternal medication during pregnancy and in 4 weeks before pregnancy (including herbal, alternative and over the counter medicines and dietary supplements)			
Medication/Treatment	**Start date**	**Stop date/ Continuing**	**Indication**
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	
	DD MM YYYY	DD MM YYYY	

Name of person completing this form	**Signature**	**Date** DD MM YYYY

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

On behalf of KRKA, thank you for providing information that will assist us in our commitment to patient safety.

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:		
			☐ White	☐ African-Caribbean	☐ Other, specify:
Partners of patients Information					
☐ Not applicable	Ethinicity:		☐ White	☐ African-Caribbean	☐ Other, specify:
Pregnancy Outcome					
Date of delivery:	DD MM YYYY		Gestation age of delivery:	DD MM YYYY	
Normal	☐ No	☐ Yes			
C-section	☐ No	☐ Yes			
Induced	☐ No	☐ Yes			
Ectopic pregnancy	☐ No	☐ Yes			
Elective termination	☐ No	☐ Yes	**Date:** DD MM YYYY		
Spontaneous abortion (≤20 weeks)	☐ No	☐ Yes	**Weeks from LMP:**		
Foetal death/stillbirth (>20 weeks)	☐ No	☐ Yes			
Were the products of conception examined?	☐ No	☐ Yes	If yes, was the foetus normal? If no describe below/Unknown		
Obstetrics Information					
Complications during pregnancy	☐ No	☐ Yes	If yes, please specify:		
Complications during labour/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 complication	☐ 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**.....inchs or .....cm		
Apgar score	1 min:..... 5 min:..... 10 min:.....		☐ Unknown		

Signature of the person completing this form (required)	**Date** DD MM YYYY

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

On behalf of KRKA, thank you for providing information that will assist us in our commitment to patient safety.