Event-Specific Questionnaire for HCP
Teratogenicity
Pregnancy Background

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Date (dd/mmm/yyyy):			
Reporter's Information			
Name, Surname			
Reporter's occupation			
Phone No		E-mail	
Institution		Country, city	
Patient's Prescribing Physician's Information			
Name, Surname		Date (dd/mmm/yyyy):	
Physician's occupation			
Phone No		E-mail	
Institution		Country, city	

Information about pregnant woman			
☐ Pregnancy of a patient ☐ Pregnancy of a patient's partner ☐ Exposure of a pregnant female			
Pregnant woman's information			
Patient code[1]:		Date of birth (dd/mmm/yyyy):	
Height:		Weight:	
Patient's information (if different)			
Patient code (who received drug):		Date of birth (dd/mmm/yyyy):	
Height:		Weight:	

1. Patient treatment information: lenalidomide capsule			
Dose		Frequency	
Start date (dd/mmm/yyyy)		Date of last dose (dd/mmm/yyyy)	
Female partner of male patient: date of exposure (dd/mmm/yyyy)			
Exposure of pregnant female: gestational age at exposure (weeks)			
Indication to use			

2. Pregnancy information			
Date of last menses dd.mmm.yyy			
Pregnancy test type:			
Pregnancy test date (dd/mm/yyyy):			
Female is currently:	weeks pregnant **OR**	☐ no longer pregnant	☐ unknown
Female has elected to:			

☐ Carry to term	Expected date of delivery:
☐ Terminate pregnancy	Date performed or pending:

[1]Please use patient initials (F,M,L) and the first three letters of the month (e.g.: JAN)

3. Prenatal Tests		
	Date (dd/mm/yyyy)	Result
Ultrasound		
Ultrasound		
Ultrasound		
Amniocentesis		
Maternal serum AFP		
Has the patient already been referred to a specialist/gyneacologist? ☐ Yes ☐ No		
If yes, please specify his/her name and contact information:		

4. Background information on reason for pregnancy

Pregnant patient / Pregnant partner of a patient

Was patient considered not to be of childbearing potential	**Yes** ☐	**No** ☐

If yes, mark 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 genotype, Turner syndrome, uterine agenesis.	**Yes** ☐	**No** ☐
If no, mark from list below what contraception was used		
• Implant	**Yes** ☐	**No** ☐
• Levonorgestrel-releasing intrauterine system (IUS)	**Yes** ☐	**No** ☐
• Medroxyprogesterone acetate depot	**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 progesteron-only pills	**Yes** ☐	**No** ☐
• Combined oral contaceptive pill	**Yes** ☐	**No** ☐
• Other intra-uterine devices	**Yes** ☐	**No** ☐
• Condoms	**Yes** ☐	**No** ☐
• Cervical cap	**Yes** ☐	**No** ☐
• Sponge	**Yes** ☐	**No** ☐
• Withdrawal	**Yes** ☐	**No** ☐
• Tubal sterilization	**Yes** ☐	**No** ☐
• Other, specify:		
• None	**Yes** ☐	**No** ☐
Mark 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** ☐
• Intentional interruption of contraception	**Yes*** ☐	**No** ☐
* If yes, please specify (e.g. wanted a child, side effects, health concerns, inconvenient to use, etc.):		

- Other, specify:

Was lenalidomide started despite patient already being pregnant?	**Yes** ☐	**No** ☐
Did the patient receive educational materials on the potential risk of teratogenicity?	**Yes** ☐	**No** ☐
Did the patient read the lenalidomide educational materials?	**Yes** ☐	**No** ☐
Did the patient understand the information in the lenalidomide educational material?	**Yes** ☐	**No** ☐
Did the patient receive instructions on need to avoid pregnancy?	**Yes** ☐	**No** ☐

5. Previous obstetric history

Number of previous pregnancies:	

Outcome of previous pregnancies:

Year of pregnancy	**Outcome**				**Gestational age**	**Type of delivery**
	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		
	☐ Spontaneous abortion	☐ Therapeutic abortion	☐ Live birth	☐ Still birth		

Birth defect

Was there any birth defect from any pregnancy?	☐ Yes	☐ No	☐ Unknown

If yes, please provide details below:

6. Maternal past medical history

Condition	From (dd/mmm/yyyy)	To (dd/mmm/yyyy)	Treatment	Outcome

7. Maternal current medical history:

Risk factors or conditions that may affect the outcome of the current pregnancy including environmental or occupational exposure e.g. hypertension, heart disease, epilepsy, diabetes, (pre)-eclampsia, thyroid disorders, autoimmune diseases, depression or other psychiatric disorders, sexual transmitted disorders (please specify):

Condition	From (dd/mm/yyyy)	Treatment

8. Maternal social history (Check all that apply)

☐ Alcohol	If yes, amount/units per day:
☐ Tobacco	If yes, amount/units per day:
☐ IV or recreational drug use	If yes, amount/units per day:

9. Family history:

History of congenital abnormality, psychomotor retardation in the family (please specify paternal/maternal and relationship) and provide details:

10. Specific questions about current pregnancy:

Were any other medicines (including herbal, alternative and over-the-counter and dietary supplements) used during pregnancy and/or in 4 weeks before pregnancy? Yes* ☐ No ☐ **If Yes, please specify below*

Name of drug(s):	*Indication for use*:
A:	A:
B:	B:
C:	C:
D:	D:

Dose, units, frequency, route used:
A:
B:
C:
D:

Adverse events(s) (AE) during pregnancy:

A: Diagnosis of adverse event. If diagnosis is not known, provide symptom(s)

Start Date (dd/mm/yyyy)	End Date or Duration (dd/mm/yyyy)	Outcome ☐ Resolved ☐ Resolving ☐ Not resolved	☐ Resolved with sequelae ☐ Fatal ☐ Unknown
Causal relationship to lenalidomide: ☐ Yes ☐ No	If no, what medication, disease states, etc, caused the adverse event?		

Is adverse event serious? ☐ Yes ☐ No	If Yes, please, select criteria below		If 'death', specify the cause
	☐ Death _ _ / _ _ / _ _ _ _ (dd /mm /yyyy) ☐ Life-Threatening ☐ Hospitalization/ Extended Hospitalization	☐ Persistent or Significant Disability/ Incapacity ☐ Congenital Abnormality or Birth Defect ☐ Other Significant Medical Event	

B: Diagnosis of adverse event. If diagnosis is not known, provide symptom(s)

Start Date (dd/mm/yyyy)	End Date or Duration (dd/mm/yyyy)	Outcome ☐ Resolved ☐ Resolving ☐ Not resolved	☐ Resolved with sequelae ☐ Fatal ☐ Unknown
Causal relationship to lenalidomide: ☐ Yes ☐ No	If no, what medication, disease states, etc, caused the adverse event?		

Is adverse event serious? ☐ Yes ☐ No	If Yes, please, select criteria below		If 'death', specify the cause
	☐ Death _ _ / _ _ / _ _ _ _ (dd /mm /yyyy) ☐ Life-Threatening ☐ Hospitalization/ Extended Hospitalization	☐ Persistent or Significant Disability/ Incapacity ☐ Congenital Abnormality or Birth Defect ☐ Other Significant Medical Event	

C: Diagnosis of adverse event. If diagnosis is not known, provide symptom(s)

Start Date (dd/mm/yyyy)	End Date or Duration (dd/mm/yyyy)	Outcome ☐ Resolved ☐ Resolving ☐ Not resolved	☐ Resolved with sequelae ☐ Fatal ☐ Unknown
Causal relationship to lenalidomide: ☐ Yes ☐ No	If no, what medication, disease states, etc, caused the adverse event?		

Is adverse event serious? ☐ Yes ☐ No	If Yes, please, select criteria below		If 'death', specify the cause
	☐ Death _ _ / _ _ / _ _ _ _ (dd /mm /yyyy) ☐ Life-Threatening ☐ Hospitalization/ Extended Hospitalization	☐ Persistent or Significant Disability/ Incapacity ☐ Congenital Abnormality or Birth Defect ☐ Other Significant Medical Event	

Were any disease course(s) complications diagnosed during pregnancy? Yes* ☐ No ☐

**Any other information should be provided here if it is not possible to provide it in the previous sections:*If Yes, please specify below*

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Teratogenicity
Pregnancy Follow-up

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Date (dd/mmm/yyyy):	**Period Covered:** From:		To:
Reporter's Information			
Name, Surname			
Reporter's occupation			
Phone No		E-mail	
Institution		Country, city	
Patient's Prescribing Physician's Information			
Name, Surname		Date (dd/mmm/yyyy):	
Physician's occupation			
Phone No		E-mail	
Institution		Country, city	
Information about pregnant woman			
☐ Pregnancy of a patient ☐ Pregnancy of a patient's partner ☐ Exposure of a pregnant female			
Pregnant woman's information			
Patient code[2]:		Date of birth (dd/mmm/yyyy):	
Height:		Weight:	
Patient's information (if different)			
Patient code (who received drug):		Date of birth (dd/mmm/yyyy):	
Height:		Weight:	
Current pregnancy			
1. Prenatal Tests			

	Date (dd/mm/yyyy)	Result
Ultrasound		
Ultrasound		
Ultrasound		
Amniocentesis		
Maternal serum AFP		
Other tests, specify:		

[2] Please use patient initials (F,M,L) and the first three letters of the month (e.g.: JAN)

2. Specific questions about current pregnancy:

Were any other medicines (including herbal, alternative and over-the-counter and dietary supplements) used during pregnancy?	Yes* ☐ **If Yes, please specify below*	No ☐

Name of drug(s):	*Indication for use*:
A:	A:
B:	B:
C:	C:
D:	D:

Dose, units, frequency, route used:
A:
B:
C:
D:

Adverse events(s) (AE) during pregnancy:

A: Diagnosis of adverse event. If diagnosis is not known, provide symptom(s)

Start Date (dd/mm/yyyy)	End Date or Duration (dd/mm/yyyy)	Outcome ☐ Resolved ☐ Resolving ☐ Not resolved	☐ Resolved with sequelae ☐ Fatal ☐ Unknown

Causal relationship to lenalidomide: ☐ Yes ☐ No	If no, what medication, disease states, etc, caused the adverse event?

Is adverse event serious? ☐ Yes ☐ No	If Yes, please, select criteria below		If 'death', specify the cause
	☐ Death _ _ / _ _ / _ _ _ _ (dd /mm /yyyy) ☐ Life-Threatening ☐ Hospitalization/ Extended Hospitalization	☐ Persistent or Significant Disability/ Incapacity ☐ Congenital Abnormality or Birth Defect ☐ Other Significant Medical Event	

B: Diagnosis of adverse event. If diagnosis is not known, provide symptom(s)

Start Date (dd/mm/yyyy)	End Date or Duration (dd/mm/yyyy)	Outcome ☐ Resolved ☐ Resolving ☐ Not resolved	☐ Resolved with sequelae ☐ Fatal ☐ Unknown

Causal relationship to lenalidomide: ☐ Yes ☐ No	If no, what medication, disease states, etc, caused the adverse event?

Is adverse event serious? ☐ Yes ☐ No	If Yes, please, select criteria below		If 'death', specify the cause
	☐ Death _ _ / _ _ / _ _ _ _ (dd /mm /yyyy) ☐ Life-Threatening ☐ Hospitalization/ Extended Hospitalization	☐ Persistent or Significant Disability/ Incapacity ☐ Congenital Abnormality or Birth Defect ☐ Other Significant Medical Event	

C: Diagnosis of adverse event. If diagnosis is not known, provide symptom(s)			
Start Date (dd/mm/yyyy)	End Date or Duration (dd/mm/yyyy)	Outcome ☐ Resolved ☐ Resolving ☐ Not resolved	☐ Resolved with sequelae ☐ Fatal ☐ Unknown
Causal relationship to lenalidomide: ☐ Yes ☐ No	If no, what medication, disease states, etc, caused the adverse event?		

Is adverse event serious? ☐ Yes ☐ No	If Yes, please, select criteria below		If 'death', specify the cause
	☐ Death _ _ / _ _ / _ _ _ _ (dd /mm /yyyy) ☐ Life-Threatening ☐ Hospitalization/ Extended Hospitalization	☐ Persistent or Significant Disability/ Incapacity ☐ Congenital Abnormality or Birth Defect ☐ Other Significant Medical Event	

3. Any other information should be provided here if it is not possible to provide it in the previous sections:

Event-Specific Questionnaire for HCP
Teratogenicity
Pregnancy Outcome

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Date (dd/mmm/yyyy):			
Reporter's Information			
Name, Surname			
Reporter's occupation			
Phone No		E-mail	
Institution		Country, city	
Patient's Prescribing Physician's Information			
Name, Surname		Date (dd/mmm/yyyy):	
Physician's occupation			
Phone No		E-mail	
Institution		Country, city	
Information about patient			
☐ Pregnancy of a patient ☐ Pregnancy of a patient's partner ☐ Exposure of a pregnant female			
Pregnant woman's information			
Patient code[3]:		Date of birth (dd/mmm/yyyy):	
Height:		Weight:	
Patient's information (if different)			
Patient code (who received drug):		Date of birth (dd/mmm/yyyy):	
Height:		Weight:	

Pregnancy outcome:

Date of delivery (dd.mm.yyy**):**		**Gestation age at delivery:**
Type of delivery:		
Normal	☐	
C-section	☐	
Induced	☐	
Elective termination	☐	Date (dd/mm/yyyy):
Spontaneous abortion	☐	Weeks from LMP:
Stillbirth	☐	
Examination of foetus (in case of elective termination, spontaneous abortion or late foetal death)	☐	Was the foetus normal? Yes ☐ No ☐Unknown☐ If no, describe below:

[3]Please use patient initials (F,M,L) and the first three letters of the month (e.g.: JAN)

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:
Live birth with congenital abnormality	☐No	☐Yes	If yes, please specify:

Sex: ☐Male ☐Female	**Birth weight:**		**Length:**	
Apgar score:	1 min:	5 min:	10 min:	☐ Unknown

Any other information should be provided here if it is not possible to provide it in the previous sections:

Event-Specific Questionnaire for Pirmary Care Physician or Pediatrician
Infant Follow-up

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vigilance@grindeks.lv

24 h phone: 21447184
safety@ejbusuttil.com

Date (dd/mmm/yyyy):			
Reporter's Information			
Name, Surname			
Reporter's occupation			
Phone No		E-mail	
Institution		Country, city	
Information about patient			
☐ Patient ☐ Patient's partner (Mother)			
Patient code[1]:		Date of birth (dd/mmm/yyyy):	
Height:		Weight:	
Name of Infant (if known):			
Please provide information for the preriod (dd/mm/yyyy):		From:	To:

Anomalies diagnosed since initial report:		
	☐ Yes*	☐ None
**If yes, please specify:*		

Developmental assessmet:
☐ Normal
☐ Abnormal, please specify:

Infant illnesses, hospitalization, drug therapies:			
Inafant illnesses	**Hospitalizations**		**Drug therapies**
	☐ Yes	☐ No	
	☐ Yes	☐ No	
	☐ Yes	☐ No	
	☐ Yes	☐ No	
	☐ Yes	☐ No	