Immunomodulatory imide Drugs (IMiDs) by Teva (Lenalidomide Teva®/ Pomalidomide Teva®)

Lenalidomide Teva/ Pomalidomide Teva - Teratogenicity - Questionnaire

INITIAL AND FOLLOW UP POST MARKETING PREGNANCY REPORT

(For mother, child and father exposure reports)

Dear physician, Please fill in the fields in English only

Table 1: REPORTER DETAILS

Reported drug: ☐ Lenalidomide Teva; ☐ Pomalidomide Teva

Table 2: GENERAL DETAILS (for Teva internal use only)

Source (multiple selection is allowed): ☐ Spontaneous; ☐ Solicited; ☐ Literature; ☐ Health Authority; ☐ Patient/Consumer; ☐ Other (specify) _____				
Report version: ☐ Initial ☐ Follow- up Follow up number: _____	Safety Database ID# (System number): _____	Local reference number (for internal use only): _____	Receiver's Name: _____	Date Received by Teva group (DD-MMM-YYYY): _____

Table 3: REPORTER DETAILS

Reporter Type: ☐ Consumer / non-Health care professional; ☐ Pharmacist; ☐ Physician; ☐ Other Health care professional; Occupation: _____			
Reporter Name: _____	Tel. No: _____	Address (includes country): _____	Does the company have the patient's permission to contact the reporter in the future for follow-up information? ☐ YES ☐ NO

Table 4: PATIENT DETAILS

Who does this report concern? ☐ MOTHER / ☐ CHILD*; Did Father take the Suspect product? ☐ YES* ☐ NO **Please complete section 6: PARENT DETAILS*					
Patient Initials: _____	Date of Birth (DD-MMM-YYYY): _____	Age: _____	Gender: _____	Weight: _____	Height: _____

Table 5: RELEVANT PATIENT MEDICAL HISTORY / LABS

Chronic diseases (i.e. diabetes, hypertension, asthma, etc.)	
Other diseases/ labs:	
Tobacco smoking:	☐ YES ☐ NO ; number of cigarettes per day: _____
Alcohol drinking:	☐ YES ☐ NO

Ver.1 Jul 2024

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Table 6: PARENT DETAILS

Parent	Initials	Date of Birth (DD-MMM-YYYY)	Age	Weight	Height
Mother (please fill this section for child report only)					
Father (please fill this section for father exposure report only)					

Table 7: PREGNANCY INFORMATION

Is the patient still pregnant? ☐ Yes ☐ No	Last menstrual period date (DD-MMM-YYYY): _____	**Pregnancy Outcome** (multiple selection is allowed):		
		☐ Normal (No foetal anomaly) ☐ Live birth with fetal AEs ☐ Congenital Malformation	☐ Spontaneous abortion ☐ Induced abortion ☐ Elective Abortion	☐ Ectopic pregnancy ☐ Foetal death (stillbirth) ☐ Other: _____
Number of fetuses: _____	Expected delivery date (DD-MMM-YYYY): _____	Delivery Date (DD-MMM-YYYY): _____	Child birth weight (kg): _____	Is the patient breast- feeding? ☐ Yes ☐ No If Yes, Start Date: _____; Stop Date: _____

In case of abnormal current pregnancy outcome, please complete Table 8.

Table 8: PREGNANCIES HISTORY INFORMATION (for past pregnancies)

Past pregnancies outcomes (number of pregnancies):

☐ Normal (_____);

☐ Abortion(_____); Specify:_____

☐ Birth defect/ Congenital abnormality; Specify:_____

☐ Foetal death (stillbirth); Specify:_____

☐ Other(_____); Specify:_____

☐ Is there Family history of birth defects / congenital abnormalities? ☐ YES ☐ NO

Specify:_____

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Table 9: ADVERSE EVENT/ SPECIAL SITUATION DETAILS DURING /AFTER PREGNANCY

Adverse Event (s):	Onset Date (DD-MMM-YYYY):	End Date (DD-MMM-YYYY):	Outcome*: (please use the legend below)	Serious?	Seriousness criteria**: (please use the legend below)	Reporter Causality***: (please specify which suspect drug the causality concerns) (please use the legend below)
				☐ YES ☐ NO		Suspect Drug 1 _____ Suspect Drug 2 _____ Suspect Drug 3 _____
				☐ YES ☐ NO		Suspect Drug 1 _____ Suspect Drug 2 _____ Suspect Drug 3 _____
				☐ YES ☐ NO		Suspect Drug 1 _____ Suspect Drug 2 _____ Suspect Drug 3 _____

***Outcome:** Recovered/ resolved =1; Recovering/Resolving =2; Not recovered/ not resolved =3; Recovered/ resolved with sequel =4; Fatal=5; Unknown =6.

****Seriousness criteria:** Death =1; Disability or permanent damage =2; Important Medical Event =3; Life threatening = 4; Congenital anomaly/Birth Defect =5; Hospitalization =6.

*****Causality:** Possible =1; Not related =2; Not assessable =3; Not reported =4.

Table 10: SUSPECT DRUG(s) INFORMATION

Brand Name	Active Ingredient	Admin Route	Unit Dose	Frequency	Daily Dose	Start Date (DD-MMM-YYYY)	Stop Date (DD-MMM-YYYY)	Batch No.	Indication	Trimester Exposed*: (please use the legend below)	Action Taken**: (please use the legend below)

***Trimester Exposed:** Stopped before conception =0; First =1; Second =2; Third =3 (it may be more than one trimester)

****Action Taken:** Dosage maintained=1; Drug discontinued =2; Dose increased=3; Dose reduced=4; Not applicable=5; Unknown=6.

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Table 11: CONCOMITANT/ PAST DRUG(s) DETAILS

Brand name	Active ingredient	Dosing regimen	Start date	Stop date	Indication	Action Taken

Table 12: NARRATIVE

Table 13: LINKED CASES (i.e. Child-Mother, Twins, for use by LSO)

Ver.1 Jul 2024