Adverse Event Report (Mifepristone and/or Misoprostol) Form

Pharmacovigilance case reference number _____

Send back to : Service Pharmacovigilance 254 Bd St Germain 75007 Paris Tel: + 33 (0) 1 70 37 28 01 Email : pv@exelgyn.com

I. PATIENT DATA

Patient Initials (First Name/ Last Name)	Age (years)	☐ Date of last menstruation period (DD/MM/YYYY): __/__/____ ☐ No ☐ Unknown	Height ____ cm	Weight ____ kg	Country _____	Is Patient participating in a study? ☐ No ☐ Yes, Study/Patient codes: _____
__/__	___					

II. SUSPECTED ADVERSE REACTION(S)

II.1. Information on reported adverse events

Event description	Start / Stop Dates (DD/MM/YYYY)	Name of product suspected	Drug causality	Outcome
1) _____	__/__/____ __/__/____	_____	☐ Probable ☐ Possible ☐ Doubtful ☐ Not related	☐ On-going, no change ☐ Improving ☐ Resolved with no sequelae ☐ Resolved with sequelae: _____ ☐ Fatal, date of death __/__/____ Autopsy: ☐ No ☐ Yes ☐ Unknown ☐ Unknown
Seriousness criteria:	☐ Results in death ☐ Life threatening	☐ Congenital anomaly / Disabling/Incapacitating ☐ Caused/Prolonged hospitalisation		☐ Medically significant condition ☐ Non serious event
2) _____	__/__/____ __/__/____	_____	☐ Probable ☐ Possible ☐ Doubtful ☐ Not related	☐ On-going, no change ☐ Improving ☐ Resolved with no sequelae ☐ Resolved with sequelae: _____ ☐ Fatal, date of death __/__/____ Autopsy: ☐ No ☐ Yes ☐ Unknown ☐ Unknown
Seriousness criteria:	☐ Results in death ☐ Life threatening	☐ Congenital anomaly / Disabling/Incapacitating ☐ Caused/Prolonged hospitalisation		☐ Medically significant condition ☐ Non serious event
3) _____	__/__/____ __/__/____	_____	☐ Probable ☐ Possible ☐ Doubtful ☐ Not related	☐ On-going, no change ☐ Improving ☐ Resolved with no sequelae ☐ Resolved with sequelae: _____ ☐ Fatal, date of death __/__/____ Autopsy: ☐ No ☐ Yes ☐ Unknown ☐ Unknown
Seriousness criteria:	☐ Results in death ☐ Life threatening	☐ Congenital anomaly / Disabling/Incapacitating ☐ Caused/Prolonged hospitalisation		☐ Medically significant condition ☐ Non serious event

II.2. If an abortion failure after Mifegyne® and / or Misoone®/Topogyne® is it:

☐ Total failure (fœtus not expulsed) ☐ Total failure with choice to continue her pregnancy ☐ Partial failure (incomplete retentions)

Complementary information:

☐ Curettage/SToP, date: ☐ Spontaneous expulsion, date: ☐ Outcome Unknown

☐ Additional drug intake, specify (tradename, dose) : _____

☐ Other, specify :

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II.3. **Description of adverse event(s) *:** *diagnosis, medical symptoms, curative treatments, others tests and results, hospitalisation & prolongation of hospitalisation dates, autopsy results, outcome…*

* if more space is needed, please fill complementary information on a blank page.

III. DRUG(S) GIVEN BEFORE ONSET OF SUSPECTED ADVERSE REACTION

Drug(s)/Trade name	Total dosage	Route of administration	Treatment dates (DD/MM/YYYY)	Indication(s)	Suspected Causal Relationship
III.1. Mifepristone Trade Name: _____ Batch number: _____ Expiration date: __/__/____	☐ 200 mg ☐ 400 mg ☐ 600 mg ☐ Other: _____ mg	☐ Oral ☐ Buccal ☐ Vaginal ☐ Other: _____	__/__/____ And/or _____ Amenorrhea weeks	_____	☐ Yes ☐ No ☐ Unknown
III.2. Prostaglandine Trade Name: _____ Batch number: _____ Expiration date: __/__/____	Total dose (unités): _____ Number of intake(s) _____ Dose per intake: _____	☐ Oral ☐ Buccal ☐ Vaginal ☐ Other: _____	__/__/____ And/or _____ Amenorrhea weeks	_____	☐ Yes ☐ No ☐ Unknown

III.3. OTHER(S) SUSPECTED or CONCOMITANT TREATEMENT(S)

Drug(s)/Trade name	Total dosage	Route of administration	Treatment dates (DD/MM/YYYY)	Indication(s)	Suspected Causal Relationship
1) _____	_____	_____	From __/__/____ To __/__/____	_____	☐ Yes ☐ No ☐ Unknown
2) _____	_____	_____	From __/__/____ To __/__/____	_____	☐ Yes ☐ No ☐ Unknown
3) _____	_____	_____	From __/__/____ To __/__/____	_____	☐ Yes ☐ No ☐ Unknown

III.4. ADDITIONAL TESTS

Name of the test	Date of the test (DD/MM/YYYY)	Result	Unit or NA (Not Applicable)

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IV. MEDICAL HISTORY

Risk factor(s) & addiction(s): ☐ No ☐ Yes, specify:

Parity:	Gravidity (excluded the current one):

Medical:

Surgical:

Gynaecological/Obstetrical (exemple: medical abortion, surgical abortion, miscarriages, ectopic pregnancy, foetal death in utero, …):

Date(s) (DD/MM/YYYY): __/__/____
Cause(s) / Comment(s):

Relevant family medical history: ☐ No ☐ Yes, specify:

V. FOLLOW UP VISIT

☐ Date (DD/MM/YYYY): __/__/____	☐ Performed but date unknown	☐ Not performed
☐ Ultrasound exam	Date (DD/MM/YYYY): __/__/____	Conclusion:
☐ ßHCG	Date (DD/MM/YYYY): __/__/____	Result (IU/ml):

☐ Other, specify:

VI. SOURCE

☐ Physician ☐ Pharmacist ☐ Midwife ☐ Other reporter: _____ Reported to national authorities: ☐ No ☐ Yes Date (DD/MM/YYYY): __/__/____	*Name:* *Practice/Hospital/Organisation:* *Street :* *Zip Code/City:* *Phone:* *Fax:* *E-Mail:*

In accordance with the "Data Protection Act" of Law No. 78-17 of 6 January 1978 (as amended), the user has the right to access, modify, rectify and delete personal data. The user may also, for legitimate reasons, oppose the processing of his personal data