NORDIC GROUP

ADVERSE EVENT REPORT FORM
MIFEPRISTONE AND/OR MISOPROSTOL

☐ **Initial** ☐ **Follow-up**

I. PATIENT DATA

Patient Initials:	**Patient date of birth:**	**Patient sex:**	**Weight (kg):**	**Height (cm):**	**Country:**	**Is Patient participating in a study?**
___ ___ First Name Last Name	___ ___ _____ Day Month Year	☐ Male ☐ Female	_____	_____	_____	☐ No ☐ Yes, Study and patient codes: _____

On-going pregnancy:

Start date of pregnancy : ___ ___ _____ (Day Month Year) OR Last menstrual period: ___ ___ _____ (Day Month Year)

II. SUSPECTED ADVERSE REACTION

II.1. Incomplete abortion or failed abortion? ☐ No ☐ Yes: please complete **the part below**

❖ ☐ Interrupted non-expelled pregnancy, ➲please specify outcome:
- ☐ Surgical intervention, Date: ___ ___ _____ (Day Month Year)
- ☐ Additional drug(s) intake, please specify:

Trade name/Generic name:	Dose(s):	Start date: *(DD/MM/YYYY)*	Stop date: *(DD/MM/YYYY)*

❖ ☐ *Conceptus* expelled, but placental remnant still persist (incomplete abortion), ➲please specify outcome:
- ☐ Surgical intervention, Date: ___ ___ _____ (Day Month Year)
- ☐ Additional drug(s) intake, please specify:

Trade name/Generic name:	Dose(s):	Start date: *(DD/MM/YYYY)*	Stop date: *(DD/MM/YYYY)*

❖ ☐ On-going pregnancy, with CA, ➲ please specify outcome:
- ☐ The patient choose to keep the pregnancy, specify **Estimated date of delivery**: (additional information will be requested) ___ ___ _____ (Day Month Year)
- ☐ Surgical intervention, Date: ___ ___ _____ (Day Month Year)
- ☐ Additional drug(s) intake, please specify:

Trade name/Generic name:	Dose(s):	Start date: *(DD/MM/YYYY)*	Stop date: *(DD/MM/YYYY)*

II.2. Vomiting after taking Mifepristone: **Start date:** **Stop date:**

☐ No ☐ Yes, specify time-to-onset after intake (minutes): _____ ___ ___ _____ (Day Month Year) ___ ___ _____ (Day Month Year)

Vomiting after taking prostaglandin (/Misoprostol):

☐ No ☐ Yes specify time-to-onset after intake (minutes) : _____ ___ ___ _____ (Day Month Year) ___ ___ _____ (Day Month Year)

II.3. Other suspected adverse reaction: _____ **Start date:** ___ ___ _____ (Day Month Year) **Stop date:** ___ ___ _____ (Day Month Year)

II.4. Further description (diagnostics, laboratory values, therapy, course): _____

Serious criteria:
- ☐ Results in death
- ☐ Life threatening
- ☐ Caused/Prolonged hospitalisation
- ☐ Disabling/Incapacitating
- ☐ Congenital anomaly/Birth defect
- ☐ Other medically significant condition

Outcome:
- ☐ Unknown
- ☐ On-going
- ☐ Recovered/Resolved with no sequelae
- ☐ Recovered/Resolved with sequelae
- ☐ Fatal, date of exitus: ___ ___ _____ (Day Month Year)

Autopsy:
- ☐ No
- ☐ Yes, specify results: _____

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

Drug(s)/Generic name	Total dosage	Route of administration	Therapy dates	Indication(s)	Suspected Causal Relation-ship
III.1. Mifepristone **Trade Name:** ____ Batch number: ____ Expiration date: ____	☐ 200 mg ☐ 400 mg ☐ 600 mg ☐ Other: ____ mg	☐ Oral ☐ Vaginal ☐ Other: ____	__ __ ____ Day Month Year Time: __ H __ min Term: __ (w post LMP) + _ Day(s)		☐ Yes ☐ No ☐ Unknown
III.2. Prostaglandin **Trade name:** ____ ☐ Misoprostol (µg) ☐ Gemeprost (mg) ☐ Other: ____	Total dosage: ____ Intake 1: ____ Intake 2: ____ Intake 3: ____ Intake 4: ____	☐ Oral ☐ Vaginal ☐ Other: ____	__ __ ____ Day Month Year Time Intake 1: __ H __ min Time Intake 2: __ H __ min Time Intake 3: __ H __ min Time Intake 4: __ H __ min		☐ Yes ☐ No ☐ Unknown

III.3. Prostaglandin storage condition

The blister is cut and given to the patient? ☐ No ☐ Yes

The prostaglandin tablet are deconditioned or conditioned in another container before intake? ☐ No ☐ Yes, how many time before intake? ____

OTHER CONCOMITANT THERAPIES

Drug(s)/Generic name	Total dosage	Route of administration	Therapy dates	Indication(s)	Suspected Causal Relation-ship
III.4.			__ __ ____ Day Month Year **to** __ __ ____ Day Month Year		☐ Yes ☐ No* ☐ Unknown
III.5.			__ __ ____ Day Month Year **to** __ __ ____ Day Month Year		☐ Yes ☐ No* ☐ Unknown

* ➲ **If, no suspected causal relationship with drug(s), please specify other suspected cause (e.g. basic disease, concomitant diseases):**

IV. MEDICAL HISTORY

Smoker: ☐ No ☐ Yes, number/day: ____ | Other addiction(s): ☐ No ☐ Yes, specify: ____

Parity: ____ | Gravidity (excluded the current one): ____

Medical: ____

Surgical: ____

Gynaecological: ____

Obstetric, specify (Medical abortion / Surgical abortion / Miscarriages / Ectopic pregnancy / Foetal death in utero): ____

Date(s): __ __ ____
Day Month Year

Cause(s) / Comments: ____

V. FOLLOW UP VISIT

☐ Date: __ __ ____ Day Month Year ☐ Unknown ☐ Not attended

☐ Ultrasound exam Date: __ __ ____ Day Month Year

☐ ßHCG Date: __ __ ____ Day Month Year Value (IU/ml): ____

☐ Other, specify: ____

VI. SOURCE

☐ Physician ☐ Pharmacist ☐ Other reporter: ____

Reported also to: ____

Date: __ __ ____ Day Month Year

Name: ____
Practice/Hospital/Organisation: ____
Street : ____
Zip Code/City: ____
Phone: ____
Fax: ____
E-Mail: ____

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