SUSPECT ADVERSE REACTION REPORT

2025A-1400635

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE Years	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year			Day	Month	Year
Masked	PANAMA	UNK	UNK	UNK	20	Female	30	Jun	2025

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)

1) Expulsion of the device (Expulsion of device (10015716), Device expulsion (10012578))
(30-Jun-2025 - 30-Jun-2025) - Recovered/Resolved
2) The patient began to experience discomfort (Discomfort (10013082), Discomfort (10013082))
(30-Jun-2025 - 30-Jun-2025) - Recovered/Resolved
3) Pain in the lower abdomen (Lower abdominal pain (10024940), Abdominal pain lower (10000084))
Unknown

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ LIFE THREATENING
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION
- ☐ RESULTS IN PERSISTENCE OR SIGNIFICANT DISABILITY/INCAPACITY
- ☐ CONGENITAL ANOMALY
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S)INFORMATION

14. SUSPECT DRUG(S)(include generic name)

1) MAHELY_(LEVONORGESTREL_52_MG)_DISPOSITIVO_VAGINAL_INTRA-UTERINO_POR_1 (LVNL>LEVONORGESTREL, LEVONORGESTREL) (Suspect) (Vaginal device)(BHI0037)

Continued

20. DID EVENT ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☑ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
1) (20 microgram(s), in 1 Day)	1) Vaginal

21. DID EVENT REAPPEAR AFTER REINTRODUCTION ☐ YES ☐ NO ☑ NA

(NA : Not Applicable)

17. INDICATION(S) FOR USE

1) Contraceptive [10010808 - Contraception]

18. THERAPY DATE(S) (from/to)	19. THERAPY DURATION
1) (31-Mar-2025 - 30-Jun-2025)	1) 92 Days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

No concomitants used/reported

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

UNK

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

Name : ABBOTT GPV
Thomas Nisslein,
Freundallee 9A, Hannover, 30173, GERMANY
pv.qppv@abbott.comand49-3514-5116750

24.REPORT NULLIFIED	24b. MFR CONTROL NO.
☐ YES ☐ NO	2025A-1400635
24c. DATE RECEIVED BY MANUFACTURER: 04-Aug-2025	24d. REPORT SOURCE: ☐ STUDY ☐ LITERATURE ☑ HEALTH PROFESSIONAL
DATE OF THIS REPORT: 14-Aug-2025	25a. REPORT TYPE: ☐ INITIAL ☑ FOLLOWUP

= Continuation attached sheet(s)..

Continuation Sheet for CIOMS report

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) (Continuation...)

Event Description :

This is a Pregna case migrated to the Abbott safety database.

On 03-Jul-2025 a spontaneous valid report was received from a Physician in PANAMA concerning a 20 Year(s) old Female patient, who experienced Pain in the lower abdomen, Expulsion of the device and The patient began to experience discomfort, under treatment with MAHELY_(LEVONORGESTREL_52_MG)_DISPOSITIVO_VAGINAL_INTRA-UTERINO_POR_1.

The patient initiated treatment on MAHELY_(LEVONORGESTREL_52_MG)_DISPOSITIVO_VAGINAL_INTRA-UTERINO_POR_1 on 31-Mar-2025. MAHELY_(LEVONORGESTREL_52_MG)_DISPOSITIVO_VAGINAL_INTRA-UTERINO_POR_1 was administered as Vaginal device, Vaginal, (20 microgram(s)), from 31-Mar-2025 to 30-Jun-2025. Indication for use was Contraceptive. The lot number was reported as BHI0037. Additional Drug Information: Lot Expiration Date: Unknown.

On 30-Jun-2025 the patient experienced Expulsion of the device. The event was considered non serious.
On 30-Jun-2025 the patient experienced The patient began to experience discomfort. The event was considered non serious.
On an unknown date the patient experienced Pain in the lower abdomen. The event was considered non serious.

The event Expulsion of the device resolved on 30-Jun-2025.
The event The patient began to experience discomfort resolved on 30-Jun-2025.
The outcome of the event Pain in the lower abdomen was unknown.

The status of the MAHELY_(LEVONORGESTREL_52_MG)_DISPOSITIVO_VAGINAL_INTRA-UTERINO_POR_1 medication is unknown.

Concomitant medications were not reported.
There were no concomitant diseases reported.
There was no past medical history reported.

Causality assessment for MAHELY_(LEVONORGESTREL_52_MG)_DISPOSITIVO_VAGINAL_INTRA-UTERINO_POR_1
Reporter causality for the event Expulsion of the device: Not Reported
Reporter causality for the event The patient began to experience discomfort: Not Reported
Reporter causality for the event Pain in the lower abdomen: Not Reported

Following information was reported:
The patient began to feel discomfort and pain in her lower abdomen, and when she went to the bathroom, she realized the IUD strings were outside her body. She pulled them, and the IUD came out easily.

Follow up information was received on 04-Aug-2025:
Onset and end date of "The patient began to experience discomfort” added, and frequency time update to per day.

Along with follow up information, upon internal review onset date for the event “Expulsion of the device” was updated to 30-Jun-2025, action taken for the event “The patient began to experience discomfort” and “Pain in the lower abdomen” updated to unknown.

Following information was reported:
The first follow-up attempt was made on 29 JUL 2025, the physician answered on 04 AUG 2025.
In this follow-up it was added the following:
- Additional information
- Onset and end date of "The patient began to experience discomfort"
Prescribed dosage: per day
Onset date of "The patient began to experience discomfort" upon expulsion
Onset and end dates of "Pain in the lower abdomen" are unknown

Pharmacovigilance Comments :

Additional Report Source:

Continuation Sheet for CIOMS report

Spontaneous,Spontaneous

14.SUSPECT DRUG(S) (Continuation...)

Product-Reaction Level

1) Drug	: MAHELY_(LEVONORGESTREL_52_MG)_DISPOSITIVO_VAGINAL_INTRA-UTERINO_POR_1 (LVNL>LEVONORGESTREL)
Active Substance	: LEVONORGESTREL
Drug Characterization	: Suspect
Form of Admin	: Vaginal device
Lot Number	: BHI0037
Daily Dose	: (20 microgram(s), in 1 Day)
Route of Admin	: Vaginal
Indications	: Contraceptive [10010808 - Contraception]
Therapy Dates	: From : 31-Mar-2025 To :30-Jun-2025
Therapy Duration	: 92 Days
Action(s) Taken With Drug	: Not applicable

Causality

1) Expulsion of the device (Expulsion of device - 10015716, Device expulsion - 10012578)

Causality as per reporter	: Not Reported
DeChallenge	: Not applicable
ReChallenge	: Not Applicable

2) The patient began to experience discomfort (Discomfort - 10013082, Discomfort - 10013082)

Causality as per reporter	: Not Reported
DeChallenge	: Not applicable
ReChallenge	: Not Applicable

3) Pain in the lower abdomen (Lower abdominal pain - 10024940, Abdominal pain lower - 10000084)

Causality as per reporter	: Not Reported
DeChallenge	: Not applicable
ReChallenge	: Not Applicable