SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET Day	Month	Year
PRIVACY	COSTA RICA		PRIVACY		Unk	Unk	Unk		Unk	

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)

product spilled from the edges of the syringe [No adverse effect]

Case Description: This case has been considered invalid as No AE.

This is a spontaneous report received from a Consumer or other non HCP from product quality group.

A patient (age and gender not provided) received medroxyprogesterone acetate (SAYANA), (Lot number: FY8970, Expiration Date: 28Feb2025).

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Sayana (MEDROXYPROGESTERONE ACETATE) Suspension for injection {Lot # FY8970; Exp.Dt.
#2) Sayana (MEDROXYPROGESTERONE ACETATE (DEVICE **(Continued on Additional Information Page)**

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☒ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) UNK	#1) Unknown
#2)	#2) Unknown

17. INDICATION(S) FOR USE
#1) Unknown
#2) Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☒ NA

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) Unknown	#1) Unknown
#2) Unknown	#2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

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

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates — Type of History / Notes — Description
Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pfizer S.A.
Laura Arce Mora
Avenida Escazú, Torre Lexus, piso 7. Escazú
San Jose, COSTA RICA

26. REMARKS

24b. MFR CONTROL NO.
202500044560

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
14-MAY-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL ☒ OTHER: Spontaneous

DATE OF THIS REPORT
20-MAY-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

Mfr. Control Number: 202500044560

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The patient's relevant medical history and concomitant medications were not reported.
The following information was reported: DEVICE LEAKAGE (non-serious), outcome "unknown", described as "product spilled from the edges of the syringe".

Additional information: During the administration, the product spilled from the edges of the syringe. The unit involved remained in the custody of our client.

Product Quality Group provided investigational results on 12May2025 for medroxyprogesterone acetate (device constituent): Investigation Summary and Conclusion: Site Investigation (Pfizer Manufacturing Site): Container Leaking During Prep/Use. The complaint for "During application, the product is spilled (leakage) at the ends of the syringe." of SAYANA PRESS was investigated. The investigation included reviewing the involved batch records, deviation investigation, the complaint sample pictures, evaluation of reference samples, an analysis of the complaint history for the involved scope. Quantity of returned complaint sample(s): pictures The reported defect was not present on the returned complaint sample pictures. The complaint is not confirmed. No root cause or CAPA were identified as the complaint was not confirmed. No related quality issues were identified during the investigation. There is no impact on product quality, regulatory, validation, stability. The Issue Escalation (NTM) process determined that no regulatory notification was required. The final scope was determined to be the associated lot(s) of the reported lot GC6862. The reported defect is not representative of the quality of the batch, and reported lot remains acceptable for further distribution.

Causality for "product spilled from the edges of the syringe" was determined associated to device constituent of medroxyprogesterone acetate (malfunction).

No follow-up attempts are possible.

Follow-up (14May2025, 14May2025 and 15May2025): This is a follow-up report from product quality group.
Updated Information: This case is being deleted from the database for the following reason: No adverse effect. Suspect product is out of scope for DCHU assessment and only a product complaint was reported.

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#1) Sayana (MEDROXYPROGESTERONE ACETATE) Suspension for injection {Lot # FY8970; Exp.Dt. 28-FEB-2025}; Regimen #1	UNK; Unknown	Unknown	Unknown; Unknown
#2) Sayana (MEDROXYPROGESTERONE ACETATE (DEVICE CONSTITUENT)) Suspension for injection; Regimen #1	; Unknown	Unknown	Unknown; Unknown