SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

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

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

☐ PATIENT DIED

☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION

☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY

☐ LIFE THREATENING

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

Other Serious Criteria: Medically Significant
had a severe outbreak of multiple sclerosis [Multiple sclerosis]

Case Description: This is a spontaneous report received from a Consumer or other non HCP from medical information team.

A male patient received BNT162b2 (BNT162B2 NOS), as dose number unknown, single (Batch/Lot number: unknown) for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported.

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) BNT162B2 NOS (BNT162B2) Solution for injection

(Continued on Additional Information Page)

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

15. DAILY DOSE(S)
#1) DOSE NUM (Continued on Additional Information Page)

16. ROUTE(S) OF ADMINISTRATION
#1) Unknown

17. INDICATION(S) FOR USE
#1) COVID-19 immunization (COVID-19 immunisation)

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

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

19. THERAPY DURATION
#1) 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.
202500117897

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

24c. DATE RECEIVED BY MANUFACTURER
09-JUN-2025

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

DATE OF THIS REPORT
13-JUN-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

Mfr. Control Number: 202500117897

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

The following information was reported: MULTIPLE SCLEROSIS (medically significant), outcome "unknown", described as "had a severe outbreak of multiple sclerosis".

Clinical course: Reporter reported that, after 3 weeks to a month, he had a severe outbreak of multiple sclerosis. It had left him practically disabled. He could no longer work, could not walk, and he was having trouble breathing. He wanted to come to an agreement so that he could resolve this problem. He needed compensation for the permanent damage and for the suffering and pain as he was going through every day after having received the vaccine. he had his vaccination card, which matched the subsequent MRI.

The information on the batch/lot number for BNT162b2 will be requested and submitted if and when received.

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) BNT162B2 NOS (BNT162B2) Solution for injection; Regimen #1	DOSE NUMBER UNKNOWN, SINGLE; Unknown	COVID-19 immunization (COVID-19 immunisation)	Unknown; Unknown