

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) <b>PRIVACY</b>	1a. COUNTRY DOMINICAN REPUBLIC	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  <input type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING
		Day	Month	Year	Unk	Male	Unk	Day	Month	Year	
			<b>PRIVACY</b>						<b>Unk</b>		

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?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> 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. <b>202500117897</b>	25b. NAME AND ADDRESS OF REPORTER NAME AND ADDRESS WITHHELD.
24c. DATE RECEIVED BY MANUFACTURER <b>09-AUG-2025</b>	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT <b>09-AUG-2025</b>	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input checked="" type="checkbox"/> FOLLOWUP: 1	

09-Aug-2025 04:41

---

**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.  
Follow-up (09Aug2025): Follow-up attempts are completed. Batch/lot number is not provided, and it cannot be obtained.

**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