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
CCZ	COSTA RICA	11	AUG	1947	77 Years	Female	61.00 kg	19	MAR	2025

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

Terrible flu [Influenza]
Cough [Cough]
Sore throat [Oropharyngeal pain]
Patient discontinued treatment for 2 days in February [Therapy interrupted]

Case Description: This non-serious post market survey report originated from Costa Rica was received by Viatris on 25-Mar-2025.

The patient participated in 9790: Increase adherence of our chronic

(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
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) Lipitor 20 mg (ATORVASTATIN) Tablet, 20 milligram

15. DAILY DOSE(S)
#1) 20 milligram, qd (daily)

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) Cholesterol (Blood cholesterol)

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

19. THERAPY DURATION
#1) Unknown

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

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

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 to Ongoing	Current Condition	Cholesterol (Blood cholesterol)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
MYLANLABS
Balwant Heer
Building 4, Trident Place, Mosquito Way
Hatfield, Hertfordshire AL10 9UL UNITED KINGDOM
Phone: 44 01707853232

26. REMARKS
Medically Confirmed: No
World Wide #: CR-MYLANLABS-2025M1026615
Study ID: 9790

24b. MFR CONTROL NO.
2025M1026615

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

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

DATE OF THIS REPORT
03-JUN-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

25b. NAME AND ADDRESS OF REPORTER
C C Z

COSTA RICA

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

patients by ensuring proper patient stay on treatment and compliance. Our Program is designed to accompany the patient and provide benefits throughout their treatment

This initial case, received from consumer, non-healthcare professional in Costa Rica, involved a 77-years-old female patient who reportedly experienced influenza, cough and oropharyngeal pain while receiving Lipitor 20 mg (atorvastatin).

Medical history and concomitant medications were not reported.

Current condition included blood cholesterol.

Unknown date (since approximately 2010): The patient initiated atorvastatin 20 milligram tablet at a dose of 20 milligram qd (daily) via oral route (batch/lot number and expiration date were unknown) for cholesterol.

Unknown date in Feb-2025: She also reported that she missed three days of her pill because she did not have enough money.

19-Mar-2025: She mentioned that she had a terrible flu, symptoms including a cough and sore throat.

No action was taken with atorvastatin in response to the events.

On 25-Mar-2025, at the time of reporting the patient had not yet recovered from the events influenza, cough and oropharyngeal pain.

Follow-up information was received by Viatris on 27-May-2025 which was significant. The following information was added/updated: event added.

Unknown date in 2025 (Jan or Feb): The reporter stated that during Jan or Feb 2025, without confirming the exact date, she did not take her medicine for two days, because she could not access the web page and request for the discount.

Case Comment: The reporter assessed the events flu, cough and sore throat as not related and certain for event therapy interrupted with atorvastatin.

Company Comment: Non-serious: Influenza, cough, therapy interrupted and oropharyngeal pain are unlisted events as per company RSI of atorvastatin. Causality has been assessed as possible for events influenza, cough and oropharyngeal pain as the contributory role of suspect drug cannot be completely excluded with available information. Causality has been assessed as possible for event therapy interrupted based on convention as it can occur with the product and not due to the drug.