CIOMS FORM

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	FRANCE		PRIVACY		55 Years	Female	70.00 kg	10	OCT	2022

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
Oedema Quincke's [Oedema Quincke's]

Case Description: Initial information regarding an unsolicited valid serious case received from France downloaded from EudraVigilance database without narrative (level 2A), was received on 21-Dec-2022 from Health Authorities of France via a pharmacist (E2B Authority number: FR-AFSSAPS-TO20223588. The following narrative is based on the information retrieved from all other accessible data.

(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) METRONIDAZOLE (METRONIDAZOLE) Unknown
#2) SPIRAMYCINE (SPIRAMYCIN) Unknown

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1) 1.5 MIU/250mg - 1 dose	#1) Oral
#2) 1.5 MIU/250mg - 1 dose	#2) Oral

17. INDICATION(S) FOR USE
#1) Tooth abscess (Tooth abscess)
#2) Tooth abscess (Tooth abscess)

18. THERAPY DATES(from/to)	19. THERAPY DURATION
#1) 10-OCT-2022 / 10-OCT-2022	#1) 1 day
#2) 10-OCT-2022 / 10-OCT-2022	#2) 1 day

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	Historical Condition	Hypothyroidism (Hypothyroidism)
Unknown	Historical Condition	Carpal tunnel syndrome (Carpal tunnel syndrome)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Sanofi US
Heather SCHIAPPACASSE, PharmD, MBA Sanofi US for itself and affiliated Sanofi Companies 55 CORPORATE DRIVE, MS 55B-220A
BRIDGEWATER, NJ 08807 UNITED STATES
Phone: 1 908.981.7289

26. REMARKS
Medically Confirmed: Yes

24b. MFR CONTROL NO.
2022SA517173

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

24c. DATE RECEIVED BY MANUFACTURER
21-DEC-2022

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

DATE OF THIS REPORT
23-DEC-2022

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

This case involves a 55 year-old female patient who experienced oedema quincke's while being treated with metronidazole and spiramycin [spiramycine].

The patient's past medical history included Carpal tunnel syndrome.
The patient's past medical treatment(s), vaccination(s) and family history were not provided.
At the time of the event, the patient had hypothyroidism.

On 10-Oct-2022, the patient started taking metronidazole 1.5 MIU/250mg - 1 dose and spiramycine (spiramycin) 1.5 MIU/250mg - 1 dose with unknown dosage form, batch/lot number and expiration date via oral route for Tooth abscess.

On 10-OCT-2022 the patient developed a serious oedema quincke's (angioedema) (same day) following the first dose intake of metronidazole and spiramycin. This event was assessed as medically significant. The patient was hospitalized for this event.

No lab data has been provided.

Spiramycin (spiramycine) and metronidazole were discontinued on 10-Oct-2022.

It was not reported if the patient received a corrective treatment for the event (Oedema Quincke's).

At time of reporting, the outcome was Not Recovered / Not Resolved for the event oedema quincke's.