CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET		
		Day	Month	Year	Years		Day	Month	Year
PRIVACY	ITALY	12	01	202	32	F	05	04	202

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Tiredness (PT fatigue)
Nausea (PT Nausea)
Metabolic Acidosis (PT Metabolic acidosis)
off label use (PT off label use)

This is a initial case received received from a doctor specialized in gynecology on 10 April 2024 regarding a 32-year-old woman with a medical history of polycystic ovaries. The patient presented to the emergency room on 05 April 2024 with tiredness and nausea that began on 05 April 2024.
The patient had been taking Metformin (Pharma X) since 30 March 2024 at a dose of 500

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

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

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
Metformin Pharma X

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

15. DAILY DOSE(S)
1500 mg

16. ROUTE(S) OF ADMINISTRATION
oral

17. INDICATION(S) FOR USE
polycystic ovaries

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

18. THERAPY DATES (from/to)
30 March 2024-05 April 2024

19. THERAPY DURATION
7 days

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
Not Applicable

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)
polycystic ovaries

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
Pharma X via Carducci y Milano (Italy)

24b. MFR CONTROL NO.
2024-00453

24c. DATE RECEIVED BY MANUFACTURER
10 April 2024

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☑ HEALTH PROFESSIONAL

DATE OF THIS REPORT
15 April 2024

25a. REPORT TYPE
☑ INITIAL ☐ FOLLOWUP