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	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
M.Z.	TR		41	Female		○ PATIENT DIED ○ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ○ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY ○ LIFE THREATENING ○ CONGENITAL ANOMALY ● OTHER MEDICALLY IMPORTANT CONDITION

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

Application site necrosis - MedDRA LLT (10003048) Application site necrosis

Telephone meeting was made with the reporter on 12.03.2024. During the meeting, the reporter said that necrosis occurred after 0.2 mL IV administration of the drug to the patient's leg region. Information was received that there was crust development and necrosis on the application site. The adverse reaction (necrosis occurrence) has been contunied for 3 weeks. Reporter was informed that treatment will be administered once the crust is lifted. The patient has a past history of allergic asthma. Patient sometimes uses ventolin. There are no additional suspected drugs.

Action taken: The medicine was withdrawn. Reporter's assessment: Reporter assessed adverse reaction (necrosis occurrence) as serious (other medically important condition) and there was no drug administration error. Causality was not reported. Case assessment: Adverse reaction related to necrosis may be related to drug administration error.

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)	20. DID REACTION ABATE AFTER STOPPING DRUG?
I) Veindocanol %0.5 Solution for Injection (Lauromacrogol400 (polidocanol))	○ YES ● NO ○ NA

15. DAILY DOSE(S) I) 0.2 (mL)	16. ROUTE(S) OF ADMINISTRATION I) IV	21. DID REACTION REAPPEAR AFTER REINTRO-DUCTION? ○YES ● NO ○ NA
17. INDICATION(S) FOR USE I) MedDRA LLT (10039721) Sclerotherapy		
18. THERAPY DATES (from/to) I) N/A - N/A	19. THERAPY DURATION I) N/A	

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.) The patient has a past history of allergic asthma. Patient sometimes uses ventolin.

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER CA Group Pharma		
ORIGINAL REPORT NO TR-PLK-CAG-S-2024-0001	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER TR-PLK-CAG-S-2024-0001 / 12.03.2024	24d.REPORT SOURCE. ○ STUDY ○ LITERATURE ● HEALTH PROFESSIONAL ○ OTHER	

DATE OF THIS REPORT 12.03.2024	25a. REPORT TYPE ● INITIAL ○ FOLLOWUP	