

Indberetning af SUSAR

EU CT nr.:	KONTAKTINFORMATION PÅ INDMELDER (minimum navn, telefon og mail)	
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I. REACTION INFORMATION

PATIENT INITIALS (first, last)	COUNTRY	DATE OF BIRTH			AGE Years	SEX	REACTION ONSET			CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
DESCRIBE REACTION(S) (including relevant tests/lab data)										☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING
CAUSALITY ASSESSMENT FOR REAKTION(S):										

II. SUSPECT DRUG(S) INFORMATION

SUSPECT DRUG(S) (include generic name and lot/batch number)		DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
DAILY DOSE(S)	ROUTE(S) OF ADMINISTRATION	DID REACTION REAPPEAR AFTER REINTRO- DUCATION? ☐ YES ☐ NO ☐ NA
INDICATION(S) FOR USE		
THERAPY DATES (from/to)	THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

NAME AND ADDRESS OF MANUFACTURER

V. REPORT INFORMATION

REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL	REPORT TYPE ☐ INITIAL ☐ FOLLOWUP
DATE OF THIS REPORT	