

SUSPECT ADVERSE REACTION REPORT																				
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I. REACTION INFORMATION

1. PATIENT INITIALS	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6. REACTION ONSET			8-13 CHECK ALL APROPRIATE TO ADVERSE REACTION <input type="checkbox"/> RECOVERY WITHOUT CONSEQUENCES <input type="checkbox"/> RECOVERY WITH CONSEQUENCES <input type="checkbox"/> ADVERSE REACTION ONGOING <input type="checkbox"/> DEATH <input type="checkbox"/> THREAT TO LIIFE <input type="checkbox"/> UNKNOWN
		Day	Month	Year			Day	Month	Year	
7+13 DESCRIBE REACTION(S) (including relevant tests/lab.data)										
13. CAUSAL LINK BETWEEN ADVERSE REACTION AND SUSPECT MEDICINAL PRODUCT 1. Certain 2. Most likely 3. Possible 4. Not likely 5. Can not be classified										

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (incl.generic name, proprietary name, pharmaceutical form and strength)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
15. SINGLE AND DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION OF THE DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A
17. INDICATION(S) FOR USE		
18. THERAPY DATES	19. THERAPY DURATION	

III. CONCOMITANT DRUGS AND HISTORY

22. CONCOMITANT DRUGS AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergic, pregnancy etc.)

IV. SOURCE INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER		26. REPORTER	
24b. BATCH NO.	24c. DATE OF THIS REPORT	HEALTHCARE INSTITUTION:	
24d. REPORT SOURCE		NAME OF THE HEALTHCARE PROFESSIONAL, SPECIALITY	
25. REPORT TYPE <input type="checkbox"/> SPONTANEOUS <input type="checkbox"/> FROM CLINICAL STUDY <input type="checkbox"/> TARGET MONITORING OF THE MEDICINAL PRODUCT TOLERABILITY		ADDRESS:	
		CONTACT TEL:	
		E-MAIL:	
		SIGNATURE:	
<input type="checkbox"/> HOSPITAL <input type="checkbox"/> NON HOSPITAL SOURCE <input type="checkbox"/> GENERAL PRACTITIONER <input type="checkbox"/> SPECIALIST <input type="checkbox"/> OTHER			