



A. Patient information		
1. Patient Initials [ ][ ] [ ][ ]	2. Age at time of event: _____ or _____ Date of Birth: dd / mm / yyyy	3. Gender: <input type="checkbox"/> M <input type="checkbox"/> F
4. Weight: _____ Kg.	5. Country: _____	

B. Adverse Event
6. Date when event started (dd/mm/yyyy): ____/____/____
7. Date of recovery (dd/mm/yyyy): ____/____/____
8. Describe event:   
9. Relationship of event to the suspected medication <input type="checkbox"/> Related <input type="checkbox"/> Not related

13. Relevant tests/ laboratory data, including dates   
14. Other relevant history, including pre-existing medical conditions (e.g., allergies, race, pregnancy, smoking alcohol use, hepatic/renal dysfunction, etc.)   
15. Seriousness of the event : Is the event Serious <input type="checkbox"/> or Non serious <input type="checkbox"/> If Serious, then choose the criteria  <input type="checkbox"/> Death (dd/mm/yyyy) ____/____/____ <input type="checkbox"/> Results in persistent or significant disability/incapacity <input type="checkbox"/> Life threatening <input type="checkbox"/> congenital anomaly/ Birth defect <input type="checkbox"/> requires inpatient hospitalization or prolongation of hospitalization <input type="checkbox"/> other medically important condition
16. Outcomes <input type="checkbox"/> Fatal <input type="checkbox"/> Continuing <input type="checkbox"/> Recovering <input type="checkbox"/> Recovered <input type="checkbox"/> Unknown <input type="checkbox"/> Other (specify) _____

C. Suspected medication(s)										
Sr. No.	10. Name (brand and / or generic name)	Manufacturer (If known)	Batch No. / Lot No. (If known)	Exp. Date (If known)	Dose used	Route used	Frequency	Therapy dates (if unknown, give duration)		Reason for Use or prescribed for
								Date started	Date stopped	
i										
ii										
iii										
iv										

11. Action taken with respect to Suspect Drug <input type="checkbox"/> None <input type="checkbox"/> Dose reduction Date of dose reduction : ____/____/____ (dd/mm/yyyy) <input type="checkbox"/> Drug temporarily discontinued Date stopped : ____/____/____ (dd/mm/yyyy) Date re-started : ____/____/____ (dd/mm/yyyy) <input type="checkbox"/> Drug permanently discontinued Date stopped : ____/____/____ (dd/mm/yyyy) <input type="checkbox"/> Dose increased Date of dose increased : ____/____/____ (dd/mm/yyyy)
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12. Concomitant medical products and therapy dates including self medication and herbal remedies (exclude those used to treat event)	<b>D. Reporter</b> <input type="checkbox"/> Healthcare Professional <input type="checkbox"/> Consumer <input type="checkbox"/> Other
	17. Name and Address: _____ _____ _____ Pin code: _____ E-mail: _____ Cell No./Tel. No. with STD Code: _____ Specialty: _____ Signature: _____
18. Occupation: _____	19. Date of this report (dd/mm/yyyy) ____/____/____