Internal office use:		
Local Reference number:	Company Number:	Date received:

Report Type: (please tick)

□ Spontaneous	□ Solicited	Protocol number: _____ Title: _____ _____ _____

Patient information:

Initials:	DOB:	Age at onset:	Units: Years/Days/Hours/Months/Minutes/Decades	Age group:	Gender:

Reporter Information:

Name:	Profession: □ Consumer □ Health care professional □ Other (please specify):
Organisation:	Telephone:
Address:	Fax:
City/Country:	Email:

Product Information:

Brand name:	Active Ingredient:	Route of Admin:
Dose:	Indication:	
Start Date:	Stop Date:	Action taken:

Adverse Event (AE) and/or Special Situation[1] (with or without AE):

Event terms: _____ _____ _____ _____	 Start Date: __/___/____ Stop Date: __/___/____ Start Date: __/___/____ Stop Date: __/___/____ Start Date: __/___/____ Stop Date: __/___/____ Start Date: __/___/____ Stop Date: __/___/____
Did the event result in hospitalisation? Yes □ No □ Unknown □	Did the event result in death? Yes □ No □ Unknown □
Was the event considered medically significant? Yes □ No □ Unknown □	Was the event life threatening? Yes □ No □ Unknown □
Did the event result in persistent or significant disability/incapacity? Yes □ No □ Unknown □	Did the event result in congenital anomaly? Yes □ No □ Unknown □

[1] Refer to EU GVP Module VI.B.6. Special situations for Definition

Outcome:

Recovered: □		Recovered with Sequalae: □	
Not Recovered: □		Unknown: □	
Fatal: □	Date of death: __/___/____	Cause of Death: _____	Autopsy performed: Yes □ No □ Unknown □

Co-Suspect Medication:

Name _____	Dose _____ Frequency _____	Route:_____	Indication: _____	Start Date: __/___/____	Stop Date: __/___/____
Name _____	Dose _____ Frequency _____	Route:_____	Indication: _____	Start Date: __/___/____	Stop Date: __/___/____
Name _____	Dose _____ Frequency _____	Route:_____	Indication: _____	Start Date: __/___/____	Stop Date: __/___/____

Concomitant Medication:

Name _____	Dose _____ Frequency _____	Route:_____	Start Date: __/___/____	Stop Date: __/___/____
Name _____	Dose _____ Frequency _____	Route:_____	Start Date: __/___/____	Stop Date: __/___/____
Name _____	Dose _____ Frequency _____	Route:_____	Start Date: __/___/____	Stop Date: __/___/____
Name _____	Dose _____ Frequency _____	Route:_____	Start Date: __/___/____	Stop Date: __/___/____

Medical History:

Event Description: *(including relevant Lab results)*

Signature:

Reporter Name:	Signature:	Date: