Form for reporting of ADR/Lack of efficacy and quality complaint

HEALTHCARE PROFESSIONAL / REPORTER

Full name:

Job title:

Office address:

Phone:

Date of receipt of information:

Treatment: ☐ outpatient ☐ inpatient ☐ self-treatment

Report: ☐ initial

☐ follow up (initial report date _____)

PATIENT DATA

Initial letters:

Sex: ☐ M ☐ F

Age: _____ Body weight (kg): _____

Pregnancy ☐ Gestational age _____wks

Hepatic impairment ☐ yes ☐ no ☐ unknown

Renal impairment ☐ yes ☐ no ☐ unknown

Allergy (indicate the allergen):

MEDICINAL PRODUCT No. 1 presumably caused ADR

International Nonproprietary Name (INN)		**Trade name**	
Manufacturer		Country		Batch No.	

Indication:	Route of administration	Single dose/daily dose	Start date of treatment	End date of treatment	Drug caused the ADR
			/ /	/ /	

MEDICINAL PRODUCT No. 2 presumably caused ADR

International Nonproprietary Name (INN)		**Trade name**	
Manufacturer		Country		Batch No.	

Indication:	Route of administration	Single dose/daily dose	Start date of treatment	End date of treatment	Drug caused the ADR
			/ /	/ /	

MEDICINAL PRODUCT No. 3 presumably caused ADR

International Nonproprietary Name (INN)		**Trade name**	
Manufacturer		Country		Batch No.	

Indication:	Route of administration	Single dose/daily dose	Start date of treatment	End date of treatment	Drug caused the ADR
			/ /	/ /	

OTHER DRUGS received during last 3 months including those received by patient's own motion

Indicate **«NO»** if patient didn't receive other drugs

International Nonproprietary Name (INN)	Trade name	Route of administration	Start date of treatment	End date of treatment	Indication
			/ /	/ /	
			/ /	/ /	
			/ /	/ /	
			/ /	/ /	
			/ /	/ /	

Description of Case:

Start date of ADR
___/_____/_____

End date of ADR
___/_____/_____

Did the event resolve after stopping drug? ☐ yes ☐ no ☐ didn't stopped ☐ not applicable

Did the ADR reappear after reintroduction? ☐ yes ☐ no ☐ didn't reintroduced ☐ not applicable

Measures taken:

☐ Without treatment
☐ Stopping the suspect drug
☐ Dose reduction of the suspect drug
☐ Stopping the concomitant drug
☐ Drug therapy
☐ Non-drug treatment (including surgery)
☐ Other, indicate _____

Treatment of ADR (if required)

Outcome:

☐ recovery without consequences
☐ condition improved
☐ condition without changes
☐ recovery with consequences (specify)_____
☐ death
☐ unknown
☐ not applicable

Criteria for seriousness (specify if applicable):

☐ death
☐ life-threatening condition
☐ inpatient hospitalization or prolongation of existing hospitalization
☐ congenital malformations
☐ incapacity / disability
☐ not applicable

Relevant additional information

Data from clinical, laboratory, X-ray investigations, and autopsy, including determination of drug concentration in the blood/tissues, if there are any and if they are associated with the ADR (please indicate dates).
Concomitant diseases. History data, suspected drug interactions.
For congenital abnormality, specify all other medicinal products taken during pregnancy and the date of last period. Please attach additional pages if necessary.