

This is not an official form but the translation of the French form for the courtesy of the English readers.

NATIONAL PHARMACOVIGILANCE CENTRE

Adverse Event Notification Form for Drugs, Vaccines, Health Products N°.....

Region:..... District:..... Healthcare facility ☐ Pharmacy ☐

Name of healthcare facility/pharmacy :

Type of healthcare facility /pharmacy: Private ☐ Public ☐ Service.....

Bed.....

Notifier Profile: Physician ☐ Pharmacist ☐ Dentist ☐ Nurse ☐ Midwife ☐

Other :.....

PATIENT Surname (first 3 letters): First name (first 2 letters): Sex: F ☐ M ☐ Telephone: Address:	Date of birth: Age : Weight: Kg Height : cm	If a newborn, the products have been taken By the newborn ☐ When breastfeeding ☐ By the mother during her pregnancy ☐ Pregnancy trimester: _ Write 1, 2,3	Declarant's stamp and signature Telephone: Completed, on
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Medical and medication history / Risk factors :

Suspected product(s)

Name	Lot number	Administration route	Dosage	Date of first dose	Date of last dose	Indication
1.						
2.						
3.						
4.						
5.						
6.						

Discontinued and readministered products

Name	Date of discontinuation of medicine	End of adverse event	Reintroduction of the drug (Yes/No/possibly)	Dosage after reintroduction	Reappearance of signs after reintroduction (Yes/No/possibly*)
1.					
2.					
3.					
4.					

*Possibly: No information

Effect	Seriousness	Progress	Grade
Date of occurrence:	Hospitalization or prolongation of hospitalization ☐	Resolved without sequelae ☐	Grade:
End date:	Permanent incapacity or disability ☐	Death due to adverse event ☐	Specify the scale used:
Event:	Life-threatening prognosis ☐	Deaths unrelated to the adverse event ☐	
Nature and description of adverse event (including medical reviews) : <i>use the VERSO framework</i>	Death ☐	Subject has not yet recovered ☐	

Description of adverse event

GUIDE FOR COMPLETION

Patient identity :

- Note the first 2 letters of the surname and the first 3 of the first name, do not fill in the form number
- Fill in all boxes
- Confirm possible pregnancy or breastfeeding.

Medications:

- All medicines or any other product (traditional medicines, vaccine) taken by the patient must be listed
- The dose and dose regimen are essential.
- For the method of obtaining the medication, simply tick the route by which the patient got his medicine:

1 Any prescription following medical consultation, **2** Any self-medication with the different places of purchase of the medicine.

Adverse event:

- Time of onset is the time elapsed between taking the medicine(s) and/or other product(s) and the onset of the adverse event.
- The description of the event: this is any abnormality noted or reported by the patient, the description must be simple and include the essentials; additional information can be attached to the sheet if necessary for a more detailed description.

Notifier:

Specify: surname, first name, profession, organisation and sign.