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

Adverse Event Notification Form for Healthcare Products*

N°..... (For AIRP only)

1. Notifying Healthcare Facility

Date of notification: ... .

1.1 Region:..... District:..... Healthcare facility □ Pharmacy □

1.2 Name of healthcare facility/pharmacy/traditional medicine centre: .....

1.3 Status of healthcare facility/pharmacy: Private □ Public □ Denominational □ Service..... Bed..... *File number*.....

2.PATIENT		
2.1 Surname (first 3 letters): | | | | First name (first 2 letters): | | | Sex: F □ M □ Residential address: ..... Telephone contact number:	2.2 Date of birth: | | | || | | | Age : | | | days/weeks/months/years (cross out where not applicable) Weight: | | | Kg Height : | | | | cm	2.3 If a newborn, the products have been taken By the newborn: *Directly* *via breast milk* By the mother during pregnancy Indicate the trimester of pregnancy: ..... By the father
2.4 Risk factors and medical or medication history: Tobacco Alcohol Traditional treatment Chronic treatment Pregnancy(s)/miscarriage/abortion Transfusion history Medical history Drug history/ Type of drug ..... Surgical history Other.....		

3.Product(s) administered

Name (trade name or INN) and dose	Tick the correct box	Product type	Batch number	Expiry date	Administration route	Dose regimen	Date of first dose	Date of last dose	Indication
1.	Suspected product Associated treatment								
2.	Suspected product Associated treatment								
3.	Suspected product Associated treatment								
4.	Suspected product Associated treatment								
5.	Suspected product Associated treatment								

*For vaccines and labile blood products, specify the batch number of the solvent:
Batch number of the solvent..... Date and time of reconstitution/delivery

1. Was the suspect product discontinued when the adverse event occurred? Yes / No
IF YES: a) Which one(s) (specify the serial number in the table above):
.....
b) Result after discontinuation of the product: Regression of the effect Disappearance of the effect
2. Has the discontinued product been re-administered? Yes / No
IF YES: a) Which one(s) (specify the serial number in the table above):
.....
b) Has the effect reappeared? Yes No

4. Adverse event(s)

4.1 Timing	**4.2 Severity**	**4.3 Progress**
Date of AE occurrence: AE end date: Duration of AE: .....days/weeks/months/years Description of the AE:	☐ **YES (tick the severity category)** Hospitalisation or prolonged hospitalisation ☐ Permanent incapacity or disability ☐ Life-threatening prognosis ☐ Congenital anomaly or malformation ☐ Death ☐ ☐ **NO**	☐ Resolved ☐ without sequelae ☐ with sequelae ☐Subject has not yet recovered ☐ Unknown ☐ Death Date of observation of progress .....

4.5 Description of adverse event(s)

(History of the disease, self-medication, additional examination(s) including biological and radiological, management of the effect ...)

5.Notifier

Surname, first names, signature and stamp:

Phone/ Mobile:

Email:

Notifier profession: Physician □ Pharmacist □ Dentist ☐ Nurse □ Midwife □ Traditional medicine practitioner □ Other:.....

NB: Send the completed form to the national pharmacovigilance centre /
Autorité Ivoirienne de Régulation Pharmaceutique

AIRP contact details:
ke.kouame@airp.ci / f.adou@airp.ci / secretariat@airp.ci
Tel: 22 00 83 09