**PHARMACOVIGILANCE QAP Annex 6.2**

**Confidential Adverse Effects Reporting Form**

Date (*dd/mm/yy*)

1. **Rapporteur (***Information marked with an asterisk* **\*** *is mandatory***)**

Name\*: Surname: Title:

Tel: E-mail\*:

Occupation : Health facility:

1. **Patient**

Initials: Age: Sex : Man/Woman Weight (in kg) :

1. **Adverse reactions**
   1. **. Symptom(s) and/or diagnosis :**

1. Beginning and end date (dd/mm/yy): / / - / /

2. or duration of the adverse reaction:

3. Evolution of adverse reaction:

4. Additional information on adverse reaction:

* 1. **. Severity of the adverse reactions**

From your point of view, do you think the adverse reaction is serious? YES NO

If yes, for which reasons?

* Need for hospitalization;
* Life threatening;
* Lethal;
* Permanent disability;
* Adverse reaction associated with a major medical event.
  + If yes, which one?

If the report concerns a drug taken during pregnancy, did the adverse reaction led to congenital anomaly?

**3.3. Did you report the adverse reaction to the holder of the record?** YES NO**3.4. Have there been any lab tests and/or medical exams related to this adverse reaction?**

If yes, which tests and what are the results?

Nature of the test and the exam Date of the test and the exam Result or additional information

1. / /

2. / /

3. / /

**4. Suspected drugs**

**Drug**

* Name (specialty or active ingredient)  :
* Dosage form (e.g. tablets…) :

**Dosage: e.g. 120 mg :**

2 times a day :

Or description :

**Method of administration :**

**Treatment duration**

Beginning and end date (*dd/mm/yyyy*) :

Or duration of the treatment :

**Indication:**

**What action have you taken in relation to the suspected drug?**

**In case the drug administered again, did it trigger the same adverse reaction?**

1. **Other(s) drug(s) taken by the same patient simultaneously**

Drug\* Dosage Method of administration Beginning and end date Indication

or duration of the treatment

1.

2.

1. **Clinical data about the patient (optional)**

Please mention other important clinical data or conditions (such as pregnancy, allergies, diseases ...)

Clinical data / condition beginning and end date Description/additional information

1. / / - / /

2. / / - / /

3. / / - / /

1. **Additional data that could be useful for the report**Other important information or specific questions, comments or suggestions for this report.