HPVC No. ..... Reference no. of reporter/source of report .....

Health Product Adverse Event Report Form

(all information will be held confidentially by the government)

❑ **Initial**
❑ **Follow up No. .....**
Ref no.....

Source of Report ❑ **Spontaneous Reporting** ❑ **Intensive Monitoring** ❑ **Clinical Trial**

Patient Information

Patient ID ❑ HN..... ❑ AN.....	**Patient type** ❑ IPD ❑ OPD	**Race** ❑ Thai ❑ Other specify	**Age**	**History of allergies** ❑ No ❑ Yes (please specify) .....
Patient Initials (first, last)	**Gender** ❑ Male ❑ Female		**Weight**	**Underlying disease / other relevant conditions** (specify ICD code, if known).....

Health Product Information

Type of Health Product ❑drug/narcotics, and psychotropic substance ❑ new drug (SMP) ❑ food ❑ cosmetic ❑ medical device ❑ hazardous substance

Product Name (Generic name/Trade name, dosage form, let no and exp. date for biological product, and part use for herbal product)	**S , O I ***	**Dose and Administration** (strength, quantity, unit, frequency, route)	**Starting date** (d/m/y)	**Discontinuing date** (d/m/y)	**Disease/reason for use** (specify ICD code, if known)	**Source of product** (1 or 2)

***S** = Suspected product , **O** = Other/concomitant product , **I** = Product interaction **Source of product**: 1 = hospital , 2 = other source (please specify)

Adverse Event Information

Adverse Events (describe event and/or technical term)	Labeled or non-labeled ADR	Positive laboratory findings and physical evidence
Date of onset (d/m/y).....		

Seriousness
- ❑ non-serious
- ❑ Serious (choose only one)
  - ❍ Death (d /m /y).....
  - ❍ Life-threatening
  - ❍ Hospitalization-initial or prolonged
    - △ in-patient hospitalisation
    - △ prolongation of hospitalization
  - ❍ Persistent or significant disability/incapacity
  - ❍ Causes a congenital anomaly/birth defect
  - ❍ Medical significant

(please specify) .....

- ❑ Dechallenge
  - ❍ Definite improvement
  - ❍ No improvement
  - ❍ Unknown
- ❑ Continued use
  - ❍ Same dose
  - ❍ Reduced dose
  - ❍ Changed administration
- ❑ Rechallenge
  - ❍ Recurrence
  - ❍ No Recurrence
  - ❍ Unknown
- ❑ No rechallenge performed

Outcome (after the adverse event)
- ❑ Recovered without sequelae
- ❑ Recovered with sequelae
- ❑ Recovering
- ❑ Not yet recovered
- ❑ Died -
  - ❍ due to adverse reaction
  - ❍ drug may be contributory
  - ❍ unrelated to drug (please specify) .....
- ❑ Loss of follow up

Source of Event/Reporter Information

Person making diagnosis .....

Occupation ❑ Physician ❑ Pharmacist ❑ Nurse ❑ other (please specify) .....

Evaluator/reporter.....

Occupation ❑ Physician ❑ Pharmacist ❑ Nurse ❑ other (please specify) .....

Date of report (d/m/y).....

Source of event.....

Province .....Tel.....

Source of reporter.....

Province .....Tel.....

Cause of Event

❑ **Product reaction (ADR/vaccine reaction) -** Causality assessment categories
- ❍ Certain
- ❍ Probable
- ❍ Possible
- ❍ Unlikely
- ❍ Unclassified (please specify reason) .....

- ❑ **Medication error**
- ❑ **Programmatic error** (vaccine)
- ❑ **Coincident** (vaccine)
- ❑ **Product defect**
- ❑ **Accident**
- ❑ **Suicide**
- ❑ **Misuse/in appropriate use**
- ❑ **Other** (please specify reason) .....