

HPVC No. :

Date of input into database:

Reference No. of reporter/source of report :

Health Product Adverse Event Report Form

(All information will be held confidentially by the government)

Type of report <input type="radio"/> Spontaneous report <input type="radio"/> Intensive monitoring <input type="radio"/> Report from study <input type="radio"/> Other	Type of Report from study <input type="radio"/> Clinical trials <input type="radio"/> Other study designs	<input type="radio"/> Initial <input type="radio"/> Follow-up No.....
Study name (please specify, if any)	Sponsor study number (please specify, if any)	

Part 1 Source of Event/Reporter Information		
Reporter's name <input type="radio"/> Physician <input type="radio"/> Pharmacist <input type="radio"/> Nurse <input type="radio"/> Other	Reporter's surname	
Date of awareness	Country origin <input type="radio"/> Thai <input type="radio"/> Other specify	
Person making diagnosis's name <input type="radio"/> Physician <input type="radio"/> Pharmacist <input type="radio"/> Nurse <input type="radio"/> Other	Date of report	
Source of event	Person making diagnosis's surname	
Source of event code	Province	
Telephone	E-mail address	
Source of reporter		
Source of reporter code	Province	
Telephone	E-mail address	
Part 2 Patient Information		
ID code	HN	AN
Name	Surname	
Sex <input type="radio"/> Male <input type="radio"/> Female <input type="radio"/> Unknown	Race <input type="radio"/> Thai <input type="radio"/> Other specify	
Date of birth	Age	[Age unit]
Weight (kg)	Height (cm)	
Address	Patient type <input type="radio"/> OPD <input type="radio"/> IPD	
Underlying disease / other relevant conditions	<input type="radio"/> Yes <input type="radio"/> No <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Hypertension <input type="checkbox"/> Dyslipidemia <input type="checkbox"/> Ischaemic heart disease <input type="checkbox"/> Hepatic function abnormal <input type="checkbox"/> Renal insufficiency <input type="checkbox"/> Other specify	History of drug allergy/ADR <input type="radio"/> Yes please specify the product and reaction ... <input type="radio"/> No

Part 3 Health Product Information**3.1 For medicine, narcotics, vaccine, herb, food, cosmetic, and hazardous substance product**

Generic name	[type of health product]	[drug role]
Trade name	License No.	
Manufacturer	<input type="radio"/> Thai <input type="radio"/> Other please specify	
Batch/Lot No.	Expiry date	
Source of product	Country <input type="radio"/> Thai <input type="radio"/> Other please specify	
Disease/reason for use	ICD-10 code	
Dose/administration [dose] [unit] [frequency] [interval]	[Route of administration]	

Additional information on product use

Start date	End date
Site of injection	Dose (e.g. 1 st , 2 nd , etc.)
Diluent	Date of reconstitution
Batch/Lot No.	Expiry date
Action taken	Reaction(s)/event(s) recurred after rechallenge the health product
<input type="radio"/> Performed rechallenge	
<input type="radio"/> Recurrence (specify reaction(s)/event(s) recurred)	
<input type="radio"/> No recurrence	
<input type="radio"/> No rechallenge performed	
<input type="radio"/> Unknown rechallenge performed	

3.2 For medical device

Product name	License/notification/registration No.
Name of Manufacturer/distributor	<input type="radio"/> Thai <input type="radio"/> Other please specify
Model No.	Catalog/Serial No.
Batch/Lot No.	Intended use
Additional information on product use	
Start date	End date
Action taken	<input type="radio"/> I have already informed the company at [date]

Part 4 Adverse Event Information

Adverse Event	<input type="radio"/> Labeled <input type="radio"/> Non-labeled
Date of onset	<input type="radio"/> Preventable <input type="radio"/> Non-preventable
Date of end of event	Outcome of event
Intervention done	Detail of event
Adverse Event	<input type="radio"/> Labeled <input type="radio"/> Non-labeled
Date of onset	<input type="radio"/> Preventable <input type="radio"/> Non-preventable
Date of end of event	Outcome of event
Intervention done	Detail of event

Adverse Event	<input type="radio"/> Labeled <input type="radio"/> Non-labeled
Date of onset	<input type="radio"/> Preventable <input type="radio"/> Non-preventable
Date of end of event	Outcome of event
Intervention done	Detail of event
Seriousness	Causality assessment
<input type="radio"/> Serious <input type="radio"/> Results in death (please specify date) <input type="radio"/> due to adverse event <input type="radio"/> health product may be contributory <input type="radio"/> unrelated to health product <input type="radio"/> Life threatening <input type="radio"/> Caused/prolonged hospitalization <input type="radio"/> Disabling/Incapacitating <input type="radio"/> Congenital anomaly/birth defect <input type="radio"/> Other medically important condition <input type="radio"/> Non-serious	Method of assessment <input type="radio"/> WHO-UMC system <input type="radio"/> Thai algorithm <input type="radio"/> Naranjo algorithm <input type="radio"/> Other please specify Result <input type="radio"/> Certain/Definite <input type="radio"/> Probable/Likely <input type="radio"/> Possible <input type="radio"/> Unlikely/Doubtful <input type="radio"/> Conditional/Unclassified <input type="radio"/> Unassessable/Unclassifiable

Part 5 Cause of Event

<input type="radio"/> Product reaction <input type="radio"/> Medication error <input type="radio"/> Product issues <input type="radio"/> Accident <input type="radio"/> Misuse <input type="radio"/> Inappropriate use <input type="radio"/> Suicide <input type="radio"/> Coincident <input type="radio"/> Other please specify	5.1 For Medication Error	
	Type of error <input type="radio"/> Prescribing error <input type="radio"/> Transcribing error <input type="radio"/> Dispensing error <input type="radio"/> Administration error <input type="radio"/> Monitoring error	Cause of medication error <input type="checkbox"/> Sound alike product <input type="checkbox"/> Look alike product <input type="checkbox"/> Label issue <input type="checkbox"/> Lack of knowledge/experience <input type="checkbox"/> Other please specify
	5.2 For Product issues	
	Type of product issues <input type="radio"/> Product contamination Specify <input type="radio"/> Product adulteration Specify	<input type="radio"/> Quality defect <input type="radio"/> Unregistered/unlicensed <input type="radio"/> Product transportation issue <input type="radio"/> Product storage issue

Part 6 Laboratory findings and physical evidence

Date	Test group	Test name	Result	Unit