# NOTIFICATION OF THE THAI FOOD AND DRUG ADMINISTRATION
# RE: PRESCRIPTION OF REPORT FORMS
# UNDER THE NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
# RE: CRITERIA, PROCEDURES AND CONDITIONS FOR PREPARATION OF REPORTS ON MEDICAL DEVICE DEFECTS OR ADVERSE EVENTS OCCURRING TO CONSUMERS AND REPORTS ON FIELD SAFETY CORRECTIVE ACTIONS FOR MEDICAL DEVICES, B.E. 2563 (2020)*

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By virtue of the provision of clause 5 of the Notification of the Ministry of Public Health Re: Criteria, Procedures and Conditions for Preparation of Reports on Medical Device Defects or Adverse Events Occurring to Consumers and Reports on Field Safety Corrective Actions for Medical Devices, B.E. 2563 (2020), dated 22nd October B.E. 2563 (2020), the Secretary-General of the Thai Food and Drug Administration hereby issues the Notification as follows:

**Clause 1.** Business premise registrants, market authorization holder s, specification providers, or notifiers shall prepare the reports on medical device defects or adverse events occurring to consumers, as well as the reports on field safety corrective actions for medical devices to be submitted to the Thai Food and Drug Administration using the forms annexed to this Notification, as follows:

(1) Medical Device Defect or Adverse Event Report Form for a Domestic Case, in accordance with Form Ror Mor Por 1;

(2) Device Defect and Adverse Event Summary Report Form for Foreign Cases, in accordance with Form Ror Mor Por 2;

(3) Field Safety Corrective Action Report Form Both Domestic and Foreign Cases, in accordance with Form Ror Mor Por 3.

**Clause 2.** This Notification shall come into force as from the day following the date of its publication in the Government Gazette.

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* Published in the Government Gazette, Vol. 138, Special Issue, Part 27d, page 17, dated 4th February B.E. 2564 (2021)

Announced on the 20th day of January B.E. 2564 (2021)

Paisan Dankum

Secretary-General of the Thai Food and Drug Administration

Company's reference No. .....

HPVC-MD1- .....

# Medical Device Defect or Adverse Event Report Form for a Domestic Case

| | | | | |
|---|---|---|---|---|
| ○ Device defect | ○ Adverse event | | | |
| Report type | ☐ Initial ☐ Follow-up No. ..... ☐ Final ☐ Trend | | | |
| **1. Company information** | | | | |
| Type of reporter | ☐ Manufacturer ☐ Importer ☐ Seller License holder ☐ Other, specify ..... | | | |
| Establishment License No./Seller's License No. | | | | |
| Company's name | | | | |
| Address | | | | |
| Reporter | | Position | | |
| Telephone No. | | E-mail | | |
| Other regulatory authorities to which this report was also sent | | | | |
| | | | | |
| **2. Device details** | | | | |
| Trade name | | | | |
| Common name | | | | |
| GMDN code | | | | |
| Type of medical device | ○ IVD ○ Non-IVD | Risk classification | ○ Class I ○ Class II ○ Class III ○ Class IV | |
| Indication/intended use | | | | |
| | | | | |
| Device regulatory status | ○ Licensed medical device No. ..... ○ Notified medical device No. ..... ○ Listed medical device No. ..... ○ Other, specify ..... | | | |
| Catalogue No. | | Model No. | | Lot/Batch No. |
| Serial No. | | Software version | | |
| Accessories | | | | |
| | | | | |
| Physical manufacturer | | | | |
| Address | | | | |
| Country | | E-mail | | |
| Product owner | | | | |
| Address | | | | |
| Country | | E-mail | | |

| 3. Healthcare facility information | | | |
|---|---|---|---|
| Facility's name | | | |
| Address | | | |
| Contact person's name | | Position | |
| Telephone No. | | E-mail | |
| Current location of device | | | |

| 4. Information of device defect/adverse event | |
|---|---|
| Classification of incident | ○ Serious<br>○ Serious threat to public health<br>○ Death<br>○ Serious injury<br>○ Non-serious |
| Medical device problem (IMDRF Annex A) | |
| Clinical signs, symptoms and conditions (IMDRF Annex E) | |
| Event description | |
| | |

| Date of incident | | Company awareness date | |
|---|---|---|---|
| Have any of the similar events occurred? | ○ Yes (specify the country) .....<br>○ No<br>○ Unknown | | |
| Have any of other AE occurred by using the medical device for the same cause? | ○ Yes, country .....<br>frequency of occurrence .....<br>○ No ○ Unknown | | |
| User of device at the time of the event | ○ Healthcare professional<br>○ Patient<br>○ Patient/sick animal caregiver<br>○ Other, specify ..... | | |
| Usage of device | ○ Initial use<br>○ Reuse of a single use device<br>○ Reuse of a reusable device<br>○ Re-service/Refurbished<br>○ Other, specify ..... | | |
| Number of patients involved | | Number of devices involved | |

| **5. Patient information (only for adverse event)** | |
|---|---|
| Affected person | ○ Patient ○ Sick animal<br>○ Patient/sick animal caregiver<br>○ Healthcare professional<br>○ Other, specify .....<br>○ Unknown |
| Gender | ○ Male ○ Female ○ Unknown |
| Age at the time of the incident | ..... (year/month/day) ○ Unknown |
| Weight | ..... kg. |
| Health impact (IMDRF Annex F) | |
| Treatment of affected person | |
| | |
| Patient outcome | ○ Death (Date: ...../...../.....)<br>○ Not yet recovered<br>○ Recovered (Date: ...../...../.....)<br>○ Other, specify ..... |
| **6. Results of investigation/inspection from manufacturer/product owner** | |
| Type of investigation (IMDRF Annex B) | |
| Investigation findings (IMDRF Annex C) | |
| Investigation conclusion (IMDRF Annex D) | |
| Component (IMDRF Annex G) | |
| Is there any policy created for Field Safety Corrective Action? | |
| ○ No ○ Yes (HPVC-MD3-.....) | |
| Remedial action/corrective action/preventive action | |
| | |
| **7. Other information** | |
| | |

☐ I attest that the information submitted is true and accurate as I have been informed.

Signature : .....

Name of reporting person : .....

Date of this report : .....

Company's reference No. .....

HPVC-MD2- .....

# Device Defect and Adverse Event Summary Report Form for Foreign Cases

Reporting period ○ Jan-Jun ○ Jul-Dec in the year .....

| **1. Company information** | | | |
|---|---|---|---|
| Type of reporter | ☐ Manufacturer ☐ Importer ☐ Seller License holder<br>☐ Other, specify ..... | | |
| Establishment License No./Seller's License No. | | | |
| Company's name | | | |
| Address | | | |
| Reporter | | Position | |
| Telephone No. | | E-mail | |
| **2. Device details** | | | |
| Trade name | | | |
| Common name | | | |
| GMDN code | | | |
| Indication/intended use | | | |
| | | | |
| Device regulatory status | ○ Licensed medical device No. .....<br>○ Notified medical device No. .....<br>○ Listed medical device No. .....<br>○ Other, specify ..... | | |
| Physical manufacturer | | Country | |
| Product owner | | Country | |

| **Model number** | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **No. of devices supplied by model** | | | | | | | | | | | | |
| No. of devices supplied worldwide (including Thailand) | | | | | | | | | | | | |
| No. of devices supplied in Thailand | | | | | | | | | | | | |
| **No. of Device Defect/Adverse Event (AE) by model** | | | | | | | | | | | | |
| **Device Defect/AE** | **①** | | **②** | | **③** | | **Total** | | **% Rate** | | **RA action** | **Trending report** |
| | **WW** | **TH** | **WW** | **TH** | **WW** | **TH** | **WW** | **TH** | **WW** | **TH** | | |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |

| Model number | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **No. of devices supplied by model** | | | | | | | | | | | | |
| No. of devices supplied worldwide (including Thailand) | | | | | | | | | | | | |
| No. of devices supplied in Thailand | | | | | | | | | | | | |
| **No. of Device Defect/Adverse Event (AE) by model** | | | | | | | | | | | | |
| **Device Defect/AE** | **①** | | **②** | | **③** | | **Total** | | **% Rate** | | **RA action** | **Trending report** |
| | **WW** | **TH** | **WW** | **TH** | **WW** | **TH** | **WW** | **TH** | **WW** | **TH** | | |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |
| | | | | | | | | | | | Y/N/NA | Y/N/NA |

☐ I attest that the information submitted is true and accurate as I have been informed.

Signature : .....

Name of reporting person : .....

Date of this report : .....

Notes:

1. ① = serious threat to public health, ② = death, ③ = serious injury, WW = worldwide, TH = Thailand.
2. %Rate = "(No. of Device Defect/AE ÷ No. supplied) × 100".
3. RA action = are there any regulatory/corrective actions/notification by the manufacturer? (Y = Yes, N = No, NA = Not available).
4. Trending Report = Is %Rate exceeding the threshold? (Y = Yes, N = No, NA = Not available).
5. One brand name/report.

Company's reference No. .....

HPVC-MD3- .....

# Field Safety Corrective Action Report Form Both Domestic and Foreign Cases

| | | | | |
|---|---|---|---|---|
| Report type | ☐ Initial ☐ Follow-up No. ..... ☐ Final | | | |
| **1. Type of Field Safety Corrective Action (FSCA)** | | | | |
| ☐ Product recall<br>○ Class I ○ Class II ○ Class III<br>☐ Device modification<br>☐ Retrofit<br>☐ Change to the labeling or design change<br>○ Permanent ○ Temporary<br>☐ Software upgrades<br>☐ Modification to the clinical management of patients | | | ☐ Device exchange<br>☐ Device destruction<br>☐ Advice given by product owner regarding the use of the device<br>☐ Other, specify ..... | |
| **2. Company information** | | | | |
| Type of reporter | ☐ Manufacturer ☐ Importer ☐ Seller License holder<br>☐ Other, specify ..... | | | |
| Establishment License No./Seller's License No. | | | | |
| Company's name | | | | |
| Address | | | | |
| Reporter | | | Position | |
| Telephone No. | | | E-mail | |
| **3. Device details** | | | | |
| Trade name | | | | |
| Common name | | | | |
| GMDN code | | | | |
| Type of medical device | ○ IVD<br>○ Non-IVD | Risk classification | ○ Class I ○ Class II<br>○ Class III ○ Class IV | |
| Indication/intended use | | | | |
| | | | | |
| Device regulatory status | ○ Licensed medical device No. .....<br>○ Notified medical device No. .....<br>○ Listed medical device No. .....<br>○ Other, specify ..... | | | |

| | | | |
|---|---|---|---|
| Catalogue No. | | | |
| Model No. | | | |
| Lot/Batch No. | | | |
| Serial No. | | | |
| Software version | | | |
| Accessories | | | |
| Physical manufacturer | | | |
| Address | | | |
| Country | | E-mail | |
| Product owner | | | |
| Address | | | |
| Country | | E-mail | |
| **4. FSCA information** | | | |
| Reason for the FSCA | ☐ Device Defect .....<br>☐ Adverse Event .....<br>☐ Other, specify ..... | | |
| Health Hazard Evaluation Report | | | |
| | | | |
| FSCA strategy | | | |
| | | | |
| **The FSCA communication of corrective action that sent to all consignees** | | | |
| ☐ In Thailand | ☐ Food and Drug Administration<br>Date sent .....<br>☐ Medical center/Healthcare professional/Patient<br>Expected date to be sent .....<br>Completed date ..... | | |
| ☐ Other countries | Date sent ..... | | |
| **Corrective action for safety** | | | |
| ☐ In Thailand | Expected date of action .....<br>Date of action .....<br>Expected date to be completed ..... | | |
| ☐ Other countries | Expected date of action .....<br>Date of action ..... | | |
| Number of affected medical device | | | |
| Number of affected medical device sold/distributed | | | |
| Number of affected medical device remaining | | | |
| Number of affected medical device expected to be imported | | | |

| Product status (only follow-up and final report) | | | | | | | |
|---|---|---|---|---|---|---|---|
| Model No. | Batch No. & Manufacturing or expiry date | Quantity manufactured or imported | Quantity exported | Quantity remaining in warehouse | Quantity sold | Quantity recalled | Quantity corrected |
| | | | | | | | |

**5. Final report**

| FSCA has been completed on | |
|---|---|

Effectiveness checks on operational conduct of FSCA

Final risk evaluation (if different from the initial risk evaluation)

Summary of product owner's corrective and preventative action and effectiveness checks

**6. Action taken on affected products**

I confirm that the action has been completed on .....

I will be

○ returning the affected stocks to the product owner as approved by the Thai FDA

○ destroying the affected stocks as approved by the Thai FDA at (location & date) .....

○ taking other action(s) as approved by the Thai FDA, please specify

.....

**7. Other information**

☐ I attest that the information submitted is true and accurate as I have been informed.

Signature : .....

Name of reporting person : .....

Date of this report : .....