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)*

Whereas it is expedient to revise 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 to ensure that it is suitable to and compatible with the present situations, with a view to safeguarding the health and safety of consumers as well as to gather information for appropriate risk management of medical devices;

By virtue of the provisions of section 5 paragraph one of the Medical Devices Act, B.E. 2551 (2008) and section 41 (4) of the Medical Devices Act, B.E. 2551 (2008) as amended by the Medical Devices Act (No. 2), B.E. 2562 (2019), the Minister of Public Health hereby issues the Notification as follows.

Clause 1. 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to Consumers and Reports on Field Safety Corrective Actions dated the 22nd day of March B.E. 2559 (2016) shall be repealed.

Clause 2. In this Notification:

"consumer" means a patient, a sick animal, a user of the medical device or any other person affected by a medical device;

"device defect" means a malfunction or deterioration in characteristic or or performance of a medical device, or display of inccorect/erroneous result, or result which deviates from a specification, or defect in design of a medical device, or incorrect or incomplete statement on the label, package insert or instruction for use, or use error;

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“adverse event” means any event resulting from a malfunction or deterioration in characteristic or performance of a medical device or a use error which causes, may be a cause of or contributes to the death or injury of a consumer;

“field safety corrective action” means any action taken by the product owner to reduce risk from a serious threat to public health or risks of consumer’s death or serious harm which are resulted from the use of a medical device;

“serious threat to public health” means an event resulting in imminent risk of death, serious deterioration in state of health or serious illness which requires a remedial action; this includes the following events:

(1) an event that is of significant and unexpected nature such that it became alarming as potential public health hazard, such as Human Immunodeficiency Virus (HIV), Creutzfeldt-Jacob Disease (CJD); or

(2) an event of multiple deaths occurring at short intervals;

“serious injury” means any of the following conditions of a consumer:

(1) life-threatening illness or injury;

(2) permanent impairment of body function or permanent damage to a body structure;

(3) a condition necessitating medical or surgical intervention to prevent, permanent impairment of a body function or permanent damage to a body structure

“product owner” means a natural person or a juristic person who:

(1) sells a medical device under his or her own name or under a trademark, design, trade name, other name or other mark which he or she owns or controls, and;

(2) is responsible for designing, manufacturing, assembling, processing, display of label or packaging, irrespective of whether it is done by him or her or by another person entrusted to act on his or her behalf.

Clause 3. The business premises registrant, market authorization holder, specification provider or notifier shall prepare reports on device defects or adverse events occurring to consumers as well as reports on field safety corrective actions for medical device, whether the device defects or adverse events occur within or outside the country, in compliance with the following criteria:

(1) a report on medical device defects or adverse events occurring to consumers with one of the following outcomes:

(a) a serious threat to public health;

(b) death or a serious injury;

(c) a case where there is scientific data or evidence indicating that a recurrence of the incident may lead to the death or a serious injury of consumers;

(2) a report on field safety corrective actions for medical device taken by the product owner to reduce risks from medical device defects or adverse events occurring to consumers.

Clause 4. The business premise registrant, marketing authorization holder, specification provider or notifier shall prepare reports under clause 3 for submission to the Thai Food and Drug Administration within the prescribed period as follows:

(1) reporting of device defects or adverse events occurring to consumers:

(a) cases of events occurring within the country:

1) initial report:

1.1 in cases of serious threat to public health, the report shall be submitted immediately or within forty-eight hours at the latest from the awareness date;

1.2 in cases of death or a serious injury, the report shall be submitted immediately or within ten days at the latest from the awareness date;

1.3 in cases where there is academic data or evidence indicating that a recurrence of the incident may lead to the death or a serious injury of consumers, the report shall be submitted within thirty days from the awareness date;

2) the follow-up report shall be submitted within thirty days from the date of submission of the initial report;

(b) cases of events occurring outside the country: the report shall be submitted twice a year. A report on events occurring between January and June shall be submitted by August, and a report on events occurring between July and December shall be submitted by February. The events shall also be reported as requested by the Thai Food and Drug Administration, except for those concerning a medical device manufactured and sold in the country which shall be reported in accordance with (a);

(2) reporting of field safety corrective actions for medical device both in the country and outside the country:

(a) The initial report shall be submitted within forty-eight hours from the date on which the field safety corrective action for the medical device is known to have been carried out;

(b) The follow-up report or final report shall be submitted within twenty-one days from the date of the previous report.

Clause 5. The report shall be made in the form of report specified in the Notification by the Secretary-General of the Thai Food and Drug Administration.

Clause 6. This Notification shall come into force after the expiration of sixty days from the date of its publication in the Government Gazette.

Announced on the 22nd day of October B.E. 2563 (2020)

Anutin Charnvirakul

Minister of Public Health