NOTIFICATION OF THE MINISTRY OF PUBLIC HEALTH
RE: RULES, PROCEDURES AND CONDITIONS FOR PREPARATION OF REPORTS ON MEDICAL DEVICE MALFUNCTIONS 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: Rules, Procedures and Conditions for Preparation of Reports on Medical Device Malfunctions 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 and benefits the protection of health and the monitoring of safety of consumers as well as the preparation of information for appropriate management of risks with respect to 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: Rules, Procedures and Conditions for Preparation of Reports on Medical Device Malfunctions 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to Consumers and Reports on Field Safety Corrective Actions dated the 22nd day of March B.E. 2559 (2016) shall be repealed.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 the medical device;

"medical device malfunction" means malfunctions or deterioration of properties or performance of a medical device, or display of erroneous results, or deviation from the specifications, or defects in design of a medical device, or incorrect or incomplete statements on the label, package insert or user's manual, or use errors;

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"adverse event occurring to a consumer" means any event resulted from a malfunction or deterioration of properties or performance of a medical device or a use error which causes, may result in or contributes to the death or injuries of a consumer;

"field safety corrective action for medical device" means any action determined by the product owner to reduce risks 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 risks of death, serious harms or serious illness which requires an immediate corrective action, and shall include the following events:

(1) an event causing serious and unanticipated harms that may result in risks to the general public, such as Human Immunodeficiency Virus (HIV), Creutzfeldt-Jacob Disease (CJD); or

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

"serious harm condition" means any of the following conditions of a consumer:

(1) grievous injury or life-threatening illness;

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

(3) a condition which requires a treatment or a surgery to prevent disability or permanent physical injury;

"product owner" means a natural person or a juristic person who—

(1) sells a medical device under his or her own name or under any trademark, design, trade name or other name or other mark owned or controlled by him or her; and

(2) is responsible for the design, manufacturing, assembling, operation, display of labels 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 establishment registrant, licensee, specification declarer or notifier shall prepare a report on medical device malfunctions or adverse events occurring to consumers as well as a report on field safety corrective actions for medical device, whether the malfunctions or adverse events occur within or outside the country, in compliance with the following rules:

(1) a report on medical device malfunctions or adverse events occurring to consumers in any of the following cases:

(a) a serious threat to public health;

(b) death or a serious harm condition;

(c) a case where there is academic data or evidence indicating that if such event is to recur, it may lead to the death or a serious harm condition of consumers;

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

Clause 4. The establishment registrant, licensee, specification declarer or notifier shall prepare a report under clause 3 for submission to the Food and Drug Administration within the prescribed period as follows:

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

(a) cases of events occurring within the country:

1) preliminary report:

1.1 in cases of a serious threat to public health, it shall be reported immediately or within a period not exceeding forty-eight hours at the latest from the date of knowledge;

1.2 in cases of death or a serious harm condition, it shall be reported immediately or within ten days at the latest from the date of knowledge;

1.3 in cases of a case where there is academic data or evidence indicating that if such event is to recur, it may lead to the death or a serious harm condition of consumers, it shall be reported within thirty days from the date of knowledge;

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

(b) cases of events occurring outside the country: The report shall be submitted twice a year. An event occurring in January to June shall be reported by August, and an event occurring in July to December shall be reported by February. The event shall also be reported as requested by the Food and Drug Administration, except for that 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 preliminary 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 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