(Draft)

Notification of the Food and Drug Administration

Re: Prescribing information, document, or evidence that do not require to be submitted in accordance with the ministerial regulations governing permission and issuance of licensing/notification approval of medical device manufacturing/importation.

B.E. ...

Whereas it is appropriate to prescribe information, document, or evidence that do not require to be submitted in accordance with the ministerial regulations governing permission and issuance of licensing approval of manufacturing/import of medical devices B.E. 2564 and the ministerial regulations governing permission and issuance of notification approval of manufacturing/import of medical devices B.E. 2564, according to the format for evaluating documents in the scope of efficiency and safety. This is to reduce redundancy in evaluating academic information while maintaining quality, efficiency, and safety, to make the evaluation process more efficient and completed on time, to facilitate people in operating the business of manufacturing and importing medical devices, and to encourage economic drivers in the medical device industry.

By virtue of Clause 3 of the ministerial regulations governing permission and issuance of licensing approval of manufacturing/import of medical devices B.E. 2564 and Clause 3 of the ministerial regulations governing permission and issuance of notification approval of manufacturing/import of medical devices B.E. 2564, the Secretary General of the Food and Drug Administration issued the following:

Clause 1 This notification shall come into force the day after its publication in the Royal Gazette.

Clause 2 The applicant is not required to submit the following information, document, or evidence according to the ministerial regulations.

(1) Full evaluation; the applicant is not required to submit the following.

1) Declaration letter – Letter of certification of the intended use/indication/packaging, Letter of certification of label and instruction for use from manufacturer or product owner

2) Marketing history declaration

3) Safety declaration

4) Proof of approval from medical device regulatory authority in foreign countries

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(2) Concise evaluation – by referring to evidence of approval from authority in foreign countries that certified by the Food and Drug Administration; the applicant is not required to submit the following.

1) Design verification and validation documents

2) Risk analysis

3) Destruction method, disposal of waste generated after use.

In this regard, medical devices that will request concise evaluation must meet the following conditions.

(a) It is a medical device that has been registered with at least one of the following authorities which is certified by the Food and Drug Administration.

1) Therapeutic Goods Administration: TGA

2) Health Canada: HC

3) European Union Notified Bodies: EU NB

4) Japan Ministry of Health Labour and Welfare: MHLW

5) US Food and Drug Administration: US FDA

6) WHO Prequalification of in Vitro Diagnostics (IVD)

7) Other agencies specified by the Food and Drug Administration

However, product registration must be approved or permitted for one year or more.

(b) Trade name, intended use, indications, labeling, instruction for use, and packaging of the medical device must be the same as those approved or permitted under (a).

(c) This does not include cases where medical devices are specifically controlled by the Ministry of Public Health announcement,

Clause 3 In the event that there is a doubt regarding the standard quality, efficiency, and safety of medical devices. Officials may request information, documents, and evidence to verify.

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