



26 March 2026

(26-2411)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>PHILIPPINES</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: Atty. Paolo S. Teston Director General Food and Drug Administration
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], Other:
4. Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): Medical equipment (ICS code(s): 11.040)
5. Details of notified document(s) (title, number of pages and languages, means of access): FDA Circular: Guidelines on the Maintenance of Importation and/or Distribution Records, and the Reporting of Product Complaints, Adverse Events, and Field Safety Corrective Actions for Medical Devices; (15 page(s), in English) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://members.wto.org/crnattachments/2026/TBT/PHL/26_01689_00_e.pdf https://members.wto.org/crnattachments/2026/TBT/PHL/26_01689_01_e.pdf https://members.wto.org/crnattachments/2026/TBT/PHL/26_01689_02_e.pdf https://www.fda.gov.ph/draft-for-comments-guidelines-on-the-maintenance-of-importation-and-or-distribution-records-and-the-reporting-of-product-complaints-adverse-events-and-field-safety-corrective-actions-for-medical/ Dr. Valeriano V. Timbang, Jr. Officer-in-Charge, Director IV Center for Device Regulation, Radiation Health, and Research (CDRRHR) Email: cdrhr@fda.gov.ph
6. Description of content: The proposed FDA Circular provides guidelines on the maintenance of importation and/or distribution records and the reporting of product complaints, adverse events (Aes), and field safety corrective actions (FSCAs) for medical devices. It applies to all registered medical devices and in vitro diagnostic (IVD) medical devices placed on the Philippine market. The Circular defines the responsibilities of Marketing Authorization Holders (MAHs) and dealers in maintaining traceability records and supporting post-market surveillance (PMS). The Circular also sets clear criteria for determining reportable AEs and FSCAs. It establishes standardized reporting formats, timelines, and submission procedures for AE and FSCA notifications to the FDA. The Circular provides guidance on complaint handling, record retention, and follow-up reporting. It further outlines procedures for FSCA initiation, implementation, and closure, including FDA review and concurrence. The measure aligns national post-market

<p>requirements with the ASEAN Medical Device Directive (AMDD), particularly Annex 5 on the Post-Marketing Alert System.</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: The objective of the proposed FDA Circular is to strengthen the PMS of medical devices to ensure the continued safety, quality, and performance of products placed on the Philippine market. The measure addresses gaps arising from inconsistent record-keeping and non-uniform reporting of product complaints, AEs, and FSCAs. Without standardized requirements, the ability of the regulatory authority to promptly identify safety signals and implement risk mitigation measures may be limited. The Circular establishes clear obligations for MAHs and dealers, thereby improving traceability and regulatory oversight. It also supports timely regulatory intervention in cases involving serious risks to public health. It is aligned with international best practices and commitments under the AMDD. No urgent or emergency situation is being addressed; rather, the measure is preventive in nature. Overall, the regulation seeks to enhance patient safety and public confidence in medical devices through a transparent and harmonized post-market regulatory framework.</p>
<p>8. Relevant documents:</p> <ul style="list-style-type: none"> • Republic Act 9711 "Food and Drug Administration (FDA) Act of 2009" • Administrative Order No. 2018-0002 "Guidelines Governing the Issuance of an Authorization for a Medical Device based on the ASEAN Harmonized Technical Requirements • ASEAN Medical Device Directive (AMDD). September 2015. ASEAN Agreement on Medical Device Directive.
<p>9. Proposed date of adoption: To be determined</p> <p>Proposed date of entry into force: Fifteen (15) days from the date of its publication in the Official Gazette or in any national newspaper of general circulation.</p>
<p>10. Provision of comments</p> <p>Final date for comments: 25 May 2026</p> <p>[X] 60 days from notification</p> <p>Contact details of agency or authority designated to handle comments regarding the notification:</p> <p>Mr. Neil P. Catajay Director Bureau of Philippine Standards Department of Trade and Industry 3F Trade and Industry Building 361 Sen. Gil Puyat Avenue Makati City Philippines 1200 Tel: (632) 751 4700; (632) 7913128 Email: bps@dti.gov.ph Website: http://www.bps.dti.gov.ph</p>