



21 February 2023

(23-1223)

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Committee on Import Licensing

Original: English

AGREEMENT ON IMPORT LICENSING PROCEDURES

NOTIFICATION UNDER ARTICLE 5.1 TO 5.4 OF THE AGREEMENT¹

PHILIPPINES

The following notification dated 14 February 2023, is being circulated at the request of the delegation of the Philippines.

	Category	Notification details
1	Notifying Member	Philippines
2	Title of new legislation/procedure	FDA Circular No.2021-014 – Guidelines for the Use of the Food and Drug Administration (FDA) eServices Portal System for License to Operate (LTO) Application of Traders and Distributors including Wholesalers, Importers, and Exporters of Medical Devices, Equipment or Devices Used for Treating Sharps, Pathological and Infectious Waste and Water Treatment Devices/Systems
3	Date of Publication	24 June 2021
4	Date of entry into force	26 July 2021
5	Website link/Official publication of the new regulation/procedure	https://www.fda.gov.ph/fda-circular-no-2021-014-guidelines-for-the-use-of-the-food-and-drug-administration-fda-eservices-portal-system-for-license-to-operate-lto-application-of-traders-and-distributors-including-who/
6	Have you attached a copy of the regulation (PDF) to the Secretariat	[X] Yes. (Please attach a copy of the regulation to the notification.) [] No.
7	Type of notification	[X] (a) New licensing regulation/procedure ² ; (please answer question 8 to 14) [] (b) Changes to a regulation/procedure which has been previously notified in document: _____; (please answer question 15 and 16)
8	List of products subject to licensing	9033.00.00 - Parts and accessories (not specified or included elsewhere in Chapter 90) for machines, appliances, instruments or apparatus of Chapter 90 Initial, renewal and variation to License to Operate for Traders and Distributors (Wholesalers/Importers/Exporters) of medical and health related devices, equipment or devices used for treating sharps, pathological and infectious waste and water treatment devices/system.
9	Nature of licensing	Automatic: [] Non-Automatic: [X]

¹ It is understood that the notifying Member has also completed its notification obligations under Article 1.4(a) and Article 8.2(b) regarding the relevant law/regulation/procedure notified for by filling this form in a full and complete manner.

² "New licensing regulation/procedure" is understood to refer to any newly introduced law, regulation or procedure, and those which are in force but being notified for the first time to the Committee.

	Category	Notification details
10	Administrative purpose/measure being implemented	(a) <input type="checkbox"/> Protect public morals; (b) <input type="checkbox"/> Protect human, animal or plant life and health; protect environment; (c) <input type="checkbox"/> Collect trade statistics or market surveillance; (d) <input type="checkbox"/> Protection of patents, trademarks and copyrights, and the prevention of deceptive practices; (e) <input type="checkbox"/> Pursue obligations under the UN Charter and other international treaties (<i>i.e. CITES, Basel Convention, Rotterdam Convention, UNSC Resolutions etc.</i>) (f) <input type="checkbox"/> Quota (including TRQ) administration; (g) <input type="checkbox"/> Regulate imports of arms, ammunition or fissionable materials and safeguard national security; (h) <input checked="" type="checkbox"/> Other: <u>To provide guidelines on the FDA eServices Portal in applying for LTO</u>
11	Administrative body(ies) for submission of applications	Ministry/authority and Department: Food and Drug Administration Address: 1781 Civic Dr, Alabang, Muntinlupa, 1781 Metro Manila Website: https://eservices.fda.gov.ph/ Telephone: +632 8 857-1900 E-Mail: info@fda.gov.ph
12	Contact point for information on eligibility	Ministry/authority and Department: Food and Drug Administration Address: 1781 Civic Dr, Alabang, Muntinlupa, 1781 Metro Manila Website: https://eservices.fda.gov.ph/ Telephone: +632 8 857-1900 E-Mail: info@fda.gov.ph
13	Expected duration of licensing procedure	Ongoing.
14	A summary of the notification in one of the WTO official languages	The FDA eservices Portal System has been developed to provide a streamlined online platform for FDA authorization applications.
15	In the case of 7(b), please indicate the type of new change(s)	(a) <input type="checkbox"/> Termination (b) <input type="checkbox"/> Suspension (c) <input type="checkbox"/> Modification of specific details in existing procedures: <input type="checkbox"/> Product coverage; <input type="checkbox"/> Administrative purpose; <input type="checkbox"/> Automatic or Non-automatic; <input type="checkbox"/> Duration of licensing; <input type="checkbox"/> Change the nature of quantity/value restriction; <input type="checkbox"/> Eligibility of applicants; <input type="checkbox"/> Contact information on eligibility; <input type="checkbox"/> Administrative body(ies) for submission of application; <input type="checkbox"/> Documentation requirements (including application form); <input type="checkbox"/> Period for Application; <input type="checkbox"/> Administrative body(ies) to issue licence; <input type="checkbox"/> Processing time for issuing licence; <input type="checkbox"/> Licence fee/administrative charge; <input type="checkbox"/> Deposit/advance payment and relevant conditions; <input type="checkbox"/> Appeal regulations/procedures; <input type="checkbox"/> Validity of licence; <input type="checkbox"/> Other conditions of licence (extension, transferability, penalty of non-use etc.); <input type="checkbox"/> Foreign exchange requirements; <input type="checkbox"/> Other: _____ (please specify).

	Category	Notification details
16	Please elaborate the changes in detail (in one of the WTO official languages)	
