WORLD TRADE ORGANIZATION

G/LIC/N/2/PHL/189

21 February 2023

(23-1220)

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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 AGREEMENT[1]

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**	DOH Administrative Order No.2020-0017 – Revised Guidelines on the Unified Licensing Requirements and Procedures of the Food and Drug Administration Repealing AO No.2016-0003
3	**Date of Publication**	21 May 2020
4	**Date of entry into force**	5 June 2020
5	**Website link/Official publication of the new regulation/procedure**	https://www.fda.gov.ph/wp-content/uploads/2020/05/Administrative-Order-No.2020-0017.pdf
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: All medical devices, Radiation-emitting devices, In-vitro diagnostic device and reagents, Refurbished medical devices, Equipment or devices used for treating sharps, Pathological and infectious waste, Water treatment devices/systems,

[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
		And other health-related devices as determined by the FDA.
9	**Nature of licensing**	Automatic: [ ] Non-Automatic: [X]
10	**Administrative purpose/measure being implemented**	(a) ☐ Protect public morals; (b) ☐ Protect human, animal or plant life and health; protect environment; (c) ☐ Collect trade statistics or market surveillance; (d) ☐ Protection of patents, trademarks and copyrights, and the prevention of deceptive practices; (e) ☐ Pursue obligations under the UN Charter and other international treaties (*i.e. CITES, Basel Convention, Rotterdam Convention, UNSC Resolutions etc.)* (f) ☐ Quota (including TRQ) administration; (g) ☐ Regulate imports of arms, ammunition or fissionable materials and safeguard national security; (h) ☒ Other: To simplify the requirements and processes for initial, renewal and variation to License to Operate
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://www.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://www.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 said issuance redefined the coverage of activities and establishment regulated by the FDA and repealed AO No. 2016-0003.
15	**In the case of 7(b), please indicate the type of new change(s)**	**(a)** ☐ **Termination** **(b)** ☐ **Suspension** **(c)** ☐ **Modification of specific details in existing procedures:** ☐ Product coverage; ☐ Administrative purpose; ☐ Automatic or Non-automatic; ☐ Duration of licensing; ☐ Change the nature of quantity/value restriction; ☐ Eligibility of applicants; ☐ Contact information on eligibility; ☐ Administrative body(ies) for submission of application; ☐ Documentation requirements (including application form); ☐ Period for Application; ☐ Administrative body(ies) to issue licence; ☐ Processing time for issuing licence; ☐ Licence fee/administrative charge; ☐ Deposit/advance payment and relevant conditions; ☐ Appeal regulations/procedures; ☐ Validity of licence; ☐ Other conditions of licence (extension, transferability, penalty of non-use etc.); ☐ Foreign exchange requirements;

	Category	Notification details
		☐ Other: _____ (please specify).
16	**Please elaborate the changes in detail (in one of the WTO official languages)**	