WORLD TRADE ORGANIZATION

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21 February 2023

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Page: 1/2

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**	FDA Circular No.2021-021 – Guidelines on the Licensing of Retailers of Medical Devices in the Philippines
3	**Date of Publication**	7 October 2021
4	**Date of entry into force**	2 February 2022
5	**Website link/Official publication of the new regulation/procedure**	https://www.fda.gov.ph/wp-content/uploads/2021/10/FDA-Circular-No.2021-021.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**	Retailers of medical devices 9033.00.00 - Parts and accessories (not specified or included elsewhere in Chapter 90) for machines, appliances, instruments or apparatus of Chapter 90
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;

[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
		(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 specify establishment classified as retailers of medical devices; to clarify the licensing of drug outlets which are also retailers of medical devices; to provide specific requirements for and responsibilities of qualified persons and for post licensing inspection of retailers of medical devices
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**	This FDA Circular was issued to provide specific guidelines supplementing the provisions of AO No. 2020-0017 on the licensing of retailers of medical devices.
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; ☐ Other: _____ (please specify).
16	**Please elaborate the changes in detail (in one of the WTO official languages)**	