



26 January 2024

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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 submission, originally received on 13 December 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. 2020-0030 – Guidelines for the Use of the FDA eServices Portal System for License to Operate (LTO) Application of Drug Distributors, Drug Traders, Drugstores, Retail Outlets for Non-Prescription Drugs (RONPD), Clinical Research Organization (CRO), and Sponsors
3	Date of Publication	16 October 2020
4	Date of entry into force	16 October 2020
5	Website link/Official publication of the new regulation/procedure	https://www.fda.gov.ph/wp-content/uploads/2020/10/FDA-Circular-No.-2020-030-1.pdf
6	Have you attached a copy of the regulation (PDF) to the Secretariat	[X] Yes. <i>(Please attach a copy of the regulation to the notification.)</i> [] 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: _____; <i>(please answer question 15 and 16)</i>
8	List of products subject to licensing	(a) Drug products, including vaccines, biologics, veterinary medicines and animal health products, medical gases, traditional medicine, and herbal medicines for commercial distribution (b) Drug products for personal use: <ul style="list-style-type: none">• Over-the-counter (OTC) drugs – 50 g• Prescription drugs – the imported quantity or volume should correspond to the quantity or volume specified in the prescription with the corresponding physician's Professional Regulatory Commission (PRC) License Number, or its equivalent for prescriptions issued by foreign physicians.• Vitamins, supplements, and other health supplements intended as maintenance – 500 g in total.

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
		(c) Imports of FDA-DOH-regulated products may be brought into the Philippines without prior clearance from the FDA; provided that such products are: <ul style="list-style-type: none"> • For personal use; • In quantities not exceeding the limits • Brought into the Philippines in any of the following ways: <ul style="list-style-type: none"> i. In passenger baggage, whether accompanied or unaccompanied; ii. In balikbayan boxes; or iii. In parcels sent through mail or delivery services.
9	Nature of licensing	Automatic: [] Non-Automatic: [X]
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.e. CITES, Basel Convention, Rotterdam Convention, UNSC Resolutions etc.) (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: To provide guidelines on the new FDA eServices Portal System in applying for LTO
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 was developed to provide a streamlined online platform for FDA Authorized Applications. Initial, renewal, and variation of License to Operate (LTO) applications for Drug Distributors (Importer/Exporter/Wholesaler), Drug Traders, Drug retailers (Drugstore and Retail Outlet for Non-Prescription Drugs), Clinical Research Organizations (CROs), and Sponsors.
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: <ul style="list-style-type: none"> <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;

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