WORLD TRADE ORGANIZATION

G/LIC/N/2/VNM/17

16 December 2019

(19-8722)

Committee on Import Licensing

Original: English

AGREEMENT ON IMPORT LICENSING PROCEDURES

NOTIFICATION UNDER ARTICLE 5.1 TO 5.4 OF THE AGREEMENT[1]

VIET NAM

The following notification, dated 29 November 2019, is being circulated at the request of the delegation of Viet Nam.

	Category	Notification details
1	**Notifying Member**	Viet Nam
2	**Title of new legislation/procedure**	1. Decree No. 54/2017/ND-CP dated 8th May 2017 on guidelines for implementation of the law on pharmacy 2. Decree No. 155/2018/ND-CP dated 12th November 2018 on amendments to some articles related to business conditions under state management of the Ministry of Health.
3	**Date of Publication**	1. 8th May 2017 2. 27th December 2017
4	**Date of entry into force**	1. 1st July 2017 2. 1 January 2018
5	**Website link/Official publication of the new regulation/procedure**	1. http://vbpl.vn/TW/Pages/vbpq-toanvan.aspx?ItemID=123255&Keyword=n%C4%91%2054%202017 2. http://vbpl.vn/TW/Pages/vbpq-toanvan.aspx?ItemID=127635&Keyword=n%C4%91%20155%202018
6	**Have you attached a copy of the regulation (PDF) to the Secretariat**	☒ Yes. (*Please attach a copy of the regulation to the notification.*) ☐ No.
7	**Type of notification**	☒ (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**	See the attached Annex
9	**Nature of licensing**	Automatic: ☐ Non-Automatic: ☒
10	**Administrative purpose/measure being implemented**	(a) ☐ Protect public morals; (b) ☒ Protect human, animal or plant life and health; protect environment;

[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) ☐ 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: _____ *(please specify)*
11	**Administrative body(ies) for submission of applications**	Ministry/authority and Department: Pharmaceutical Business Management – Drug Administration of Viet Nam Address: Building A, 138A Giang Vo street, Ba Dinh District, Ha Noi Website: https://dav.gov.vn/ Telephone: +84 24 3846 2011 E-Mail: chienpc.qld@moh.gov.vn
12	**Contact point for information on eligibility**	Ministry/authority and Department: Pharmaceutical Business Management – Drug Administration of Viet Nam Address: Building A, 138A Giang Vo street, Ba Dinh District, Ha Noi Website: https://dav.gov.vn/ Telephone: +84 24 3846 2011 E-Mail: chienpc.qld@moh.gov.vn
13	**Expected duration of licensing procedure**	Ongoing
14	**A summary of the notification in one of the WTO official languages**	Import licensing procedure of medicines, pharmaceutical starting materials
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)**	

ANNEX

LIST OF MEDICINES, PHARMACEUTICAL STARTING MATERIALS SUBJECT TO IMPORT LICENSING

1. Medicines, pharmaceutical starting materials eligible for exemption of import licensing:

Medicines, pharmaceutical starting materials that are pharmaceutical substances granted marketing authorization in Viet Nam, pharmaceutical starting materials that are pharmaceutical substances for manufacturing medicines in accordance with the drug registration dossier granted marketing authorization in Viet Nam, except for controlled medicines, pharmaceutical starting materials.

2. Medicines, pharmaceutical starting materials subject to import licensing:

a) Medicines without marketing authorization in Viet Nam

b) Pharmaceutical starting materials that are pharmaceutical substances without marketing authorization in Viet Nam

c) Controlled medicines, pharmaceutical starting materials

3. Controlled medicines are specified as follows:

a) The list of radioactive substances used in the health sector as provided in Annex IV in conjunction with Decree No. 54/2017/ND-CP

b) The list of narcotic pharmaceutical substances specified in Annex I in conjunction with Circular No. 20/2017/TT-BYT dated 10 May 2017 of the Minister of Health detailing specific provisions in the Pharmacy Law and Decree No. 54/2017/ND-CP dated 8 May 2017 of the Government on controlled medicines and pharmaceutical starting materials;

c) The list of psychotropic pharmaceutical substances specified in Annex II in conjunction with Circular No.20/2017/TT-BYT dated 10 May 2017 of the Minister of Health detailing specific provisions in the Pharmacy Law and Decree No. 54/2017/ND-CP dated 8 May 2017 of the Government on controlled medicines and pharmaceutical starting materials;

d) The list of precursors for medicine production specified in Annex III in conjunction with Circular No.20/2017/TT-BYT dated 10 May 2017 of the Minister of Health detailing specific provisions in the Pharmacy Law and Decree No. 54/2017/ND-CP dated 8 May 2017 of the Government on controlled medicines and pharmaceutical starting materials;

e) The list of medicines, pharmaceutical substances in the list of substances the use of which is banned in specific sectors, areas as specified in Annex VII in conjunction with Circular No. 20/2017/TT-BYT dated 10 May 2017 of the Minister of Health detailing specific provisions in the Pharmacy Law and Decree No. 54/2017/ND-CP dated 8 May 2017 of the Government on controlled medicines and pharmaceutical starting materials;

f) The list of toxic medicines and toxic pharmaceutical starting materials for medicine production issued in conjunction with Circular No. 06 /2017/TT-BYT dated 3rd May 2017 by the Minister of Health on the publication of List of toxic medicines and toxic pharmaceutical starting materials used in medicine production.

4. The list of HS Code of all medicines, pharmaceutical starting materials:

Circular No. 06 /2018/TT-BYT dated 6th April 2018 of the Minister of Health on publication of the List of medicines, pharmaceutical starting materials for human use and cosmetics for export, import with identified HS codes according to the List of Vietnamese goods for export, import (attached herewith).