WORLD TRADE ORGANIZATION

G/TBT/N/VNM/290

24 January 2024

(24-0542)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** VIET NAM **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Drug Administration of Viet Nam Ministry of Health 138A Giang Vo Street – Ba Dinh District – Ha Noi Tel: (84-4) 37366483 - Fax: 38234758 - Email: cqldvn@moh.gov.vn **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** PHARMACEUTICAL PRODUCTS (HS code(s): 30)
5.	**Title, number of pages and language(s) of the notified document:** Draft Law amending and supplementing a number of articles of the Law on Pharmacy; (23 page(s), in Vietnamese)
6.	**Description of content:** This draft Law amends and supplements a number of articles of Law No. 105/2016/QH13 on Pharmacy. These Articles include 2, 4, 6, 7, 8, 10, 17, 24, 28, 32, 33, 34, 35, 37, 42, 43, 44, 46, 47, 48, 49, 53, 54, 55, 56, 58, 59, 60, 61, 64, 65, 76, 78, 79, 87, 89, 107, 109, 110, 112, 113; This draft Law abolishes point c and d, clause 26, Article 2, point a, clause 10, Article 6, point b, clause 4, Article 7 of Law No. 105/2016/QH13 on Pharmacy. Transitional provisions: 1. Certificates of drug information and advertising content issued under the provisions of Law No. 105/2016/QH13 on Pharmacy will continue to be used until the expiry of the Certificate's validity 2. Dossier submitted before the entry into force of this draft Law and requesting the issuance, extension, amendment or supplementation of the registration certificate for the circulation of drugs and medicinal ingredients shall be implemented in accordance with the provisions of Law No. 105/2016 /QH13 on Pharmacy, except in cases where the establishment requests to comply with the provisions of this draft Law. 3. For dossiers applying for a License to import toxic drugs and toxic medicinal ingredients; drugs and medicinal ingredients that are on the list of substances whose use

	is prohibited in a number of industries and fields used for testing, research, and manufacturing of drugs for export in accordance with the provisions of the 2016 Law on Pharmacy and its guiding Decrees. 4. Chain pharmacy businesses that have had a chain pharmacy system prior to the effective date of this Law shall complete procedures to apply for a certificate of authority to do business as a chain within 45 days of the effective date of this draft Law. The regulations on granting, extending, amendment and supplementing circulation registration certificates for drugs and medicinal ingredients, except for regulations on issuing medical oxygen product declaration forms, shall be applied from January 1, 2025 The Draft Law was formulated based on the basis of 05 policies submitted to the Government and the National Assembly of Vietnam in the proposal No. 09/TTr-BYT dated on January 5th, 2023 as well as other difficulties and issues encountered during the implementation process, as follows: 1. Policy 1: Further strengthen the sufficient and timely supply of quality-assured medicines to meet people's need for disease prevention and treatment. 2. Policy 2: Ensure sufficient and timely supply of drugs that meet the demands of security, national defense, coping with the consequences of natural disasters, and preventing epidemics and diseases in the new situation 3. Policy 3: Improve the efficiency of import/export management of drugs/medicinal materials to the socio-economic development situation and international practice 4. Policy 4: Promote the development of the pharmaceutical industry with emphasis on research, technology transfer and production of high-tech drugs, biological drugs/medicinal materials, standardized herbal medicines, and raw materials from domestically available pharmaceutical sources. 5. Policy 5: Organize and rearranging the business and distribution system for drugs/medicinal materials to cope with socio-economic development and international integration.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Reducing trade barriers and facilitating trade
8.	**Relevant documents:** Law No. 105/2016/QH13 on Pharmacy
9.	**Proposed date of adoption:** October 2024 **Proposed date of entry into force:** 1 July 2025
10.	**Final date for comments:** 60 days from notification
11.	**Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Drug Administration of Viet Nam 138A Giang Vo Street – Ba Dinh District – Ha Noi Tel : (84-4) 37366483 - Fax: 38234758 - Email: cqldvn@moh.gov.vn https://members.wto.org/crnattachments/2024/TBT/VNM/24_00694_00_x.pdf