WORLD TRADE ORGANIZATION

G/TBT/N/VNM/336

10 February 2025

(25-0924)

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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):** Pharmaceuticals
5.	**Title, number of pages and language(s) of the notified document:** Draft Decree to provide guidelines for a number of articles and implementation of the revised Pharmaceutical Law; (264 page(s), in Vietnamese)
6.	**Description of content:** The Draft Decree will provide guidelines on the Law No. 44/2024/QH 15 revising the Pharmaceutical Law No. 105/2016/QH13, including: + Provisions on policies of pharmaceuticals. + Provisions on investment incentives for promoting the development of the pharmaceutical industry. + Provisions on updating and sharing judicial record database for receiving agencies. + Provisions on establishment of mobile drug retail in ethnic minorities, mountainous, island, socio-economically disadvantaged or extremely disadvantaged areas. + Provisions on disclosure of all information regarding to business licenses, pharmacy practice certificate of the responsible pharmacists, approved information on drug. + Provisions on wholesale and retail of medicinal products and pharmaceutical ingredients via e-commercial method. + Provisions on responsibility of the Ministry of Finance in regular sharing with MOH information on special controlled drug cleared for import and export. + Detailed provisions on: (i) Criteria, documentation, procedures, timelines for granting and withdrawing import and export licenses for medicinal products and pharmaceutical ingredients as specified in Clauses 2, 3, 4, and 5 of Article 60 of the 2016 Law on

	Pharmacy (as amended and supplemented); (ii) Catalogue of medicinal products and pharmaceutical ingredients prohibited from import and manufacture; (iii) Forms for declaration serving the import of clinical trial drugs and dossiers, procedures, processing time for the change of purpose of use of ingredients;(iv) the transfer of drugs as stipulated in Point c, Clause 2, Article 60 of the 2016 Pharmaceutical law (as amended and supplemented), provision of drugs imported by medical examination and treatment establishments for special treatment needs of other medical examination and treatment establishments. + Specific provisions on withdrawal of pharmaceutical ingredients, procedures for managing withdrawn pharmaceutical ingredients. + Specific provisions on pharmaceutical advertising content, documentation, procedures for submission, assessment, and approval of advertising content; provisions on the responsibilities of entities and individuals engaged in and involved in pharmaceutical advertising. + Specific provisions on the publication and republication of anticipated wholesale drug prices for prescription medicines and Clauses 4 and 10 of Article 107 of the 2016 Law on Pharmacy (as amended and supplemented). + Revise and amendment of some Articles of Decree No. 54/2017/NĐ-CP dated 08/5/2017 providing guidelines on implementation of Pharmaceutical Law (as amended and supplemented by the Decree Noe 155/2018/NĐ-CP dated 12/11/2018, Decree No 88/2023/NĐ-CP dated 11/12/2023) to timely address the difficulties and in line with the current situations. + Incorporate other provisions of Decree No. 54/2017/ND-CP (as amended and supplemented by Decree No. 155/2018/ND-CP and Decree No. 88/2023/ND-CP of the Government) that are consistent with Law No. 44/2024/QH15 and do not pose any implementation challenges.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** - Pursuant to the 2015 Law on the Promulgation of Legislative Documents (as amended and supplemented in 2020), Decree No. 34/2016/ND-CP dated May 14, 2016 of the Government providing details on a number of articles and measures for the implementation of the 2015 Law on the Promulgation of Legislative Documents (as amended and supplemented by certain articles in Decree No. 154/2020/ND-CP dated December 31, 2020 of the Government). - Implementing the Prime Minister's Decision No. 1610/QD-TTg dated December 19, 2024 to provide guidance on the Law No. 44/2024/QH15 and promptly address difficulties and obstacles arising from Decree No. 54/2017/ND-CP dated May 8, 2017 of the Government (as amended and supplemented by Decree No. 155/2018/ND-CP dated November 12, 2018, and Decree No. 88/2023/ND-CP dated December 11, 2023 of the Government) - Ministry of Health is the focal point to develop the Decree providing guidelines on implementation of the pharmaceutical Law and submit to the Government for approval (to replace the Decree No. 54/2017/NĐ-CP as amended and supplemented by the Decree No. 155/2018/NĐ-CP, Decree No. 88/2023/NĐ-CP); Protection of human health or safety
8.	**Relevant documents:** -
9.	**Proposed date of adoption:** April 2025 **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
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https://members.wto.org/crnattachments/2025/TBT/VNM/25_01270_00_x.pdf