WORLD TRADE ORGANIZATION

G/TBT/N/VNM/345

2 April 2025

(25-2331)

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):** Medicinal finished products and medicinal ingredients
5.	**Title, number of pages and language(s) of the notified document:** Draft Circular guiding the registration of drugs and pharmaceutical ingredients; (529 page(s), in Vietnamese)
6.	**Description of content:** This draft Circular details: a) Documentation requirements, procedures for issuance, renewal, revision and revocation of the marketing authorization of modern medicines, vaccines, biologicals, herbal drugs and medicinal materials (including active ingredients, semi-finished herbal ingredients, excipients, and capsule shells) for human use in Vietnam; b) Required clinical data for assurance of safety and efficacy in the application; c) Requirements for exemption from clinical trial or certain stages thereof in Vietnam; drugs that have to undergo Stage 4 clinical trial; d) Rules for validation of marketing authorization applications (hereinafter referred to as "marketing application") for drugs/medicinal materials, renewal and revision thereof; d) Rules for validation of applications for licenses to import drugs that are yet to be approved for marketing authorization (hereinafter referred to as "unapproved drugs") in the cases specified in Point a Clause 43 Article 5 of Decree No. 155/2018/ND-CP dated November 12, 2018 providing amendments to regulations on business conditions under state management of the Ministry of Health of Vietnam (hereinafter referred to as "Decree No. 155/2018/ND-CP"); g) Rules for the organization and operation of Marketing Authorization Advisory Board (hereinafter referred to as "the Advisory Board");

	h) Organizing and operating principles of the Advisory Council for the issuance of marketing authorization of drugs and pharmaceutical ingredients (hereinafter referred to as the Council).
7.	**Objective and rationale, including the nature of urgent problems where applicable:** To guide the implementation of drug registrations for circulation in accordance with the provisions of the Law on Pharmacy No. 105/2016/QH13 dated 6 April 2016, on September 5, 2022, the Minister of Health issued Circular No. 08/2022/TT-BYT regulating the registration of drugs and pharmaceutical ingredients (hereinafter referred to as Circular 08) Since its effective date (October 20, 2022), Circular 08 has contributed to improving the quality, safety and effectiveness of drugs registered for circulation on the market. However, during the implementation process, Circular 08 has some contents that need to be amended and supplemented to suit the reality. In addition, in the draft Law amending and supplementing a number of articles of the Law on Pharmacy, which is being submitted to the National Assembly, and expected to be approved in October 2024, the Ministry of Health has proposed amending and supplementing regulations related to drug registration and these regulations will take effect from January 1, 2025. On that basis, the Drug Administration of Vietnam has coordinated with the Legal Department and relevant units to draft a Circular regulating the registration of drugs and pharmaceutical ingredients.; Protection of human health or safety
8.	**Relevant documents:** -
9.	**Proposed date of adoption:** 5 June 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 Tel : (84-4) 37366483 - Fax: 38234758 - Email: cqldvn@moh.gov.vn https://members.wto.org/crnattachments/2025/TBT/VNM/25_02615_00_x.pdf