WORLD TRADE ORGANIZATION

G/TBT/N/VNM/331

21 November 2024

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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 - Viet Nam 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:** The draft Circular guiding the registration of finished medical products and medicinal ingredients; (516 page(s), in Vietnamese)
6.	**Description of content:** 1. This draft Circular specifies: a) Documentation requirements, procedures for the issuance, renewal, revision and revocation of marketing authorization for 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 to ensure safety and efficacy in the application; c) Requirements for exemption from clinical trial or certain phases thereof in Vietnam; drugs to be subjected to Stage 4 clinical trial; d) Rules for the validation of marketing authorization applications (hereinafter referred to as "marketing application") for drugs/medicinal materials, their renewal and revision; dd) Rules for the validation of applications for license 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");

	e) Organizing and operating principles of the Advisory Council for issuance of marketing authorization of drugs and pharmaceutical ingredients (hereinafter referred to as the Council); g) Procedures for the assessment of applications for the granting, extension, variation of marketing authorizations for finished medical products and medicinal ingredients; procedures for the assessment of applications for import licenses of drugs without marketing authorization. h) Dossier and procedures for granting certificates of circulation of drugs in the form of reference and recognition; i) Regulations on drugs that must undergo bioequivalence testing and requirements for dossiers reporting bioequivalence research data in drug circulation registration in Vietnam. 2. This draft Circular does not apply to the cases specified in Point a, b, Clause 2, Article 54 of the Law on Pharmacy, excipients, capsule shells, and semi-finished medicinal products for the manufacture of drugs according to drug registration dossiers that have a Certificate of Drug Circulation Registration in Vietnam; capsule shells, excipients used for testing, research or manufacturing of exported drugs and semi-finished medicinal products produced by the manufacturing facility itself for the manufacture of finished drugs, except in cases where the registration facility voluntarily request it.
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 entry to force (October 20, 2022), Circular 08 has contributed to improving the quality, safety and effectiveness of drugs registered for placing on the market. However, in the implementation of Circular 08, there are 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 being submitted to the National Assembly, expected to be approved in October 2024, the Ministry of Health has proposed to amend and supplement the regulations on drug registration and these regulations will take effect from January 1, 2025.; Harmonization
8.	**Relevant documents:** • Circular No. 08/2022/TT-BYT guiding the registration of finished medical products and medicinal ingredients; • Decree No. 54/2017/ND-CP dated May 8, 2017 of the Government detailing a number of articles and measures to implement the Law on Pharmacy Referenced Notification(s): • G/TBT/N/VNM/215 • G/TBT/N/VNM/215/Add.1
9.	**Proposed date of adoption:** December 2024 **Proposed date of entry into force:** 15 February 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:

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https://members.wto.org/crnattachments/2024/TBT/VNM/24_07902_00_x.pdf