



24 April 2025

(25-2858)

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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: <u>VIET NAM</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Traditional Medicine Administration Ministry of Health 138A Giang Vo Street – Ba Dinh District – Ha Noi Tel: (84-4) 62732247 - Fax: 38464098 - Email: ydct@moh.gov.vn / dct.moh@gmail.com 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 [], 2.10.1 [X], 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): Traditional medicines and medicaments.
5. Title, number of pages and language(s) of the notified document: Draft Circular regulating the registration of circulation of traditional medicines, medicinal ingredients, and medicinal herbs; (33 page(s), in Vietnamese)
6. Description of content: 1. This Circular regulates in details of the following contents: a) Dossier, procedures for granting, extending, changing, supplementing, and revoking certificates for circulation of traditional medicines, medicinal ingredients, and medicinal herbs for human use in Vietnam. b) In case traditional medicines are recognized by the Ministry of Health as exempt from some or all phases of clinical trials; compulsory to undergo phase 4 clinical trials; compulsory to conduct full clinical trials of all phases and clinical data requirements to ensure safety and effectiveness in the registration dossier for circulation of traditional medicines. c) Principles for organization and operation of the Advisory Council for granting registration certificates for circulation of traditional medicines and experts for assessing registration dossiers for circulation of traditional medicines, traditional medicinal ingredients, and medicinal herbs. 2. This Circular applies to domestic and foreign agencies, organizations, and individuals related to the registration of circulation of traditional medicines, medicinal ingredients, and medicinal herbs in Vietnam.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety

8. Relevant documents:

- Circular No 01/2018/TT-BYT dated January 18, 2018 on labelling and package inserts of drugs and medicinal ingredients;
- Circular No 23/2023/TT-BYT dated November 30, 2023 on amendments to Circular No 01/2018/TT-BYT dated January 18, 2018 on labelling and package inserts of drugs and medicinal ingredients;
- Circular No 35/2018/TT-BYT dated November 22, 2018 on good manufacturing practices for pharmaceutical products and pharmaceutical starting materials;
- Circular No 05/2010/TT-BYT dated March 01, 2010 on guiding the keeping of confidentiality of trial data in medicine registration;
- Circular No 13/2024/TT-BYT dated August 26, 2024 on issuance of list of techniques in medical examination and treatment.

9. Proposed date of adoption: 15 May 2025**Proposed date of entry into force:** 1 July 2025**10. Final date for comments:** 10 May 2025**11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

Traditional Medicine Administration

Ministry of Health

138A Giang Vo Street – Ba Dinh District – Ha Noi

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