



3 July 2025

(25-4295)

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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 (Articles 3.2 and 7.2):
2. Agency responsible: Administration Science, Technology and Training Ministry of Health 138A Giang Vo Str., Ba Dinh Dist., Ha Noi, Viet Nam Tel: (84-24) 33846688 - Fax: 32373236 Email: cuck2dt@moh.gov.vn
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 codes or national tariff lines. ICS numbers may be provided in addition, where applicable): Medicinal products
5. Details of notified document(s) (title, number of pages and languages, means of access): Draft Circular Stipulating Clinical Trial Regulations for Medicinal Products; (29 page(s), in Vietnamese) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://members.wto.org/crnattachments/2025/TBT/VNM/25_04308_00_x.pdf
6. Description of content: Draft Circular providing regulations on the following matters: <ul style="list-style-type: none">• Promulgation and application of Good Clinical Practice (GCP);• Assessment of compliance with Good Clinical Practice and the documentation and procedures for conducting clinical drug trials.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: <ul style="list-style-type: none">- This draft Circular is issued pursuant to the Law on Promulgation of Legal Documents (2015, as amended in 2020), Decree No. 34/2016/ND-CP (as amended by Decree No. 154/2020/ND-CP), and Decision No. 1610/QD-TTg dated 19 December 2024 of the Prime Minister, which assigns ministries to draft implementing regulations for laws adopted at the 8th session of the 15th National Assembly;- The Circular provides detailed regulations for the implementation of Law No. 44/2024/QH15 and addresses difficulties and inconsistencies in the implementation of

<p>Decree No. 54/2017/ND-CP (as amended by Decrees No. 155/2018/ND-CP and No. 88/2023/ND-CP) guiding the implementation of the Law on Pharmacy.</p> <p>Relevant notifications:</p> <ul style="list-style-type: none">• G/TBT/N/VNM/336• G/TBT/N/VNM/15/Add.1• G/TBT/N/VNM/15	
9.	<p>Proposed date of adoption: 1 October 2025</p> <p>Proposed date of entry into force: 1 January 2026</p>
10.	<p>Provision of comments</p> <p>Final date for comments: 1 September 2025</p> <p>[X] 60 days from notification</p> <p>Contact details of agency or authority designated to handle comments regarding the notification:</p> <p>Administration Science, Technology and Training Ministry of Health 138A Giang Vo Str., Ba Dinh Dist., Ha Noi, Viet Nam Tel: (84-24) 33846688 - Fax: 32373236 Email: cuck2dt@moh.gov.vn</p>