WORLD TRADE ORGANIZATION

G/TBT/N/VNM/203

28 July 2021

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Page: 1/2

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, Hanoi Tel: +(84 24) 37366483 Fax: +(84 24) 38234758 Email: cqldvn@moh.gov.vn Website: https://dav.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 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Drugs subject to bioequivalence study and requirements for bioequivalence studies dossiers in registration for marketing authorization in Vietnam
5.	**Title, number of pages and language(s) of the notified document:** Draft Circular Regulating on drugs subject to bioequivalence study and requirements for bioequivalence studies dossiers in registration for marketing authorization in Vietnam (15 page(s), in Vietnamese)
6.	**Description of content:** The Circular regulates drugs subject to bioequivalence study and requirements for bioequivalence study dossiers registration for marketing authorization in Vietnam. The Circular applies to: • Generic containing active ingredients or dosage forms must have bioequivalence study reports when registering for marketing authorization in Vietnam; • Bioequivalence study dossiers of generic; • These guidelines in this Circular only apply to chemical drugs that have systemic effects after being absorbed into the body systemic circulation.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Other
8.	**Relevant documents:** • Drug Law dated 06/4/2016;

	• Decree no 54/2017/ND-CP dated 08/5/2017 of the Government detailing a number of articles and measures for implementing Pharmaceutical law;
9.	**Proposed date of adoption:** 1 October 2021 **Proposed date of entry into force:** 1 April 2022
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, Ministry of Health 138A Giang Vo street, Ba Dinh district, Hanoi Tel: +(84 24) 37366483 Fax: +(84 24) 38234758 Email: cqldvn@moh.gov.vn Website: https://dav.gov.vn/ https://members.wto.org/crnattachments/2021/TBT/VNM/21_4863_00_x.pdf