WORLD TRADE ORGANIZATION

G/TBT/N/VNM/268

31 July 2023

(23-5194)

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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 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):** HS code: 30 - Pharmaceutical Products
5.	**Title, number of pages and language(s) of the notified document:** Draft Circular regulating the registration of toll manufactured medicines and technology transfer medicines in Vietnam; (23 page(s), in Vietnamese)
6.	**Description of content:** This draft Circular provides general provisions on the registration of toll manufactured medicines and technology transfer medicines in Vietnam; This draft Circular also regulates the dossiers and procedures for granting, extending, amending, supplementing and withdrawing registration documents of toll manufactured medicines and technology-transferred medicines (pharmaceutical drugs, vaccines, biological products, herbal drugs) in Vietnam. This draft Circular shall amend, supplement or repeal some provisions of Circular 23/2013/TT-BYT and has been updated in accordance with the following legal texts in the field of pharmaceuticals, toll manufacturing and technology transfer
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety; Quality requirements
8.	**Relevant documents:** Pharmaceutical Law No. 105/2016/QH13 dated 06/4/2016; Commercial Law No. 36/2015/QH11 dated 14 June 2005; Foreign Trade Management Law No. 05/2017/QH14dated 12 June 2017; Technology Transfer Law No. 07/2017/QH14dated 19 June 2017;

	Decree No. 69/2018/ND-CP dated 15 May 2018 of the Government detailing a number of articles of the Foreign Trade Management Law; Decree No. 95/2022/ND-CP dated 15 November 2022 of the Government defining the roles, responsibilities, jurisdiction and organizational structure of the Ministry of Health; Decree no 54/2017/ND-CP dated 8 May 2017 of the Government detailing a number of articles and measures for implementing Pharmaceutical Law 2016; Decree No. 155/2018/ND-CP dated 12 November 2018 of the Government amending and supplementing a number of regulations related to business investment conditions under the scope of state management of the Ministry of Health.
9.	**Proposed date of adoption:** 26 September 2023 **Proposed date of entry into force:** 10 November 2023
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:** https://members.wto.org/crnattachments/2023/TBT/VNM/23_11384_00_x.pdf https://members.wto.org/crnattachments/2023/TBT/VNM/23_11384_01_x.pdf https://members.wto.org/crnattachments/2023/TBT/VNM/23_11384_02_x.pdf