WORLD TRADE ORGANIZATION

G/TBT/N/VNM/215

3 December 2021

(21-9089)

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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, Hanoi Tel: (+84 24) 37366483 Fax: (+84 24) 38234758 Email: dangkythuoc.qld@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:** Administration of Sciences, Technology and Training, Ministry of Health. 138B Giang Vo street, Ba Dinh District, Hanoi. Tel: (+84 24).33846688 Fax: (+84 24).32373236 Email: cuck2dt@moh.gov.vn Website: http://asttmoh.vn
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):** Medicinal finished products and medicinal ingredients
5.	**Title, number of pages and language(s) of the notified document:** Draft Circular amending some provisions in Circular No. 32/2018/TT-BYT dated November 12, 2018 of the Minister of Health guiding the registration of medicinal finished products and medicinal ingredients for the circulation in Vietnam. (87 page(s), in Vietnamese)
6.	**Description of content:** Amending, supplementing or abolishing some provisions in Circular No. 32/2018/TT-BYT dated November 12, 2018 of the Minister of Health guiding the registration of medicinal finished products and medicinal ingredients for the circulation in Vietnam: 1. Supplementing Article 4a; 2. Amending and supplementing Clause 2, Clause 4, Clause 5, Clause 6 Article 6; 3. Removing words "except for vaccines" in Clause 3, Article 6; 4. Supplementing Clause 3a Article 6; 5. Supplementing point c clause 3 Article 9; 6. Supplementing Article 9a; 7. Supplement to Article 9b; 8. Amending and supplementing Clause 1, Article 12; 9. Amending and supplementing Article 16;

	10. Amending and supplementing regulations on CPP in Clauses 3 and 4, Article 23; 11. Amending and supplementing Clause 13, Article 23; 12. Amending and supplementing Clause 16, Article 23; 13. Amending and supplementing Clauses 1 and 3, Article 25; 14. Supplementing point c clause 7 Article 25; 15. Removing the word "extension" in Article 26, Article 27; 16. Amending and supplementing Clause 1, Article 36, Item 3, Point c, Clause 4, Article 37; 17. Amending and supplementing Clause 2, Article 37, Point a, Clause 1, Article 38, Point a, Clause 1, Article 39; 18. Supplementing Clause 5, Article 37; 19. Amending and supplementing Clause 2, Article 38, Clause 2, Article 39, Clause 4, Article 40; 20. Amending and supplementing Clause 3, Article 40; 21. Amending and supplementing Clause 7 Article 40; 22. Amending and supplementing Clauses 1 and 2, Article 44; 23. Supplementing Clause 5, Article 47; 24. Amending point l clause 1 Article 50; 25. Amending Appendix II; 26. Supplementing Addendum VI; 27. Amending form 06/TT, 07/TT and supplementing form 15/TT. Transitional provision - Abolishing point c, đ Clause 5 Article 1 of Circular 29/2020/TT-BYT dated December 31st 2021 of the Minister of Health amending and abolishing some legal documents issued by the Minister of Health or by Intersectoral Ministers; - Abolishing point h, Clause 3, Article 14 of Circular 01/2018/TT-BYT dated January 18, 2018 of the Minister of Health guiding the label and leaflets of medicinal finished products and medicinal ingredients.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Harmonization; Reducing trade barriers and facilitating trade
8.	**Relevant documents:** • Pharmaceutical Law dated 06/4/2016; • Decree No. 75/2017/ND-CP dated June 20, 2017 of the Government defining the functions, tasks, powers and organizational structure of the Ministry of Health; • Decree no 54/2017/ND-CP dated 08/5/2017 of the Government detailing a number of articles and measures for implementing Pharmaceutical law 2016; • Decree No. 155/2018/ND-CP dated November 12, 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:** 31 December 2021 **Proposed date of entry into force:** 15 February 2022
10.	**Final date for comments:** 30 December 2021

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/2021/TBT/VNM/21_7507_00_x.pdf