

WORLD TRADE ORGANIZATION

G/TBT/N/VNM/15
17 May 2011

(11-2496)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| 1. Notifying Member: VIET NAM If applicable, name of local government involved (Article 3.2 and 7.2): |
| 2. Agency responsible: THE MINISTRY OF HEALTH 138A Giang Vo Str Ba Dinh Pro Ha Noi City Viet Nam Tel.: (84-4) 62732273 Fax: 38464051 E-mail: byt@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 [], other: |
| 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): - |
| 5. Title, number of pages and language(s) of the notified document: Circular Guidelines for clinical drug trial (20 pages, in Vietnamese and English). |
| 6. Description of content: This circular prescribes guidelines on the types of drug that require clinical trials, clinical trial exemption, exemption of certain clinical trial stages; sequences, procedures, conditions, records, rights and obligations of the parties concerned, evaluation process, approval, development, monitoring, supervision, inspection and acceptance assessment for the clinical trial research in Vietnam in order to serve the study, and permit the circulation of drugs, vaccines and medical biologicals used for the diagnosis, treatment and prevention of diseases directly administered to a person (hereinafter referred to as drugs). |
| 7. Objective and rationale, including the nature of urgent problems where applicable: To ensure safety and health of users of Vietnam in diagnosis, treatment and prevention. |
| 8. Relevant documents: - Pharmacy Law dated 14/6/2005 - Decree No 79/2006/ND-CP dated 09/8/2006 of the Government detailing the implementation of some articles of the Pharmacy Law |

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| 9. | Proposed date of adoption: Proposed date of entry into force: } To be determined |
| 10. | Final date for comments: 60 days from date of notification |
| 11. | Text available from: National enquiry point [X], or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: Internet URL: http://www.tbtvn.org/Ti%20liu%20upload%20cho%20QCKT/TT%20Bo%20Yte.doc.pdf |