



24 September 2014

(14-5348)

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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: 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: The Ministry of Health 138A Giang Vo Str., Ba Dinh Dist., Ha Noi City, Viet Nam Tel (84-4) 62732273 Fax: (84-4) 38464051 Email: byt@moh.gov.vn Website: http://www.moh.gov.vn
3. Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [X], 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
5. Title, number of pages and language(s) of the notified document: Draft Circular on the Conduct of Bioavailability and Bioequivalence Studies of Drugs (21 pages, in Vietnamese)
6. Description of content: This draft Circular regulates conditions, registration, scope of organization conducting Bioavailability and Bioequivalence Studies of Drugs in Vietnam.
7. Objective and rationale, including the nature of urgent problems where applicable: Bioavailability and Bioequivalence studies are conducted in human subjects. However, there are no legal documents related to the guidance of conducting Bioavailability and Bioequivalence studies of drugs in Vietnam and no specific regulations in supervising, managing the quality of these studies aimed to ensure the safety of research objects.
8. Relevant documents: <ul style="list-style-type: none">• Drug law 34/2005/QH11 dated June 14th, 2005;• Decree 79/2006/NĐ-CP dated August 9th, 2006 of Government regulates the implementation of the drug law;• Decree 63/2012/ND-CP dated August 31, 2012 of Government regulates function, tasks, right and structure of Ministry of Health.
9. Proposed date of adoption: 25 November 2014 Proposed date of entry into force: 2 January 2015
10. Final date for comments: 60 days after notification date

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Or can be downloaded at:

<http://www.tbtvn.org/Ti%20liu%20upload%20cho%20QCKT/QCKT/C1.PDF>