THE MINISTRY OF HEALTH No.: 05/2010/TT-BYT	**SOCIALIST REPUBLIC OF VIETNAM** **Independence – Freedom - Happiness**

Hanoi, March 01, 2010

CIRCULAR

ON GUIDING THE CONFIDENTIAL PROTECTION OF TRIAL DATA IN DRUG REGISTRATION

THE MINISTRY OF HEALTH

Pursuant to Law No. 34/2005/QH11 on pharmacy dated June 14, 2005;

Pursuant to Law No. 50/ 2005/QH11, on Intellectual Property dated November 29, 2005, which was amended and supplemented by Law No. 36/2009/QH12 dated June 19, 2009 Amending and Supplementing a Number of Articles of the Law on Intellectual Property;

Pursuant to the Government's Decree No. 188/2007/ND-CP dated December 27, 2007, defining the functions, tasks, mandate and organizational structure of the Ministry of Health;

Pursuant to the Government's Decree No. 103/2006/ND-CP dated September 22, 2006, detailing and guiding the implementation of a number of articles of the Law on Intellectual Property on industrial property;

The Ministry of Health guides the protection of confidentiality of trial data in drug registration as follows:

Chapter I

GENERAL PROVISIONS

Article 1. Scope of regulation

1. This Circular guides the request and procedures for protecting confidentiality of trial data in drug registration.

2. This Circular applies only to finished drug products containing new active ingredients and does not apply to medicine materials.

Article 2. Subjects of application

This Circular is applicable to Vietnamese and foreign organizations and individuals who conduct activities related to medicine registration in Vietnam.

Article 3. Interpretation of terms

In this Circular, the following terms and expressions are construed as follows:

1. *Drug* means a substance or mixture of substances for human use for disease prevention, treatment or diagnosis or adjustment of physiological functions of human body, including finished drug products, drug materials, vaccines and medical biological other than functional foods.

2. *Active ingredient* (also *pharmaceutical active ingredient* or *pharmakon*) means in substance or mixture of substances having a therapeutic treatment and used in drug manufacture.

3. *New active ingredient* means an active ingredient that has never been permitted for market in Vietnam and not yet permitted for market in anywhere else in the world for 12 months counting back from the date of filing the application for registration of a drug containing such ingredient in Vietnam.

4. *Data confidentiality protection and trial data* (herein collectively referred to as "*data confidentiality protection*") means protection the confidentiality of pharmaceutical trial data in drug registration as specified in Article 128 of the Law on Intellectual Property and Article 20 of the Government's Decree No. 103/2006/ND-CP of September 22, 2006, detailing and guiding the implementation of a number of articles of the Law on Intellectual Property on industrial property.

5. Circular on Drug Registration means the Minister of Health's Circular No. 22/2009/TT-BYT of November 24, 2009, on drug registration.

Article 4. Responsibility to protect confidential data

The Vietnam Drug Administration is the competent agency responsible for protecting data confidentiality in drug registration under this Circular.

Chapter II

REQUIREMENTS FOR DATA CONFIDENTIALITY PROTECTION

Article 5. Data eligible for confidential protection

A data that is eligible for being confidentially protected shall include the data of clinical trials of drugs containing new active ingredients provided by drug-registration establishments in drug registration dossiers (to use for proving the safety and efficiency of drugs in accordance with the Circular on Drug Registration) and meet requirements as specified in Article 6 of this Circular.

Article 6. Requirements for the data to be confidently protected

A data shall be protected confidentially if it fully satisfies the following requirements:

1. Being a business secret, which meet requirements for protection as specified in Paragraph 23 in Article 4 and Article 84 of the Law on Intellectual Property;

2. Being the outcome of a considerable investment of effort;

3. Having the request for confidentiality protection as specified in Para 1, Article 7 of this Circular.

Chapter III

REQUIREMENTS FOR AND ORDER OF RECEIPT OF DRUG REGISTRATION DOSSIERS CONTAINING REQUESTS FOR DATA CONFIDENTIALITY PROTECTION

Article 7. Requirements for the receipt of drug registration dossiers having requests for data confidentiality protection

1. Apart from general requirements on dossiers as specified in the Circular on drug registration, a drug registration dossier having the request for protection data confidentiality must also contain at least following documents:

a. The application shall be made in the form attached to the Circular on Drug Registration, in which the drug-registration establishments shall express their request for protecting data confidently ticking in an appropriate box for such request and list documents containing data requested for confidential protection;

b. Documents containing data to be confidently protection must be presented in a form of clinical reports as prescribed in the Circular on Drug Registration.

2. All the above documents must be sealed by a "confidential" stamp, enveloped in a separate package, which is also sealed and appended with a "confidential" stamp.

Article 8. Order of receipt of drug registration dossiers having requests for data confidentiality protection

A drug registration dossier having the request for data confidentiality protection shall be filed to the Vietnam Drug Administration in the following order:

1. Identifying contents requested for data confidentiality protection as indicated in drug registration dossiers according to Para 1, Article 7 of this Circular.

2. Checking the appearance of the confidential document package before breaking the seal, and checking formality of documents contained therein in accordance with Point b, Para 1, Article 7 of this Circular.

3. Matching up documents contained in the confidential document package to documents listed in the request for data confidentiality protection.

4. Recording the request for data confidentiality protection in the register of receiving dossiers and dossier receipts, and at the same time re-sealing the confidential document package for dossiers satisfying requirements specified in Article 7 of this Circular. If drug registration dossiers having requests for data confidentiality protection fail to meet requirements specified in Article 7 of this Circular, the Vietnam Drug Administration shall only receive drug registration dossiers of drug-registration establishments who withdraw their request for data confidentiality protection.

Chapter IV

PROTECTION OF DATA CONFIDENTIALITY

Article 9. Acceptance of the request for data confidentiality protection

1. With respect to received drug registration dossiers having requests for data confidentiality protection (except those referred to in Article 10 of this Circular), the Vietnam Drug Administration shall accept such requests and take measures to protect it confidentially as specified in Article 12 of this Circular.

2. Decisions on acceptance of requests for data confidentiality protection shall be notified by the Vietnam Drug Administration to drug registration establishments and published on the Vietnam Drug Administration's website, together with notices of decisions on grant of market approval numbers.

Article 10. Refusal of data confidentiality protection

1. In the following cases, the Vietnam Drug Administration shall to protect data confidentiality:

a. The data requested for being protected confidentially is not fallen into those listed in Article 5 of this Circular;

b. The drug in the registration dossier having the request for data confidentiality protection is not permitted for marketing in Vietnam;

d. There is a firm ground to determine that the requested data fails to satisfy one of requirements specified in Article 6 of this Circular;

dd. The confidential protection of data might cause serious impacts on human health.

2. Notices of refusal to protect data confidentiality shall be sent by the Vietnam Drug Administration to drug-registration establishments together with notices of decisions on granting or refusal of drug registration numbers, clearly stating reasons for refusal.

Article 11. Opinions of third parties on data confidentiality protection

1. From the date of accepting the request for data confidentiality protection is published, all organizations and individuals may request the Vietnam Drug Administration to terminate such protection in accordance with Article 14 of this Circular.

2. The request for termination must be made in writing by the form provided in this Circular, and accompanied by documents or indications of sources to support the request.

3. Within 15 working days as of receiving the request for termination, the Vietnam Drug Administration shall notify in writing such request to the drug-registration establishment whose data are kept confidential. Within 03 working months as of the signing date of the notice by Vietnam Drug Administration, the drug-registration establishment shall respond in writing to the Vietnam Drug Administration, and provide with necessary documents and evidences as requested in the notice.

4. Based on results of consideration of the request for termination and opinions by interested parties, the Vietnam Drug Administration, if finding such request is well-grounded, shall issue a decision to terminate the data confidentiality protection and publish such decision on its website; or issue a decision on refusal to terminate the data confidentiality protection and notify such to organizations/individuals who request for termination of such decision if finding the such request is invalid.

Article 12. Measures of data confidentiality protection

In case of the request for data confidentiality protection is accepted, the Vietnam Drug Administration shall take the following measures to:

1. Archive and manage documents containing data requested for confidential protection in accordance with legal provisions on management of secret documents.

2. Prevent any third party from accessing to confidential data unless the access by a competent agency to assess clinical trial results, safety and efficiency of a drug or to protect the public health.

3. Prevent the disclosure of data unless the disclosure is necessary to protect the public health.

4. Temporarily refuse to consider and grant market approval to drug-registration establishments who file their registration dossiers later than accepted dossier if the later dossiers refer to data currently confidentially protected without the consent of the earlier drug-registration establishment and without evidence of their independent creation from the confidential data.

Article 13. Term of data confidentiality protection

1. The measures of data confidentiality protection as specified in Paras 1, 2 and 3 of Article 12 shall be applied from the filing date of the data to the disclosure date of the data. However, the term of the data confidentiality protection shall not exceed the term of the management of secret documents as prescribed by applicable laws and regulations.

2. The measures of data confidentiality protection as specified in Para 4, Article 12 shall be applied from the filing date of the request to the expiration of the 5-year counting from the date on that drug-registration establishment is granted the market approval for that drug.

Article 14. Termination of the data confidentiality protection

The data confidentiality protection shall be terminated partially or wholly in the following cases:

1. The data no longer meets the requirements as specified in Article 6 of this Circular.

2. A competent agency has firm grounds to determine that the drug-registration establishment owning the confidential data has no lawful right to use the data.

3. The decision on granting the market approval for the drug having confidential data is no longer valid or the drug registration number is revoked or the drug-registration establishment voluntarily revocate the registration number.

4. A competent agency issues a compulsory license of a patent relating to the drug containing the confidential data.

5. A competent agency on settlement-disputes invalidates the decision on acceptance of the request for data confidentiality protection.

6. The termination of the data confidentiality protection is necessary to protect the public health and to meet urgent needs of the society.

Chapter V

RIGHTS AND OBLIGATIONS OF ESTABLISHMENTS HAVING THE CONFIDENTIAL DATA

Article 15. Rights of establishments having the confidential data

Drug-registration establishments having the confidential data have following rights:

1. To prevent other drug-registration establishments from using the confidential data for unfair commercial purposes, including illegal use of data to apply for drug registration.

2. To appeal with the Vietnam Drug Administration if they are suspected on illegal disclosure or use of the confidential data to apply for drug registration.

Article 16. Obligations of drug registration establishments having the confidential data

Drug-registration establishments having the confidential data have following obligations:

1. To prove their ownership of the data, and satisfies the requirements for confidential protection of the data at the request of the Vietnam Drug Administration in cases specified Para 3, Article 11 of this Circular.

2. To evidence illegal disclosures and/or uses of the confidential data for unfair commercial purposes in case they exercises their rights as provided in Article 15 of this Circular.

Chapter VI

IMPLEMENTATION ARRANGEMENTS

Article 17. Come into effect

1. This Circular shall come into effect after 45 days as of the signing date.

2. This Circular shall replace the Minister of Health's Decision No. 30/2006/QD-BYT dated September 30, 2006, promulgating the Regulation on data confidentiality protection in drug registration dossiers. Dossiers having requests for data confidentiality protection filed with the

Vietnam Drug Administration before the effect date of this Circular shall be examined and communicated in accordance with this Regulation.

3. Any matter arising during implementation of this Circular should be promptly informed and reported to the Ministry of Health (the Vietnam Drug Administration) for consideration and settlement.

FOR THE MINISTER OF HEALTH

DEPUTY MINISTER

(signed and sealed)

CAO MINH QUANG

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