REGULATION ON DATA SECURITY OF DRUG REGISTRATION RECORDS
(Promulgated together with the Health Minister's Decision No. 30/2006/QD-BYT of September 30, 2006)

Chapter I

GENERAL PROVISIONS

Article 1.- Scope of regulation and subjects of application

1. Scope of regulation: This Regulation provides the order and procedures related to the security of data of drug registration records.

2. Subjects of application: This Regulation applies to domestic and foreign organizations and individuals that carry out drug registration procedures in Vietnam and to concerned agencies in charge of state management of pharmacy.

Article 2.- Interpretation of terms

In this Regulation, the terms below are construed as follows:

1. Drug means a substance or a mixture of substances for human use for the purposes of disease prevention, treatment or diagnosis or rehabilitation of human physical functions, including finished drugs, drug materials, vaccines and medical biologicals, except functional foodstuff.

2. Pharmaceutical substance (also referred to as active ingredient) means a substance or a mixture of substances having treatment active-ingredients which are used in drug manufacture.

3. New drug means a drug containing a new pharmaceutical substance or drug with a new combination of circulated pharmaceutical substances.

4. Clinical drug test means a scientific research into drugs on humans in a systematic manner with a view to verifying clinical efficiency, identifying and discovering harmful effects of the researched products; the ability of such products to absorb, distribute, transform or discharge, aiming to determine the safety and effectiveness of drugs.

5. Additional indication, formula or preparation form means a new indication, new formula or new preparation form of a new drug which has been granted a circulation registration number.

6. Business secret means information received from financial investment or intellectual activities which has not been revealed and can be used in business activities.

7. Data security means the application of necessary measures to ensure that data are neither used for unhealthy commercial purposes nor revealed, unless when the revelation is necessary for the protection of people.

Article 3.- Types of data to be secured

1. Test results related to toxicity and clinical drug test data of new drugs which have never been publicized or revealed.

2. Other data (except additional indications, formulas and preparation forms) which meet the conditions specified in Article 4 of this Regulation.

Article 4.- Conditions for data to be secured

Data to be secured must fully meet the following conditions:

1. Being business secrets.

2. Being results of investment of significant efforts.

3. Being supplied by drug-registering establishments under current regulations on drug registration.

4. Being requested to be secured by drug-registering establishments under the provisions of Article 5 of this Regulation.

Article 5.- Required documents for data security consideration

1. Required documents include:

a/ An application for enforcement of data security (made according to a set form);

b/ A document proving that data which need be secured fully meet the conditions specified in Clause 1, Article 4 of this Regulation.

c/ A document proving that data which need be secured are under lawful ownership of the drug-registering establishment which requests the enforcement of data security.

2. The application for enforcement of data security and proof documents specified in Clause 1 of this Article constitute part of a drug registration dossier and must be submitted together with the dossier. Applications and documents submitted after drug registration dossiers shall not be considered.

Article 6.- Forms of applications and documents related to data security enforcement request

1. An application for enforcement of data security and enclosed documents must be made in Vietnamese or English, signed and stamped for certification by the drug-registering establishment on every page of those documents.

2. Legal documents (diplomas, certificates, etc.) must be originals or copies notarized in Vietnam. Diplomas and certificates which are issued, notarized or authenticated by foreign agencies or organizations must be legalized by consular offices and translated into Vietnamese. The translations must be notarized in accordance with Vietnamese law.

3. Parts of a dossier which contain data to be secured must be sealed and appended with a confidentiality stamp of the drug-registering establishment.

Chapter II

PROCEDURES FOR SUBMISSION AND RECEIPT OF DRUG REGISTRATION DOSSIERS CONTAINING DATA TO BE SECURED

Article 7.- Submission of dossiers

1. A drug registration dossier containing data which need be secured and relevant proof documents shall be submitted directly at the drug circulation-licensing agency or at the place of receipt of dossiers designated by the drug circulation-licensing agency, or shall be sent by registered mail.

2. If, at the time the drug registration dossier is being submitted (or arriving at the drug circulation-licensing agency), the parts of data which need be secured no longer have confidentiality signs or intact seals, the drug circulation-licensing agency shall not be responsible for data security.

Article 8.- Receipt of dossiers

Upon receiving a drug registration dossier containing data which need be secured, the drug circulation-licensing agency shall:

1. Inspect the intactness of the dossier and its confidentiality seal.

2. Check documents in the dossier against those listed in the application for enforcement of data security.

3. Append a stamp on the application and all enclosed documents, certifying the date of receipt of the dossier; and write down necessary information in the dossier receipt book.

4. Temporarily keep data which need be secured according to current regulations until it officially accepts or rejects the application for enforcement of data security.

Chapter III

RESPONSIBILITIES OF THE DRUG CIRCULATION-LICENSING AGENCY

Article 9.- Consideration of and reply to a data security enforcement request

1. Within six months after receiving a drug registration dossier containing data which need be secured, the drug circulation-licensing agency shall evaluate the application for enforcement of data security and relevant documents required in Articles 3, 4, 5 and 6 of this Regulation and notify in writing the drug-registering establishment of its acceptance or rejection of the data security enforcement request.

2. If rejecting a data security enforcement request, the drug circulation-licensing agency shall clearly state the reasons therefor.

Article 10.- Security enforcement and duration

1. For data to be secured, the drug circulation-licensing agency shall take necessary security measures as stipulated in Clause 1, Article 128 of the Intellectual Property Law until those data no longer meet the conditions specified in Article 4 of this Regulation.

2. Except the case defined at Point d, Clause 2, Article 125 of the Intellectual Property Law, within 5 years after the drugs for which the drug registration dossier containing confidential is submitted to the drug circulation-licensing agency are granted circulation permits, the drug circulation-licensing agency may not license any drug-registering establishments which submit later dossiers with the same confidential data without consent of the person who has submitted those data.

Article 11.- Processing of data after security duration

At the end of the security duration stipulated in Article 10 of this Regulation, the submitted data shall be archived by the drug circulation-licensing agency like data which need not be secured.

Chapter IV

HANDLING OF VIOLATIONS

Article 12.- Handling of violations

Organizations or individuals that violate the provisions of this Regulation shall, depending on the severity of their violations, be disciplined, administratively sanctioned or examined for penal liability in accordance with law.

Minister of Health
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