Notification of 0401022

April 1, 2005

To: The Prefectural Governors

Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labor and Welfare

Using electromagnetic records and electronic signatures for application for approval or licensing of drugs

Regarding materials and evidence of materials so called raw-materials (here after “raw-materials”) of application, notification or report (here after “ applications”) for approval or licensing of drugs, quasi-drugs, cosmetics and medical devices (here after “drugs”), and for registration of conformity certification bodies, following instructions of retention and submission of materials and raw-materials by electromagnetic records are summarized, therefore your understanding and notification to companies within your jurisdiction would be appreciated.
This notification also delivered to the head of the Federation of Pharmaceutical Manufacture's Associations of Japan.

NOTES

1. Purpose

Regarding materials of applications for drugs, they are permitted to retain and submit by electromagnetic records by “Law concerning the use of information and telecommunications technology on administrative procedures” (Law No.151 of 2002) and “Laws concerning the usage of information technology for saving the documentations by private businesses” (Law No. 149 of 2004, here after e-Document Law).
And also regarding materials submitting to MHLW, there are instructions by “the notification of data items and specifications of message of Individual Case Safety Report” (March 30, 2001 Notification No. 39 by Division of Licensing and Safety, Notification No.334 by Division of Evaluation) and “the partially amendment notification of “the notification of electronic specifications for common technical documents”” (May 27, 2004 Notification of 0527001 by chief of Divisions of Evaluation, Pharmaceutical and Food Safety Bureau, MHLW).
Applicants can submit materials by electronically for applications for drugs by above laws and notifications. In terms of the purpose of the Pharmaceutical Affairs Law, to secure the reliability of submission materials by electromagnetic records, we decided to establish notes of retaining or submitting materials and raw-materials by electromagnetic records.

2. Requirements for using electromagnetic records and electronic signatures

Attached guideline shall be considered when applicants using electromagnetic records and electronic signatures for creating materials and raw-materials regarding applications under the Pharmaceutical Affairs Law.

3. Scope

Attached guideline shall be applied as following circumstances.

(1) When applicants use electromagnetic records and/or electronic signatures for materials of application, notification or report for approval or licensing of drugs, quasi-drugs, cosmetics and medical devices and for registration of conformity certification bodies according to the Pharmaceutical Affairs Law and related regulations.
(2) When applicants use electromagnetic records and/or electronic signatures for raw-materials and other materials obliged to retain by the Pharmaceutical Affairs Law.

When paper materials, which are materials and raw-materials of application, notification or report for approval or licensing of drugs, quasi-drugs, cosmetics and medical devices and for registration of conformity certification bodies and other materials obliged to retain according to the Pharmaceutical Affairs Law and related regulations are created based on electromagnetic records and/or electronic signatures, it is also desirable to follow this guideline as well as possible.

4. Applied date

This guideline is applied materials submitted or retained on and after April 1st 2005 in principle.

5. Reconsider of guideline

This guideline will be reconsidered according to the progress of technology and circumstances of foreign countries' regulations.

Attachment

Guideline for using electromagnetic records, electronic signatures for application for approval and licensing of drugs

1. Purpose

This guideline set forth the requirements when applicants use electromagnetic records and electronic signatures for materials and raw-materials of application, notification or report (here after, “applications”) for approval or licensing of drugs, quasi-drugs, cosmetics and medical devices (here after “drugs”) and for registration of conformity certification bodies.

2. Definitions

Definitions using this guideline are described in “Laws concerning the usage of information technology for saving the documentations by private businesses” and following additional.

(1) Electronic storage media means a media which stores electromagnetic records like magnetic disk, optimal disk and magnetic tape and so on.
(2) Electronic signature means an electronic data compilation of series of symbols created, adopted, confirmed or authorized by an individual or company to electromagnetic records to be equivalent of the handwritten signature or seal.
(3) Digital signature means an electronic signature based upon cryptographic methods of originator authentication.
(4) Closed system means an environment in which system access is controlled by persons who are responsible for the content of electromagnetic records that are on the system.
(5) Open system means an environment in which system access is not controlled by persons who are responsible for the content of electromagnetic records that are on the system.
(6) Audit Trail means a series of operational records with accurate time stamp (date recorded by computer automatically).

3. Requirements for using electromagnetic records

3.1 Managing method of electromagnetic records

Following items shall be established by electromagnetic records system and its operating procedures. In this case, ensuring the system reliability by computerized system validation of the electromagnetic records system is premised.

3.1.1. Authenticity of electromagnetic records

Electromagnetic records are complete, accurate and reliable, and also responsibilities of its creation, modification and deletion are definite.

It is necessary to comply with following requirements to establish authenticity.

(1) Rules and procedures of maintaining securities of the system are documented and practicing them appropriately.
(2) Distinction of the creator of maintained information shall be definite. And also when modify the maintained information, previously recorded information shall be stored, and distinction of the modifier shall be definite. Audit trail shall be recorded by automatically, and recorded audit trail is desirable to be confirmed by predetermined procedure.
(3) The procedure of backup of electromagnetic records is documented and practicing appropriately.

3.1.2. Readability of electromagnetic records

The contents of electromagnetic records shall be output (output to display, output to paper and copy to electronic storage media) as human readable format.

3.1.3. Storability electromagnetic records

Electromagnetic records shall be maintained with keeping its authenticity and readability.
Following requirements shall be complied to establish storability.
(1) The procedure shall be documented to establish storability such as administration of electronic storage media, etc, and practicing it appropriately.
(2) When maintained electromagnetic records will be migrated into other electronic storage media or method, migrated electromagnetic records shall be established its authenticity, readability and storability.

3.2. Using closed system

Persons who use closed systems to create, modify, maintain, retrieve or transmit electromagnetic records shall meet requirements described in 3.1. Also, persons who use electronic signature shall meet requirements described in 4.

3.3. Using open system

Persons who use open systems to create, modify, maintain, retrieve or transmit electromagnetic records shall meet requirements identified in 3.1, additionally shall employ appropriate controls to ensure integrity and confidentiality of electromagnetic records from the point of their creation to the point of their receipt. Such controls shall include such as document encryption and use of appropriate digital signature. Also, persons who use electronic signature shall meet requirements identified in 4.

4. Requirements for using electronic signatures

Persons who use electronic signatures shall meet following requirements to ensure the reliability of electronic signatures.
(1) Employ procedures to manage and maintain of electronic signatures according to “Law on Electronic Signatures and Certification Services” (Law No.102 of May 31, 2000), and practicing them appropriately.
(2) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.
(3) Signed materials by electromagnetic records shall contain information associated with the signing that clearly

indicates all of the following:

- The printed name of the signer
- The date and time when the signature was executed
- The meaning (such as creation, confirmation or approval) associated with the signature.

(4) Electronic signatures executed to electromagnetic records shall be linked to their respective electromagnetic records to refrain from injustice operation that the signatures cannot be excised, copied, etc. by ordinary means.

5. Others

Persons who uses electromagnetic records and electronic signatures for materials and raw-materials of applications for approval or licensing of drugs, and for registration of conformity certification bodies shall prepare documents described persons in charge, managers, organizations, equipments and training for using electromagnetic records and electronic signatures.