

The Japanese Pharmaceutical Affairs Law (PAL) will be drastically revised in 2005. This article presents major points of the revision.

The current Pharmaceutical Affairs Law (PAL) was introduced in 1961 to implement regulations necessary for ensuring the quality, effectiveness, and safety of drugs and medical devices. The PAL has since been revised several times. However, with the advent of the 21st century, the following shortcomings have been identified with regard to the PAL in its current form:

- The PAL may not be keeping up with international standards and with changes in socioeconomic circumstances.
- Some of the current legal framework may not be relevant to the control of new drug classes that make use of bio/genomic technology.

Thus it was decided to make revisions to the PAL from the perspectives indicated in Table 1.

Table 1: Points of the revision

- Improvement of post-marketing safety measures and revision of approval/authorization system
- Clarification of corporate responsibility for safety measures
- Revision of manufacturing approval system based on international harmonization
- Legislative preparations to ensure the safety of biological products
- Major revision of safety measures for medical devices
- Respond to new medical devices that use varied technologies and materials

Revision of Approval System

The strictures of the PAL in its current guise are based entirely on the premise that each drug is developed by a manufacturer that makes the product at its own manufactory. The new PAL will be changed from a system that is focused on the act of manufacturing to that of an integrated sales and marketing system. Therefore instead of having an authorized drug producer with a manufactory as the necessary founding premise for drug approval, under the revised plan it will be necessary to have a manufacturer/marketing company with quality control

and post-marketing safety management structures in operation.

Another important change under the revised plan is that any factory that manufactures drugs must have approved buildings and facilities and must have obtained authorization to manufacture drugs. Overseas factories must be certified rather than authorized, after going through a similar procedure.

Manufacturing approval will be granted after a review of quality, effectiveness, and safety has been conducted. In addition, manufacturing and marketing approval may be granted once it is verified that the factory has a requisite permit and that its product(s) conform(s) to the GMP. With the adoption of the new procedures, the present manufactured item-based authorization, which focused on the act of manufacturing as its basic premise, will be abolished. In another development, drug substances that were subject to production approval are no longer so under the new manufacturing and marketing approval system, because they are not distributed to medical institutions. As a consequence, the DMF system implemented in the USA and Europe was adopted in the form of a drug substance register. Other matters to be considered in the future are listed in Table 2.

Table 2: Other topics under review

- Manufacturing and marketing company authorization
- Standards related to quality control methods
- Standards related to post-manufacturing and marketing safety management methods
- Production industry authorization
- Standards related to plant building and facilities
- Certification of foreign manufacturers
- Certification methods
- Manufacturing and marketing approval
- Review methods
- Extent of minor changes that do not require application for partial change of approval
- Drug Master File
- Items that should be registered
- Biological products
- Labeling/record storage, etc.



*World No.1 Speciality Enzyme Producer
More than 100 years of service, since 1899*

<http://www.amano-enzyme.co.jp/>

New address

AMANO ENZYME U.S.A. CO., LTD.

2150 Point Blvd., Suite 100

Elgin, IL 60123, U.S.A.

Tel: 1-847-649-0101

1-800-446-7652

Fax: 1-847-649-0205

E-mail: aeu@amanoenzymeusa.com

AMANO ENZYME INC. (Publisher)

Head Office:

2-7, 1-chome

Nishiki, Naka-Ku, Nagoya,

460-8630 Japan

Tel: +81-(0)52-211-3032

Fax: +81-(0)52-211-3054

E-mail: info@amano-enzyme.co.jp

Tokyo Office:

1-1, 1-chome

Uchisaiwai-cho,

Chiyoda-ku, Tokyo

100-0011 Japan

Tel: +81-(0)3-3597-0521

Fax: +81-(0)3-3597-0527

AMANO ENZYME EUROPE LTD.

Roundway House, Cromwell Park, Chipping Norton,

Oxfordshire, OX7 5SR, U.K.

Tel: +44-(0)1608-644677

Fax: +44-(0)1608-644336

E-mail: sales@amano.co.uk