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Act on medical devices in Japan

Act on medical devices (PMD Act) was launched on November 25, 2014

Practice-oriented summary of the most important aspects and requirements contained in Japanese regulations on medical devices.

Amendments to the Japanese Pharmaceutical Affairs Law (PAL) were adopted in November 2013. The amendments were launched as of November 25, 2014. This Med-Info provides you with an overview of the amendments to the Japanese regulations.

Changes to the Act

1. Title

The title "Pharmaceutical Affairs Law (PAL)" was changed to "Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, medical devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (PMD Act)".

2. Scope

The PAL covered pharmaceuticals (medicines), quasi-drugs, cosmetics, in-vitro diagnostic reagents, and medical devices. In addition to the current scope of the PAL, the PMD Act covers regenerative and cellular therapy products as well as gene therapy products. Regulations pertaining to the extended scope are not described in this Med-Info.

3. Objectives of amendments

There were three main objectives of these amendments:

1) Addition of regenerative and cellular therapy products and gene therapy products to the scope of the Act
2) Changes to the regulatory scheme appropriate to medical devices (please refer to 4. below and the next section in this Med-Info for details)
3) Global harmonization of regulatory schemes for medical devices

4. Changes to regulatory schemes under consideration of characteristics of medical devices

The regulations governing the Marketing Authorization Holders (MAH) and manufacturing sites of medical devices and in-vitro diagnostic (IVD) reagents are defined in a different chapter than the one for products such as pharmaceuticals and cosmetics. Please refer to the next section in this Med-Info for details.

5. Enhancing safety measures

Package inserts for class IV medical devices must be submitted to PMDA[1] before release or change.

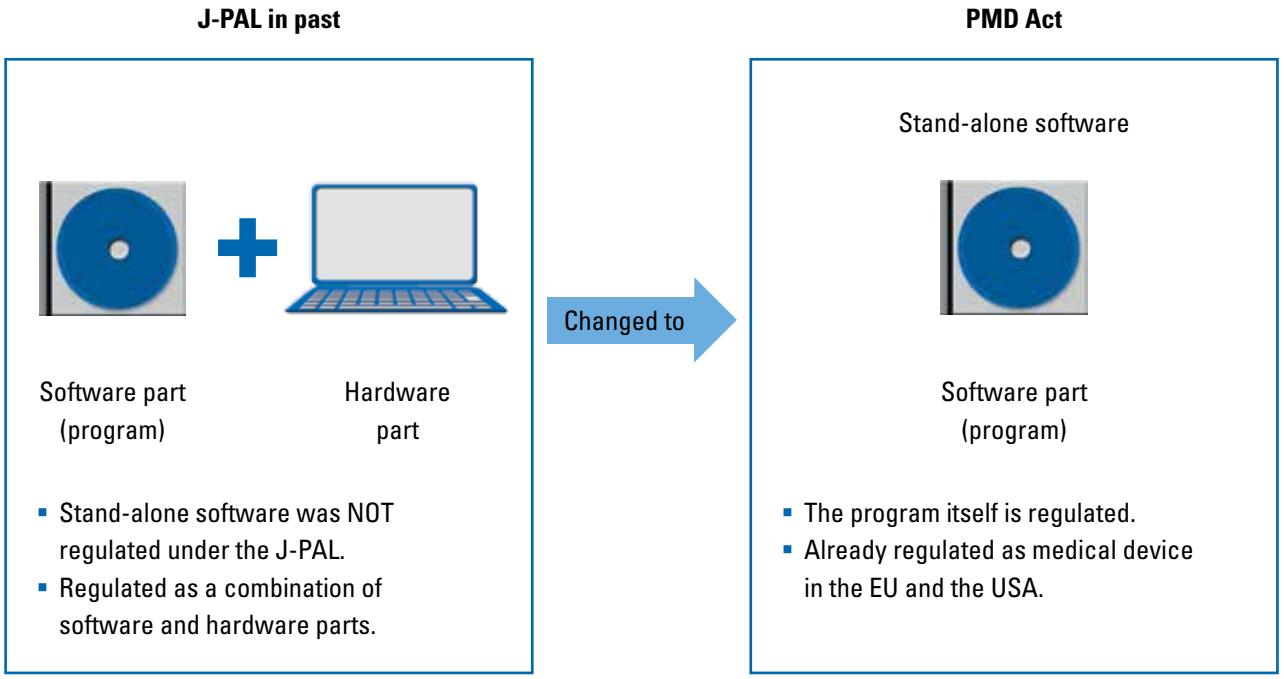
[1] PMDA: Pharmaceuticals and Medical Devices Agency, an independent administrative legal entity which is responsible for review of all medicines, certain types of medical devices, and IVD reagents. Based on PMDA's review results, the MHLW (Ministry of Health, Labour and Welfare) formally approves them.

Changes to regulations on medical devices

1. Stand-alone medical device software is regulated as a medical device.

In contrast to Europe and the USA, stand-alone software which provides information for diagnosis, treatment, and/or prevention of diseases had previously not been regulated in Japan. It is now also regulated in Japan.

Figure 1: Regulation on stand-alone software



We provide another Med-Info concerning foreign manufacturers of stand-alone medical device software as there are several important actions to be taken. Please refer to Med-Info “Software as medical device” for details.

2. Foreign Manufacturer Accreditation (FMA) is no longer required.
All manufacturing facilities which manufacture products to be certified or approved were previously required to hold a business license in Japan or an FMA. Under the revised regulations, listing of manufacturing facilities is required, but a business license or FMA is not longer necessary.

The manufacturing facilities to be listed are:

- Main design facility with overall responsibility for design activities
- Main manufacturing facility which performs main manufacturing processes such as assembly, inspection, etc., and has overall responsibility for product realization
- Manufacturing facility which performs sterilization
- Warehouse or distributor in Japan which launches the final products in Japan

Table 1: Listing of facilities

Activity in facility	Business license in Japan or FMA under J-PAL (previous)	Listing under revised regulation (with immediate effect)
Design and development	Not required	Required
Manufacturing (e.g. assembling, inspection)	Required	Required
No “main” manufacturing (e.g. sub-assembling, incoming inspection, packing)	Required	Not required
Sterilization	Required	Required
Final release of products (in Japan)	Required	Required
Supplier of critical parts/materials	Not required	Not required

These changes aim to foster a climate that encourages new entries to the market.

Please refer to Med-Info “FAQs on Japanese Regulations” for details on transitional measures.

3. "Me-too" medical devices in class III are certified by an RCB[2].

In order to market class II, III, and IV medical devices or class II and III IVD reagents in Japan, a marketing certificate or approval for each model is required. The criteria for marketing approval or certificate, shown in the table below, have not changed significantly.

Table 2: Criteria for marketing approval/certificate

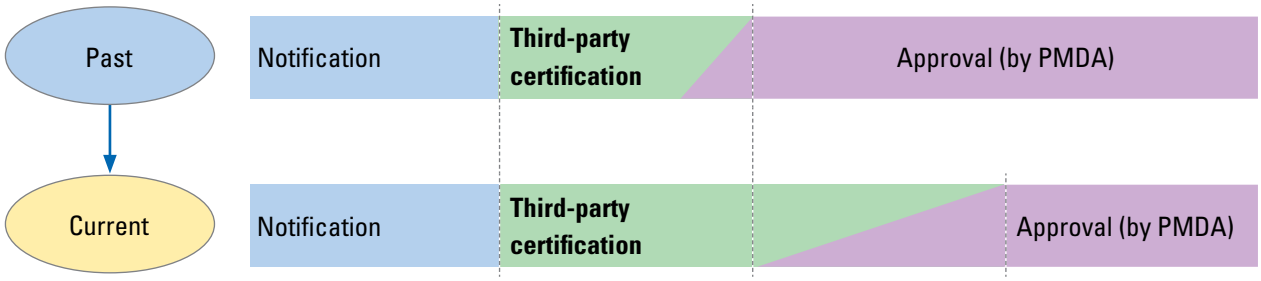
Criteria for approval	Criteria for certificate
The applicant holds a valid business license as MAH. **Unchanged**	As left
If a foreign manufacturer wants to hold the approval, a designated MAH is assigned. **Unchanged**	If a foreign manufacturer wants to hold the certificate, a designated MAH is assigned (as left).
Before All facilities in Japan which manufacture the product in question hold a business license as manufacturer. All foreign facilities which manufacture the product in question hold an FMA. **After** Main facilities both in and outside Japan, including main design facilities, are listed.	As left
The following aspects are confirmed by PMDA review: - The product's efficacy and performance is as stipulated. - There are no serious side effects compared to efficacy and performance. **Unchanged**	The product in question fulfills the certification criteria. **Unchanged**
Before The quality management system of all facilities which manufacture the product in question fulfill the J-QMS Ordinance. **After** The quality management system which covers the product in question fulfills the revised J-QMS Ordinance.	As left

RCBs such as TÜV SÜD Japan have certified class II Medical Devices and IVD reagents since 2005. The certification of "me-too" Medical Devices in class III, which so far has been the responsibility of the PMDA, is partially transferred to the RCBs.

[2] RCB: Registered Certification Body under PMD Act,
third party authorized to certify a certain type of medical devices and IVD reagents. TÜV SÜD Japan is one of the biggest RCBs.

Figure 2: Classification of medical devices for marketing approval/certificate

Classification	Class 1	Class 2	Class 3	Class 4
Definition	Extremely little risk to the human body even if they fail	Relatively little risk to the human body even if they fail	Relatively high risk to the human body if they fail	Highly invasive for the patient; may directly endanger the patients' life if they fail
Examples	IVD instrument, surgical knife forceps, X-ray films	Ultrasound equipment, blood pressure meter (electrical), MRI	Dialyzer, respirator	Pacemaker, artificial heart valve

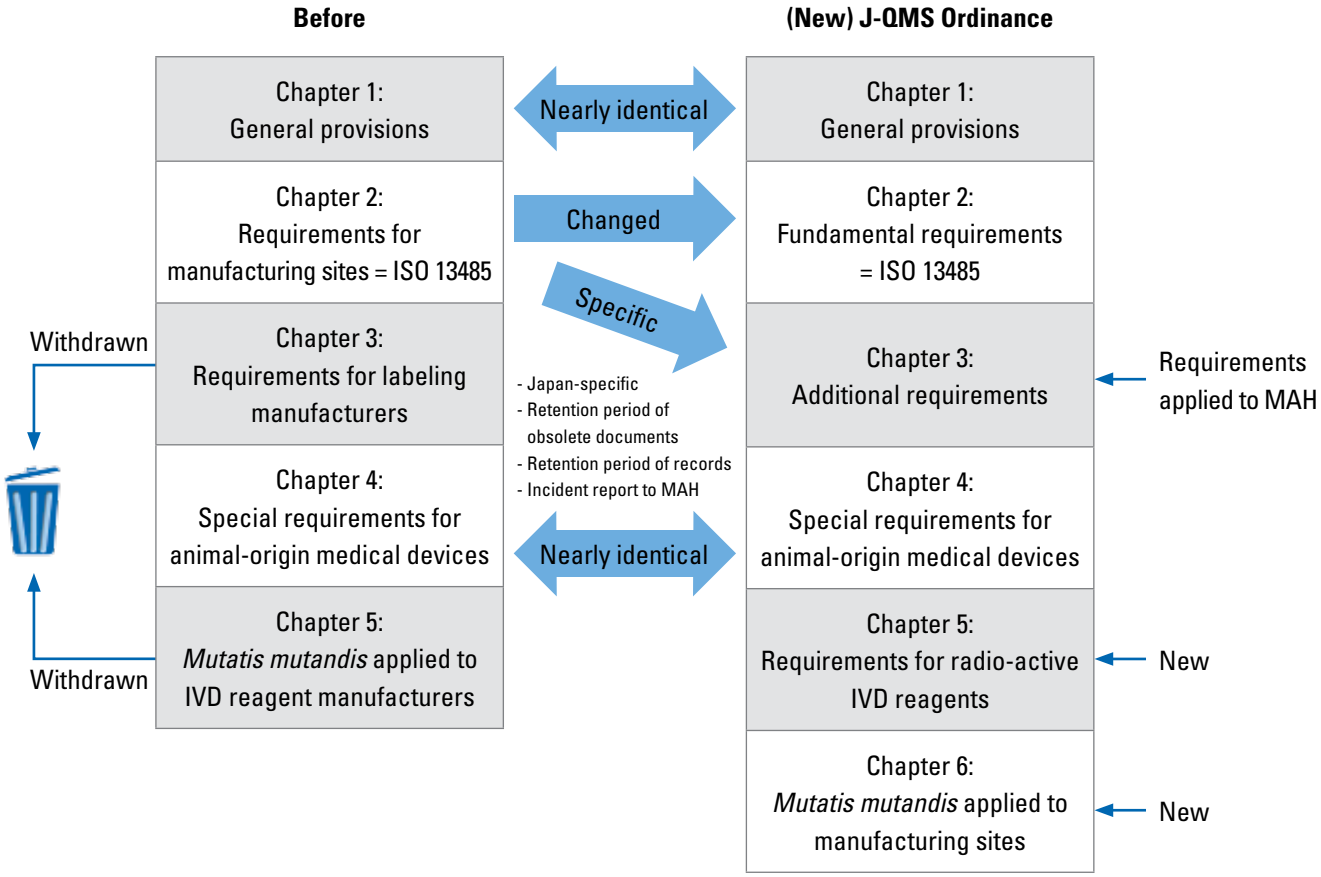


Class 3 medical devices, that RCB certifies, are listed on TÜV SÜD Japan Webpage.
http://www.tuv-sud.jp/jp-en/news-media-1/newsroom

4. QMS audits are streamlined.

Quality management systems in manufacturing sites were one of the criteria for the award of marketing certificates or approvals. Audit is performed to verify whether the system fulfills the relevant MHLW[3] Ordinance No. 169 from 2004, known as the J-QMS Ordinance. The J-QMS Ordinance was revised and applies to MAHs in addition to the manufacturing sites. The main part of the revised J-QMS Ordinance, chapter 2, is identical to ISO 13485:2003.

Figure 4: Changes of the configuration of the QMS Ordinance



Changes apply to both requirements and the handling of audit results. Please refer to Med-Info "QMS requirements in Japan" for details.

TÜV SÜD as your partner for J-QMS

TÜV SÜD Japan is one of the biggest RCBs and has been certifying Class II medical devices and IVD reagents since 2005, as well as Class III me-too medical devices under revised regulation. The global TÜV SÜD group provides J-QMS audits. J-QMS audits can be performed in combination with usual audits based on ISO 13485, MDD, and/or CMDCAS.

Furthermore, TÜV SÜD

- offers reliable and flexible assistance and acts promptly;
- has long-standing experience with the Japanese Quality System requirements > PMD Act and J-QMS Ordinance;
- has detailed knowledge of all criteria that must be fulfilled to succeed MAH or foreign manufacturer J-QMS audits.

Your contact partner at TÜV SÜD Product Service can provide further information.

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[3] MHLW: Ministry of Health, Labour and Welfare, responsible for medical care.

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