



# Pharmaceutical, quasi-pharmaceutical products and cosmetics

Product requirements in Japan under the EU-Japan EPA



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## 1. General Information

- Japan Pharmaceutical Manufacturers Association (JPMA): [Information on Japanese Regulatory Affairs—Pharmaceutical Administration and Regulations in Japan \(2019\)](#) (English)
  - [Overall information concerning pharmaceutical administration and regulations in Japan](#) (English)
- Practical Law: [Medicinal product regulation and product liability in Japan—overview](#) (English)

### 1.1 Tariff Rates

- For more detailed information on tariff rates please refer to [My Trade Assistant](#)

### 1.2 Definitions of Pharmaceuticals and Quasi-Pharmaceutical Products and Cosmetics in Japan

The definitions of “Pharmaceuticals”, “Quasi-Pharmaceutical Products” and “Cosmetics” are prescribed in Article 2 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices as follows:

- **Pharmaceuticals:** items listed in the Japanese Pharmacopoeia, items which are intended for use in the diagnosis, treatment or prevention of disease in humans or animals and items which are intended to affect the structure and functioning of a human’s or animal’s body.
- **Quasi-Pharmaceutical Products:** products which have mild effects on the human body and are listed in Article 2-2 of the Act.
- **Cosmetics:** products which are intended to be used on the human body by rubbing, sprinkling or other similar means, aiming to clean, beautify and increase attractiveness, alter appearance or to keep skin or hair in good condition, and which have mild effects on the human body.

The main difference between normal cosmetics and quasi-pharmaceutical cosmetics is whether they contain effective ingredients. [The effective ingredients are listed in a notification by the Ministry of Health, Labour and Welfare \(MHLW\)](#) (Japanese).

## 2. Pharmaceuticals and Quasi-Pharmaceutical Products

### 2.1 Required licenses

In Japan, in connection with the manufacturing and marketing of pharmaceuticals and quasi pharmaceutical products , there are three type of licenses: , (i) a license concerning manufacturing (Manufacturing License 製造業許可 (*seizo gyo kyoka*)) and accreditation as a foreign manufacturer (Foreign Manufacturer Accreditation 外国製造業者認定 (*gaikoku seizogyo-sha nintei*)), (ii) a license concerning marketing (Marketing License 製造販売業許可 (*seizo hanbai gyo kyoka*)), and (iii) a marketing approval for individual medical products(Marketing Approval 製造販売承認 (*seizo hanbai shonin*)).

- PMDA: [Procedures required for manufacturing, exporting, and selling pharmaceuticals and quasi-pharmaceutical products in Japan](#) (Japanese)
  - The following explanatory materials (PDF files) are available at the website above:
    - PMDA: [Procedures required for manufacturing\\* and selling pharmaceuticals in Japan](#) (Japanese). \*Manufacturing outside of Japan is included.
    - PMDA: [Procedures required for manufacturing\\* and selling quasi-pharmaceutical products in Japan](#) (Japanese)

Laws and regulations which require the licenses listed above are available at the following websites:

- Act on Securing Quality, Efficacy, and Safety of Products, Including Pharmaceuticals and Medical Devices ([English](#) and [Japanese](#))
  - The English translation at the above link is outdated. The latest text is available only in Japanese.
- Regulation for Enforcement of the Act on Securing Quality, Efficacy, and Safety of Products, Including Pharmaceuticals and Medical Devices ([English](#) and [Japanese](#))
  - The English translation at the above link is outdated. The latest text is available only in Japanese.

#### 2.1.1 Manufacturing License

A foreign manufacturer intending to manufacture pharmaceutical products, quasi-pharmaceutical products, or medical devices in foreign countries and export them to Japan must be accredited by the Minister of Health, Labor, and Welfare as an “Accredited Foreign Manufacturer” as specified in Article 13-3 of the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices.

- PMDA: [Accreditation of Foreign Manufacturers](#) (English)
  - The following explanatory materials (PDF files) are available at the website above:
    - [An Explanation of the Application for Accreditation of Foreign Manufacturers](#) (English)
    - [The Category of Accreditation of Foreign Manufacturers](#) (English)
    - [Examination Fees](#) (English) However, the English material related to the examination fees is outdated. The most recent version of the list of examination fees is available only in [Japanese](#).
    - [A List of Accredited Foreign Manufactures](#) (Japanese)

## 2.1.2 Marketing License

A foreign manufacturer intending to export pharmaceuticals, quasi-pharmaceutical products to Japan must obtain a “special approval regarding foreign manufacturing”, on a product-by-product basis. Before submitting an application for a special approval regarding foreign manufacturing the foreign manufacturer must appoint an entity which has obtained a marketing license. This appointment is a requirement of marketing approval for individual medical products, which is explained below. After the foreign manufacturer obtains special approval regarding foreign manufacturing, the designated entity may market the product of that foreign manufacturer pertaining to such approval.

## 2.1.3 Marketing Approval for Individual Medical Products

### 2.1.3.1 General

An application for marketing approval for each medical product should be submitted to the PMDA (in the case of products to be approved by the minister of MHLW), or to each prefecture’s pharmaceutical affairs division (in the case of products to be approved by the governor of each prefecture). Although Article 14 (1) of the Act on Securing the Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices, established that the approval should be obtained by the MHLW, Item 5 of Article 80 (2) of the order for the enforcement of this Act established that review of certain products is delegated to the prefecture. The products to be approved by each prefecture are listed in the Public Notice of the MHLW No. 366 of 1970. With regard to the products to be approved by the MHLW, the PMDA is entrusted to review the medical products.

- MHLW: [Public Notice of the MHLW No. 366 of 1970](#) (Japanese)
- Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices ([English](#) and [Japanese](#))
  - The English translation at the above link is outdated. The latest text is available only in Japanese.

- Order for the Enforcement of the Act on Securing the Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices ([English](#) and [Japanese](#))
  - The English translation at the above link is outdated. The latest text is available only in Japanese.
- PMDA: [Review process for drug or medical device applications](#) (English)
- PMDA: [Application for marketing approval for individual medical products](#) (Japanese)
- Bureau of Social Welfare and Public Health, Tokyo Metropolitan Government: [Application for marketing approval for Pharmaceuticals and Quasi-Pharmaceutical Products](#) (Japanese)

#### 2.1.3.2 Good Manufacturing Practice (GMP)

For certain pharmaceuticals and quasi-pharmaceutical products, GMP (Good Manufacturing Practice) compliance is a requirement of the marketing approval. GMP Compliance Inspections include (1) Inspections that are conducted at the point of application for new marketing approval or of application for partial changes of approved information, and (2) Inspections that are conducted every five years following the obtainment of marketing approval. GMP Compliance inspection is conducted by PMDA.

- PMDA: [GMP Inspection](#) (Japanese)
  - Some of the documents available on this Japanese website are accompanied by English translations.
- PMDA: [GMP](#) (English)
  - The explanation of GMP, the kind of pharmaceuticals which is subject to the GMP inspection and the way of application could be obtained from the above website. Please note that PMDA explains that the English translations in the above English website are tentative. In connection with GMP, the following explanatory materials (PDF files) are available at the English website above:
    - [Overview Guidance of GMP Compliance Inspection for Foreign Manufacturers](#) (English)
    - [Documents for application of GMP inspection](#) (English)
    - [GMP Ministerial Ordinance \(Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs\)](#) (English)
    - [Administrative Notice on Application of PICs GMP Guide](#)
    - [Administrative Notice on Application of PICs GMP Guide](#) (Q and A)

## 2.2 Other Regulations

### 2.2.1 Regulation Regarding Advertising and Providing Information on Sales

- MHLW: [Regulation and notifications regarding advertisement of products including pharmaceuticals and medical devices](#) (Japanese)
- ICLG: [Japan Pharmaceutical Advertising 2019](#) (English)
- MHLW: [Guidelines for Providing Information on Sales of Pharmaceuticals Used with Prescriptions](#) (Japanese)

#### **Related regulations and guidelines in connection with advertising:**

- Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices ([English](#) and [Japanese](#))
  - The English translation at the above link is outdated. The latest text is available only in Japanese.
- MHLW: [Standards for Fair Advertising Practices Concerning Pharmaceuticals etc.](#) (Revised on September 29th, 2019) (Japanese)

### 2.2.2 Intellectual Property

- Practical Law: [Pharmaceutical IP and competition law in Japan](#) (English)
  - The above website provides an overview of applications for and revocations of patents and trademarks, the protections granted under patents and trademarks, the problem areas in which infringement of patents and trademarks is likely to occur, and the points to note in connection with the regulations under competition law.

## 3. Cosmetics

### 3.1 Required Licenses

As with pharmaceuticals and quasi-pharmaceutical products, for manufacturing and marketing of cosmetics, (i) a license concerning manufacturing (Manufacturing License 製造業許可(*seizo gyo kyoka*)) and accreditation as a foreign manufacturer (Foreign Manufacturer Accreditation 外国製造業者認定 (*gaikoku seizogyo-sha nintei*)), (ii) a license concerning marketing (Marketing License 製造販売業許可 (*seizo hanbai gyo kyoka*)), and (iii) a marketing approval for individual cosmetics (Marketing Approval 製造販売承認(*seizo hanbai shonin*)) are required (See: **2.1 Required Licenses**)

However, if the cosmetics to be exported to Japan meet the requirements under the Standards for Cosmetics, Foreign Manufacturer Accreditation and Marketing Approval for individual cosmetics will no longer be required, as described below. Instead, only a notification will be necessary. Please note that, according to the Tokyo Metropolitan Institute of Public Health, in many cases, foreign-made cosmetics meet the requirements of the Standards for Cosmetics because the Standards are internationally harmonized.

- MHLW: [Website of Cosmetics and Quasi-Pharmaceutical Products](#) (Japanese)

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryuu/iyakuhin/keshouhin/index.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/iyakuhin/keshouhin/index.html)

- MHLW: Standards for Cosmetics ([English](#) and [Japanese](#))

**General information about importing cosmetics into Japan can be obtained from the following websites:**

- Tokyo Metropolitan Institute of Public Health: [Manufacturing, Marketing and Importing of Cosmetics](#) (Japanese)
- MIPRO: [Importing and Marketing of Cosmetics](#) (Japanese)
- Manual (pdf) for [Importing and Marketing of Cosmetics](#) (Japanese)

### 3.2 Notification regarding a Foreign Manufacturer

As with pharmaceuticals and quasi-pharmaceutical products, a foreign manufacturer intending to manufacture cosmetics in foreign countries and export them to Japan must be accredited by the Minister of Health, Labor, and Welfare as an “Accredited Foreign Manufacturer” (See: **2.1.1 Manufacturing License**)



If the cosmetics produced by those foreign manufactures meet the requirements under the Standards for Cosmetics and all ingredients are labelled in a way which observes the requirements under the laws and regulations, only a notification regarding a foreign manufacturer or a foreign marketer and of the entity which sells the product in Japan is required. (Article 76 (2) of the Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and Article 267 of the Regulations for the Act) The application for approval and the notification should be submitted to the PMDA.

- Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ([English](#) and [Japanese](#))
  - The English translation at the above link is outdated. The latest text is available only in Japanese.
  
- Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ([English](#) and [Japanese](#))
  - The English translation at the above link is outdated. The latest text is available only in Japanese.
  
- PMDA: [Required forms of approval and notification](#) (Japanese)

### 3.3 Marketing License for Cosmetics

In Japan, only an entity which has a marketing license can market cosmetics (Article 12 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices). Foreign manufactures which do not have the license have to entrust the marketing to an entity which has a marketing license.

If the foreign manufacturer or its subsidiaries intend to obtain a marketing license, the procedure for obtaining a license and the required forms can be obtained from each prefecture's bureau of pharmaceutical affairs. Regarding Tokyo, please refer to the following website:

- Tokyo Metropolitan Institute of Public Health: [Review of Pharmaceuticals, Quasi-Pharmaceutical Products and Cosmetics](#) (Japanese)
  - [Required form of marketing license for cosmetics](#)

## 3.4 Marketing Notification for Individual Cosmetics

Please note that the system to obtain a marketing approval for individual cosmetics is the same as that for pharmaceuticals and quasi-pharmaceutical products explained in **Section 2.1.3**.

Regarding the cosmetics which meet the requirements under the Standards of Cosmetics, a notification must be submitted for each cosmetic instead of obtaining an approval. In this case, the notification should be submitted to each prefecture's bureau of pharmaceutical affairs where the marketing entity has obtained a marketing license for cosmetics.

- Tokyo Metropolitan Institute of Public Health: [Notification Regarding Marketing](#) (Japanese)
  - Required forms of notification for individual cosmetics are available here

## 3.5 Other Regulations

### 3.5.1 Regulations regarding Advertising and Providing Information on Sales

- Tokyo Metropolitan Institute of Public Health: [Labelling of Cosmetics](#) (Japanese)
- MHLW: [Standards for Fair Advertising Practices Concerning Medicinal Products etc.](#) (Revised as of September 29, 2019) (Japanese)
  - Those standards apply not only to pharmaceuticals and quasi-pharmaceutical products, but also cosmetics.

### 3.5.2 Optional Labelling System and Optional Guidelines in Japan

- Japan Cosmetic Industry Association (JCIA): [Overview](#) (English)
  - [Guidelines for Appropriate Advertising of Cosmetics](#) (Japanese)
  - [List of Cosmetic Ingredient Labelling Names](#) (Japanese)

In Japan, in principle, labelling of all ingredients of cosmetics is mandatory. The names to be used for the cosmetic ingredients are managed by the JCIA. The above website is the database for such ingredient names.

- [Application for Japanese Labelling Names](#) (English)

## 3.6 Environmental Regulations which apply to Imported Goods in General

### 3.6.1 Labelling Requirements Prescribed under the Act on the Promotion of Effective Utilization of Resources

- Ministry of Economy, Trade and Industry (METI): [Description of the Act on the Promotion of Effective Utilization of Resources](#) (Japanese)
  - Description of the requirement to put an identification mark on paper and plastic containers/packages which indicates that those containers/packages are made of paper or plastics that is recyclable.
- Act on the Promotion of Effective Utilization of Resources ([English](#) and [Japanese](#))
  - The English translation at the above link is outdated. The latest text is available only in Japanese.

### 3.6.2 Requirement to Recycle Containers/Packages Made of Paper, Plastic, PET, or Glass

- METI: [Description of the Act on the Promotion of Effective Utilization of Resources](#). You can find further information [here](#) (Japanese)
  - Description of the requirement to recycle paper, plastic, PET, or glass containers/packages imposed on enterprises (which meet the thresholds for turnover or number of employees, and which import these containers/packages or use these containers/packages when they sell their products). These entities can also fulfill their obligations by paying commissions to the Japan Containers and Packaging Recycling Association, which is a public interest incorporated foundation.
- Act on the Promotion of Sorted Collection and Recycling of Containers and Packaging ([English](#) and [Japanese](#))
  - The English translation at the above link is outdated. The latest text is available only in Japanese.