# Application for Accreditation of Foreign Manufacturers

*(This English document is only for reference purpose. In case of any discrepancy, the Japanese text shall prevail. For further information, please contact Ministry of Health, Labour and Welfare (MHLW) or PMDA.)*

## 1. What is Accreditation of Foreign Manufacturers?

A foreign manufacturer (a person/a company) intending to manufacture drugs, or quasi-drugs in foreign countries and export them to Japan, is required to be accredited by the Minister of Health, Labour, and Welfare as an "Accredited Foreign Manufacturer", specified in Article 13-3 of PAL, in the same way that a Japanese manufacturer is licensed. The person or the company who intends to apply for the accreditation is hereinafter referred to as an "Applicant".

However, a foreign manufacturer of the drug or medical device, etc. whose marketing approval holder has an effective importing license granted under the old PAL as of April 1, 2005, is deemed to be temporarily accredited under the revised PAL by the end of its effective period. The manufacturer satisfying the above condition is hereinafter referred to as a "Deemed Accredited Foreign Manufacturer".

In addition, a foreign manufacturer intending to manufacture only drug substances to be exported to Japan also need to obtain accreditation as an "Accredited Foreign Manufacturer". The Minister of Health, Labour and Welfare has an authority to grant accreditation to a foreign manufacturer, while PMDA examines buildings and facilities of the manufacturing establishment for accreditation. The accreditation is granted for each manufacturing establishment according to the category specified by the Enforcement Regulations.

Before applying for accreditation, a Japanese marketing approval holder for an "Applicant" needs to submit "Business Number Registration Form", reporting information on the applicant's business and manufacturing establishments, in order to obtain "Business Number".

## 2. Application for Accreditation of Foreign Manufacturers

**(1)** An "Applicant" is required to submit "Application for Accreditation" (Form No. 18 in the PAL Enforcement Regulations) that is addressed to the Minister in duplicate, and "Application for Accreditation Examination" (Form No.16-(2) in the Regulations) to Chief Executive of PMDA. Both applications need to be submitted to Administration Division II, Office of Review Administration of PMDA.

A Japanese marketing approval holder who markets drugs etc. manufactured by a foreign manufacturer can make an accreditation application on the manufacturer's behalf. However, the space of "Name of Applicant" on the application form should be filled out with the foreign manufacturer's name (when an "Applicant" is a corporation, names of the corporation and their CEO). In addition, an "Applicant" is to be responsible to renew their accreditation every 5 years.

For more details on the renewal procedure, please refer to 2-(4), “Application for Renewal of Accreditation of Foreign Manufacturers”.

Examination Fees for the accreditation differ between on-site and document examinations. However, PMDA requires only document audit fee to be paid to our bank account because, in principle, we do not conduct on-site inspection only for the purpose of examining buildings and facilities of a foreign manufacturing establishment to be accredited.

A target period to complete administrative processing (standard administrative process time) of accrediting a foreign manufacturer is not specifically set. However, the period can be estimated to be about 5 months because the Minister’s licensing process for a domestic manufacturing establishment takes about 5 months.

When an “Applicant” intends to apply for a new accreditation, they cannot apply for multiple categories in one accreditation application. They need to submit an accreditation application for one category and, at the same time, submit additional applications for the other categories (ref. 2-(3), Application for Change/Addition in Category of Accreditation of Foreign Manufacturers).

**(2) Documents to Be Attached to Accreditation Application (Article 36, Paragraph 3 of the PAL Enforcement Regulations)**

① “A curriculum vitae of the person who is responsible to the manufacturing establishment”

② “List of products” to be manufactured for exporting to Japan and “Documents on manufacturing process”

Please make a list of products to be manufactured as detail as you can figure out by the time of accreditation application. In a “Document on manufacturing process”, please organize it clearly that each of the listed products will take what/which type of manufacturing procedure at the relevant establishment.

③ “A document on buildings and facilities of a manufacturing establishment”

An “Applicant” intending to manufacture drugs (excluding *in vitro* diagnostics) and quasi-drugs needs to submit documents equivalent to the application documents for manufacturing license of drugs and quasi-drugs specified in “Enforcement of Ministerial Ordinance etc. of Partial Revision of the Regulations for Manufacturing Control and Quality Control of Drugs and Regulations for Buildings and Facilities for Pharmacies, etc.” (PAB Notification No. 1332, dated October 9, 1980).

In addition, they need to submit informative documents for examination of buildings and facilities of their manufacturing establishments such as a floor plan.

④ “When radiopharmaceuticals are included (excluding cases that the amount of

radiopharmaceuticals is equal to or less than those designated by the Minister), a document on the type of the radiopharmaceuticals and outlines of facilities for handling such radiopharmaceuticals"

⑤ "When a system for marketing license, manufacturing license, marketing approval or marketing certification of drugs or an equivalent system is established in the country where the foreign manufacturer resides, a copy of the license certificate issued by governmental organizations etc. of the country under such system". The license certificate should be currently valid.

**Note: Points to Consider (PTC) with Respect to Accreditation of Foreign Manufacturers of Quasi-drugs**

"A curriculum vitae of the person who is responsible for the foreign manufacturing establishment" does not need to be attached to an application form for accreditation of foreign manufacturers, when the marketing approval holder concerned responsibly ensures their reliability. In this case, the "Applicant" can omit filling out the space of "Address" in the section of "Person who is responsible for manufacturing establishment" and "Conditions of Disqualification of applicant" on the application form.

In addition, the "Applicant" needs to indicate the status of their intended products by showing either "Quasi-drug Subject to GMP" or "Quasi-drug Not Subject to GMP" in the remarks column.

**(3) Application for Change/Addition in Category of Accreditation of Foreign Manufacturers**

When an "Accredited Foreign Manufacturer" changes the category accredited to their manufacturing establishment or adds new categories to their accreditation, they must submit a form, "Application for Change/Addition" (Form No. 21 specified in the PAL Enforcement Regulations), in order to newly obtain the Minister's accreditation for the change or addition.

When the manufacturer intends to add new categories to their accreditation, they need to apply for addition in accreditation category.

On the other hand, applying for change in category of accreditation allows the manufacturer to be accredited to new categories while cancelling their previously accredited categories.

In both of the cases, the manufacturer also needs to submit a form of "Application for Accreditation Examination" (Form No. 16-(2) in the Regulations) in the same way of a new application as referred to in 2-(1) above.

The documents required for change or addition in category of accreditation of foreign manufacturers are as follows; (Article 31 of the PAL Enforcement Regulations shall apply mutatis mutandis to Article 37.)

1. Accreditation certificate
2. List of products whose accreditation category to be changed or added and documents on

their manufacturing processes

3. Documents on buildings and facilities of a manufacturing establishment that relates to change or addition in category of accreditation

**(4) Application for Renewal of Accreditation of Foreign Manufacturers**

Unless an "Accredited Foreign Manufacturer" renews their accreditation, using a form of "Application for Renewal of Accreditation" (Form No. 20 in the PAL Enforcement Regulations), within its 5-year effective period, their accreditation becomes null and void.

In renewing granted accreditation, they also need to submit a form of "Application for Accreditation Examination" (Form No. 16-(2) in the Regulations) in the same way to a new application as referred to in 2-(1) above.

When a "Deemed Accredited Foreign Manufacturer" applies for the first renewal of their deemed accreditation after revision of the PAL, they need to attach a copy of the certificate for their importing license, which was granted under the old PAL to their Japanese importer called marketing approval holder under the new PAL, in addition to take the same procedure as to obtain a new accreditation. On the other hand, when an "Accredited Foreign Manufacturer" renews their accreditation granted under the new PAL, they need to attach the certificate for their accreditation to an application form for its renewal.

**3. Others**

(1) **Notification on Change (Article 100 of the PAL Enforcement Regulations)** When an "(Deemed) Accredited Foreign Manufacturer" makes changes in the following matters, they must notify the fact to the Minister within 30 days by submitting a notification (Form No. 6) to PMDA.

① Name or address of the person responsible for the manufacturing establishment
② Name of the executives responsible for the services, when the manufacturer is a corporation
③ Name of the manufacturing establishment
④ Major part of buildings and facilities of the manufacturing establishment
⑤ Category and (deemed) accreditation number, when a foreign manufacturer obtains additional accreditations for another category, or discontinues operation of their accredited manufacturing establishment

**(2) Advising Division/Office with respect to Application for Accreditations**

1. General questions on applications and Inquiries about review status Administration Division II, Office of Review Administration
   FAX: +81-3-3506-9442

2. Examination of buildings and facilities of manufacturing establishment to be accredited
   Division of Inspection for Drugs, Office of Manufacturing Quality for drugs (Pharmaceuticals excluding *In vitro* diagnostics)

FAX: +81-3-3506-9465

**4. References (Notification and Related Documents)**

- "Enforcement of Ministry Ordinances Regarding Revision of Regulations on Manufacturing and Quality Control/Assurance of Drugs and Regulations on Buildings and Facilities for Pharmacies etc." Notification of Director-General of Pharmaceutical Affairs Bureau, MHW, PAB No.1332 dated October 9, 1980.

- "Points to Be Noted in Accreditation for Foreign Manufacturers of Quasi-drugs and Cosmetics", the Notification of Director of Evaluation & Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, PFSB/ELD No. 0331018 dated March 31, 2005.

- "Documents to be Attached to Applications for Accreditation of Foreign Manufacturers of Drugs and Quasi-drugs", the Notification of Director of Evaluation & Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW; PFSB/ELD No. 1024002 dated October 24, 2005.

- "Q&As on Accreditation of Foreign Manufacturers", Office Communication Letter of Evaluation & Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW; dated February 14, 2006.

- "Taxation on License and Accreditation of Manufacturers of Pharmaceuticals and Medical Devices, etc.", the Office Communication Letter of Evaluation & Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW; dated February 23, 2006.

- "Administrative Procedure for License and Accreditation of Marketing Business of Pharmaceuticals and Medical Devices etc. associated with Taxation on License and Accreditation", the Notification of Director of Evaluation & Licensing Division and Director of Pharmaceutical and Food Safety Bureau, MHLW, PFSB/ELD No. 0331025, PFSB/SB No. 0331012 dated March 31, 2006.

- "Forms to be Attached to Applications for Authorization of Manufacture of Pharmaceuticals, etc and Accreditation of Foreign Manufacturers", Notification of the Director-General of Pharmaceutical and Food Safety Bureau, MHLW PFSB No.0619002 dated June 19, 2007 (Written in Japanese but English forms are available)

- "Handling of Application for Accreditation of Foreign Manufacturers" Notification of Director of Evaluation and Licensing Division of Pharmaceutical and Food Safety Bureau, MHLW, PFSB/ELD No.0619004 dated June 19, 2007

- "Q&As on Approval Application for Pharmaceuticals, etc", the Office Communication Letter of

Evaluation & Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW; dated June 19, 2007

- "Accelerated procedures of change of manufacturing establishment or registration of additional manufacturing establishment of OTC drugs" Notification of Director of the Evaluation and Licensing Division, Director of Compliance and Narcotics Division, Pharmaceutical and Food Safety Bureau, MHLW, PFSB/ELD No.0620001, PFSB/CND No. 0620009 dated June 20, 2007

- "Revision of Forms to be Attached to Applications for Authorization of Manufacture of Pharmaceuticals, etc. and Accreditation of Foreign Manufacturers." PFSB Notification No. 1013-2, issued by the Secretary-General of Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated October 13, 2010.

- "Handling of Application for Accreditation and Registration of Foreign Manufacturers of Drugs and Quasi-drugs." PSEHB/PED Notification No. 0428-4, issued by the Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated April 28, 2021.

# Examinations in Accreditation for Foreign Manufacturers

*** In principle, document examination is required for accreditation**

