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Question & Answer for Product Registration Process for Medical Device in Taiwan and Japan.

Product Registration WG

This Q&A was made for better understanding of regulations and product registration process in Taiwan and Japan.

Taiwan to Japan

■ Product Registration

◆ Q1: The English information on MHLW or PMDA website is insufficient such as JMDN, product standards, revised regulations update. Will the information on the websites updated real-time?

◇ A1: The Japanese contents of PMDA website is translated and transferred to the English website in order of priority. Especially, the highest priority information such as safety information is immediately translated and published on the PMDA website.

As for the standard related English information such as Japanese Medical Device Nomenclature (JMDN) or Certification/Approval Standard are uploaded on the standard specific PMDA website below. Please refer to these information as appropriate.

Standard for Medical Devices

https://www.std.pmda.go.jp/stdDB/index_en.html

◆ Q2: What are the agency for product registration and certification approval of class A to class D medical devices?

◇ A2: In Japan, medical devices are classified into 4 categories, Class I to IV, based on the GHTF risk based classification. As for the class I devices, any certification or approval for product registration is not needed but submission of self-notification of the product to PMDA is required. As for the Class II and Class III medical devices which meat Japanese Certification Standards can go to the Third Party Certification Process (review and certificate by Registered Certification Body). Other medical devices including Class IV medical devices need to be submitted to PMDA for review and then approved by MHLW.

Foreign manufacturers can directly submit their application to PMDA or

Registered Certification Body, but in any case they should designate Marketing Authorization Holder located in Japan.

Please refer to the attached material.
Basic concept for Approval and Certification for Medical Devices
https://www.std.pmda.go.jp/stdDB/index_en.html
List of Registered Certification Body
https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/touroku/index.html

◆ Q3: Please provide the product registration processes and documents which shall be submitted for registration of medical devices.
◇ A3: Please refer to the attached material.
You can find formats for application in the link below (Japanese only)
https://www.pmda.go.jp/review-services/drug-reviews/procedures/0004.html

◆ Q4: When a medical device contains specifications that differ from those of predicate devices and these specifications are not specified in international standards such as ISO, IEC, or JIS, there are no suggested testing methods available. What kind of evaluation or testing is required during product registration? Are there any consultation or services for these additional evaluation or testing methods?
◇ A4: The evaluation tests of medical devices need scientifically valid evaluation methods. Evaluation methods specified in international standards are discussed by experts and are guaranteed to be scientifically valid. However, evaluation methods or conformity standards in many medical device developments are not specified in international standards, because medical devices are often developed based on applicants' own concepts and technologies. When testing medical devices by evaluation methods that are not specified in international standard, the evaluator must prove the scientific validity of evaluation methods by preliminary tests or any other references.

Evaluators can utilize consultations to request the opinion from PMDA. The consultations concerned with evaluation are following:

- Pre-development consultation for medical devices: The consultation is for discussion about the evaluation items for each medical device.
- Protocol consultation for medical devices: The consultation is for discussion about the validity of the evaluation methods.
- Evaluation consultation for medical devices: The consultation is for discussion about the validity of evaluation methods and results.

◆ **Q5: Where can the industries find the registration fee?**

◇ A5: You can find the user fee in the MHLW webpage as well as PMDA webpage below. (only Japanese)

https://web.fd-shinsei.mhlw.go.jp/application/list_device2.html

https://www.pmda.go.jp/review-services/drug-reviews/user-fees/0001.html

You can find the English list of the user fee in PMDA Annual report but please note the data will be one year behind.

https://www.pmda.go.jp/english/about-pmda/annual-reports/0001.html

◆ **Q6: Are all medical device standards included in JIS harmonized with ISO/IEC? If not, will Japan accept a test report which complied with ISO/IEC but not JIS?**

◇ A6: Some of the JIS standards for medical devices are not harmonized with ISO/IEC, however PMDA accepts a test report complied with ISO/IEC if the applicant shows the applicability.

◆ **Q7:**Regarding preclinical testing conformity assessment, such as biocompatibility test, are reports from GLP or ISO 17025 accredited laboratories acceptable? Or does Japan only accept reports that comply with

JISQ 17025?

◇ A7:The evaluation data attached to applications for marketing approval of medical devices in Japan shall be inspected on-site or in writing to ensure that they are prepared in accordance with the GCP Ordinance, GLP Ordinance, and the standards for reliability of application data.

GLP compliance certificates granted by the regulatory authorities of the OECD member countries are valid in OECD member countries. The GLP ordinance in Japan refers to the OECD-GLP, and GLP compliance certificates given to facilities inspected and granted by regulatory authorities in OECD member countries including Japan.

Japan accepts reports of non-clinical evaluation that comply with not only JIS Q 17025 but also ISO 17025. For non-clinical studies other than biological safety, compliance with the reliability criteria is required. It must be collected and prepared in accordance with the reliability standards for application data based on Articles 114-22 and 114-42 of "Regulation for Enforcement of the Act on Security Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices".

Evaluation reports are not concluded as unreliable, just because the reports are not prepared in compliance with ISO 17025 or JIS Q 17025. However, it is strongly recommended that evaluation reports are prepared in accordance with ISO 17025 or JIS Q 17025 in January 20, 2015, PFSB/ELD Notification No.0120-9 (Japanese only). The reliability of evaluation reports shall be determined in the reliability inspection that was conducted at the time of application for marketing approval.

◆ Q8: How to define a predicate and brand new medical device in Japan?

◇ A8: Brand new medical devices means devices whose structure, method of operation, intended use or effect is apparently different from approved medical device (predicate device) in Japan.

To find the approved medical device in Japan, please refer to Q7.

◆ **Q9: How can we find the medical devices which approved by MHLW? In Taiwan, TFDA provided a database for people to find the approved medical devices in Taiwan.**

◇ A9: PMDA is providing approval/certification information of certain medical devices on the webpage below. Please refer to these information as appropriate.

List of approved new and improved (with clinical data) medical devices

https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0001.html

List of medical devices certified by registered certification bodies (most of them are Class II medical devices)

https://www.pmda.go.jp/review-services/drug-reviews/about-reviews/devices/0026.html (in Japanese)

You can find the labeling of all class IV medical devices in the link below. For other medical devices, manufacturers are encourage to register the labeling of their devices to the same PMDA site. (Japanese Only)
https://www.pmda.go.jp/PmdaSearch/kikiSearch/

◆ **Q10:**The list of approved medical devices in Japan could be found from the website https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0001.html. However, some currently approved products were not list on the website. What is the updating frequency of the English website?

◇ A10: The list is first created in Japanese and then translated into English. The draft list in English needs to be reviewed by external stakeholders before it is finally published. If you want to stay updated with the latest information,

you can find the Japanese version first, as it is published before the English version.

◆ Q11: Is there on line system for industries to find the real-time status of applications?

◇ A11: If the application is submitted via FD application system, applicant see the real-time status of the review on the MHLW webpage below. (only Japanese)

https://web.fd-shinsei.mhlw.go.jp/examination/device/index.aspx

◆ Q12: What kinds of medical devices should perform clinical tests in Japan and would Japan accept the clinical research report performed outside of Japan?

◇ A12: There is no specific list of devices which are required to submit clinical trial data for approval. It depends on the novelty and risk of the device.

Data obtained from foreign clinical trial can be accepted if the trial was conducted with GCP requirement which is essentially equivalent to J-GCP and if there are no such different in medical environment or ethnic variation that affects the outcome of the clinical trial data.

In some case, utilizing the PMDA's consultation for development and conducting risk benefit analysis including post market phase, clinical trials in Japan can be committed if the trial is to evaluate conformity to the Japanese medical environment or whose additional clinical value is relatively small and risk is assumed to be not big.

◆ Q13: Is there any simplified process in reviewing the preclinical tests in Japan?

For example, if a device made of metal which is widely used in medical

device and for a long time, TFDA accepts the COA which complied with international standards, such as ASTM, to instead of biocompatibility evaluations.

◇ A13: Also in Japan, some of the pre-clinical tests including biocompatibility tests can be omitted if applicant can show the identity of the raw material to the approved medical devices. Please note, even if raw material is the same, in the case manufacturing process is different and it would affect the safety or effectiveness of the device, additional pre-clinical tests may be required.

◆ Q14: Should the submitted documents be written in Japanese or does Japan accept the English documents? Ex.: Preclinical test reports

◇ A14: Application Form and STED should be written in Japanese but test data report including pre-clinical test and clinical test can be submitted in English.

◆ Q15: What kind of information is mandatory to be shown on the package?

◇ A15: The Article 63 of the PMD Act provide information required to be stated on immediate container or wrapper of the medical devices as followings;

1. Name and address of the marketing authorization holder;
2. Name;
3. Manufacturing number or manufacturing code;
4. For a medical device designated by the Minister of Health, Labour and Welfare, the quantity of the contents in terms of weight, volume, number, etc.;
5. For medical devices that have their standards specified pursuant to the provisions of Article 41, paragraph (3), matters specified in those standards to be printed on the immediate container or immediate wrapper;
6. For medical devices that have their standards specified pursuant to the provisions of Article 42, paragraph (2), matters specified in those

standards to be printed on the immediate container or immediate wrapper;

7. Expiry date for a medical device designated by the Minister of Health, Labour and Welfare;
8. Beyond what is set forth in each of the preceding items, matters to be specified by Order of the Ministry of Health, Labour and Welfare.

■ Conditional Early Approval system

◆ Q16: About the Post-market Risk Management Plan drafted by the applicant for its innovative medical device, what are the required items that must be included in the content?

◇ A16: Post-market Risk Management Plan requires following information.

- Use-results survey implementation plan; Collecting information of individual risks.
- Risk minimization plan; Providing information for proper use in the package insert and drug guide for patients

PMDA website offers information about Risk Management Plan (RMP).
https://www.pmda.go.jp/english/safety/info-services/drugs/rmp/0001.html

MHLW issued administrative notifications regarding RMP.

- Establishment and Publication of Risk Management Plan of Medical Devices and In Vitro Diagnostics (IVDs) (Japanese only)
https://www.pmda.go.jp/files/000236898.pdf
- Risk Management Guidelines on Medical Devices and In Vitro Diagnostics (IVDs) (Japanese only)
https://www.pmda.go.jp/files/000236899.pdf

■ Improvement Design within Approval for Timely Evaluation and Notice（IDATEN）

◆ Q17: Is 「IDATEN」only applicable to innovative products

and highly unmet medical needs, or applicable to all products?

◇ A17: IDATEN is applicable to all medical products. Especially, medical devices with short life cycle, which are expected for continuous improvement, are suitable for IDATEN. (e.g. medical device with software, software as medical device (SaMD))

■ Electronic Labeling (E-Labeling)

◆ Q18: How does E-labeling system work when Marketing Authorization Holder (MAH) applying for changes of the information on IFU or label？

◇ A18: Every time the MAH changes the contents of the electronic labeling, MAH updates the information of the electronic labeling which indicates the latest safety information of the product on the PMDA website. When users scan the code on the container or wrapper of the medical device, the user can access to the latest electronic labeling.

◆ Q19: Is E-labeling code required for imported medical devices? Is it legal that the importer print E-labeling code after customs clearance?

◇ A19: As for medical devices imported to Japan, E-labeling code should be put on product container or wrapper prior to its domestic distribution.

◆ Q20: E-labeling system would not be applied to home-used medical devices. What are the home-used medical device items?

◇ A20: Medical devices to be supplied mainly for general consumers' daily use are designated by the Appended table 4-2 of the Ordinance for Enforcement of the PMD Act and the Appended table 1 and 2 of the MHLW notification No. 44 (February 15, 2021), which includes home-used medical devices and medical devices for doctors but exclusively used at home (e.g. contact lenses). MHLW notification indicates product list. (Japanese only) Please refer to '別表第一' and '別表第二' in the notification.
https://www.mhlw.go.jp/hourei/doc/hourei/H210215I0010.pdf

PMDA website offers information about E-labeling.
https://www.pmda.go.jp/safety/info-services/0003.html

Japan to Taiwan

◆ Q1: When trying to register OEM (original equipment manufacturer) products, it is required by TFDA to submit the Export Certificate (which corresponds to the Free Sales Certificate in Taiwan) stating relationship between outsourcing company (Marketing Authorization Holder: MAH) and commissioned company (manufacturer) with the names of those companies. However, the Export Certificate format which Japanese MHLW issues doesn't have a field to state it. Does TFDA accept additional documents which shows such relationship?

◇ A1: According to Article 6 and Section 4 in Appendix 2 of Regulations Governing Issuance of Medical Device License Listing and Annual Declaration, manufacture and free sale certificate of the country of origin shall record: (1) Name and specifications and/or model number of the medical device. (2) Manufacturer's name, address, manufacturing status, and actual status for domestic sale as approved in that country.

If the medical device is commissioned to be manufactured, this document may be issued by the highest health authority in the country where the contract party or the contract manufacturer is located.

If the medical device involves contract manufacturing and it is not sold in the country where the contract manufacturer is located, this document may be replaced by a free sale certificate issued by the highest health authority in the country where the contract party is located, and a manufacture certificate issued by the government of the country where the contract manufacturer is located.

As for OEM products, the name and address of manufacturers should be stated in the Export Certificate issued by Japanese MHLW. Besides, the relationships can be demonstrated by the contract for manufacturing signed by the two companies.

◆ Q2: When the name of manufacturing site changed because of company split-up and submitting for change-name application, documents describing the reason for name change is required by TFDA.
Who should be the responsible writer of such document? Parent company or subsidiary company?

◇ A2: The statement for changing manufacturer's name should be issued by the parent company.

◆ Q3: In Japan, often MAH responsible for premarket approval is different to the actual manufacturer. Certificate of approved products issued by MHLW contains information about MAH and the product but not actual manufacturer. Certificate of registered manufacturer issued by MHLW doesn't contain information about the product. What kind of document does TFDA accept to show the relationship among MAH, manufacturer and product?

◇ A3: According to Article 6 and Appendix 2 of Regulations Governing Issuance of Medical Device License Listing and Annual Declaration, the original of the manufacture and free sale certificate (FSC) of the country of origin shall be included in the submitted documents. The FSC is required to contain information about the name and address of actual manufacturer.

As for OEM products, the relationships can be demonstrated by the contract for manufacturing signed by the two companies.

◆ Q4: What kind of documents can be accepted by TFDA to prove the location of the manufacturing site is not changed when the address of manufacturer changed because of annexation of cities?

◇ A4: Firstly, your representing agent in Taiwan needs to apply for a document verifying that medical device manufacturer conforms to the Medical Device Quality Management System Regulations.

With it and other documents mentioned by Article 13 and Appendix 4 of Regulations Governing Issuance of Medical Device License Listing and Annual Declaration, the application file will be completed. Documents for change in address of manufacturing factory include:

1. Application form for change of medical device license;
2. Original license;
3. Copy of the medical device business permit (For imported medical devices, this is exempt from submission);
4. Original of the manufacture and free sale certificate of the country of origin (If the change of manufacturer's address was due to house numbering system change, this document may be exempt but certificate document issued by a government agency shall be submitted; in the case of imported medical devices, it shall be notarized by ROC overseas representative office.);
5. Original of the foreign original manufacturer authorization letter;
6. Document verifying that medical device manufacturer conforms to the Medical Device Quality Management System Regulations as issued by TFDA;
7. Original of the manufacturer's letter that explains the change;
8. Other documents and information designated by the central competent authority.

◆ Q5: What are the points to consider when there are multiple manufacturing sites involving in the same process?

◇ A5: The actual manufacturer must be responsible for the full quality management system. Generally speaking, if a manufacturing process involves multiple sites, the actual manufacturer is the site which supervises the whole quality system and carries out the final QC and product releasing in most of the time.

In general, if the MAH holds a full quality management system which meets the Medical Device Quality Management System Regulations, and each contract manufacturer is managed under it, the MAH can be considered a legal manufacturer. The QC of each manufacturing site should be recorded in the

QMS of MAH, and is not required for the medical device registration. Only final QC of the finished product is needed for registration.

If you are not sure whether your case meets these requirements, please contact TFDA.