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台灣醫療暨生技器材工業同業公會
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主旨：為推動台日醫療器材共同合作，本署公布「Position Paper for better understanding on product registration framework for Medical Device between Japan and Taiwan」及「Q&A for Product Registration Process for Medical Device in Taiwan and Japan」，惠請貴會協助轉知所屬會員，合作立場書及查驗登記問答集內容，請至本署全球資訊網站(http://www.fda.gov.tw/)(首頁> 業務專區> 醫療器材> 最新消息)下載，請查照。

正本：台灣藥品行銷暨管理協會、新北市醫療器材商業同業公會、台灣醫療器材門市發展協會、台灣醫療暨生技器材工業同業公會、中華民國醫療器材商業同業公會全國聯合會、臺北市醫療器材商業同業公會、桃園市醫療器材商業同業公會、臺中市醫療器材商業同業公會、彰化縣醫療器材商業同業公會、嘉義市醫療器材商業同業公會、台南市直轄市醫療器材商業同業公會、臺南市醫療器材商業同業公會、高雄市醫療器材商業同業公會、台灣省醫療器材商業同業公會聯合會、屏東縣醫療器材商業同業公會、高雄市直轄市醫療器材商業同業公會、台灣口腔生物科技暨醫療器材產業發展促進協會、台灣牙科器材同業交流與公益協會、台北市生物技術服務商業同業公會、社團法人中華民國助聽器同業聯合協進會、中華民國助聽器商業同業公會全國聯合會、台北市助聽器商業同業公會、桃園縣助聽器商業公會、台中市助聽器商業同業公會、彰化縣助聽器商業同業公會、高雄市助聽器商業同業公會、中華民國眼鏡發展協會、台灣區眼鏡工業同業公會、台北市眼鏡商業同業公會、台灣省鐘錶眼鏡商業同業公會聯合會、高雄市鐘錶眼鏡商業同業公會、台灣生技醫療照護輔具協會、社團

法人臺灣輔具產業發展協會、中華民國儀器商業同業公會全國聯合會、臺北市儀器商業同業公會、桃園市儀器商業同業公會、臺中市儀器商業同業公會、台南市儀器商業同業公會、高雄市儀器商業同業公會、新竹市儀器商業同業公會、台灣橡膠暨彈性體工業同業公會、台灣省橡膠製品商業同業公會聯合會、台北市國際工商協會、台灣生物產業發展協會、台灣先進醫療科技發展協會、台北市美國商會政府及公共事務部、歐洲在臺商務協會、台北市日本工商會、南港軟體工業園區二期管理委員會、財團法人金屬工業研究發展中心(高雄)、社團法人中華無菌製劑協會、台灣省進出口商業同業公會聯合會、新北市進出口商業同業公會、桃園市進出口商業同業公會、台中市進出口商業同業公會、台中縣進出口商業同業公會、台南市進出口商業同業公會、台南縣進出口商業同業公會、高雄縣進出口商業同業公會、高雄市進出口商業同業公會、台灣臨床檢驗標準協會、台灣製藥工業同業公會、中華民國西藥商業同業公會全國聯合會、台灣省西藥商業同業公會聯合會、中華生物醫學工程協進會、中華民國金屬家具商業同業公會全國聯合會、中華民國生物醫學工程學會、台灣顯示器產業聯合總會、新北市生技產業發展聯盟、財團法人台灣商品檢測驗證中心、台灣科學工業園區科學工業同業公會、財團法人工業技術研究院量測技術發展中心、財團法人生物技術開發中心、台灣區電機電子工業同業公會、台灣藥物臨床研究協會、台北市西藥商業同業公會、中華民國開發性製藥研究協會、中華民國製藥發展協會、中華民國資訊軟體協會、台灣醫藥品法規學會、台北市電腦商業同業公會、中華民國全國商業總會、中華民國全國工業總會、台灣研發型生技新藥發展協會、經濟部工業局、科技部新竹科學園區管理局、科技部南部科學園區管理局、科技部中部科學園區管理局、財團法人塑膠工業技術發展中心、財團法人醫藥品查驗中心、財團法人醫藥工業技術發展中心、台北市進出口商業同業公會、中華民國西藥代理商業同業公會、台北市西藥代理商業同業公會

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署長吳秀梅

Position Paper for better understanding on product registration framework for Medical Device between Japan and Taiwan

15 Oct. 2021

Under the Arrangement between the Interchange Association and the Association of East Asian Relations for the Establishment of the Framework of the Cooperation on the Medical Product Regulation (hereinafter, "Framework") signed 5 November 2013, the Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) and the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare have continuously collaborated information sharing on medical device product registration. This activity is to lead better understanding of regulations and product registration process in Taiwan and Japan. MHLW/PMDA and TFDA confirmed mutual position regarding these achievements as follows:

1. The purpose of this position paper is to enhance better understanding of recent regulations in Japan and Taiwan, and to reduce the gap during product registration for industry through Question and Answer (Q&A) for product registration process documents. The Q&A document is confirmed by both sides respectively.

2. This work is conducted by Product Registration Working Group between MHLW/PMDA and TFDA. Further collaboration on this issue may be discussed under the Framework.

3. Any publication which is generated under this activity needs the confirmation by both MHLW/PMDA and TFDA.

4. This document is not intended to create any legally binding obligations.

5. Any difference arising from the interpretation or implementation of this position paper will be resolved through the consultations under the Framework.

6. This position paper may be amended in the future, when it would be confirmed jointly.

This position paper was jointly prepared by

MHLW/PMDA and TFDA,

and will be opened to stakeholders in Japan and Taiwan.

2018.11
2019.11 Amended
2021.10 Amended

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: Where can the industries find the registration fee?
◇ A4: You can find the user fee in the MHLW webpage as well as PMDA webpage below. (only Japanese)
https://web.fd-shinsei.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

◆ Q5: 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?
◇ A5: 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.

◆ Q6: How to define a predicate and brand new medical device in Japan?

◇ A6: 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.

◆ Q7: 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.

◇ A7: 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/

◆ Q8: Is there on line system for industries to find the real-time status of applications?

◇ A8: 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.go.jp/examination/device/index.aspx

◆ Q9: What kinds of medical devices should perform clinical tests in Japan and would Japan accept the clinical research report performed outside of Japan?

◇ A9: 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.

◆ Q10: 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.

◇ A10: 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.

◆ Q11: Should the submitted documents be written in Japanese or does Japan accept the English documents? Ex.: Preclinical test reports

◇ A11: 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.

◆ Q12: What kind of information is mandatory to be shown on the package?

◇ A12: 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

◆ Q13: 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?

◇ A13: 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）

◆ Q14: Is 「IDATEN」only applicable to innovative products and highly unmet medical needs, or applicable to all products?

◇ A14: 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)

◆ Q15: How does E-labeling system work when Marketing Authorization Holder (MAH) applying for changes of the information on IFU or label？

◇ A15: 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.

◆ Q16: Is E-labeling code required for imported medical devices? Is it legal that the importer print E-labeling code after customs clearance?

◇ A16: As for medical devices imported to Japan, E-labeling code should be put on product container or wrapper prior to its domestic distribution.

◆ Q17: E-labeling system would not be applied to home-used medical devices. What are the home-used medical device items?

◇ A17: 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.