Provisional Translation
(as of September 2026)

独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

The Regulation of Software as a Medical Device (SaMD) under the PMD Act*

*Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

Provisional Translation (as of September 2026)
This English version of the Japanese presentation is provided for reference purposes only.
In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.
This material was used at the Software as a Medical Device Seminar held in FY2024 and is based on the information available at that time.

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This presentation outlines the regulations on Software as a Medical Device, SaMD, under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. We hope this presentation will help you grasp the overview of the regulation. Please refer to the original regulation for details.

In this presentation, "The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices" will be referred to as "PMD Act".

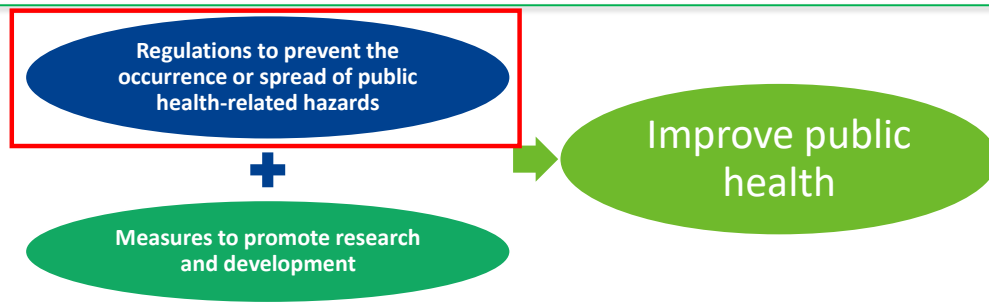
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Purpose of PMD Act

"Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices"

Article 1 The purpose of this Act is to improve health and hygiene by providing the control required for securing the quality, efficacy and safety of pharmaceuticals, quasi-pharmaceutical products, cosmetics, medical devices, regenerative medicine products (hereinafter referred to as "pharmaceuticals, etc.") and for preventing the occurrence or spread of health and hygiene-related hazards caused by the use of those pharmaceuticals, etc. by taking measures against designated substances, and by taking necessary measures for the promotion of research and development of pharmaceuticals, medical devices and regenerative medicine products which fulfill particularly high medical needs.

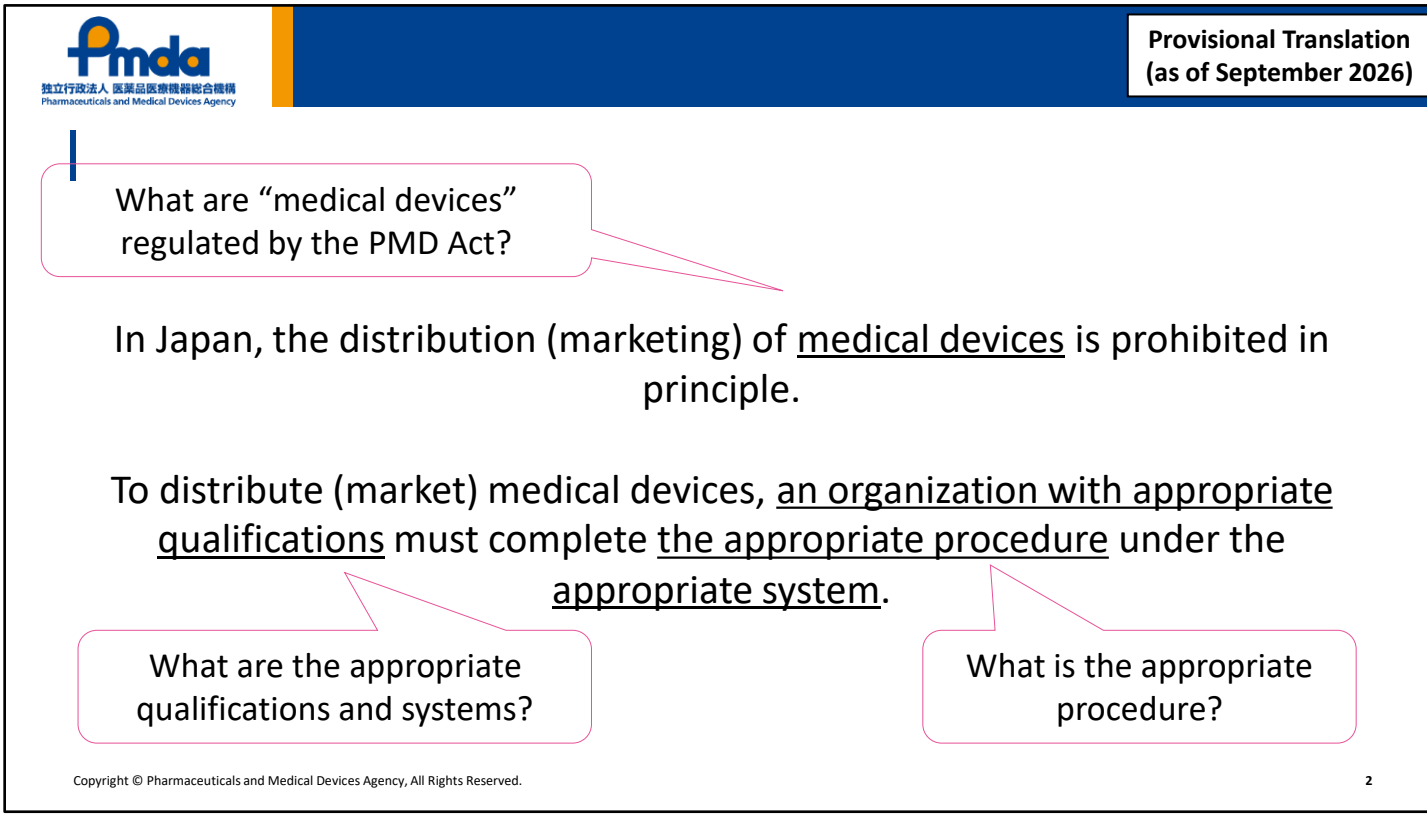


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This is the purpose of the PMD Act from the first article. The purpose of this Act is to improve public health in Japan. For this purpose, regulations are implemented to prevent the occurrence or spread of public health-related hazards, and measures are taken to promote research and development.

The approval review is part of the regulatory framework under the PMD Act.



Now, how are medical devices regulated by this PMD Act?

In Japan, the distribution of medical devices is prohibited in principle. To distribute medical devices, an organization with appropriate qualifications must complete the appropriate procedure under the appropriate system.

What are "medical devices” regulated by the PMD Act? And what are the appropriate qualifications and systems? What is the appropriate procedure?

Understanding these points will help in structuring the overview of the medical device regulation under the PMD Act.

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Outline

1. What is a Medical Device?
2. How to Market Medical Devices?
3. Approval Review

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This is the outline of this presentation.

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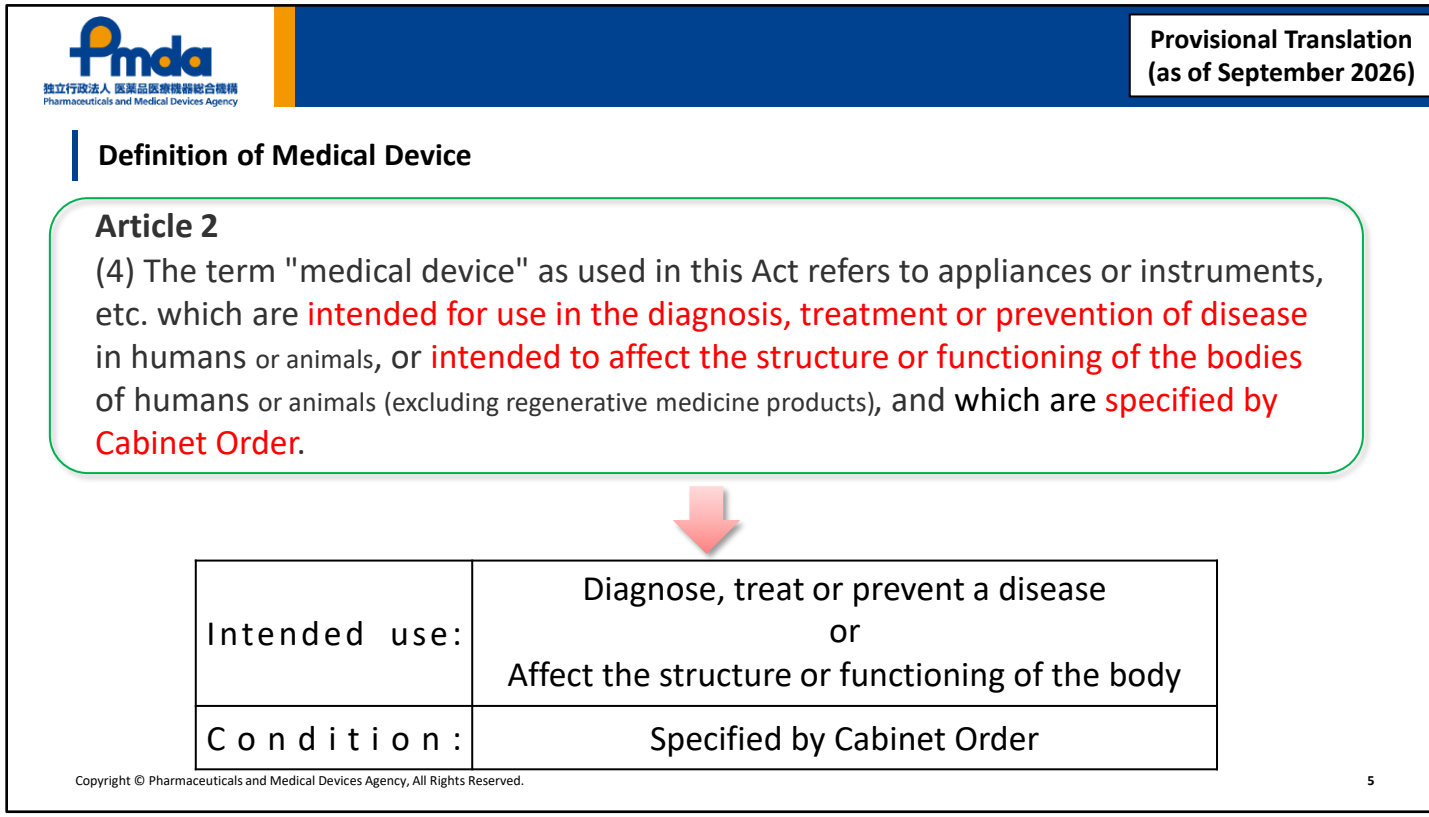
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1. What is a Medical Device?

【Keywords】Definition of a medical device, Specified by Cabinet Order, Qualification

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The first part is on medical devices regulated by the PMD Act.

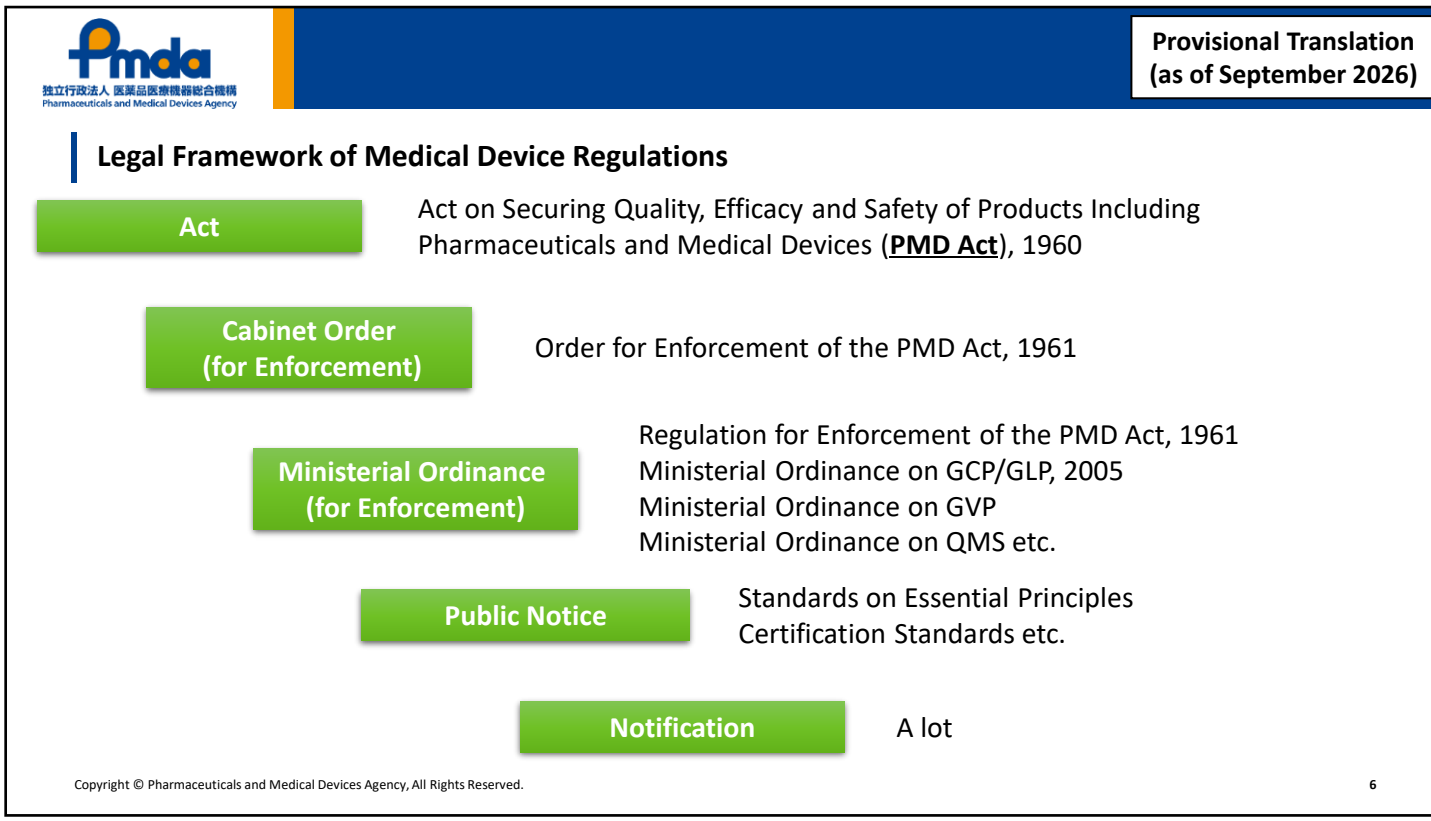


This is the definition of a medical device in the PMD Act. In the PMD Act, a medical device must meet 2 requirements. In other words, when an item satisfies these 2 requirements, its distribution in Japan becomes prohibited in principle, and requires procedures for distribution.

The first requirement is the intended use. The intended use must be to diagnose, treat or prevent a disease, or affect the structure or functioning of the body.

The second requirement is that the item is specified by Cabinet Order.

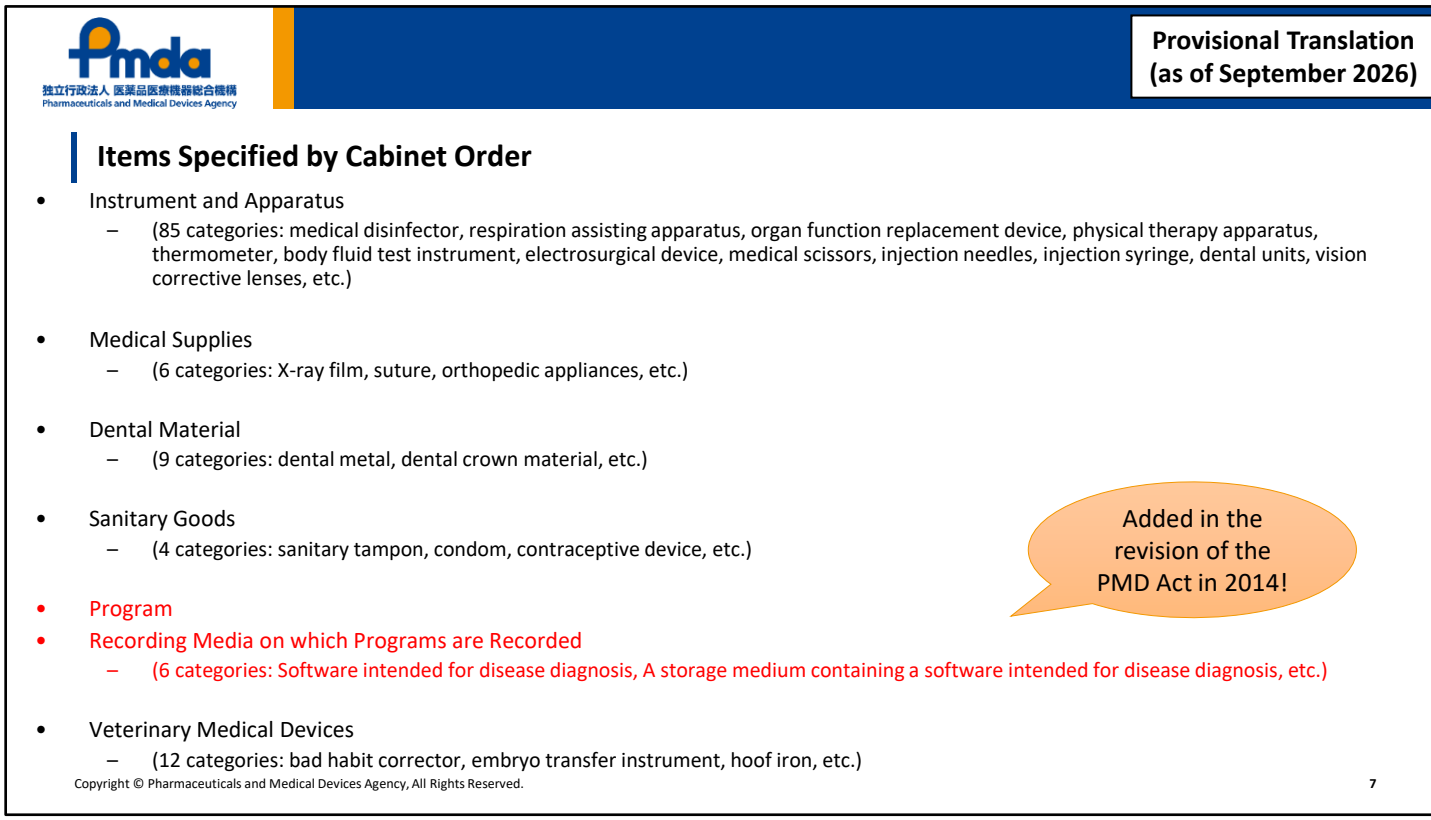
A Cabinet Order may sound unfamiliar. We will elaborate a little on this term.



This is the outline of the legal framework of medical device regulations in Japan.

The levels in this diagram indicate the degree of specificity of the document. The act is at the highest level. The lower document in this framework defines specific and individual operations.

The "Cabinet Order" stated in the definition of a medical device is just below the PMD Act.

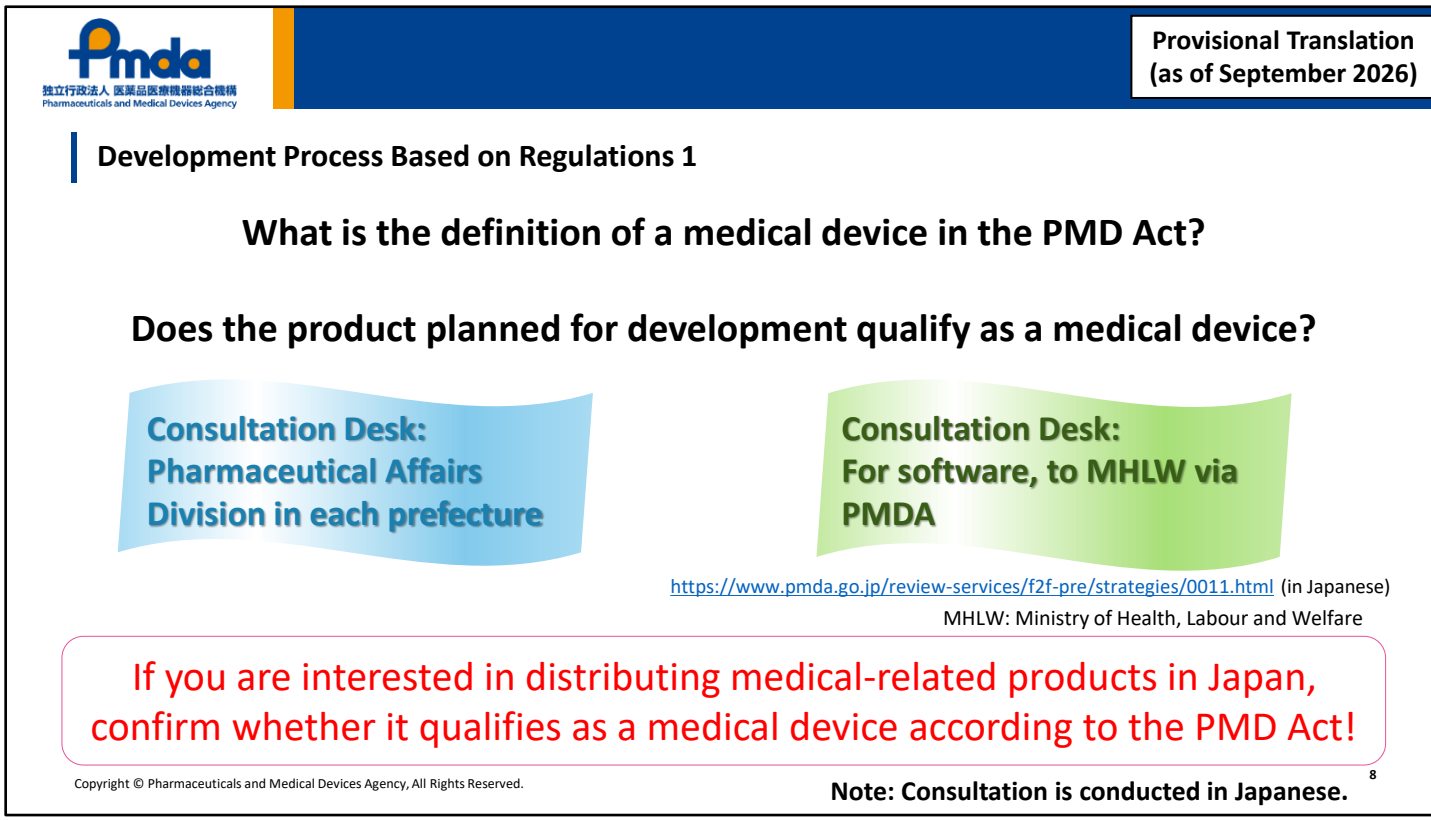


The Cabinet Order has a list of medical devices. Here are some categories from the list, which are "specified by Cabinet Order".

For example, "medical scissors" are included in "Instrument and Apparatus“. Scissors used at home to cut paper or clothing, or scissors for cooking may fall under "scissors" according to the Cabinet Order. However, since those scissors are not intended to “diagnose, treat or prevent a disease”, they do not satisfy the definition of a medical device.

In contrast, when the same scissors are "scissors used in surgery", their intended use satisfies the requirements of medical devices and they also fall under those specified in the Cabinet Order. Therefore, it is a medical device.

As a side note, standalone software is now treated as a medical device upon the revision of the PMD Act in 2014. Until then, the Cabinet Order did not have a category related to software. Because “program" was added to the Cabinet Order, standalone software now qualifies as those “specified by Cabinet Order.”



In any case, when developing a medical-related product, it is necessary to confirm whether the product qualify as a medical device according to the PMD Act.

Regarding the issues on qualification of a medical device according to the PMD Act, please contact the Pharmaceutical Affairs Division in your prefecture. For standalone software products, please contact the Ministry of Health, Labour and Welfare.

Please remember to confirm these points in the development process, as necessary.

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2. How to Market* Medical Devices?

【Keywords】Approval/Certification/Notification, Classification, License, Registration

* Market: the act of manufacturing or importing medical devices, and then selling, leasing or providing them respectively, or offering medical device programs via telecommunication lines.

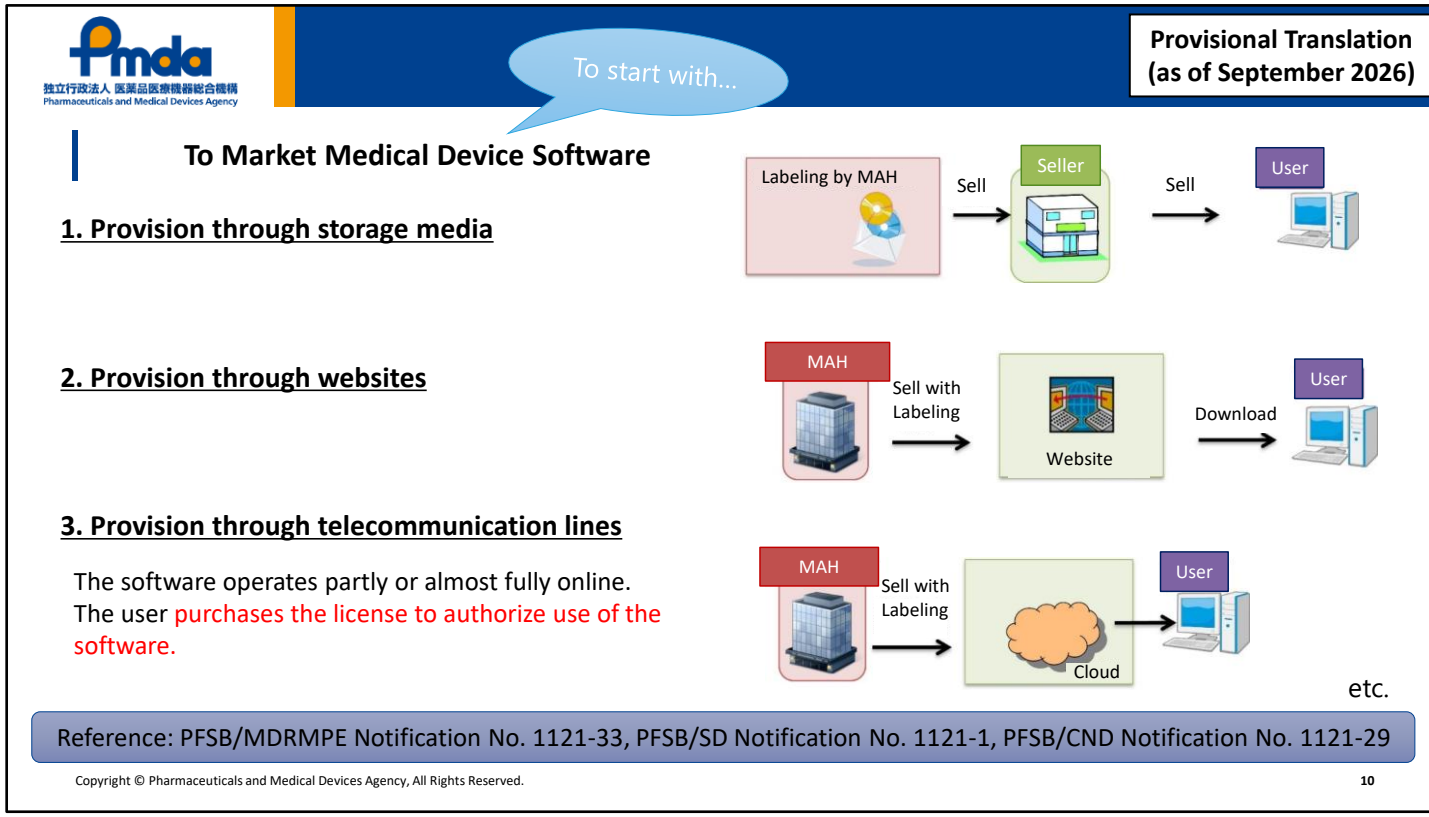
Reference: PMD Act Article 2 (13)

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Now, what should be done once you find out that your product qualify as a medical device?

So far, we have been using the term "distribute". However, in the PMD Act, it is stated as "market".

In this part, we will discuss the necessary processes to market a medical device.



Software products are more diverse than hardware products in terms of how they are marketed.

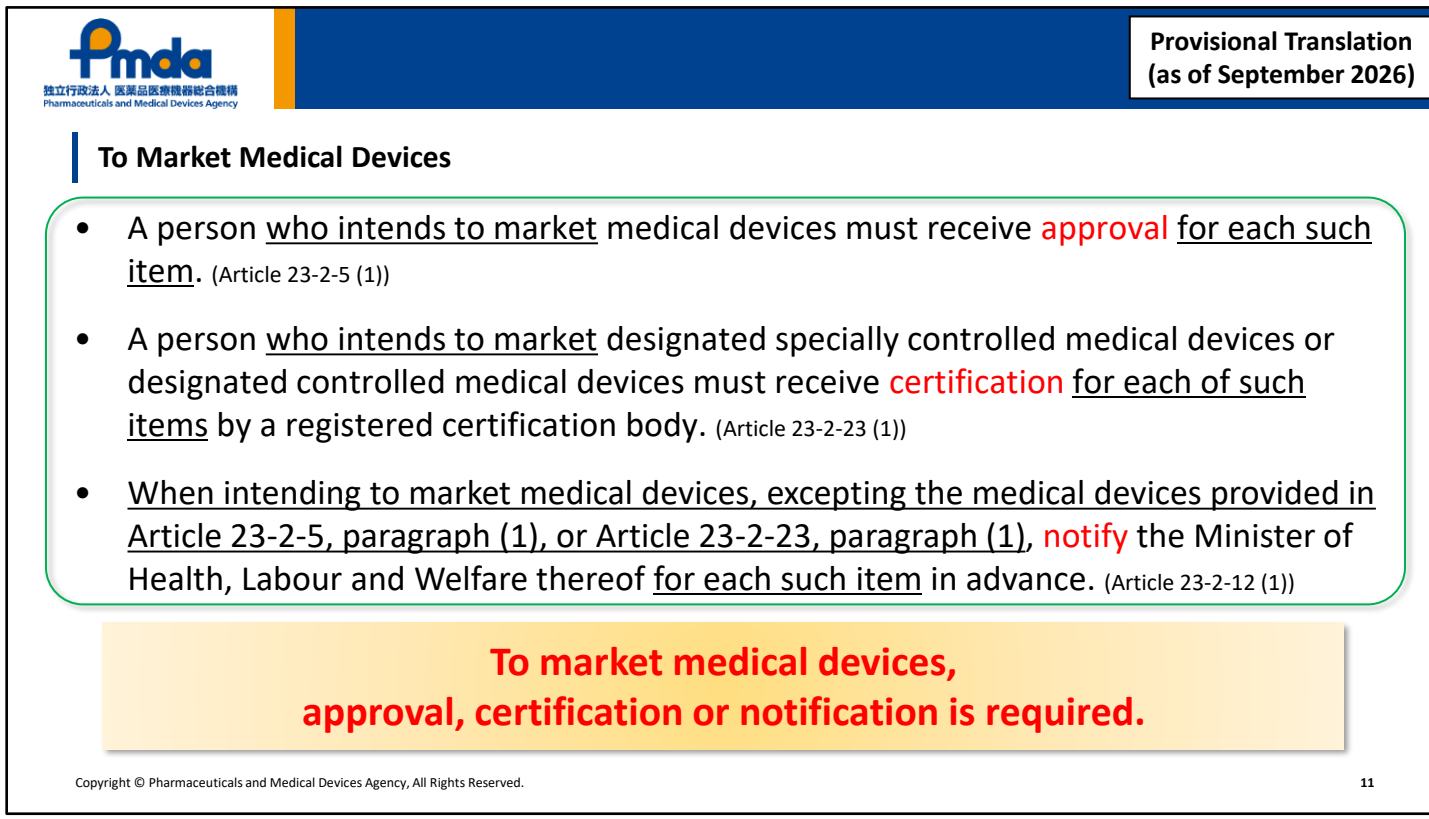
Here are 3 typical examples.

The first example is to install software from a storage media. Manufacturers distribute DVDs containing an installer file to sellers, and the users purchase and use them. This may have been the common method to purchase consumer software products.

The second example is to access websites to download installer files for use. This may be the current mainstream method for consumer software products.

The third example is when software is not installed on the user's computer, but is used on the cloud through the internet. In this case, the user purchases the right to use the software, or the software license.

In addition, there are a variety of methods to distribute medical device software. Since all methods correspond as "market", procedure according to the PMD Act must be completed before distributing the software.



Now we will go back to the first question, “How to market a medical device?”

These are excerpts from the PMD Act:

"A person who intends to market medical devices must receive approval for each such item."

"A person who intends to market designated specially controlled medical devices or designated controlled medical devices must receive certification for each of such items by a registered certification body."

"When intending to market medical devices, excepting the medical devices provided In Article 23-2-5, paragraph (1), or Article 23-2-23, paragraph (1), notify the Minister of Health, Labour and Welfare thereof for each such item in advance. "

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Making Changes to Medical Devices

- A person who intends to market* medical devices must receive approval for each such item. (Article 23-2-5 (1))
- When a person wishes to make a partial change to approved items (excluding minor changes specified by Order of the MHLW), they must receive approval for such change from the Minister of Health, Labour and Welfare. (Article 23-2-5 (11))

- A person who intends to market* designated specially-controlled medical devices and designated controlled medical devices must receive certification for each of such items by a registered certification body. (Article 23-2-23 (1))
- When a person wishes to make a partial change to the certified particulars regarding those items (excluding cases where such change is a minor change specified by Order of the MHLW), the person must receive certification for such change from the registered certification body. (Article 23-2-23 (6))

- When intending to market* medical devices, excepting medical devices provided in Article 23-2-5, paragraph (1), or Article 23-2-23, paragraph (1), notify the Minister of Health, Labour and Welfare thereof for each such item in advance. (Article 23-2-12 (1))
- When changing the particulars notified pursuant to the provisions of the preceding paragraph, notify the Ministry of Health, Labour and Welfare thereof within 30 days. (Article 23-2-12 (2))

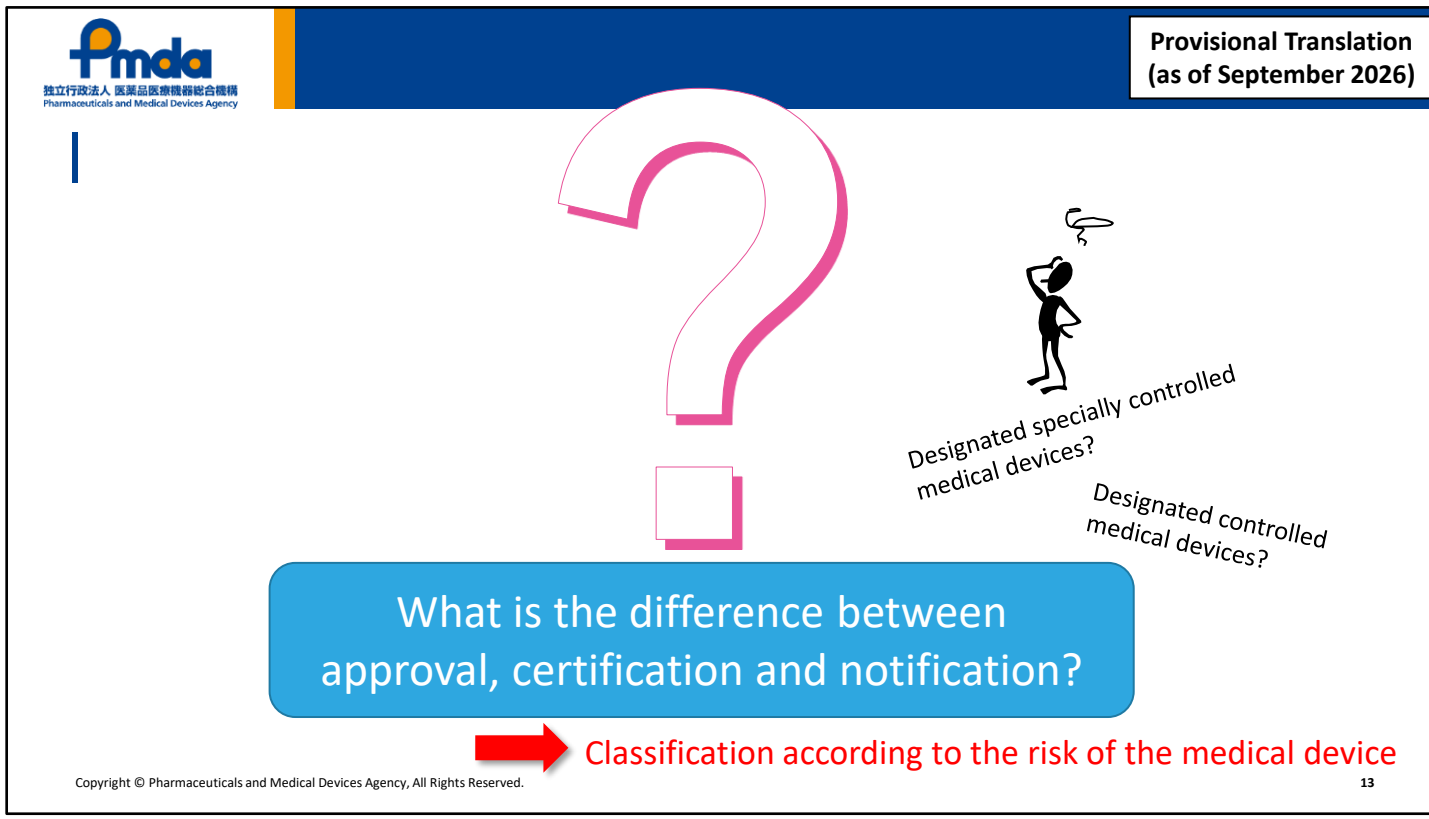
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These are more excerpts from the PMD Act about making changes to the medical devices.

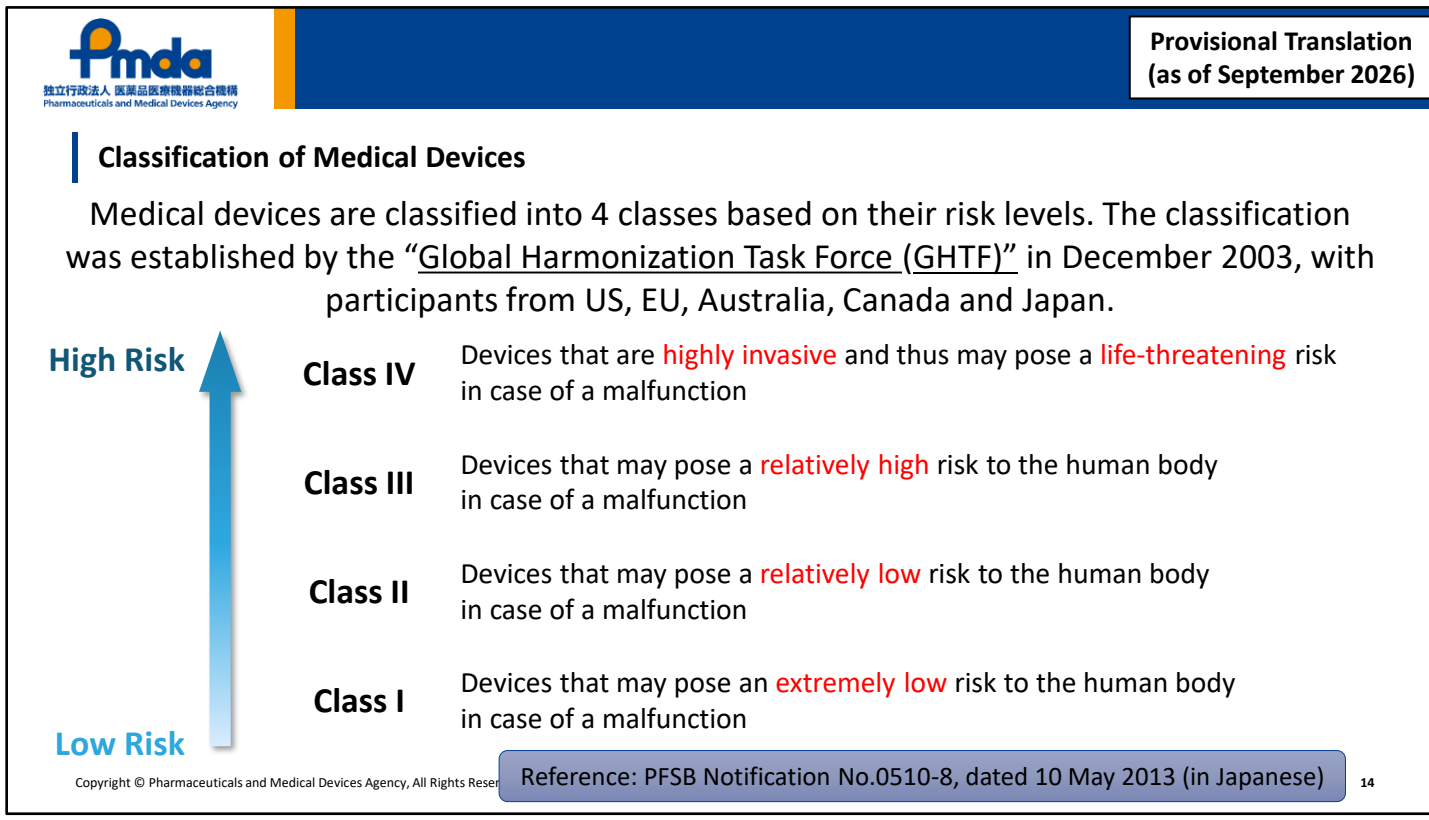
In other words, changes to medical devices requires approval, certification or notification as well.

In summary, to market a medical device, approval, certification or notification is required.



Some of you may be wondering which one to select.

Classification according to the risk of the medical device is helpful to understand this concept.



In Japan, medical devices are classified into 4 classes based on their risk levels.

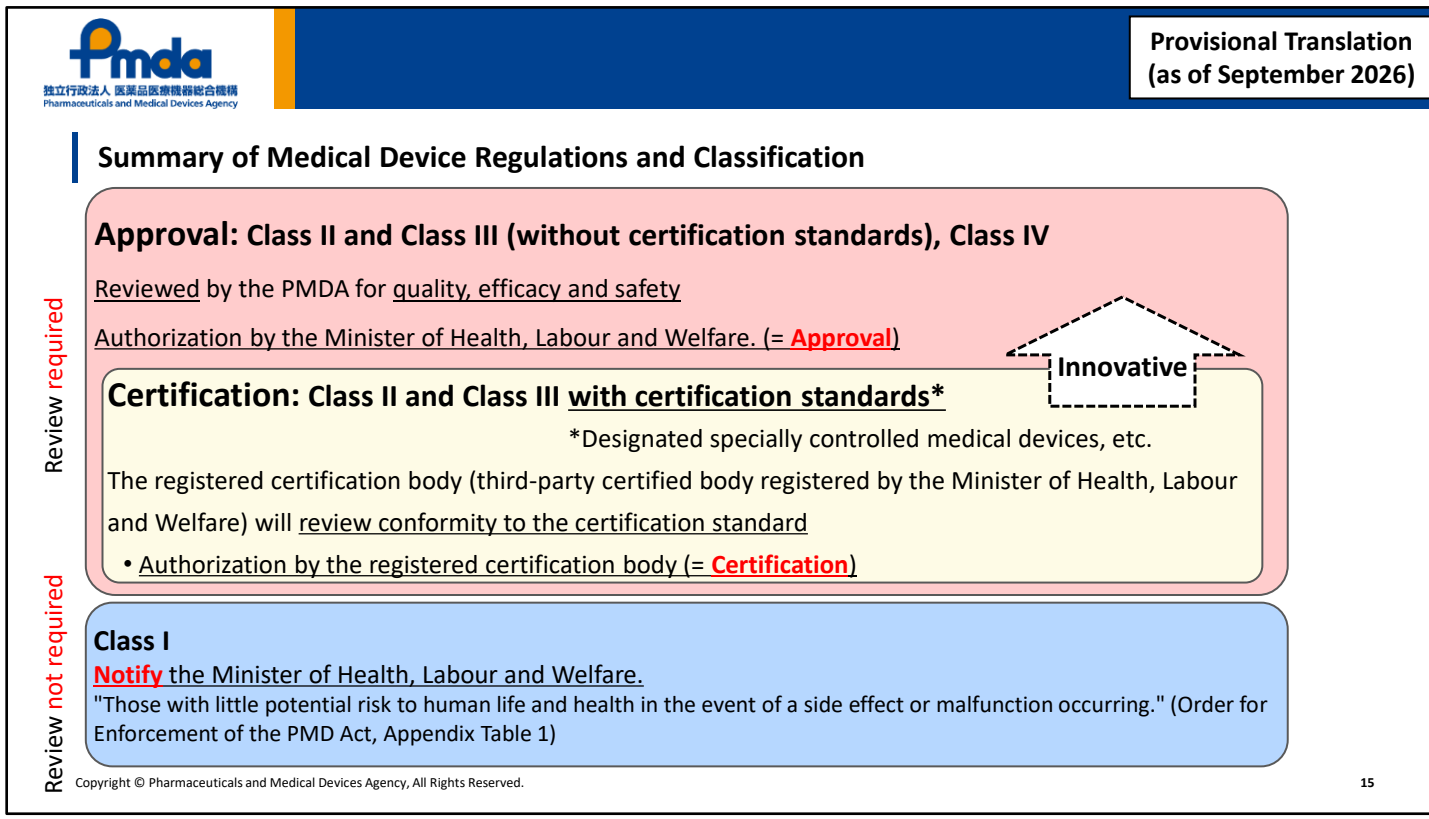
The principle of a risk level is the degree of harm to the human body in case of a malfunction.

The lowest risk is Class I, which are "devices that may pose an extremely low risk to the human body in case of a malfunction."

As the risk level increases, the classification changes to Class II and III. Class IV medical device with the highest risk are "devices that are highly invasive and thus may pose a life-threatening risk in case of a malfunction."

Principles on classification of medical devices are detailed in the notification at the bottom of this slide. Please refer to this notification if you are interested.

Please note that this notification was issued before software was treated as a medical device and therefore based on tangible products.



This classification is helpful to determine whether to aim for approval, certification or notification.

For example, Class I medical devices with the lowest risk can generally be marketed with a notification. The procedure is completed when the product is notified to the Minister of Health, Labour and Welfare. In other words, these products do not require a review due to its limited risk to human life and health.

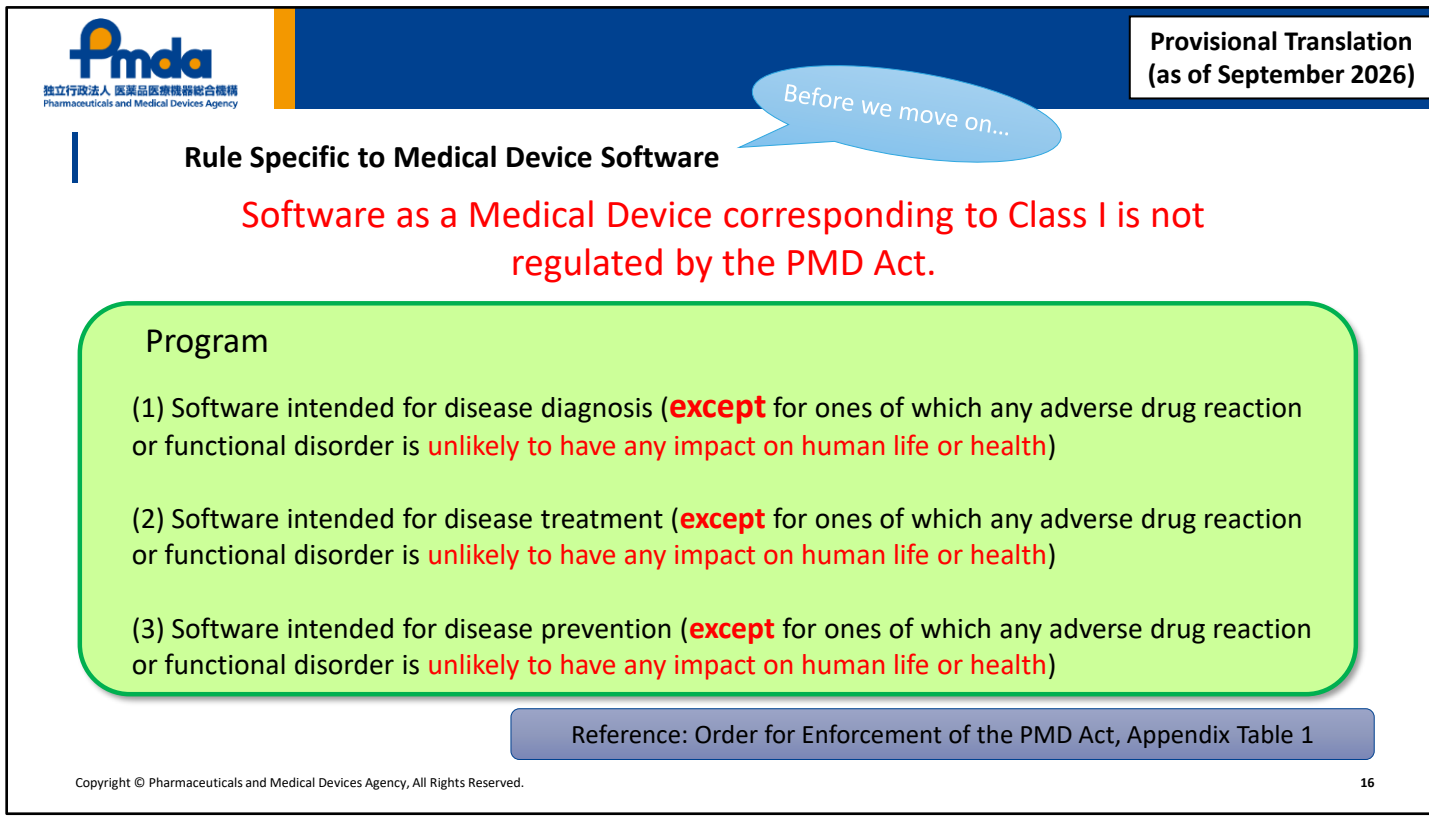
In contrast, Class IV medical devices with the highest risk level require a review by PMDA and approval by the Minister of Health, Labour and Welfare.

Class II and Class III are a little complicated. Class II and Class III medical devices are either approved or certified. The key point is the certification standard. The certification system was introduced based on the concept that, since a large number of similar products already exist, products that can be evaluated in accordance with established standards may be reviewed more efficiently by private review bodies rather than by government authorities. The established standard corresponds to the certification standard.

To summarize, products that are similar to products already on the market, and can be evaluated by an established standard, known as the certification standard, can be reviewed in a private organization called the registered certification body. The registered certification body will certify the product.

Products with existing similar products but without certification standards, or new products must be reviewed by PMDA and approved by the Minister of Health, Labour and Welfare, just like a Class IV medical device.

We'd like to talk more about principles to find relevant certification standards, but it will be omitted due to time constraints. Please remember that the procedure to market products are determined by their classification.



Before we move on, we will cover a rule specific to medical device software related to the medical device classification.

Medical device software corresponding to Class I is not regulated by the PMD Act.

As mentioned earlier, a medical device is defined as one that is "specified by Cabinet Order“.

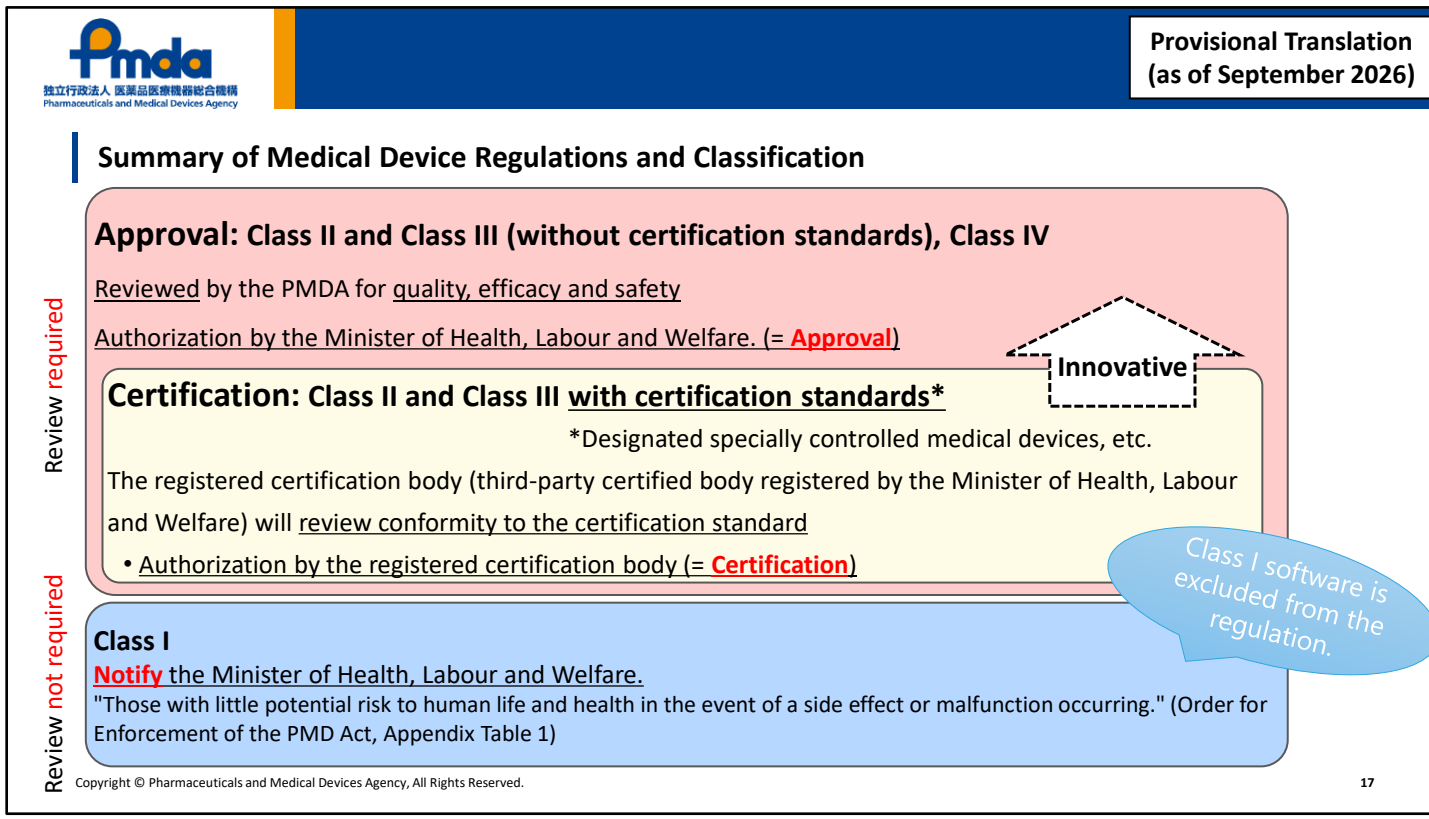
The paragraph on programs in the Cabinet Order is shown in this slide. It is stated that it applies to software "except for ones of which any adverse drug reaction or functional disorder is unlikely to have any impact on human life or health"

This corresponds to the definition of the Class I medical device.

Therefore, software corresponding to Class I is excluded from the Cabinet Order.

In other words, Class I SaMD is not regulated as a medical device in Japan.

Therefore, if a software qualifies as a medical device, it must receive some kind of review before it is placed on the market.



Therefore, please note that Class I in the previous table does not apply to software, because Class I software is not a medical device, and hence not regulated by the PMD Act.

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Who Can Distribute Medical Devices?

In accordance with the criteria for medical devices, no person other than one who has obtained a license from the Minister of Health, Labour and Welfare may engage in the business of marketing medical devices.

(PMD Act Article 23-2 (1))

Business: conducting similar acts by a person to the extent that it can be regarded as a commercial act

	First-Class Medical Device Marketing Business License	Second-Class Medical Device Marketing Business License	Third-Class Medical Device Marketing Business License
Specially Controlled Medical Device (Class III, IV)	✓		
Controlled Medical Device (Class II)	✓	✓	
General Medical Device (Class I)	✓	✓	✓

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So far, we have covered the end of product development, the marketing procedure. Now we will move on to the “appropriate organization and system“ according to the PMD Act.

To begin with, who can market medical devices? The PMD Act defines the person who can market medical devices as shown in this slide.

"In accordance with the criteria for medical devices, no person other than one who has obtained a license from the Minister of Health, Labour and Welfare may engage in the business of marketing medical devices."

There are 3 types of licenses to market medical devices. These are First-Class, Second-Class and Third-Class Medical Device Marketing Business License, respectively.

Again, the medical device classification is used to determine which license to obtain.

For example, if only Class I products with the lowest risk are handled, any type of license will cover the product.

However, to handle Class IV medical device with the highest risk level, a First-Class Medical Device Marketing Business License will be required instead of Second or Third-Class.

Therefore, the product cannot be marketed without a license corresponding to the classification of the product.

This applies not only when marketing developed products, but also when partnering with a company that market medical devices. It is necessary to confirm that the company has the license required to market the product.

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Registration of Manufacturing Facilities

A person who intends to be engaged in the business of manufacturing medical devices must obtain registration from the Minister of Health, Labour and Welfare for each manufacturing facility (of the manufacturing processes for Medical devices, limited to those for designing, assembling, sterilization and others specified by Order of the Ministry of Health, Labour and Welfare), pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

（PMD Act Article 23-2-3 (1)）

Authorization, Registration etc.	Registration (Domestic/ Overseas)
Effective Period	5 years
Authorized/ Registered by	Prefecture (Domestic), MHLW (Overseas)
Requirement for Authorization/ Registration	Disqualification Requirement
Responsible Engineering Supervisor	Required

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Manufacturing Process	Medical Device (other than the ones in the right)	Class I Medical Device	Software
Design	Yes	No	Yes
Main assembly	Yes	Yes	No
Sterilization	Yes (If sterilized)	Yes (If sterilized)	No
Domestic Storage of Final Products	Yes	Yes	Partially

Reference:
Regulation for Enforcement of the PMD Act, Article 114-8

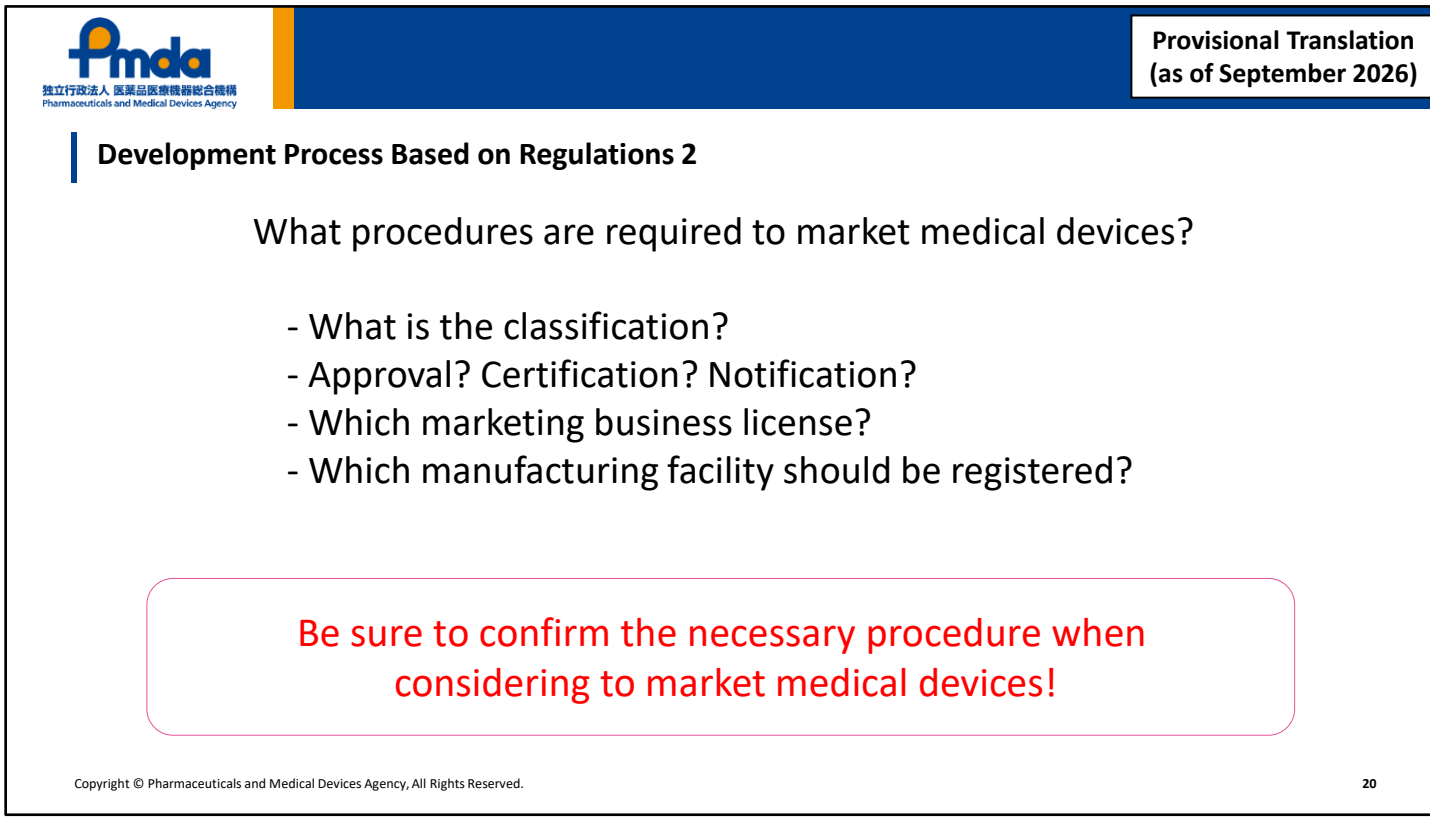
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Next, we will move on to the registration of manufacturing facilities.

Where can a medical device be manufactured?

PMD Act requires to “obtain registration from the Minister of Health, Labour and Welfare for each manufacturing facility”.

In other words, medical devices are required to specify its manufacturing facility, and to be manufactured at the registered manufacturing facility.



This is the end of part 2.

Please look back on the slides as necessary since we covered a lot of topics.

Let's summarize this part before we move on.

When you find out that your product in development qualifies as a medical device, first consider its medical device classification.

Once the classification is determined, you would have an idea whether to aim for an approval, certification or notification.

However, for SaMD products, an approval or certification would be obtained because Class I SaMD is not regulated under the PMD Act.

Preparation to obtain a marketing business license is also required. Please select the appropriate license according to the classification of the medical device.

In addition, registration of the manufacturing facility will be required.

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3. Approval Review

【Keywords】Rejection grounds, Efficacy, Safety, GLP/GCP/GPSP compliance assessment, QMS inspection

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The final part is on the approval review.

If you have been following the presentation up to this point, you may have noticed that this part is on "approval" review. Please note that "certification" review is not included in this part.

Specific principles on the approval review are covered in other presentations.

This presentation is focused on the review based on the PMD Act.

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Be Ready for These Processes Upon Application!

1. Review
2. GLP/GCP/GPSP compliance assessment
3. QMS inspection

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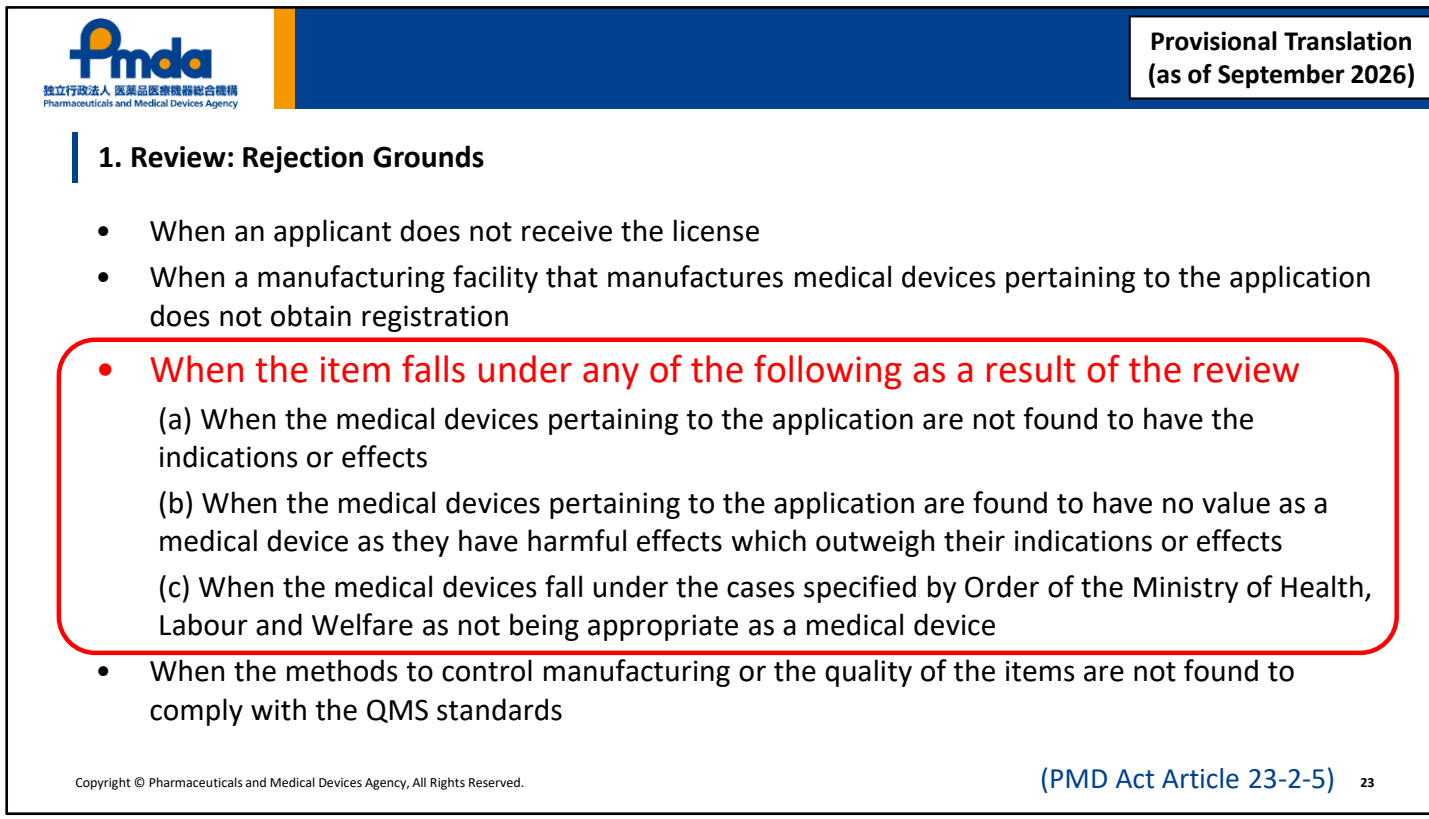
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We will assume that your product qualifies as a medical device and must receive an approval based on the classification.

Once the approval application is submitted, 3 processes should be prepared for.

The processes are review, GLP/GCP/GPSP compliance assessment and QMS inspection.

Let's look at them one by one.



We will start with the first process, the "review". This how the review is stated in the law.

In PMD Act Article 23-2-5, there is an item called "rejection grounds". If the applied product meet any of these items, the approval will not be granted.

The first two items are about the marketing business license and manufacturing facility registration that we covered in the previous part. If these are not obtained appropriately, the approval will not be granted.

The area in the red frame is related to the review.

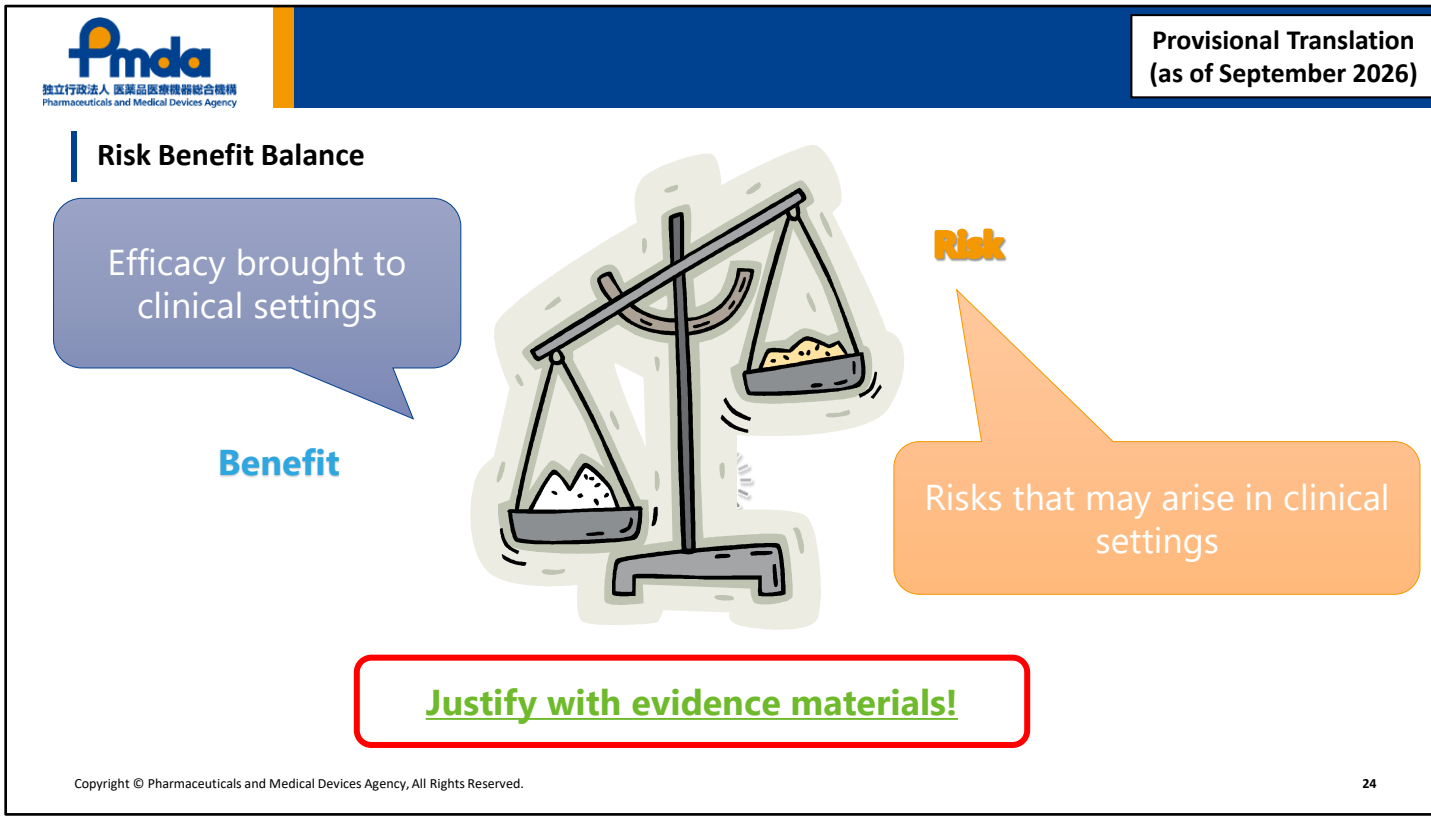
As you can see, it is stated that the product will be rejected "when the item falls under any of the following as a result of the review".

a. When the medical devices are not found to have the indication or effects. In this case, the product are rejected for approval.

b. Even when the medical devices are found to have the indication or effects, when the risks to introduce them are too high and may negatively affect the clinical settings, they are considered to have no value as medical devices and are rejected for approval.

c. Other products that the Minister of Health, Labour and Welfare determine as inappropriate are not approved.

Item c is a special case, so we will focus on items a and b.



In summary, the applicant must be able to justify that their product does not meet these rejection grounds.

For example, applicants may claim that:

"This product has sufficient efficacy because it is justified with this data."

"These are the risks that may arise in clinical settings. However, the risks are controlled in these ways, so there is value to use it as a medical device."

In other words, the reviewer will ask,

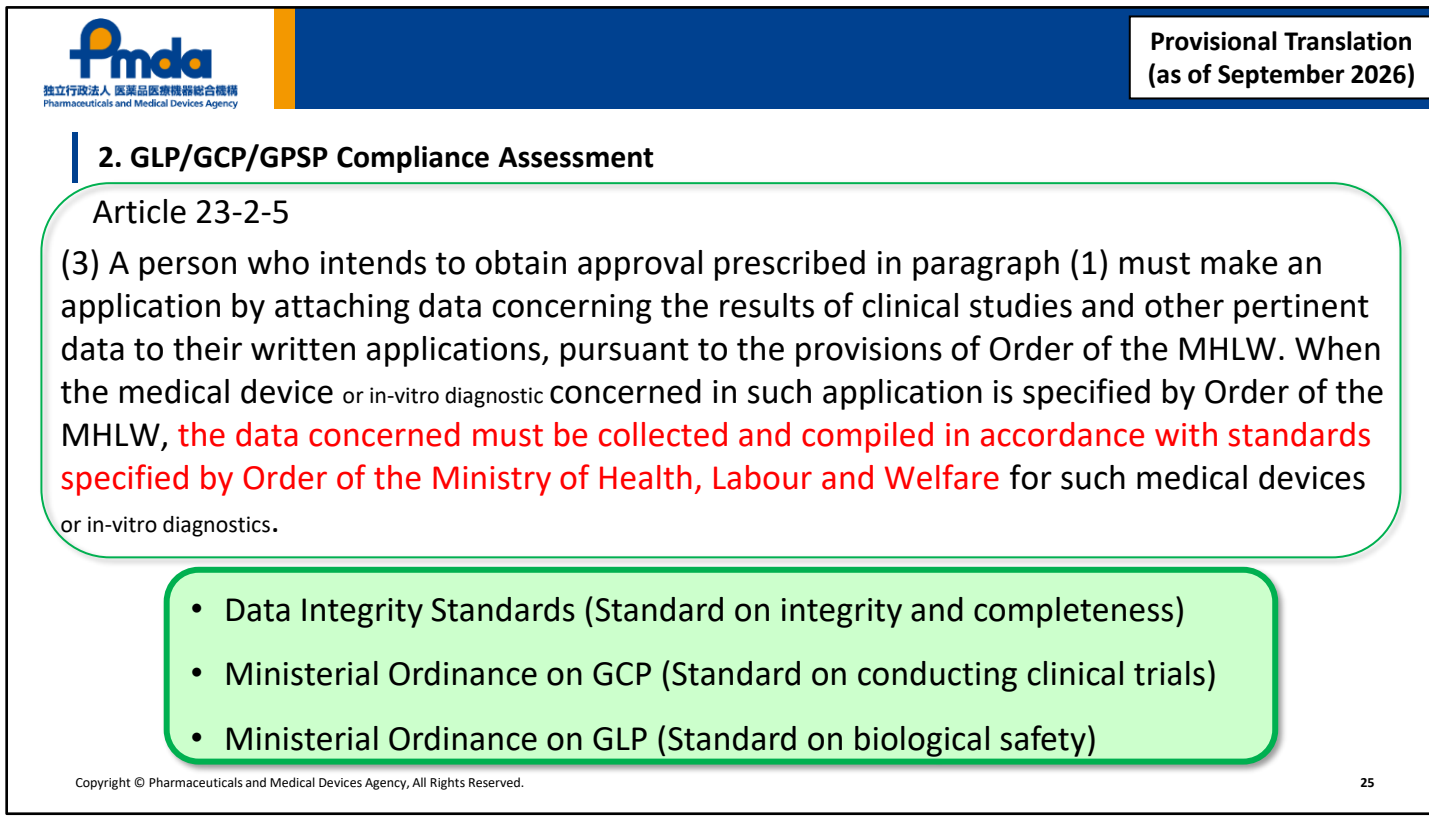
"Can you justify that there is efficacy without this kind of data?"

or

“Would such risks also arise? Are they controlled sufficiently?"

After these discussions, when it is concluded that the product does not meet the rejection grounds, the product will be approved.

Please note that these claims must be justified with evidence materials.



The second process is the "GLP/GCP/GPSP compliance assessment“.

As we discussed earlier, discussions using evidence materials are conducted in a review. There are established standards on the procedure to collect these materials.

The “Data Integrity Standards“ cover the overall process. Test reports are documented based on data obtained in the test.

For example, if there was an outlier in the test data, you may worry that the reviewer would be upset with it. However, if you remove this data, you will violate the Data Integrity Standards.

Although this is an arbitrary and extreme example, even if it was unintentional, the reviewer cannot make appropriate decisions reviewing evidence materials with many errors. Therefore, assessments are conducted to confirm that the materials are documented in compliance with the Data Integrity Standards.

In addition, if clinical study results are attached to the application, the study must be conducted in accordance with a rule called GCP. This is the rule to ensure the ethics of the subjects and the accuracy of the data in the documented material.

In addition, although it does not apply to most SaMD products, if you conduct a biological safety test to evaluate the safety of raw materials in the product, it must be conducted in a facility that comply with GLP.

In any case, please keep in mind that there is a standard on documenting materials that are subject to review.

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3. QMS Inspection

【Rejection Grounds】

- When an applicant does not receive the license
- When a manufacturing facility that manufactures medical devices pertaining to the application does not obtain registration
- When the item falls under any of the following as a result of the review

  (a) When the medical devices pertaining to the application are not found to have the indications or effects

  (b) When the medical devices pertaining to the application are found to have no value as a medical device as they have harmful effects which outweigh their indications or effects

  (c) When the medical devices fall under the cases specified by Order of the Ministry of Health, Labour and Welfare as not being appropriate as a medical device

- when the methods to control manufacturing or the quality of the items are not found to comply with the QMS standards

- Ministerial Ordinance on QMS (Standard on manufacturing and quality control)

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The third process is the QMS inspection.

This is the last item in the rejection grounds.

QMS is an abbreviation of the Quality Management System and is a standard that defines the manufacturing and quality control process of medical devices.

QMS inspections are conducted to confirm whether a system has been established to ensure that products are manufactured with a certain level of quality and that corrective measures are taken as necessary.

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Development Process Based on Regulations 3

Before submitting your application…

- Do you have the materials and data to justify the risks and benefits?
  Are you familiar with its details?
- Are you prepared to handle a GLP/GCP/GPSP compliance assessment?
- Has your quality management system conformed to the Ministerial Ordinance on QMS?
  Are you prepared to handle a QMS inspection?

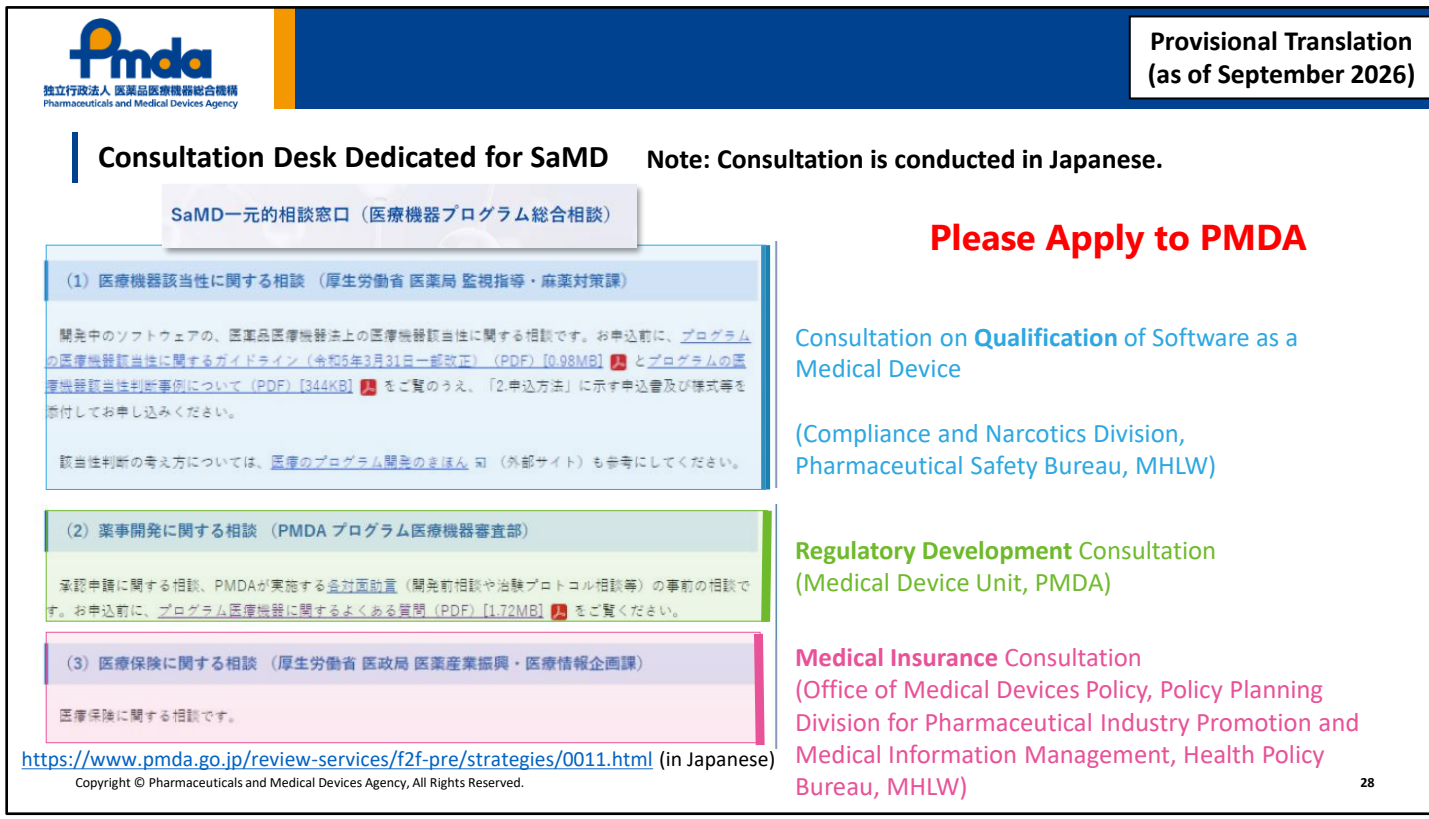
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In this part, we have covered the processes conducted after the application: the review, GLP/GCP/GPSP compliance assessment, and QMS inspection.

These processes should not be considered after the application but must be fully prepared in advance.

Please be aware of the details before submitting your application.



Here are some information that may be useful for application.

A consultation desk dedicated for SaMD is established upon request from various areas. It is called the Centralized Consultation Desk for SaMD, also known as Comprehensive Consultation for SaMD.

Consultation on the qualification of a medical device, the review process, or medical insurance, which we didn't cover in this presentation, are centralized at a desk in PMDA and will be referred to relevant divisions.

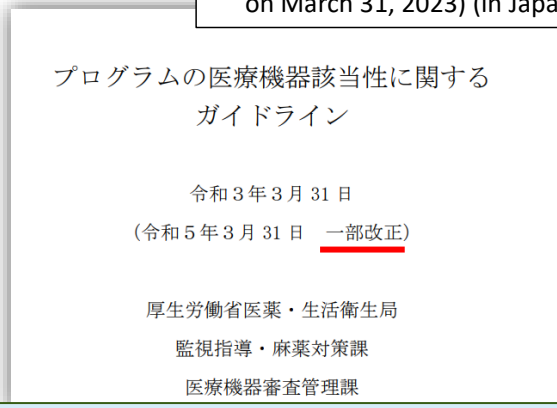
Please utilize this system as necessary.

独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Provisional Translation (as of September 2026)

A Must Read!

Guideline on Qualification of Software as a Medical Device (Partially revised on March 31, 2023) (in Japanese)

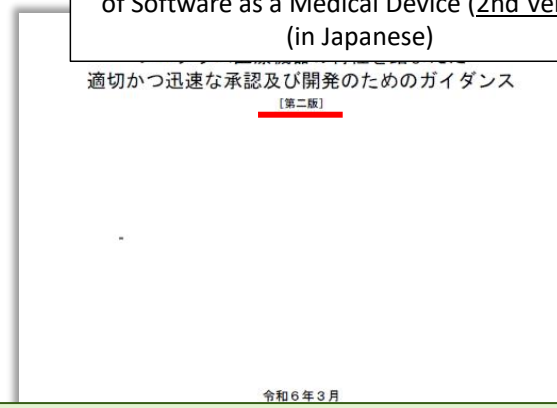

プログラムの医療機器該当性に関する
ガイドライン

令和３年３月 31 日
（令和５年３月 31 日　一部改正）

厚生労働省医薬・生活衛生局
監視指導・麻薬対策課
医療機器審査管理課

Basic principles and case studies to determine whether a product qualifies as a medical device, as well as a flowchart to determine the qualification are consolidated.

Guidance for Appropriate and Prompt Approval and Development Based on the Characteristics of Software as a Medical Device (2nd Version) (in Japanese)


適切かつ迅速な承認及び開発のためのガイダンス
［第二版］

令和６年３月

Concepts on structuring the regulatory requirement based on clinical needs, a key point in medical device development, are consolidated.

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There are documents available about principles on qualification as a medical device and on evaluation.

Please refer to them if you are considering to develop a medical-related software.

Provisional Translation
(as of September 2026)

Thank you for listening



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In this presentation we have covered the regulation on software as a medical device under the PMD Act.

We hope this presentation provided a comprehensive overview of the regulation.

Thank you for listening.