Pharmaceutical Regulations in Japan

-Generic Drug Review System, MF System-

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Pharmaceuticals and Medical Devices Agency

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Part 1. Office of Generic Drugs

Part 2. Considerations for Description of Manufacturing Method in MF and Drug Application Form for Marketing Approval

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1. What is Office of Generic Drugs?
2. Current generic drug reviews and consultations
3. Future generic drug reviews and consultations

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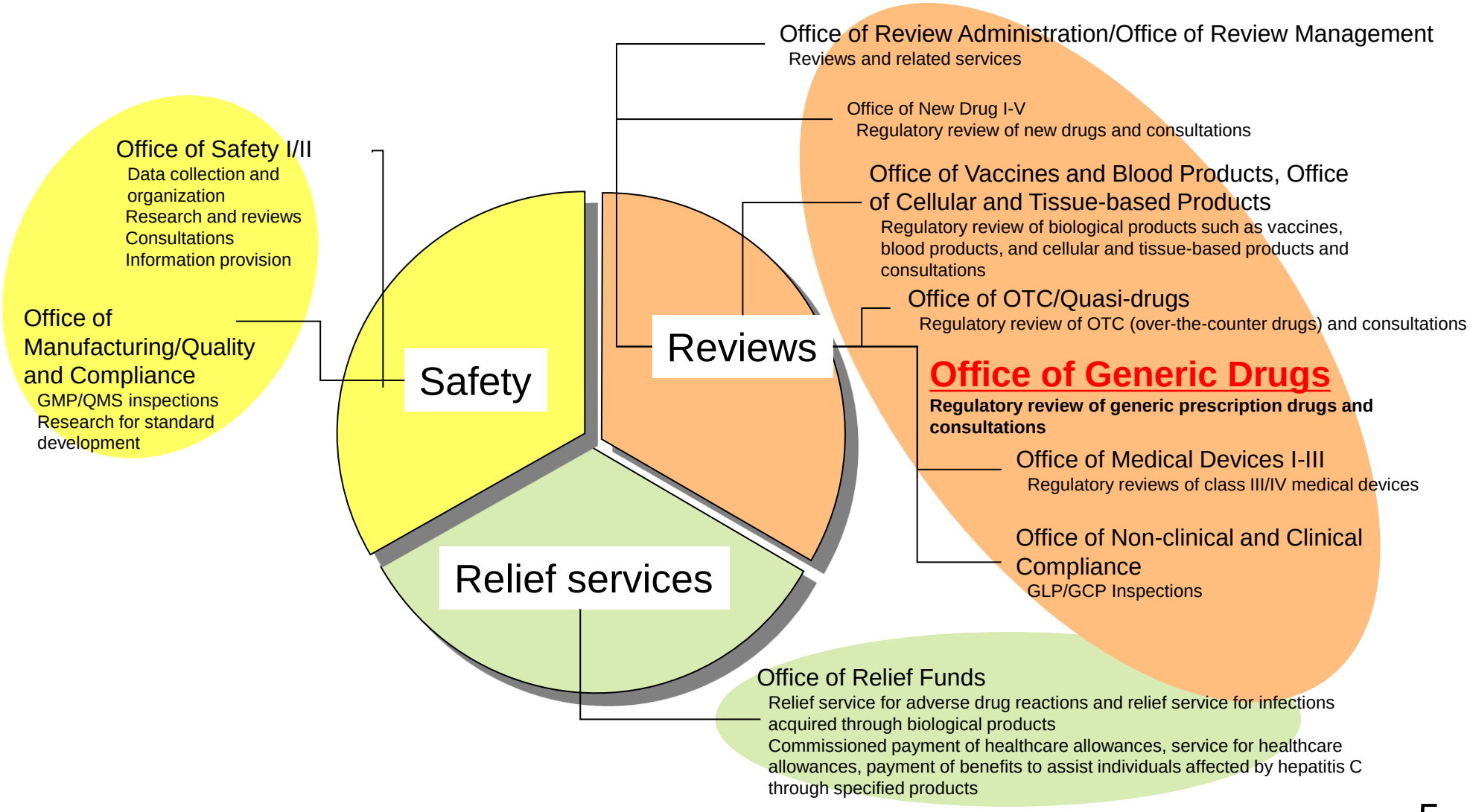
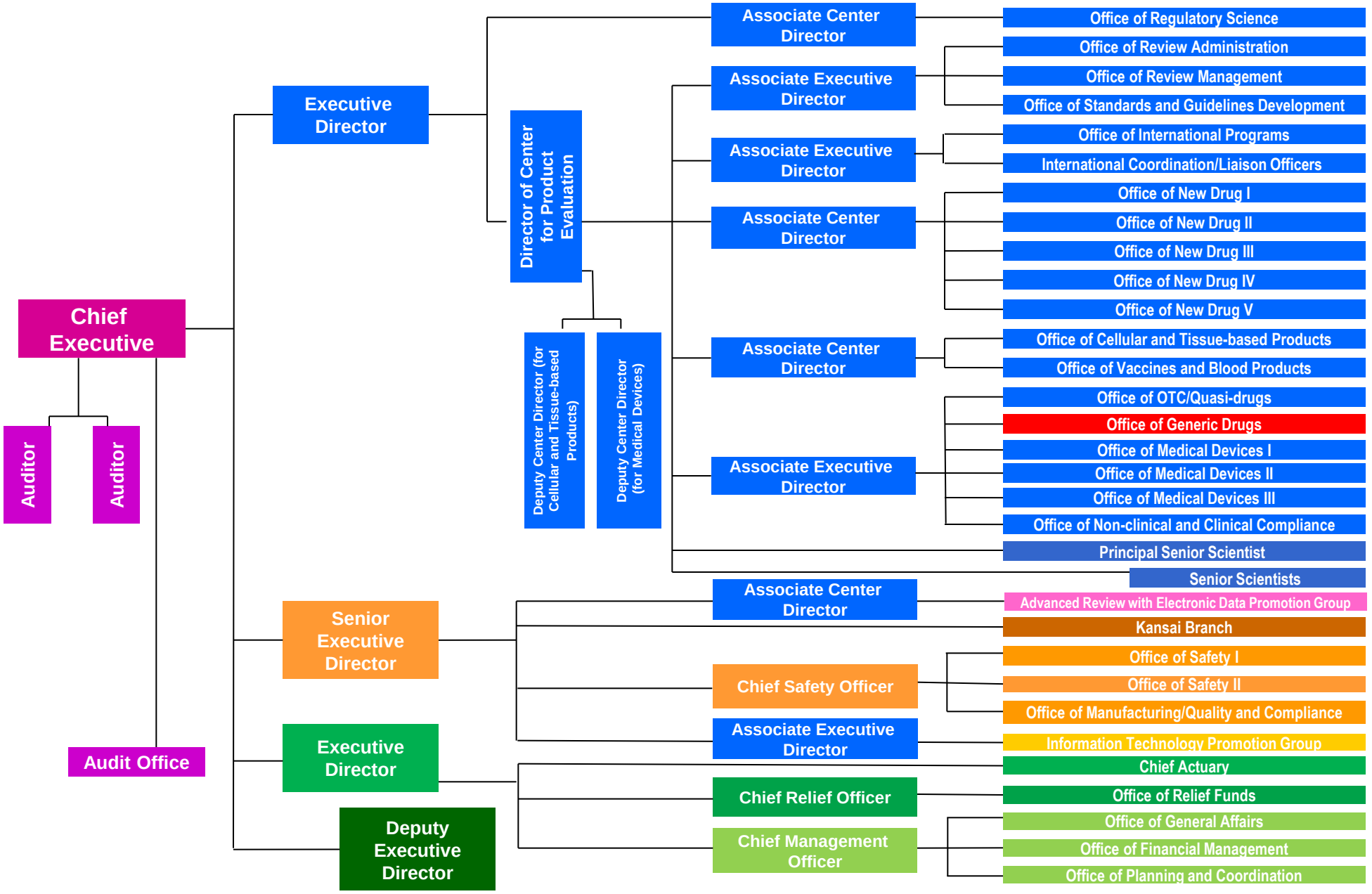
Structure of PMDA



Organizational Chart of PMDA

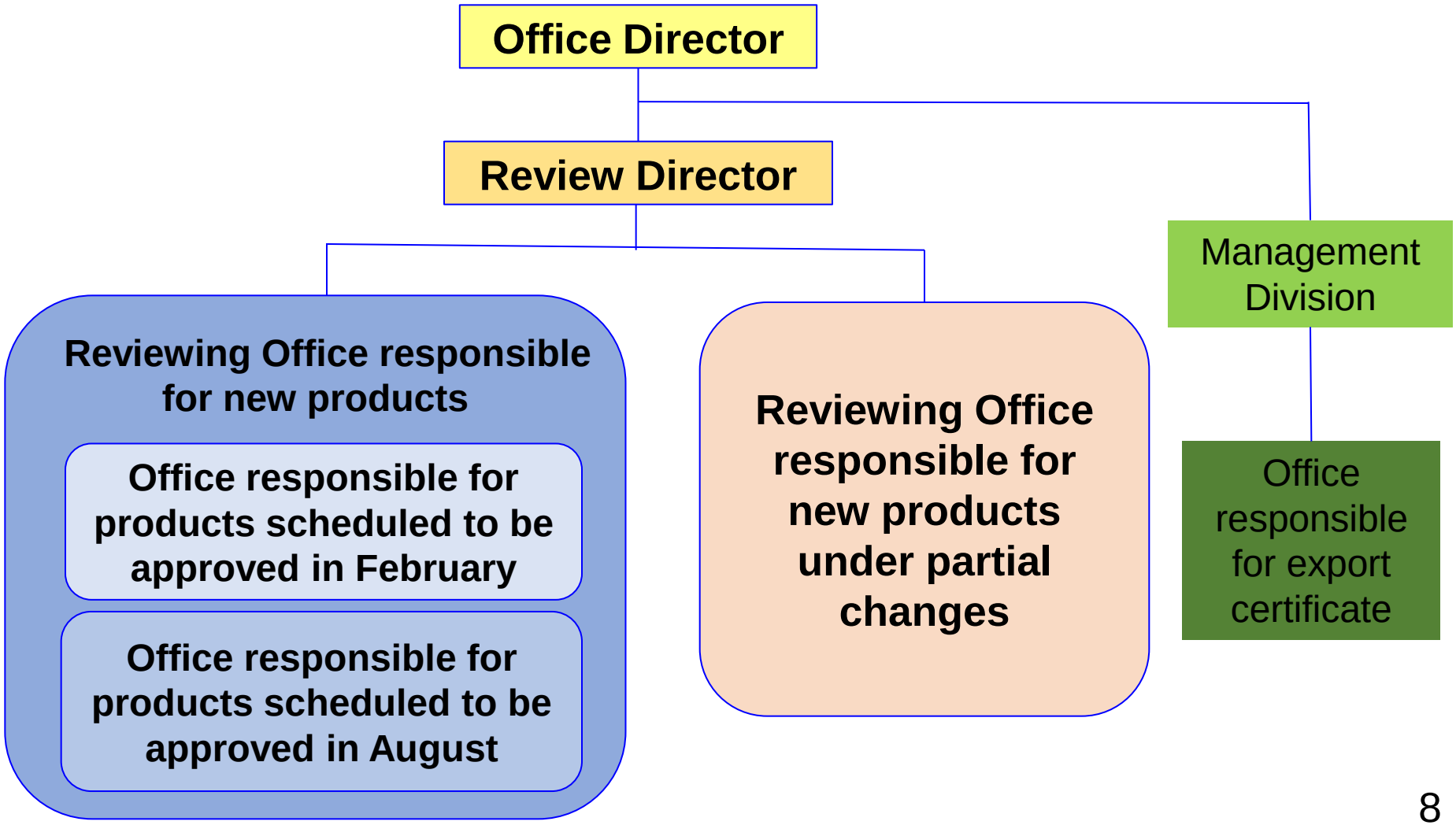
As of November 2014



Main services of Office of Generic Drugs

- Regulatory reviews of and consultations on generic prescription drugs (excluding biological products)
- Regulatory reviews of and consultations on original prescription drugs for which re-examination period was completed (excluding biological products)
- Development and review of Guidance for Bioequivalence
- Confirmation of exportation certification on prescription drugs (excluding in vitro diagnostics)

System of Office of Generic Drugs



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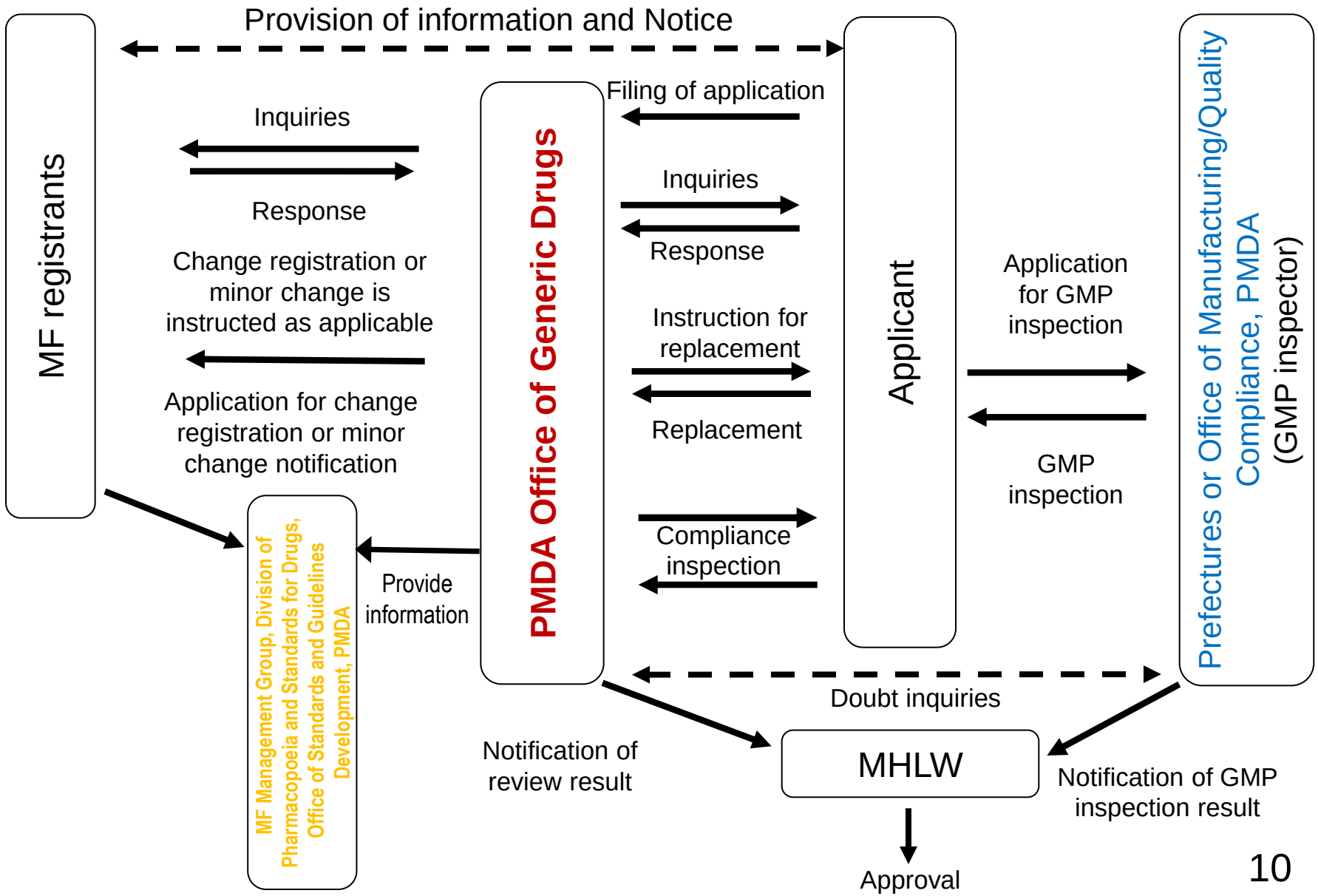
Flow from application to approval



Department in PMDA responsible for generic drugs

◇Approval Application, contact for minor change notification

A) Approval application, reception of minor change notification and MF registration/notification, and reception of request for simple consultation

- Office of Review Administration

B) MF registration, change registration, minor change notification, consultation

- Master File Management Group, Division of Pharmacopoeia and Standards for Drugs, Office of Standards and Guidelines Development

◇**Regulatory Reviews/Consultations: Office of Generic Drugs**

◇GCP on-site inspection: Office of Non-clinical and Clinical Compliance

◇GMP inspection: Office of Manufacturing/Quality and Compliance

* Each prefecture responsible for domestic manufacturing sites excluding biological products or radiopharmaceuticals.

Inspections and reviews

1. Equivalence review

   Review on equivalence to approved products in active ingredients, contents, indications, dosage and administration and quality

2. Compliance inspection

   Inspection to confirm that attached documents was prepared according to data integrity standards

   - Confirming consistency between attached documents and original materials (raw data)
   - GCP on-site inspection on bioequivalence studies, etc.

   Inspection to confirm that products are manufactured according to Good Manufacturing Practice (GMP)

   - GMP Inspection on manufacturing sites and process

3. Overall reviews to evaluate justification for approval decision

Requirements for application

1. Re-examination for the original product should be completed.
2. Comparability to the original products and bioequivalence should be ensured.
   - Generic products should be identical to original products in terms of active ingredients and their contents, dosage and administration, and indications, and comparable or more appropriate storage statement/shelf life and specifications for quality control should be specified.
   - Generic products are required to show bioequivalence.
   - In case of products with controlled-release mechanism, etc., the mechanism should not differ greatly.
3. Where re-evaluation on indications (efficacy and safety) is being designated, data on the re-evaluation should be attached.

Review products/consultations

Fiscal Year	New Products		Products under Partial Changes		Simple consulta-tions	Clinical trial consultation	
	Application	Approval	Application	Approval		BE consultation	Quality consultation
FY 2009	1,117	1,879	1,237	1,392	202	-	-
FY 2010	1,247	1,011	1,815	1,622	282	-	-
FY 2011	1,154	1,185	1,738	1,906	308	0	1
FY 2012	1,764	1,539	2,313	1,882	336	7	3
FY 2013	1,467	1,438	2,424	2,066	468	15	3

Note1: Simple consultation is easy consultation on application or MF registration (for example, consultation without data evaluation)

Note2: Clinical trial consultation is consultation with submitted data on supporting data (bioequivalence (BE) consultation and quality consultation have been experimentally conducted since January 2012.)

Scope of simple consultations

1. Consultation on application for generic drugs

   Expected application classification and attached documents, precedent of use of excipients based on planned active ingredients and their contents, indications and dosage and administration.

2. Consultation on MF registration or change, etc.

   Matters on which consultations with the regulatory authority are allowed or required in "Guidelines on Utilization of Master File for Drug Substances, etc." (PFSB/ELD Notification No. 0210004 dated February 10, 2005)

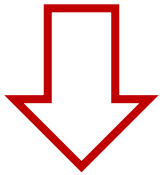
3. Other

   Matters on which consultations with the regulatory authority are allowed or required in "Guideline for Descriptions on Application Forms for Marketing Approval of Drugs, etc. under the Revised Pharmaceutical Affairs Law" (PFSB/ELD Notification No. 0210001 dated February 10, 2005)

Experimental conduct of consultations

From Jan. 2012

- Increasing demand for consultations on bioequivalence
  (Evaluation on bioequivalence not indicated by Pharmacokinetics)
- Response to application of various kinds of generic drugs
  (Development of generic drugs which properties should be considered)



As pre-application consultations different from simple consultations

[1] Consultations on bioequivalence of generic drugs

[2] Quality consultation for generic drugs

Consultation by fiscal year

Fiscal Year	Consultations		Simple consultations
	Consultations on bioequivalence	Quality consultation	
FY 2009	-	-	202
FY 2010	-	-	282
FY 2011	2	1	308
FY 2012	8	2	336
FY 2013	15	3	468
FY 2014	16	9	-

Note: PMDA started to provide consultations in January 2012 on a trial basis.

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Third Mid-term plan

Mid-term Plan of the Pharmaceuticals and Medical Devices Agency

(Notification No. 0331-44 of Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare Dated March 31, 2014)

Part 2 Measures to be taken in Order to Achieve Targets Related to Matters Regarding Improvement in Operation Management of Each Division and Matters Regarding Improvement in the Quality of Services and Other Operations Rendered to the Public

-Make effort to promote the safety triangle of reviews, safety, and relief as a mission of PMDA-

Establishment of a new office for generic drugs, etc.

Conducted on November 1, 2014 ← Third Mid-term Plan

2. Review and Related Services

(1) Make pharmaceuticals, medical devices, etc. accessible by the public more quickly

[Generic drugs, etc.]

The following measures shall be taken to promote wide use of generic drugs, etc.

a) Conduct accurate and prompt reviews

1. Establish a new office for generic drugs, etc.

- Enhance and accelerate reviews by appropriately increasing and allocating members for the generic drug, etc. group and by establishing a new office.

Ensuring of efficient and transparent reviews [1]

Third Mid-term Plan

a) Conduct accurate and prompt reviews (continued)

2. Ensure efficient and transparent reviews

- Strengthen cooperation with academia and healthcare professionals, etc. to conduct consultations and reviews based on the latest medical care trends and needs, and to promote cooperation toward appropriate use of pharmaceuticals.
- Promote establishment of standards regarding quality of pharmaceuticals, etc., such as the Japanese Pharmacopoeia, etc., established by MHLW, in order to conduct accurate and prompt reviews.
- Recommend application by CTD/eCTD format in order to increase efficiency in reviews.

Ensuring of efficient and transparent reviews [2]

Third Mid-term Plan

a) Conduct accurate and prompt reviews

2. Ensure efficient and transparent reviews (continued)

- Ensure transparency of the reviews by preparing and disclosing review reports on new generic drugs.
- Establish guidelines for bioequivalence testing in order to respond to the increased complexity of bioequivalence assessments and the diverse pharmaceutical products that are being developed.
- Cooperate with relevant offices to take appropriate measures to steadily implement the risk management plan.

Review time for new generic products

Third Mid-term Plan

b) Targets for reducing review time

- Regarding pharmaceuticals which applications were submitted after April 1, 2004, the target review times for the items approved in respective fiscal years, shall be as shown in the following table. The regulatory authority shall make efforts to achieve these targets with the cooperation of the applicants.
- The review system shall be enhanced to achieve these targets.

1. Review time for new application of generic drugs

The following targets shall be achieved at 50th percentile (median) by FY 2018.

Product	Regulatory review time
New generic drugs	10 months

Review time of application for partial change approval (standard review products)

Third Mid-term Plan

b) Targets for reducing review time (continued)

2. Review time of application for partial change approval in generic drugs (standard review products)

Targets shall be achieved at 50th percentile (median) by FY 2018, based on the following plan.

Fiscal Year	Total review time
FY 2014	15 months
FY 2015	14 months
FY 2016	13 months
FY 2017	12 months
FY 2018	10 months

Review time of application for partial change approval (products other than standard review products)

Third Mid-term Plan

b) Targets for reducing review time (continued)

3. Review time of application for partial change approval in generic drugs (products other than standard review products)

The following targets shall be achieved at 50th percentile (median) by FY 2018.

Products	Total review time
Products applied for partial change approval (change in procedure of study, etc.)	6 months
Products applied for partial change approval (expedited reviews)	3 months

Enhancement of consultation services

Third Mid-term Plan

c) Conduct smooth clinical study consultations, etc.

- All consultations shall be conducted for those requested for quality consultation or bioequivalence consultation (face to face consultation) .

→ Conducted since January 2015

- Enhance consultation services by considering whether setting up new consultation categories are necessary to meet the needs of the applicants.

Face-to-face consultations in FY 2014

Month/Year	Request	No. of consultations	BE consultation	Quality consultation
April 2014	2	2	2	0
May 2014	1	1	1	0
June 2014	2	2	0	2
July 2014	3	2	2	0
August 2014	6	2	1	1
September 2014	4	2	1	1
October 2014	6	3	2	1
November 2014	4	2	2	0
December 2014	5	3	3	0
January 2015	4	4	1	3
February 2015	1	1	0	1
March 2015	1	1	1	0
Total	39	25	16	9

Note1: Request for face-to-face consultations is accepted 2 months prior to implementation.
Note2: All consultation requested for January 2015 were performed because Office of generic Drugs had been newly created for detailed consultation service.

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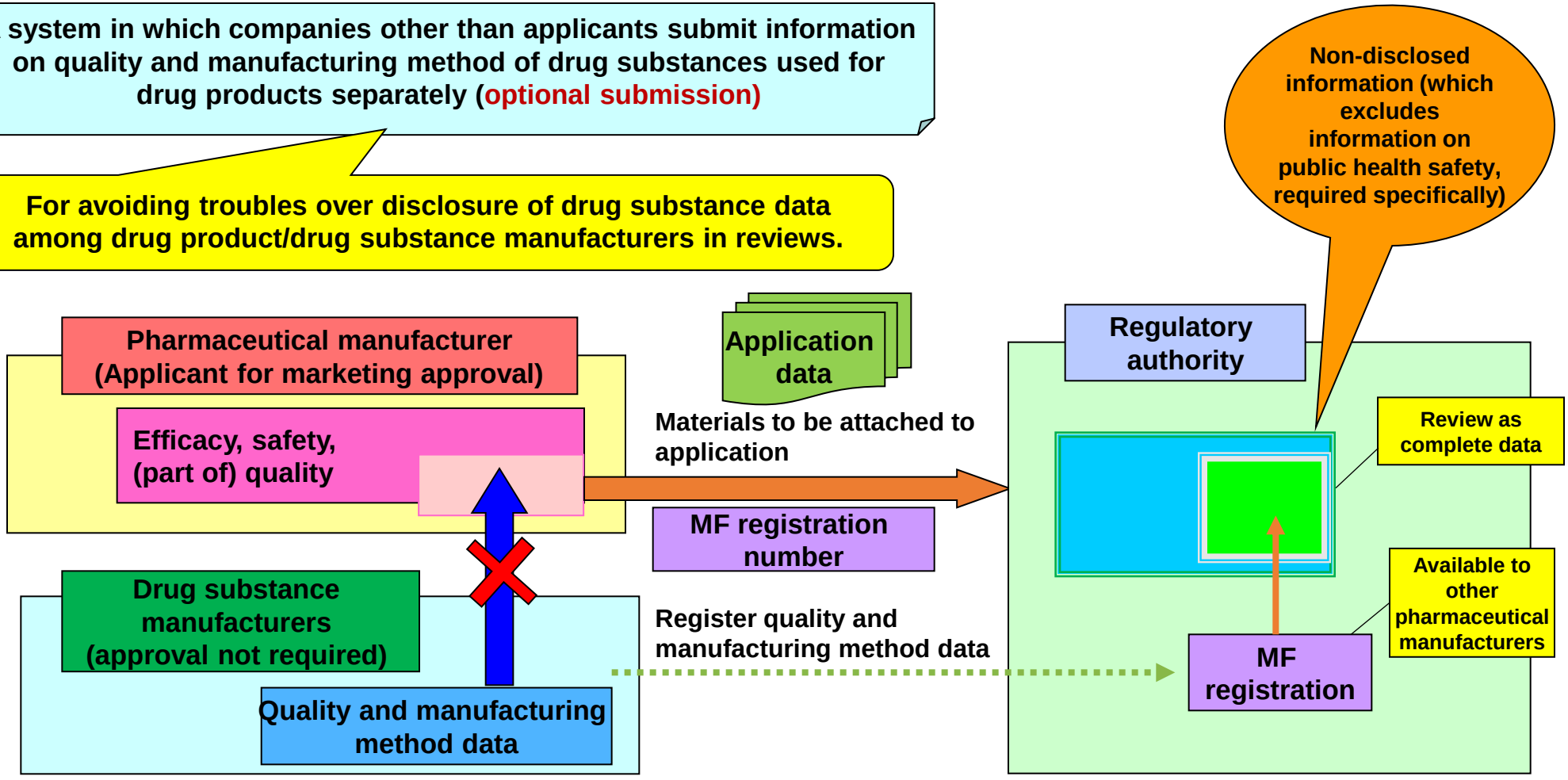
Approval reviews for drug products quoting MF

Master file is used both in US and EU

A system in which companies other than applicants submit information on quality and manufacturing method of drug substances used for drug products separately (optional submission)

For avoiding troubles over disclosure of drug substance data among drug product/drug substance manufacturers in reviews.



Issues in MF reviews

Warranty of consistency between use and non-use of MF

MF registration is optional system.

Ensure that the presence or absence of MF use makes no difference in information provided for reviews.

PFSB/ELD Notification No. 0210001
dated February 10, 2005

Does a change fall into "minor change" or "partial change application"?

In registration application, a change is classified into minor change notification or application for partial change based on the expected effect on product quality.

" " ' '

<< >>

If registrant is an overseas manufacturers, a MF registrant shall appoint a in-country caretaker who has an address in Japan and delegate MF registration application to the representative.

Sufficient cooperation between MF registrants (in-country caretaker) and marketing authorization holder is required for ensuring quality of drug product and smooth MF reviews.

Status of information registered in MF

Information registered in MF

Application form is filled in Japanese

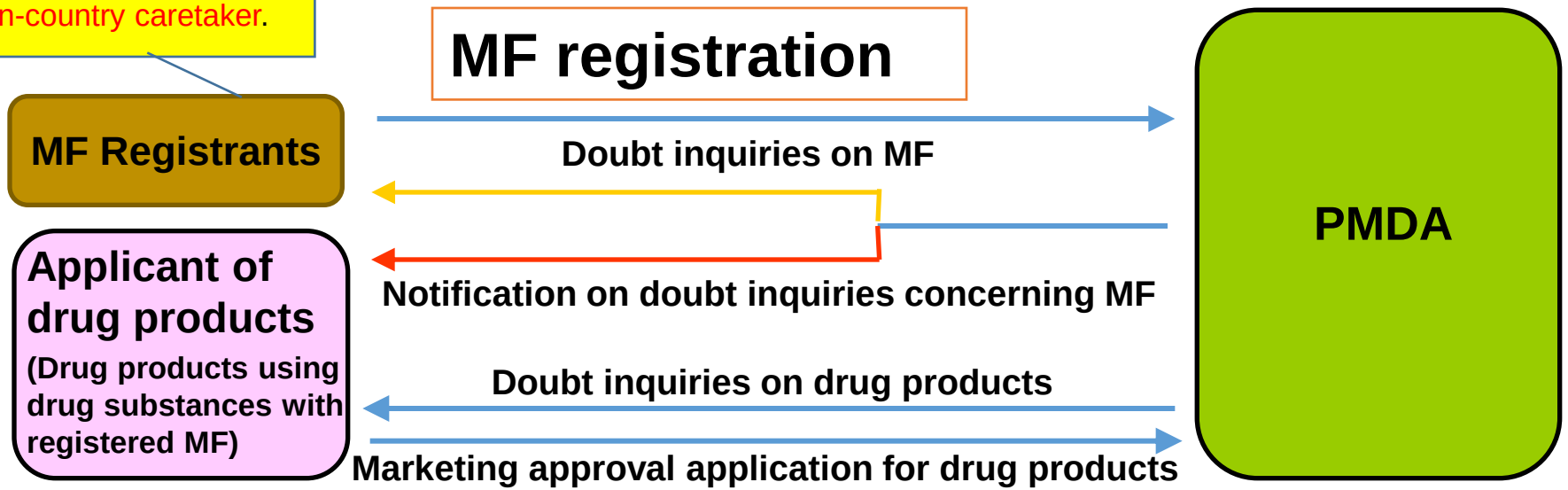
- ✓ Partial substitution for marketing approval application for a drug products
- ✓ Partial substitution for attached documents for marketing approval application for a drug products

Original documents of Module 3 of CTD can be submitted only where it is written in English.
The summary written in Japanese or Module 2 of CTD is to be submitted where required by reviewers.

- The registered information are reviewed in the approval application for the drug product using the relevant MF.
- In the review of the product, submission of data equivalent to Module 2 (Summary of Attached Data) is recommended as well as Module 3 of CTD.

Overview of approval review for drug products quoting MF

If registrant is an overseas manufacturer, inquiries are made by way of in-country caretaker.



Management of impurities and residual solvent is reviewed based on required measured data and, in some cases, results of validation of analytical procedure.

Data specified in the Enforcement Ordinance of the Pharmaceutical Affairs Law, Article 40-1-1	Scope of the left column (PFSB Notification No. 0331015 dated on March 31, 2005)
A. Origin or history of discovery and usage conditions in foreign countries etc.	1 Origin or history of discovery 2 Usage conditions in foreign countries 3 Characteristics and Comparison with other drugs
B. Manufacturing methods and specifications	1 Identification and physicochemical properties 2 Manufacturing process 3 Specifications
C. Stability	1 Long-term testing 2 Stress testing 3 Accelerated testing

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Considerations for procedure of MF registration application

- "Guidance on handling of applications submitted on flexible disk etc." (PFSB/ELD Notification No. 0320005 dated March 20, 2006) should be referred to for considerations in preparing an application form.
- Before application procedure, check carefully that application data and attached documents are complete.
- Reflect the contents of past instruction related to inquiries to a new registration application.
- If anything is unclear in registration application procedure, use simple consultation for correct application and smooth reviews.
- Check carefully that contact information (especially FAX number) on an application form is correct. Incorrect contact information causes wrong transmission of inquiries, etc.

Information on attached files

[Information on attached file] on a FD application form has [Appendix file name] and [File name of attached documents] . The difference is as follows:

[Appendix file name]

- ✓ Approved product information such as charts is required to be converted to PDF files and attached as well.

  e.g., structural formula, picture of a container
- ✓ List of drug products quoting the MF (not required to be attached where it is described in the remarks)
- ✓ Comparison table of before and after change (only for application for change registration and minor change notification)
- ✓ Statement (only for minor change notification)

[File name of attached documents]

- ✓ Reference data is required to be converted to PDF files and attached as well. Examples: "Flow diagram of manufacturing process," "Rationale for partial and minor changes," "Written reason for diverting foods and industrial products," and "particular account," etc.

Manufacturing method [1]

Administrative Notice from ELD, PMSB, MHLW, dated May 20, 2008

- Concept for description of manufacturing method

  Refer to "Question-and -Answer (Q&A) on Description of Manufacturing Method in Application Forms for Drugs"

- Concept for eligibility for minor change notification/application for partial changes
  - Each company should evaluate eligibility based on the following notifications. Simple consultation is available for a case in a gray zone.

PFSB/ELD Notification No. 0210001 dated February 10, 2005

  - "Guideline for Descriptions on Application Forms for Marketing Approval of Drugs, etc. under the Revised Pharmaceutical Affairs Law"
  - Other relevant notification and administrative notice (Q&A)
    - Administrative Notice from ELD, PFSB, MHLW, dated Nov 16, 2006
    - Administrative Notice from ELD, PFSB, MHLW, dated Dec 14, 2006
    - PFSB/ELD Notification No. 0112001 dated Jan 12, 2007
    - Administrative Notice from ELD, PFSB, MHLW, dated Jun 28, 2010
    - Administrative Notice from ELD, PFSB, MHLW, dated Jul 26, 2010
    - PFSB/ELD Notification No. 0530-8 dated May 30, 2014
    - PFSB/ELD Notification No. 0710-9 dated Jul 10, 2014

Manufacturing method [2]

PFSB/ELD Notification No. 0210001 dated February 10, 2005

- Manufacturing method of chemical drug substance
  - According to Appendix 1 of the notification, describe more than one reaction process in principle, starting with an appropriate starting material.

    Reaction process: process including formation or cutting of a covalent bond, excluding base exchange or purification process.
  - Note that only sufficiency of number of reaction processes is evaluated, not appropriateness of manufacturing method.

    →Justification for selection of a starting material

    →Evaluation on control strategy
  - Control standards for starting materials, raw materials, critical intermediates, and final intermediates are appropriately developed.
  - Control standards for raw materials after final intermediates are developed in principle.

Manufacturing method [3]

PFSB/ELD Notification No. 0210001 dated February 10, 2005

- Critical processes are established based on data collected appropriately.

  Critical process: A process impacting the quality and including process conditions, tests, and other relevant parameters in which operation within predetermined action limits to ensure conformity of drug substances to specifications is required.

  Where inquiry on rationale for critical process is made during review, the applicants should provide scientific explanation based on data, etc.

- Abbreviated description of Manufacturing method of specific drug substances listed in Appendix 1 of PFSB/ELD Notification No. 0304018 dated March 4, 2009 can be acceptable.

- Manufacturing site information, range of manufacturing process and flow diagram of manufacturing method (flow diagram is attached as appendix [PDF file]) are to be described to indicate summary of manufacturing process.

Specifications [1]

- Residual solvent in drug substance

  In view of manufacturing process and classification of solvents (Guideline for Residual Solvents) , it should be considered whether including in the manufacturing method or establishing the specifications is necessary.

  If not necessary, explanation based on scientific evidence such as actual data is given.

→ Actual data and the results of validation of analytical procedure are to be submitted at registration to explain the necessity of listing as specifications or process controls and the justification for acceptance criteria.

- Impurities in drug substances

  List all expected impurities and related substances, which are included as applicable in controls of starting materials or intermediates and specifications of final drug substances.

→List of structures of expected impurities, actual data, and the results of validation of analytical procedure are to be submitted at registration to explain the necessity of the final specifications or establishing the control values of starting materials or intermediates, and justification for acceptance criteria.

  * It should be kept in mind that insufficient confirmation on expected impurities may lead to delay of reviews.

Specifications [2]

- In cases where manufacturer's specifications are established,

✓ Full description of the specifications are required by reference to the Guideline for the Preparation of the Japanese Pharmacopoeia.

✓ Where non-pharmacopoeial reagents/test solutions are used, develop a column for reagents/test solutions in which the quality and preparation procedure are described.

✓ Check carefully that the description is correct and complete.

Manufacturing site of drug substances

- Before application/notification, check carefully that information on manufacturing site is correct.
- Where the following dummy number is used for a manufacturing site of a drug substance, confirm the justification carefully and describe appropriate information.

<Reference>

⊙For manufacturing sites of intermediates of drug substances (excluding case of diversion)

License (accreditation) No.: 99AZ666666

License (accreditation) date: April 1, 2005

⊙In cases where foods or industrial products are necessarily diverted (only when the appropriateness is established)

License/accreditation No.: 99AZ777777/AG99977777

License (accreditation) date: April 1, 2005

Considerations at replacement

At MF replacement, for all inquiries and response, the following materials should be submitted:

Both of

- A paper file
- Electronic media (CD or DVD) with text

<Precaution for submitting electronic media>

- Convert it to a PDF file with text recognition available.
- Confirm electronic media is in accord with the paper media.
  (Attention should be paid to loss or overlap of pages, integrity of order)
- Electronic media of FD application, attached documents, and inquiry responses should made separately.
- Generate a file name appropriately.
  (Too long names or symbol should not be used)
- Check for virus with the latest definition file before submission.

Other considerations

- For a in-country caretaker, prepare "in-country caretaker" column and describe it appropriately in the column, not in the remarks column.
- Check carefully that FAX number described is correct because incorrect number causes wrong FAX transmission.
- For MF registration application, data with logical explanation based on the results from sufficient evaluation and evidence is prepared.
- Check carefully before application as incorrect or incomplete description may damage the confidence in the registrants.

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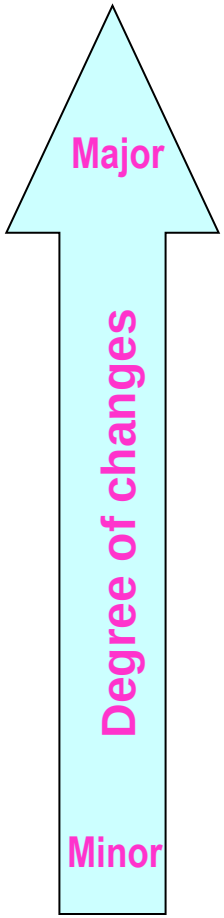
Procedure for changes in registered items



[1] Potential changes in the nature of drug substances due to changes in registered items

→ **New application for registration**

[2] Normal Changes (Changes not classified to [1] or [3])

→ **Application for change registration**

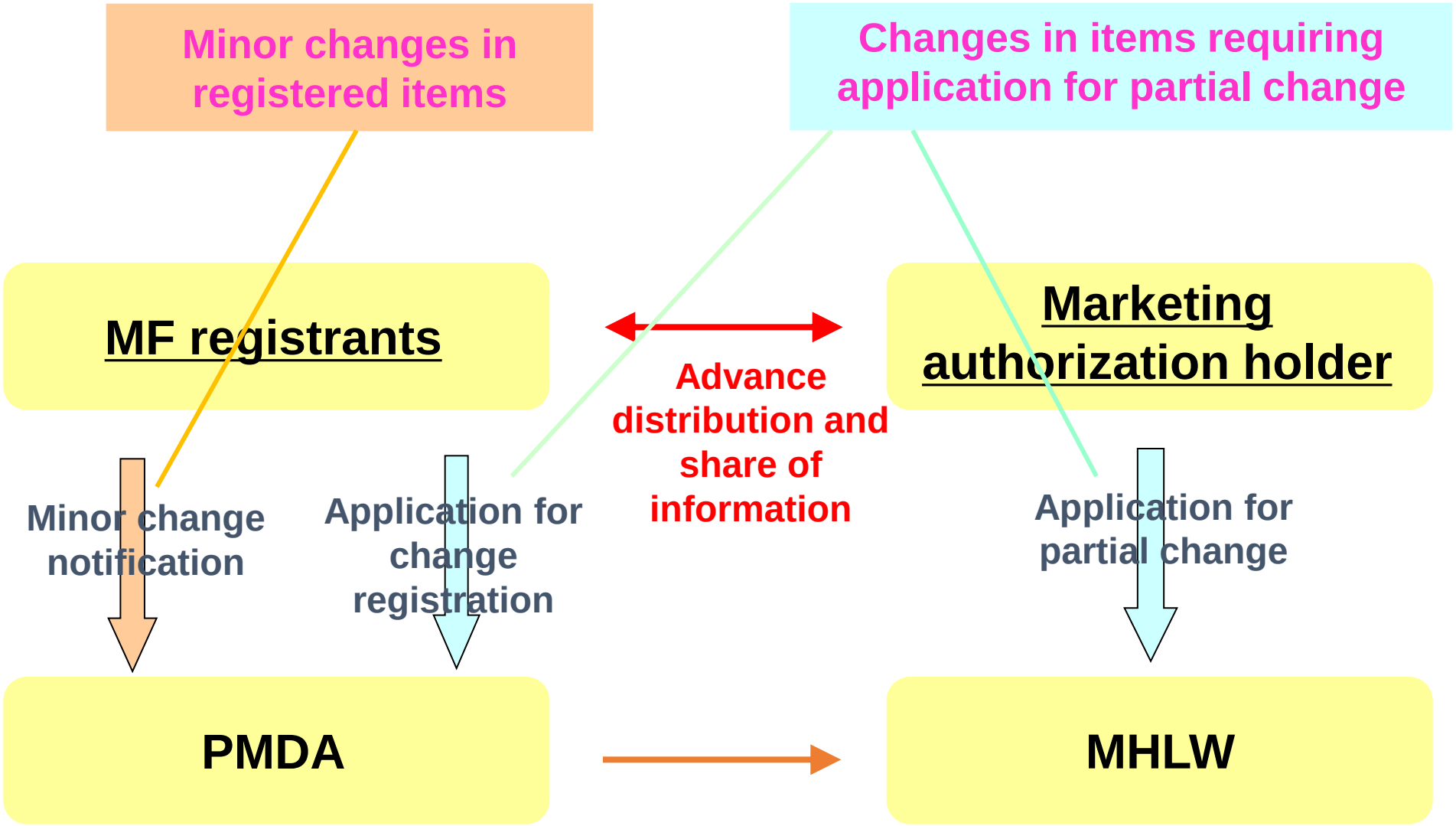
[3] Minor Change

Changes other than the following:

- Changes in the manufacturing method, etc. affecting the nature, characteristics, performance, and safety of drug substances.
- Deletion of the items listed in the specifications or changes in the specifications
- Changes in the inactivation or removal method for pathogenic factors
- Other changes which may affect the quality, efficacy, and safety.

→ **Minor change notification**

Changes in registered items in MF and partial changes of drug products



Changes in registered items [1]

- MF registrants should notify the applicants of changes in registered items in advance.

- Where a product has been already approved using the MF, the MF registrant also should notify the marketing authorization holder of the product of the change.

- In notification of minor changes in registered items, involving applicants and marketing authorization holders are notified of the change.

- As this involves not only MF registrants but also the applicants (marketing authorization holders) of drug products made with the substances, poor cooperation between them could led to troubles.

Changes in registered items [2]

- In the case of changing the items registered in MF

  MF registrants evaluate whether the change is classified to "minor change" or "not minor change" and is required to appropriately practice each procedure for the change in registered items.

If the evaluation is difficult, they should sufficiently confer with applicant (marketing authorization holder) of the drug product and confirm it.

Change registration	Not minor change (changes affecting the quality of drug substance)
Minor change notification	Minor change (changes unlikely to affect the quality of drug substance)

Changes in registered items as partial changes [1]

- Where registered items as partial changes are changed, application for change registration of MF registered items is basically required.

However,

- Even changes in items registered as minor change is required to be applied as the application of MF change registration as well where the effect of the change on the drug product are assessed not minor.

- In these cases, marketing authorization holders of drug products evaluate whether the effect of the change is acceptable in view of contents of application and should submit the applications for partial change of products.

Changes in registered items as partial changes [2]

- In the cases that effect of a change is considered to be acceptable,
  - MF registrants submit an application form for change registration of registered items to the regulatory authority.

    * Attached documents on changes in registered items

      Actual data

      Appropriate validation

      A statement for the fact that change control has been performed, etc.

  - Where content of a change is considered to have an unacceptable effect, the marketing authorization holder may not accept the change.

Changes in registered items as minor changes [1]

- A minor change notification in MF registered items is submitted basically after confirming that the effect of the change is minor.

➢ In the cases that the change is confirmed to be minor

MF registrants submit notification of the minor change in the registered items to the regulatory authority.

* Attached documents

  Appropriate validation

  A statement for the fact that change control has been performed, etc.

* In this case, a marketing authorization holder of a drug product made with MF registered drug substance is not required to notify minor change in approved items.

Changes in registered items as minor changes [2]

- Justification for a change in MF registered items notified as a minor change is not evaluated at the time of the notification in principle.
  - A MF registrant (and an applicant of a drug product) takes *self-responsibility* for the notification.
  - Justification for minor change notification is assessed on review after an application for a partial change of a drug product or on GMP inspection after the notification.

Perform routinely the change control specified in revised GMP regulation.

Changes in registered items as minor changes [3]

- A minor change notification in MF registered items is submitted basically after confirming that effect of the change is minor.

However,

- In a case where effect of a change in MF registered items expected to be minor at registration has been assessed as not minor
  - * where results that can not deny effect on the quality have been indicated at change control procedure of a MF registrant, or
  - * where a change has been assessed as not minor as a result of discussion with the marketing authorization holder of the product.

The change is canceled, re-examined, notified as an application for a partial change or registered again as a new drug substance, etc.

Changes in registered items as minor changes [4]

- *Where GMP inspection has revealed that a change in manufacturing process, etc. which should not be treated as a minor change has been notified as a minor change*
  - The minor change notification becomes invalid.
  - It is likely to constitute a violation of the Pharmaceutical Affairs Law.
  - For products manufactured in the changed process, cancel of shipping, recall, or other regulatory actions are to be taken according to risks due to the change.

Perform routinely the change control specified in revised GMP regulation. Confer sufficiently with marketing authorization holder.

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Case 1 : Manufacturing scale change

<Question>

We are planning to increase the manufacturing scale as follows. Is it acceptable to implement the change only by submitting a minor change notification?

- ✓ A new standard charge-in quantity of the starting material of 5 kg is added to the approved charge-in quantity of 1 kg.
- ✓ The standard charge-in quantities and process parameters of other raw materials will be changed proportionately.
- ✓ There will be no change in the operation principle and control items of the manufacturing equipment.

Case 1 : Manufacturing scale change

<Answer>

This scale-up can be implemented by submitting a minor change notification if the change is appropriately controlled and does not affect the quality of the final drug substance.

Case 2 : Control of starting material

<Question>

The product is manufactured with a starting material listed in the JP. Where a staring material is compendial, is the manufacturing site and process not required to be contained in the application form?

Case 2 : Control of starting material

<Answer>

Control of starting substance (raw material)

Manufacturing methods of drug substances should be controlled appropriately whether specifications of starting materials are compendial or not. In addition, manufacturing process with only one reaction process should not be described in principle.

- **PFSB/ELD notification no. 0210001 dated Feb/10/2005 “Guidelines for items to be entered on the application form for marketing approval of drugs based on revised Pharmaceutical Affairs Act, Attachment 1, 1.A.2.1**
- **ICH Q7 good manufacturing practice guide for active pharmaceutical ingredients**
- **ICH Q11 development and manufacture of drug substances (chemical entities and biotechnological / biological entities**

Case 3 : Manufacturing method change -Addition of drying process-

<Question>

In the existing manufacturing process, final purification is performed with crude crystals left moist. We currently hope to add drying operation to dry crude crystals before final purification. Is the change allowed to be treated as a minor change? Specification of the final drug substance is not changed.

Case 3 : Manufacturing method change -Addition of drying process-

<Answer>

The addition of the drying process may have an effect on the impurity profile of the drug substance because drying causes a heat load.

The addition of the drying process requires a partial change approval application because it is necessary to confirm through the review process that the change will have no effect on the quality of the final drug substance including the impurity profile.

Case 4: Manufacturing method change -Blending batches-

<Question>

In case of blending batches, is it required to be presented in an applicant form? Where it is required, is the change treated as a minor change?

Case 4: Manufacturing method change -Blending batches-

<Answer>

Blending batches is required to be presented in the applicant form.

The change is allowed to be treated as a minor change where it is confirmed not to affect the final drug substance.

Request

Where a MF registered item is changed, the procedure related to approval of the drug product is generated along with the procedure on MF registration. Sufficient information sharing and adequate regulatory measures between MF registrants and marketing authorization holder is critical.

Where you have a case in a gray zone, please request simple consultation.

Access on the PMDA website

Home→Reviews and related Services→Consultations

Pharmaceuticals and Medical Devices Agency

Thank you for your kind attention.