



PMDA Consultation Handbook

—For New Drug Development in Japan—

Office of Review Management
Pharmaceuticals and Medical Devices Agency (PMDA)

Published: May 27, 2026

Last updated: September 17, 2026

Contents

1. Purpose of This Handbook.....	4
2. Overview of the Regulatory Framework.....	5
(1) Regulatory System for Medical products.....	5
(2) Scope of “Pharmaceuticals,” “Medical Devices,” “Regenerative Medical Products,” and “In Vitro Diagnostics”.....	5
3. Flow of Marketing Authorization Applications and Reviews, and the Role of PMDA.....	8
4. Contents of Formal Consultations.....	13
(1) Significance of Formal Consultations	13
(2) Legal Position and Timing of Formal Consultation.....	14
(3) PMDA Departments Handling Formal Consultation	15
(4) Process of Formal Consultations	17
(5) Examples of Formal Consultation Topics and Topics outside the scope.....	18
(6) Consultation Types	19
5. Procedures for Formal Consultation	26
(1) Specific Procedures	26
(2) Materials to Prepare	31
(3) Fees	33
(4) Interpretation.....	34
(5) Importance of Identifying a Development Partner in Japan	35
6. Others	37
(1) Support Measures and Special Arrangements for Formal Consultations.....	37
(2) Relevant Websites, Guidance, etc.	38
(3) Revision History	42

List of Abbreviations

BCS	Biopharmaceutics Classification System
Cabinet Order	Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
CTD	Common Technical Document
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practices
GCP	Good Clinical Practice
GPSP	Good Post-marketing Study Practice
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
MHLW	Ministry of Health, Labour and Welfare
PMDA	Pharmaceuticals and Medical Devices Agency
PMD Act	Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
POC	Proof of Concept

1. Purpose of This Handbook

This handbook provides guidance on how to use PMDA consultation services (hereinafter referred to as “consultations”) offered by the Pharmaceuticals and Medical Devices Agency (PMDA), the Japanese regulatory authority, when seeking marketing authorization for pharmaceuticals, including vaccines, in Japan. It is intended to assist developers, including companies and academia, in understanding the scope, process, and procedures of consultations.

This handbook does not comprehensively cover all procedures and applicable rules related to PMDA consultations. For further details, users should refer to the Implementation Guideline for consultations and the relevant PMDA procedural documents. This handbook also identifies related publications that should be read in conjunction with this guidance.

2. Overview of the Regulatory Framework

(1) Regulatory System for Medical products

In Japan, pharmaceuticals, medical devices, regenerative medical products, and in vitro diagnostics are regulated under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the Pharmaceuticals and Medical Devices Act; PMD Act). The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) are the regulatory authorities for pharmaceutical regulations. MHLW is responsible for regulatory policy, while PMDA conducts scientific reviews and provides regulatory advice. In addition, prefectural governments are responsible for certain aspects of pharmaceutical regulation.

Under the authority of the MHLW, PMDA conducts scientific reviews and related regulatory activities. PMDA also provides guidance on the preparation of documents required for clinical trial protocols and marketing authorization applications. These interactions between PMDA and developers are referred to as “clinical trial consultations” or “formal consultations”.

For details of the PMD Act, please refer to the following websites (available in Japanese):

e-Gov Law Search: <https://laws.e-gov.go.jp/law/335AC0000000145> (effective May 21, 2026)

(2) Scope of “Pharmaceuticals,” “Medical Devices,” “Regenerative Medical Products,” and “In Vitro Diagnostics”

“Pharmaceuticals,” “medical devices,” “regenerative medical products,” and “in vitro diagnostics” are defined in Article 2 of the PMD Act. Developers are expected to determine whether the product under development meets these definitions and falls within a scope of the PMD Act.

If it is unclear whether a product falls within the scope of the PMD Act, developers (or, if they do not have a presence in Japan, their Japan-based development partners) should consult the Pharmaceutical Affairs Section of the prefectural government where they are located.

This handbook assumes, in particular, new drugs (e.g., products containing new active ingredients or products that differ from approved products in indications, dosage and administration, or route

of administration).

Definitions under Article 2 of the PMD Act

Pharmaceuticals

The term "pharmaceutical" as used in this Act refers to the following items:

1. items listed in the Japanese Pharmacopoeia
2. items which are intended for use in the diagnosis, treatment, or prevention of disease in humans or animals, and which are not medical appliances or instruments, etc. (referring to medical appliances or instruments, dental materials, medical supplies, sanitary goods, and programs (referring to instructions given to a computer and built so as to obtain a certain result; hereinafter the same applies) and recording media on which programs are recorded; hereinafter the same applies) (excluding quasi-pharmaceutical products and regenerative medical products)
3. items which are intended to affect the structure or functioning of a human or animal's body, and which are not medical appliances or instruments, etc. (excluding quasi-pharmaceutical products, cosmetics, and regenerative medical products)

Medical Devices

The term "medical device" as used in this Act refers to appliances or instruments, etc. which are intended for use in the diagnosis, treatment, or prevention of disease in humans or animals, or intended to affect the structure or functioning of the bodies of humans or animals (excluding regenerative medical products), and which are specified by Cabinet Order

Regenerative Medical Products

The term "regenerative medicine product" used in this Act refers to the following items (excluding quasi-pharmaceutical products and cosmetics), as specified by Cabinet Order*:

1. the following items intended for use in human or animal healthcare which are obtained after culturing or other processes using human or animal cells:
 - (i) reconstruction, repairing, or formation of structure or function of the bodies of humans or animals;
 - (ii) treatment or prevention of disease in humans or animals
2. items intended for use in the treatment of disease in humans or animals which are introduced into cells of humans or animals and contain genes to be expressed in their bodies.

In Vitro Diagnostics

The term "in-vitro diagnostic" as used in this Act refers to pharmaceuticals intended exclusively for use in the diagnosis of diseases, which are not directly used in the bodies of humans or animals.

*** As specified in appended Table 2 of the Cabinet Order (related to Article 1-2 of the Cabinet Order)**

Human Cell-Based Processed Products

1. Human somatic cell-based processed products (excluding those listed in the following item and item 4)
2. Human somatic stem cell-based processed products (excluding those listed in item 4)
3. Human embryonic stem cell-based processed products
4. Human induced pluripotent stem cell-based processed products

Animal Cell-Based Processed Products

1. Animal somatic cell-based processed products (excluding those listed in the following item and item 4)
2. Animal somatic stem cell-based processed products (excluding those listed in item 4)
3. Animal embryonic stem cell-based processed products
4. Animal induced pluripotent stem cell-based processed products

Gene Therapy Products

1. Plasmid vector products
2. Viral vector products
3. Gene expression therapy products (excluding those listed in the preceding two items)

Source: PMD Act; Cabinet Order for Enforcement of the Act

Reference: Japanese Pharmacopoeia

(Japanese) <https://www.pmda.go.jp/rs-std-jp/standards-development/jp/0004.html>

(English) <https://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0010.html>

3. Flow of Marketing Authorization Applications and Reviews, and the Role of PMDA

To launch prescription drugs in Japan, marketing authorization must be obtained from the Minister of Health, Labour and Welfare (Article 14 of the Pharmaceuticals and Medical Devices Act). In order to obtain marketing authorization, in addition to the application form, it is necessary to prepare supporting documents in the Common Technical Document (CTD) format, which is an internationally harmonized format established by the International Council for Harmonisation (ICH), and submit the application using [designated forms and related formats](#) (available in Japanese)(see Table 1). PMDA conducts scientific reviews of the safety, efficacy, and quality of the products for which applications for marketing authorization have been submitted. It also conducts GMP inspections of manufacturing sites, as well as GLP and GCP inspections. The results of the reviews and inspections conducted by PMDA are compiled into review reports and submitted to the Ministry of Health, Labour and Welfare (MHLW). At MHLW, a decision on whether to grant approval is made following deliberation by the Pharmaceutical Affairs Council, which is an advisory body to the Minister of Health, Labour and Welfare.

Table 1: Documents Generally Required for Marketing Authorization Applications of Drugs

Part 1 (Module 1): (Administrative information such as application forms and package inserts)

- (1) Table of contents of application, including Part 1 (Module 1)
- (2) Copy of the marketing authorization application form
- (3) Supporting documents (including statements by the person responsible for overseeing the collection and preparation of application materials, GLP/GCP-related documents, copies of contracts related to joint development, etc.)
- (4) Patent status
- (5) Background of origin or discovery and development history
- (6) Information on use of the drug in foreign countries
- (7) List of products in the same therapeutic class
- (8) Draft package insert
- (9) Documents regarding the nonproprietary name
- (10) Summary of review materials for designation of poisons, deleterious substances, etc.
- (11) Draft basic plan for post-marketing surveillance, etc.
- (12) List of attached documents
- (13) Others

Part 2 (Module 2) and subsequent parts omitted

Source: “Partial amendment to ‘Guidance on Preparation of Attached Documents for Marketing Authorization Application for New Drugs’” (PSEHB/PED Notification No. 0705-4 dated July 5, 2017), <https://www.pmda.go.jp/files/000218990.pdf> (available in Japanese)

PMDA has established an optional consultation system (referred to as “Formal Consultations”) in which discussions are conducted from a scientific perspective regarding the appropriateness of study plans and interpretation of results for various studies conducted during the development stage. Formal Consultations for drugs provided by PMDA is extensive as shown in Table 2 and is subdivided according to development stages and specific issues. Details of the roles, contents, procedures, and related matters of Formal Consultation are explained in Sections 4 and 5 below.

Table 2: Formal Consultations Available for Drug Development

Consultations involving scientific discussions on study plans, study results, and compliance with standards			
	Consultations on individual study plans, etc.		
		Consultations conducted for specific development products	Consultations not conducted for specific development products
	Before initiation of clinical trials	• Consultation on non-clinical safety studies (pharmaceuticals) • Consultation before Phase I clinical trials (pharmaceuticals)	• Consultation on pharmacogenomics and biomarkers • Consultation on registry utilization strategies (pharmaceuticals) • Consultation on database utilization strategies (pharmaceuticals) • Development pipeline meeting (pharmaceuticals)
	After initiation of clinical trials	• Consultation before early Phase II clinical trials (pharmaceuticals) • Consultation before late Phase II clinical trials (pharmaceuticals) • Consultation after Phase II clinical trials (pharmaceuticals) • Consultation before initiating Expanded Access (Compassionate Use) Programs (pharmaceuticals) • Consultation on confirmation of the pediatric drug development program (pharmaceuticals) • Consultation on registry-based study protocols (pharmaceuticals)	
	Before application for marketing authorization	• Pre-application consultation (pharmaceuticals) • Consultation on non-clinical safety studies (related to ICH S1B (R1)) (pharmaceuticals) • Consultation on application data packages • Consultation on preparation for submission of electronic study data (pharmaceuticals) • Prior assessment consultation (pharmaceuticals)	
	Post-marketing	• Consultation on post-marketing clinical trial protocols (pharmaceuticals) • Consultation after post-marketing clinical trials (pharmaceuticals)	

		• Consultation on epidemiological study procedures (pharmaceuticals) • Consultation on epidemiological study protocols (pharmaceuticals) • Consultation on package insert revision (pharmaceuticals)	
	Not limited to a specific development stage	• Consultation on quality (manufacturing, process, and controls) (pharmaceuticals) • Consultation on innovative manufacturing technologies (pharmaceuticals) • Consultation on BCS-based biowaivers (pharmaceuticals) • Additional consultation during clinical development • Post-consultation follow-up (pharmaceuticals) • Consultation on bioequivalence studies (pharmaceuticals)	
	Consultations related to compliance with various standards		
		• Consultation on GCP, GLP, and GPSP (pharmaceuticals) • Consultation on compliance with GCP, GLP, and GPSP (pharmaceuticals) • Consultation on compliance with reliability standards for re-examination (pharmaceuticals) • Consultation on reliability of supporting data for package insert revision (pharmaceuticals) • Consultation on registry reliability for marketing authorization (pharmaceuticals) • Consultation on database reliability for marketing authorization (pharmaceuticals)	-
	Consultations for specific applicants		
		• Regulatory science general consultation	-

	• Regulatory science strategy consultation	
Consultations for prior confirmation of applicability and administrative procedures, etc.		
	• Consultation on eligibility for priority review (pharmaceuticals) • Consultation on eligibility of orphan drugs for priority review (pharmaceuticals) • Consultation on eligibility for conditional approval (pharmaceuticals) • Consultation on eligibility for public knowledge-based application (pharmaceuticals) • Consultation related to the Cartagena Act • SAKIGAKE comprehensive assessment consultation • Procedural consultation for pharmaceuticals • Simplified consultation	-

4. Contents of Formal Consultations

(1) Significance of Formal Consultations

Prior to submission for marketing authorization of drugs, a wide range of studies are conducted from the perspectives of quality, nonclinical, and clinical aspects. The adequacy of these studies and the rationality of data interpretation are critical to the final decision on approval. Therefore, it is extremely important to discuss and reach agreement with regulatory authorities on compliance with regulatory requirements and the scientific validity of study plans at the planning stage, and also to understand any concerns held by the regulatory authorities, in order to facilitate smooth development.

In Formal Consultation, scientific discussions are conducted on solutions to concerns arising during development. Therefore, developers are required to clearly define their concerns and present solutions considered appropriate. If developers carefully conduct prior reviews appropriate to each development stage and identify better solutions through consultation with PMDA, it is expected that predictability will improve and efficiency in drug development will be enhanced. As a result, facilitating access to new drugs will also benefit patients and their families who are waiting for such therapies. Accordingly, PMDA recommends active use of consultations during the development process.

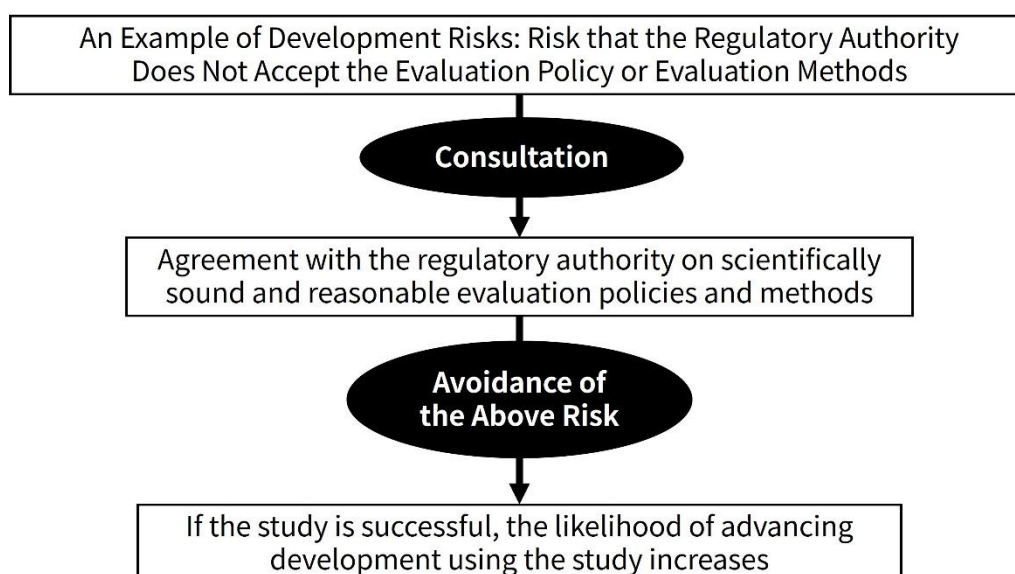


Figure 1: Improvement of development predictability through Formal Consultation

It should be noted that advice and guidance provided by PMDA in consultations do not have legal binding force. Since discussions in consultations are conducted based on the submitted materials and the current scientific knowledge available at the time of consultation, conclusions may change due to newly emerging knowledge, newly obtained study results, or scientific progress. In addition, consultation outcomes do not represent final regulatory decisions; PMDA will reevaluate submitted data during the review for marketing authorization and make the final decision.

(2) Legal Position and Timing of Formal Consultation

Use of consultation is not legally mandatory. The necessity and timing are determined by developers themselves. As shown in Table 2 in Section 3, various types of consultations are available; developers are encouraged to select the most appropriate one depending on the development stage and discussion topics.

Development plans prepared by developers often contain several points that may have a significant impact on drug development and the smooth path to marketing approval. To enhance predictability of development, PMDA and developers frequently discuss these points during Formal Consultation. Examples include whether nonclinical safety data are sufficient before initiating Phase I clinical trials, and whether patient selection criteria and endpoints of confirmatory studies designed to demonstrate the efficacy of the product under development are appropriate. These are illustrative examples; PMDA offers a wide range of consultations. Reference should also be made to typical timing and commonly used consultation types (Figure 2).

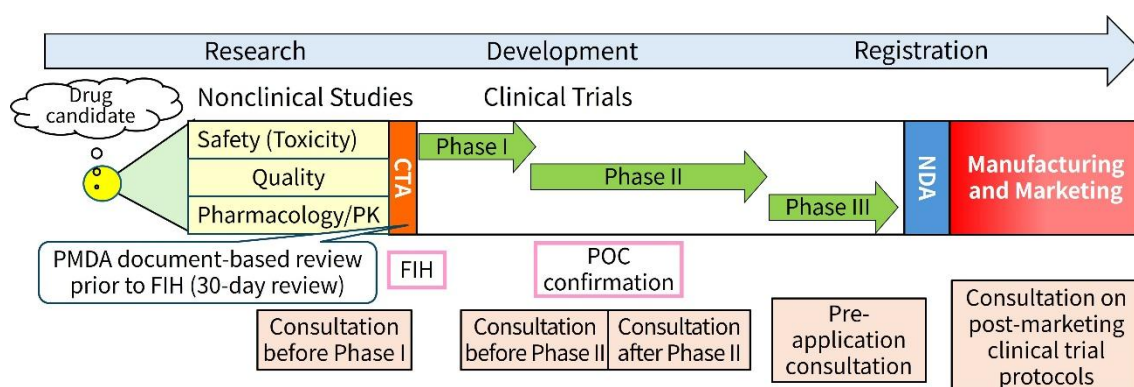


Figure 2: Timing of implementation of consultations

(3) PMDA Departments Handling Formal Consultation

Consultations are handled by review teams responsible for the regulatory review of the relevant drug. The therapeutic areas covered by each team are shown in Table 3. Consultations related to manufacturing facilities and quality control are handled by the Office of Manufacturing Quality for Drugs which is responsible for GMP inspections. Consultations related to data reliability or GLP/GCP inspections are handled by the Office of Non-clinical and clinical compliance.

The department responsible for each consultation is determined by PMDA based on the content provided by the developer when requesting a consultation.

Table 3: Review Categories for New Drugs

Review Categories	
Category 1	Gastrointestinal drugs, dermatologic drugs, immunosuppressive drugs, and others (not classified in other categories)
Category 2	Cardiovascular drugs, antiparkinsonian drugs, anti-Alzheimer's drugs
Category 3-1	Central/peripheral nervous system drugs (excluding anesthetic drugs)
Category 3-2	Anesthetic drugs, sensory organ drugs (excluding drugs for inflammatory diseases), narcotics
Category 4:	Antibacterial drugs, antiviral drugs (excluding AIDS drugs), antifungal drugs, antiprotozoal drugs, anthelmintic drugs
Category 5	Reproductive system drugs, drugs for urogenital system, combination drugs
Category 6-1	Respiratory tract drugs, anti-allergy drugs (excluding dermatologic drugs), sensory organ drugs (drugs for inflammatory diseases)
Category 6-2	Hormone drugs, drugs for metabolic disorders (including diabetes mellitus, osteoporosis, gout, and inborn errors of metabolism)
Oncology drugs	Antineoplastic drugs
AIDS drugs	Anti-HIV drugs
Radiopharmaceuticals	Radiopharmaceuticals
in vivo diagnostics	Contrast agents, reagents for function tests (excluding in vitro diagnostics)
Bio-CMC	Quality of biologics, biosimilars
Vaccines	Vaccines (only those to be used for prevention of infection), antitoxic serum, etc.
Blood products	Blood products

Notes:

1. Drugs for immunosuppression in transplantation, antidotes, drugs for kidney diseases, etc. fall into Category 1.
2. "Gastrointestinal drugs" in Category 1 include drugs for liver diseases and drugs for pancreatic diseases. "Dermatologic drugs" do not include those not intended for external use and those generally intended for systemic absorption.
3. Ophthalmic agents, etc. containing an antibiotic as an active ingredient do not fall into Category 3-1, Category 3-2, and Category 6-1. They fall into Category
4. "Combination drugs" in Category 5 mainly refer to prescription combination drugs with similar formulations. Other combination drugs fall into the respective categories of intended indications.
5. "Anti-allergy drugs" in Category 6-1 are drugs for internal use. Among "anti-allergy drugs," drugs for external use fall into Category 1.
6. "Hormone drugs, drugs for metabolic disorders" in Category 6-2 include anti-diabetic drugs, anti-osteoporosis drugs, hormone drugs other than gastrointestinal hormone, anti-gout drugs, and drugs for inborn errors of metabolism. However, among hormone drugs, drugs for urogenital system fall into Category 5, not Category 6-2.

(4) Process of Formal Consultations

Consultations begin when developers submit documents (“consultation materials”) describing their concerns and proposed solutions with scientific rationale.

PMDA reviews the materials and may request additional explanations for unclear points. Based on the materials and additional information, PMDA prepares its initial feedback and presents them to the developer.

Developers discuss, through direct interaction, any points in PMDA’s initial feedback that they would like to clarify or discuss further. On the other hand, if developers have no concerns regarding PMDA’s initial feedback, such direct interaction may not take place. Direct exchanges between developers and PMDA are typically conducted face-to-face or via online meetings using a Web conferencing system.

Based on these discussions and prior confirmations, PMDA prepares draft meeting minutes. After confirmation by the developer, PMDA finalizes the minutes and the consultation is concluded.

For new drugs, consultations concerning study plans and marketing authorization applications generally take approximately two months from application to meeting and one additional month to finalize the minutes.

Further details are provided in “5 (1) Specific Procedures.”

※Importance of Advance Preparation

It is critically important to share, in advance with PMDA, fundamental background information such as the characteristics of the target disease, existing treatment methods and their clinical challenges, as well as the characteristics and expected benefits of the product under development, in order to ensure that discussions during Formal Consultations are constructive and meaningful. In addition, by preparing explanatory materials for Formal Consultation and organizing discussion points, developers can clarify and concretize their concerns in advance, which is expected to facilitate more

substantive discussions during Formal Consultations.

A “Pre-consultation meeting” is conducted as preparation for Formal Consultation. To ensure that discussions during Formal Consultation are more meaningful, developers are strongly encouraged to utilize pre-consultation meetings. Furthermore, for overseas startups considering drug development in Japan, “General Consultation” is provided at the PMDA Washington, D.C. Office¹, where Japanese pharmaceutical regulations are introduced. Through this “General Consultation,” appropriate consultation types for discussions with review teams at PMDA headquarters in Tokyo are also guided.

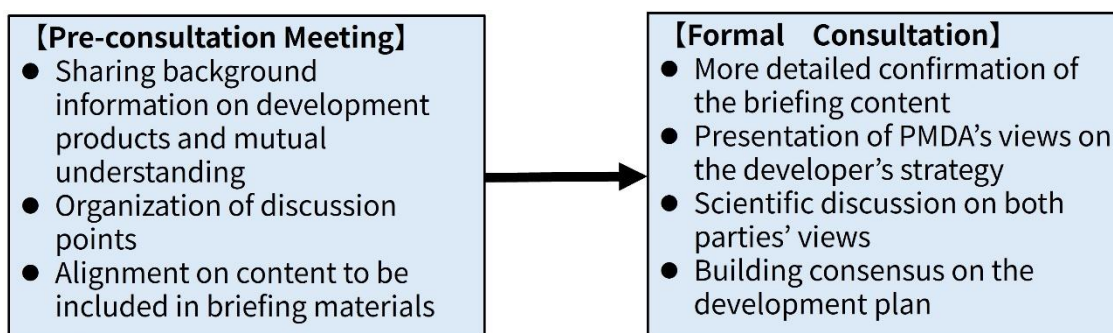


Figure 3: Relationship between Pre-consultation Meeting and Formal Consultation

(5) Examples of Formal Consultation Topics and Topics outside the scope

The points on which developers seek PMDA's views through Formal Consultation ("consultation topics") vary widely depending on the product under development and its stage of development. In addition to the key issues that may have a significant impact on development, as exemplified in Section 4(2), discussions frequently address the appropriateness of including Japan in planned multi-regional clinical trials based on factors such as clinical trial results obtained in countries or regions outside Japan, and assessments of ethnic differences related to the disease being developed for and the efficacy of the product under development.

On the other hand, issues that cannot be handled by PMDA, such as matters not related to regulatory review, are not eligible topics for consultation. These include, for example: compliance with

¹ Established in November 2024. <https://www.pmda.go.jp/english/int-activities/overseas-office/dc/0001.html>

pharmaceutical regulations unrelated to approval review (e.g., import/export procedures, voluntary recalls); matters governed by laws and guidelines other than the Pharmaceuticals and Medical Devices Act (e.g., drug pricing and reimbursement, routine vaccination programs); matters requiring administrative decisions by ministries such as MHLW (e.g., determination of whether a product is classified as a drug, ensuring stable supply); matters related to veterinary drugs; contractual issues between private companies; and recommendations of specific external evaluation bodies.

(6) Consultation Types

Consultations can be broadly categorized into two types:

- ① those involving scientific discussions on study plans, study results, and compliance with applicable standards; and
- ② those involving prior confirmation of applicability for programs such as the priority review system or administrative procedures.

This section describes category①. For category②, please refer to Section 6 (1), which describes such consultations.

Category① can be broadly divided into consultations conducted for specific development products and those conducted without specifying a development product. Furthermore, consultations conducted for specific development products can be subdivided into those related to individual study plans and those related to compliance with applicable standards.

The names of specific consultation types and their respective characteristics are described below.

<Consultation for specific development products>

a. Items Related to Individual Study Plans

Consultation types are subdivided by development stage (before initiation of clinical trials, after initiation of clinical trials, before application for marketing authorization, and post-marketing) and by subject of discussion (clinical, nonclinical, and quality). Here, key points to be considered at each development stage and appropriate consultation types are presented.

a-1. Before Initiation of Clinical Trials

Before initiating clinical trials in humans for the first time, it is critically important to ensure that the safety of the product under development has been appropriately confirmed through nonclinical studies. In addition, clinical trial protocols must be appropriately designed, including measures to ensure the safety of trial participants (e.g., dose setting, dose-escalation methods, evaluation periods for adverse events, and key adverse events requiring focused monitoring), as well as appropriate methods for pharmacokinetic evaluation.

Consultation on non-clinical safety studies	Consultation on the appropriateness of study plans and evaluation of results for nonclinical studies (pharmacokinetics, pharmacology, toxicity)
Consultation before Phase I clinical trials	Consultation on the appropriateness of non-clinical study results as well as the design of Phase I clinical trials of drugs, including starting dose, dose-escalation scheme, and safety monitoring

a-2. After Initiation of Clinical Trials

Based on the results of completed Phase I clinical trials already conducted, development proceeds to a stage where efficacy and safety in patients are further evaluated. Depending on the objectives of the clinical trials, clinical trials are broadly classified into exploratory studies, which examine appropriate dosage/regimens (e.g., dose-response and dosing interval) and estimate efficacy and safety, and confirmatory studies, which verify clinically meaningful efficacy and acceptable safety. While the discussion points differ depending on the objectives of each study, a common feature is that PMDA and developers discuss, from a scientific perspective, whether the clinical trials design can achieve its objectives while ensuring the safety of participants. In addition, there are consultations dedicated to specific purposes, such as those related to expanded access programs, and pediatric development plans and registry-based studies.

Consultation before early Phase II clinical trials	Consultation on appropriateness of study design for dose-response exploration
Consultation before late Phase II clinical trials	Consultation on appropriateness of study design for determining recommended clinical dose
Consultation after Phase II clinical trials	Consultation on appropriateness of the design of confirmatory studies

Consultation before initiating Expanded Access (Compassionate Use) Programs	Consultation on plans equivalent to Expanded Access Program / Compassionate use
Consultation on confirmation of the pediatric drug development program	Consultation on clinical trial plans for the development of the same indication in pediatric patients while a drug for adult patients is under development
Consultation on registry-based study protocols	Consultation on appropriateness of using registry data to evaluate the efficacy and safety of the product under development

a-3. Before Application for Marketing Authorization

In order to obtain marketing authorization for drugs, it is necessary that scientific evaluations of the quality, efficacy, and safety of the product under development are appropriately conducted. The primary objective of consultations at this stage is to confirm, based on the results of various studies conducted during the development process, whether there are any critical deficiencies in information necessary for obtaining marketing authorization. Therefore, rather than conducting a comprehensive review of the details of application materials, discussions are focused on major issues related to whether a marketing authorization application can be submitted. In addition to these, there are also consultation types specifically designed for prior evaluation of materials planned to be submitted for marketing authorization.

Pre-application consultation	Consultation on the adequacy of clinical trial data that forms the basis of the application for marketing authorization
Consultation on non-clinical safety studies (related to ICH S1B (R1))	Consultation focusing on the appropriateness of carcinogenicity assessment in nonclinical studies based on the ICH S1B(R1) Guideline
Consultation on application data packages	Consultation focusing on the adequacy of application materials, as well as the clinical trial design that serve as key evidence supporting the efficacy and safety of the product, particularly for drugs deemed to have high medical necessity by the national authorities or developed through clinical trials planned and conducted by physicians (investigator-initiated clinical trials)
Consultation on preparation for	Consultation on compliance with submission rules, submission methods, and applicability for exemption regarding electronic

submission of electronic study data	clinical trial data submitted at the time of application
Prior assessment consultation	Consultation involving prior evaluation of materials planned for submission for marketing authorization (results of various studies related to quality, nonclinical, and clinical aspects) in order to identify issues and organize challenges; corresponding to a so-called rolling submission approach

a-4. Post-marketing

After a drug has been approved, there is a system called “re-examination,” in which information from use in clinical practice is collected to confirm the appropriateness of the evaluations of efficacy and safety at the time of approval. Consultation types are provided to discuss plans for surveys and studies conducted for such re-examination.

Consultation on post-marketing clinical trial protocols	Consultation on the appropriateness of plans for surveys and clinical trials conducted post-marketing
Consultation after post-marketing clinical trials	Consultation on the adequacy of materials for re-examination applications based on post-marketing surveys and clinical trials
Consultation on epidemiological study	Consultation on the appropriateness of procedures and plans for post-marketing surveys conducted using epidemiological methods
Consultation on package insert revision	Consultation on whether revisions are acceptable for parts of the package insert (e.g., precautions related to indications or dosage and administration, and clinical study results) based on post-marketing clinical data, where such revisions do not require an application for marketing authorization

a-5. Not Limited to a Specific Development Stage

These consultation types provide scientific discussions across development stages, including concerns related to ensuring product quality and the appropriateness of evaluation methods associated with formulation changes during development.

Consultation on quality (manufacturing, process, and controls)	Consultation on the appropriateness of specifications and test methods (e.g., sustained-release formulations) and comparability in cases of manufacturing changes for biopharmaceuticals
--	--

Consultation on innovative manufacturing technologies	Consultation on development strategies and quality management strategies at the stage of introducing innovative manufacturing technologies aimed at future commercial production
Consultation on BCS-based biowaivers	Consultation on the appropriateness of approaches to confirm bioequivalence without conducting bioequivalence studies in humans
Additional consultation during clinical development	Consultation conducted when new data evaluation becomes necessary for issues that could not be resolved in previous Consultations
Post-consultation follow-up	Consultation conducted for issues not resolved in previous Consultation that do not require new data evaluation
Consultation on bioequivalence studies	Consultation on the appropriateness of bioequivalence study plans (e.g., following formulation changes) and other consultations involving data evaluation that do not fall under other categories

※ The drug safety consultation introduced in “a-1. Before initiation of clinical trials” may, depending on the discussion content, also be conducted across development stages.

b. Compliance with Various Standards

Data from studies conducted for marketing authorization applications and post-marketing surveys must be ensured to be reliable, and standards for ensuring such reliability (e.g., GLP, GCP, GPSP) have been established.

Accordingly, PMDA provides the following consultation types to confirm compliance with such reliability standards.

Consultation on GCP, GLP, and GPSP	Consultation on compliance with standards for clinical trials (GCP), nonclinical studies (GLP), and post-marketing surveys (GPSP)
Consultation on compliance with GCP, GLP, and GPSP	Consultation to discuss compliance of application data with reliability standards, targeting drugs subject to priority review or those that have undergone prior assessment consultation
Consultation on compliance with reliability standards for re-examination	Consultation to confirm compliance with reliability standards for materials used in re-examination applications
Consultation on reliability of supporting data for package insert revision	Consultation to confirm compliance of clinical trials data supporting revisions with reliability standards

Consultation on registry/database reliability for marketing authorization	Consultation on the approach to ensuring the reliability of specific registries/databases to be used for marketing authorization applications
---	---

<Consultations without specifying a particular development product>

Consultation types are available to support scientific discussions on development approaches without specifying a particular development product.

Consultation on pharmacogenomics and biomarkers	Consultation on general approaches to the use of biomarkers and evaluation of data suitability
Consultation on registry utilization strategies	Consultation for registry holders (e.g., academia) on general approaches to improving quality and ensuring reliability of medical registries
Consultation on database utilization strategies	Consultation for database operators on general approaches to improving quality and ensuring reliability of medical databases
Development pipeline meeting	Consultation in which developers and PMDA share and freely discuss characteristics and evaluation approaches of development pipelines

Regardless of the consultation type used, the use of “pre-consultation meetings,” in which discussion points are organized and the adequacy of supporting materials is confirmed in advance, is encouraged in order to conduct meaningful consultation.

※Consultation for specific applicants

For new drug candidates being developed by academia or venture/startup companies without prior experience in obtaining marketing authorization, consultation support by personnel with experience in pharmaceutical development within pharmaceutical companies is also provided.

- Regulatory Science General Consultation:
Consultation providing an overview of PMDA consultation types and introduces guidance considered useful for general drug development
- Regulatory Science Strategy Consultation:
Consultation that conducts scientific discussions, based on data evaluation, regarding

development-related concerns within the scope described below

The scope of this consultation covers study plans and related matters from the stage after selection of development candidates (i.e., after completion of seed discovery) up to before obtaining proof-of-concept (POC) suggestive of clinical usefulness. Accordingly, consultations on matters such as the design of confirmatory studies intended to demonstrate efficacy, or the adequacy of clinical data packages necessary to establish the rationale for marketing authorization applications, fall outside the scope of Regulatory Science Strategy Consultation.

Developers are advised to utilize the “pre-consultation meeting” available under Regulatory Science Strategy Consultation to identify appropriate consultation type.

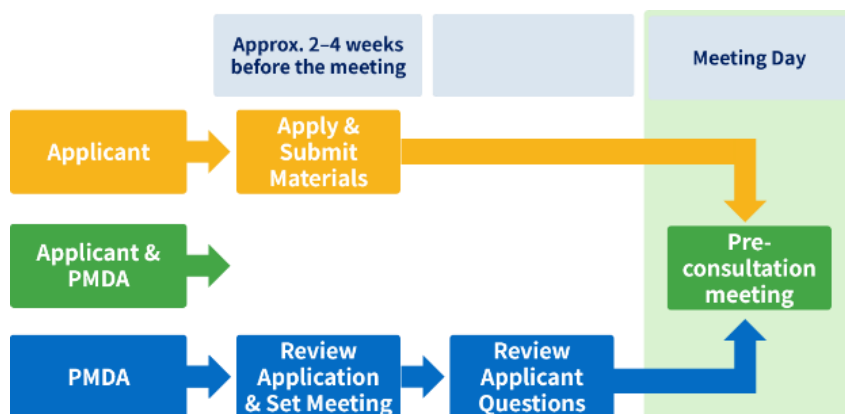
5. Procedures for Formal Consultation

(1) Specific Procedures

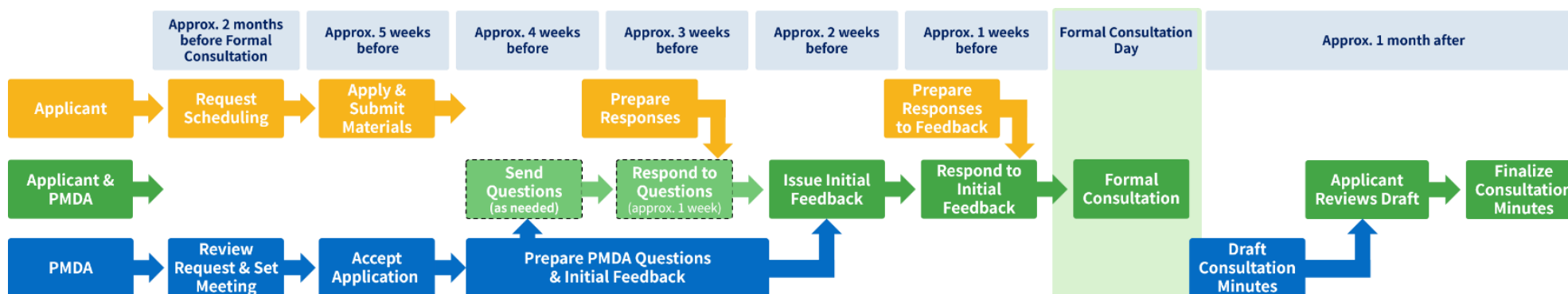
This section outlines the procedures for clinical trial consultations for new drugs (pre-consultation meetings and formal consultations).

An overview is provided in Figure 4. When submitting an application, applicants should follow the procedures by referring to the PMDA website and [the Implementation Guidelines for pre-consultation meetings and formal consultations](#) (available in Japanese).

<Pre-consultation Meeting>



<Formal Consultation>



Note: The schedule shown is approximate and may vary.

Figure 4: Procedures for Pre-consultation Meetings and Formal Consultations (Overview)

A. Pre-consultation Meeting

A pre-consultation meeting is conducted to organize the key issues of consultation topics and to confirm the contents of materials necessary for examining the consultation topics, to facilitate efficient formal consultations. No minutes are prepared for pre-consultation meetings. Each meeting is conducted within 20 minutes. The meeting is free of charge.

A-1. Submission of Questions and Consultation Materials

The applicant fills in the required information (applicant name/contact information, investigational product code/generic name, questions, preferred meeting date, etc.) in the Pre-consultation Question Application Form and submits it to PMDA by e-mail.

A-2. Notification of Schedule, etc.

PMDA will inform the applicant of the pre-consultation meeting date and other details after the scheduling arrangements.

A-3. Examination of Questions

PMDA examines in detail the consultation materials and the questions submitted by the applicant.

A-4. Conduct of Pre-consultation Meeting

The applicant and PMDA conduct a pre-consultation meeting. The meeting may be conducted face-to-face, via online meeting, or a combination of both.

B. Formal Consultation

A formal consultation is conducted to provide PMDA's scientific views on the consultation topics submitted by the applicant. Each consultation session is conducted within 120 minutes. A fee is required. After the pre-consultation meeting, applicants should follow the instructions of the relevant PMDA office. They should refer to the procedures for clinical trial consultations for new drugs and apply for an appropriate consultation category.

B-1. Request for Scheduling

The applicant fills in the required information (applicant name/contact information, outline of the investigational drug, outline of consultation content, preferred date and time for formal

consultation, etc.) in the Request Form for Scheduling and submits it to PMDA by e-mail. As a general rule, requests must be submitted at the beginning of the month, approximately two months before the month in which the consultation will take place. Please confirm the designated acceptance date and time for submission of the Request Form for Scheduling on the PMDA website.

B-2. Notification of Schedule, etc.

PMDA arranges the schedule with the applicant and, in principle, sends a notification of formal consultation schedule to the applicant within 5 business days after receiving the Request Form for Scheduling.

B-3. Fee Payment and Application

The applicant shall pay the fee by the earlier of the following dates:

- 15 business days from the day following the schedule notification in B-2, or
- the consultation material submission date.

The applicant then submits the Application Form for Formal Consultation for Drugs to PMDA, attaching a copy that confirms the payment details such as the transfer receipt.

B-4. Submission of Consultation Materials

The applicant submits consultation materials to PMDA by the date specified by PMDA (in principle, 3:00 p.m. JST on the first business day five weeks prior to the formal consultation date). Refer to “Section 5(2) Materials to Prepare” for required materials.

B-5. Notification of Formal Consultation Schedule

PMDA informs the applicant of the formal consultation schedule, including:

- the date of sending PMDA questions,
- the deadline for responses,
- the date of sending PMDA initial feedback,
- the deadline for responses, and
- the meeting date.

B-6. Preparation and Sending of PMDA Questions

PMDA’s review team reviews the consultation materials in detail. PMDA requests clarification from the applicant regarding unclear points in the consultation materials.

B-7. Preparation and Issuance of PMDA Initial Feedback

The responsible review office of PMDA prepares its opinions on the consultation topics and presents them to the applicant no later than 4 days before the formal consultation date. If agreed by both the applicant and PMDA, the consultation may be concluded with written advice without holding a meeting.

B-8. Conduct of Formal Consultation

The applicant and PMDA conduct the formal consultation. The meeting may be conducted face-to-face, via online meeting, or a combination of both.

B-9. Preparation of Consultation Minutes

PMDA prepares the consultation minutes, and the applicant confirms its contents.

B-10. Finalization of Consultation Minutes

PMDA finalizes the consultation minutes approximately one month after the formal consultation and sends it to the applicant.

C. Submission Address for Application Forms, etc.

Review Management Division, Office of Review Management,
Pharmaceuticals and Medical Devices Agency
shinyaku-uketsuke@pmda.go.jp

D. Others

For specific procedures of Regulatory Science Strategy Consultation, please refer to [the PMDA website](#).

(2) Materials to Prepare

<Formal Consultation>

A formal consultation is an important opportunity to obtain substantive and specific advice on development issues within a limited time. In particular, at stages where evaluation of the efficacy and safety of the investigational drug has progressed and concrete development strategies toward marketing authorization application are being considered, detailed and accurate information becomes even more important. Therefore, information based on objective and scientific evidence is indispensable for developers and regulatory authorities to share a common understanding, clarify issues, and engage in constructive discussions. This includes the background of the consultation topics, characteristics of the product under development, comparison with existing treatments, and development progress. If necessary materials are not provided, the advice may lack specificity or result in discrepancies in understanding, potentially leading to the need for re-consultation or delays in the development schedule. On the other hand, if sufficient materials are provided, concrete and practical insights can be obtained regarding compliance with regulatory requirements and future development strategies. Thus, preparing appropriate materials is important to maximize the use of formal consultations, make accurate development decisions, and establish a foundation that supports early and efficient product development.

<Examples of Materials to Prepare>

- ① Consultation topics (please clearly identify concerns)
- ① Current treatment options for the disease (description of currently used treatments, drugs, and similar drugs)
- ② Issues with existing therapies and the anticipated advantages of the investigational drug (e.g., adverse effects and variability in efficacy of existing therapies, and how these can be improved by the development product)
- ③ Package inserts from the US and Europe (with Japanese translations)
- ④ Development history diagram (including formulation design, timelines of nonclinical studies and domestic/overseas clinical trials, planned timing of consultations in Japan and abroad, and planned timing of marketing application)
- ⑤ Clinical trial data package (clearly indicate whether overseas data are used and whether there is

a bridging strategy)

- ⑥ Latest Investigator's Brochure (including mechanism of action, safety, and the latest nonclinical and clinical data)
- ⑦ Draft clinical trial protocol (in some cases, an outline consisting of several pages may be acceptable), and draft informed consent document
- ⑧ List of clinical trials
- ⑨ List of toxicity studies
- ⑩ Relevant publications
- ⑪ Previous formal consultation minutes (if applicable)

<Pre-consultation Meeting>

The primary purpose of pre-consultation meetings is to organize the key issues of consultation topics and confirm submitted materials (preliminary arrangement). This helps ensure that formal consultations are conducted smoothly and meaningfully. In formal consultations, since substantive advice must be obtained within a limited time, the submitted materials need to be sufficiently organized. Therefore, at the pre-consultation meeting stage, it is important to clarify the structure of consultation materials and the key discussion points for formal consultation, and to share the preparation status with PMDA. This enables companies and PMDA to share an understanding of the current status of development and related issues, allowing more accurate preparation for formal consultations. At this stage, not all materials need to be complete; however, if the overall picture cannot be grasped, it may be difficult to share key discussion points, which could hinder the conduct of formal consultations. Pre-consultation meetings are not merely administrative confirmations but are part of the preparation to effectively utilize formal consultations. Therefore, please prepare in advance an overview and structure of materials to be submitted for formal consultation, schedule, responses to previous comments, and proposed consultation topics.

<Examples of materials and information for pre-consultation meetings>

- ① Proposed consultation topics for formal consultation (clearly describe matters to be discussed with PMDA and matters to be confirmed with PMDA)
- ② History of previous consultations and status of responses to past PMDA comments

- ③ List of materials planned for submission at formal consultation (draft protocol, Investigator's Brochure, clinical trial data, references, etc.)
- ④ Preferred timing for formal consultation

<Points to Consider When Using Pre-consultation Meetings>

By clarifying the background and key discussion points enables effective exchange of opinions. Summarize the consultation contents, including overview and key discussion points, in logical text, and use figures or tables as necessary.

<Notes>

This handbook presents examples of typical materials to be prepared for formal consultations. However, depending on each consultation category, such as safety-related consultations or quality management-related consultations, the required documentation and the content expected in the consultation materials may differ. For details on each consultation category, please refer to the PMDA's "Implementation Guidelines for Formal Consultation and Investigation of Verification of Certifications, etc." (available in Japanese):

<https://www.pmda.go.jp/files/000219237.pdf>

(3) Fees

In PMDA's consultation services, fees vary depending on the consultation type. In general, pre-consultation meetings involving clarification of consultation topics for the forthcoming formal consultation are free of charge, while formal consultations involving data evaluation or provision of official opinions are fee-based. The fees for each consultation type may be subject to change; therefore, please confirm the information available at the time of application on the official PMDA website.

For specific procedures for formal consultations, including fee payment, please refer to Section 5(1).

<Where to Confirm Fees for Formal Consultation>

PMDA website > Reviews and Related Services > Review Fees and Fees for Formal Consultations, etc.

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

Fees:

Section “1.(2) Fees for Formal Consultations, Safety Study Inspections, Export Certification Confirmation, etc.”

Payment procedures and related information:

Sections “2. Payment of Fees,” “3. How to Complete the Payment Form,” “4. Handling of Refunds,” and “5. Consumption Tax and Invoices”

Contact point:

Administration Division I, Office of Review Administration (iyaku-tetsuzuki@pmda.go.jp, [template](#) (available in Japanese))

For refunds:

Review Management Division, Office of Review Management, (shinyaku-uketsuke@pmda.go.jp, [template for refunds specific to formal consultations](#) (available in Japanese))

<Notes>

- Direct payment of fees from outside Japan is also possible; however, as remittance procedures and confirmation may take time, please contact the following contact point in advance.

Contact point for payment of formal consultation fees from outside Japan:

shinyaku-uketsuke@pmda.go.jp

- Since the preparation period required and application destination differ depending on the consultation type, be sure to confirm the latest Implementation Guideline when applying for formal consultations.

(4) Interpretation

Communications related to application procedures, such as applications for formal consultations, are in principle conducted in Japanese. Although some forms, such as application forms, include item names in both English and Japanese, English translations of documents such as the Implementation Guidelines are provided for reference only; therefore, please note that they are provided for reference only.

In pre-consultation meetings and formal consultations, some communication in English may be possible; however, as the primary language used by PMDA is Japanese, applicants who invite overseas participants are recommended to arrange for professional interpretation services (preferably simultaneous interpretation) with expertise in the pharmaceutical field. While consecutive interpretation services may also be used, please note that they may require approximately twice as much time for communication, which could result in insufficient discussion or inadequate depth of understanding. In addition, as full-scale drug development in Japan is expected to commence after the formal consultation, it is recommended to refer to Section 5(5) and identify in advance a development partner in Japan who is familiar with handling formal consultations.

(5) Importance of Identifying a Development Partner in Japan

In order to market pharmaceuticals in Japan, it is necessary to comply with the “Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices” (commonly referred to as the PMD Act), which regulates the manufacturing, distribution, and other aspects of pharmaceuticals. The PMD Act includes a wide range of regulations. These includes requirement for manufacturing, sale, import, and pharmacy operations of pharmaceuticals, as well as reliability standards for marketing authorization application materials and the collection, analysis, and reporting of post-marketing safety information.

During drug development, there are various requirements that developers must comply with, including standards to ensure the reliability of toxicity and clinical trial results, notifications to ensure the quality of investigational products, and guidelines on evaluation methods. Furthermore, when conducting clinical trials, collaboration with medical institutions in Japan is required.

Drug development involves collaboration and cooperation among various stakeholders, and it is important to establish an optimal development framework at each stage. Therefore, when conducting drug development in Japan, it is highly beneficial to identify a partner who is familiar with Japanese regulations and business practices and can work closely with the developer (hereinafter referred to as a “development partner”).

At present, PMDA does not act as such a development partner or introduce development partners. Please consider utilizing public programs such as MEDISO, which provide various supports to healthcare ventures as projects commissioned by the Ministry of Health, Labour and Welfare (MHLW), as well as private consultation services.

6. Others

(1) Support Measures and Special Arrangements for Formal Consultations

In Japan, various support measures have been established with the aim of addressing drug lag/drug loss and promoting the development of drugs with high medical needs. This section provides an overview of these support measures for startup companies, as well as pharmaceutical companies and academic researchers considering drug development in Japan. These measures include special arrangements related to regulatory review and formal consultations. Whether a product is eligible for these support measures is determined on a case-by-case basis; therefore, prior consultation and coordination with PMDA and other relevant organizations is recommended.

<Priority review>

For certain drugs that address significant unmet medical needs (i.e., drugs that fall under the following five categories), a priority review system has been established in which reviews are conducted preferentially compared to other drugs. For details on each category, please refer to the relevant MHLW notifications indicated in parentheses. The target review period for drugs designated by MHLW as eligible for priority review is nine months (normally twelve months).

- ① Orphan drugs designated as eligible for priority review (PSEHB/PED Notification No. 0116-1 and related Notification dated January 16, 2024)
- ② Drugs designated under the former SAKIGAKE Designation System (pilot-based: no longer open for new designations)
- ③ Drugs designated under the current SAKIGAKE Designation System (PSEHB/PED Notification No. 1222-6 dated December 22, 2023)
- ④ Drugs designated for specific use (PSEHB/PED Notification No. 0831-5 dated August 31, 2020)
- ⑤ Other drugs recognized as having significant clinical value (PSEHB/PED Notification No. 0116-2 and related Notification dated January 16, 2024)

In addition, the following categories are also subject to priority review:

- ⑥ drugs subject to the former Conditional Approval System (PSEHB/PED Notification No. 1023-2 dated October 23, 2024)
- ⑦ drugs subject to the current Conditional Approval System (PSEHB/PED Notification No. 0227-

6 dated February 27, 2026).

The designation procedures for categories ① through ⑦ are administered by MHLW.

PMDA provides consultation services to discuss eligibility for categories ①, ⑤, and ⑦ (i.e., Consultation on eligibility for priority review, Consultation on eligibility for conditional approval). Those considering designation are encouraged to use these services. In addition, drugs designated under categories ① to ④ are eligible for special arrangements related to PMDA formal consultations. For example, requests for formal consultations can be submitted outside the designated application acceptance periods specified by PMDA. The special arrangements available vary depending on the designation system.

<SAKIGAKE pharmaceutical products>

For drugs designated as SAKIGAKE pharmaceutical products (including those designated under the former SAKIGAKE Designation System), a dedicated PMDA liaison (“concierge”) is assigned, and PMDA coordinates schedules among relevant stakeholders through this concierge and provides support to facilitate efficient development, in addition to the support measures described above. Furthermore, to facilitate smooth regulatory review of such products, PMDA offers the SAKIGAKE comprehensive assessment consultation. Under this framework, planned application materials are evaluated in advance prior to submission in order to identify potential issues and organize key discussion points. Sponsors of SAKIGAKE pharmaceutical products are encouraged to use this consultation at an appropriate stage of development.

(2) Relevant Websites, Guidance, etc.

MHLW: (Japanese) <https://www.mhlw.go.jp/index.html>

(English) <https://www.mhlw.go.jp/stf/english/index.html>

PMDA: (Japanese) <https://www.pmda.go.jp>

(English) <https://www.pmda.go.jp/english/index.html>

For Industry – for development in Japan (English only):

<https://www.pmda.go.jp/english/int-activities/industry/0001.html>

URLs provided in each section are listed again below. In addition, other URLs that may be helpful are as follows.

Overview	Japanese page URL	English page URL
Section 2: Overview of the Regulatory Framework		
Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices	https://laws.e-gov.go.jp/law/335AC0000000145 (Enforced on May 21, 2026)	(Reference English translations of some laws and regulations are available in the Japan Law Translation database. However, as these translations may not reflect the latest amendments, links are omitted in this document. Please refer to the Japanese original for accurate content.)
Japanese Pharmacopoeia	https://www.pmda.go.jp/rs-std-jp/standards-development/jp/0004.html	https://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/0010.html
Section 3: Flow of Marketing Authorization Application and Review, and the Role of PMDA		
Administrative notifications on preparation of application dossiers	Partial amendment to “Notification Concerning the Marketing Authorization Application of Drugs” (Notification No. 1009-1 dated October 9, 2024): https://www.pmda.go.jp/files/000271440.pdf	https://www.pmda.go.jp/files/000278032.pdf
	Partial amendment to “Points to Note for Marketing Authorization Applications for Drugs” (Notification No. 1009-1 dated October 9, 2024): https://www.pmda.go.jp/files/000271441.pdf	https://www.pmda.go.jp/files/000278033.pdf
	Partial amendment to “Guidance on Preparation of Attached Documents for Marketing Authorization Application for New Drugs” (Notification No. 0705-4 dated July 5, 2017): https://www.pmda.go.jp/files/000218990.pdf	
Role of PMDA	Flowchart of review services: https://www.pmda.go.jp/review-services/drug-reviews/0001.html	https://www.pmda.go.jp/english/review-services/reviews/0001.html

Overview	Japanese page URL	English page URL
Section 4: Contents of Formal Consultations		
Overview of Formal Consultation	Formal Consultation: https://www.pmda.go.jp/review-services/f2f-pre/0001.html	https://www.pmda.go.jp/english/review-services/consultations/0002.html
	Implementation Guideline: https://www.pmda.go.jp/files/000219237.pdf	https://www.pmda.go.jp/files/000279410.pdf
	Pre-consultation meeting: https://www.pmda.go.jp/review-services/f2f-pre/consultations/0001.html Implementation Guideline (see Appendix 16): https://www.pmda.go.jp/files/000219237.pdf	(For the English overview, please use your browser language settings) https://www.pmda.go.jp/files/000279410.pdf
PMDA Washington D.C. Office	Overview of the Office: https://www.pmda.go.jp/int-activities/overseas-office/dc/0001.html General Consultation (English only): https://www.pmda.go.jp/english/int-activities/overseas-office/dc/0002.html	https://www.pmda.go.jp/english/int-activities/overseas-office/dc/0001.html https://www.pmda.go.jp/english/int-activities/overseas-office/dc/0002.html
Evaluation guidance, etc.	https://www.pmda.go.jp/rs-std-jp/standards-development/guidance-guideline/0001.html	https://www.pmda.go.jp/english/review-services/regulatory-info/0002.html
Early consideration	https://www.pmda.go.jp/rs-std-jp/standards-development/guidance-guideline/0003.html	https://www.pmda.go.jp/english/review-services/regulatory-info/0005.html
Review reports, etc.	(Please search via the package insert search system) https://www.pmda.go.jp/PmdaSearch/iyakuSearch/	English review reports (partial): https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html
Package inserts	(Please search via the package insert search system) https://www.pmda.go.jp/PmdaSearch/iyakuSearch/	(The package insert search system does not support browser language switching)
Section 5: Procedures for Formal Consultation		

Overview	Japanese page URL	English page URL
Procedures for Formal Consultation, etc.	(Please select the consultation service from the URL below and check the displayed procedure) https://www.pmda.go.jp/review-services/f2f-pre/consultations/0017.html	(Please use your browser language settings for English translation)
Section 6: Others		
Overview of key designations and early access systems	Orphan drug designation: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000068484.html SAKIGAKE designation system: https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryoku/iyakuhin/tp150514-01_00001.html https://www.pmda.go.jp/review-services/drug-reviews/0002.html Drugs Designated for Specific Use: https://www.mhlw.go.jp/stf/newpage_12717.html Conditional Approval System: https://www.pmda.go.jp/review-services/drug-reviews/0045.html	Orphan drug designation: https://www.pmda.go.jp/english/review-services/reviews/0011.html (For other information, please use your browser language settings for English translation)
Drug development support programs	National Institutes of Biomedical Innovation, Health and Nutrition, Department of Strategy and Research Support: https://www.nibn.go.jp/activities/promote/index.html	https://www.nibn.go.jp/en/activities/research-support.html
	MEDISO (Medical Innovation Support Office): https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000186912_00006.html https://mediso.mhlw.go.jp/	https://mediso.mhlw.go.jp/en/?en=1

(3) Revision History

September 17, 2026:	Minor updates to text
June 8, 2026:	Minor updates to text
May 27, 2026:	Original publication

