NEWSLETTER

NISHIMURA & ASAHI

# 2025 Amendments to Pharmaceutical and Medical Device Act of Japan

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## 1. Introduction

This past September marked the five-year anniversary of the enforcement of the major amendments to the Pharmaceutical and Medical Device Act[1] (the "**2019 Amendments**"),[2] which were called the "Great Amendments in the Reiwa-Era," on September 1, 2020. In one of the supplementary provisions of the 2019 Amendments, it was provided that each law after the 2019 Amendments would be reviewed approximately five years after enforcement, and necessary measures would be taken based on the results of that review.[3] Based on this provision, discussions reflecting the status of enforcement had been underway since April 2024; as a result, on May 14, 2025, the 2025 amendments to the PMD Act (the "**2025 Amendments**") were enacted.[4] This newsletter provides an outline of the 2025 Amendments, focusing on the major points that will have an impact on pharmaceutical company practices.

The 2025 Amendments cover a wide range of revised items, including minor ones. However, according to the explanation by the Ministry of Health, Labour and Welfare ("**MHLW**"), they can be broadly classified into the following four categories. This newsletter will also provide explanations according to these classifications.

1. **Strengthening Assurance Framework for Pharmaceutical Quality and Safety**
2. **Enhancing Stable Supply Systems for Prescription Drugs**
3. **Creating Environment to Accelerate Drug Discovery**
4. **Strengthening Pharmacy Functions to Ensure Proper Access to Medicines**

## 2.1 Strengthening Assurance Framework for Pharmaceutical Quality and Safety (Effective by May 2027)

In the 2019 Amendments, various measures were introduced to ensure the quality and safety of pharmaceuticals,[5] including obligating marketing authorization holders and manufacturers of pharmaceuticals to establish regulatory compliance systems and introducing an administrative surcharge payment order for false or exaggerated advertising. However, since the 2019 Amendments, inappropriate manufacturing cases, mainly among generic drug manufacturers, have continued to occur. Responding to these issues, the following amendments have been incorporated into the 2025 Amendments to further strengthen governance regarding quality assurance and safety management at marketing authorization holders and pharmaceutical

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1 The Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145 of August 10, 1960, as amended) (the "**PMD Act**").

2 Act No. 63 of 2019.

3 Supplementary Provisions, Article 14 of Act No. 63 of 2019.

4 Act No. 37 of 2025.

5 Quasi-drugs, cosmetics, medical devices, and regenerative medicine products are also included.

manufacturers.

**(a) Order to Change Responsible Officers (*Sekinin-Yakuin*)**

In the 2019 Amendments, the position of an officer responsible for pharmaceutical affairs (*sekinin-yakuin*) was newly introduced, and in the 2025 Amendments, a system has been introduced whereby the Minister of Health, Labour and Welfare can order a marketing authorization holder or a manufacturer of pharmaceuticals to change its responsible officer.[6] This system was considered for introduction in the 2019 Amendments but was deferred at that time; however, due to the continued occurrence of inappropriate manufacturing cases after the 2019 Amendments, it has now been introduced in the 2025 Amendments.

Since orders to change responsible officers, once issued, have a significant impact on company governance, it is said that their application will be handled with caution. For example, if a responsible officer discovers wrongdoing and responds appropriately without concealing it, or if improvements in business operations can be expected through an order to improve business operations or administrative guidance, a change order will not be issued. This view has been presented by the Director of the Pharmaceutical Safety Bureau of the MHLW.[7] In this regard, the MHLW is expected to announce specific guidelines regarding the issuance of orders to change responsible officers. Therefore, it will be important to closely monitor upcoming notifications and guidelines.

**(b) Establishing Legal Grounds for Quality Assurance Managers and Pharmaceutical Safety Control Managers**

Previously, pharmaceutical marketing authorization holders were required to appoint a Marketing Director (*sōseki*), a Quality Assurance Manager (*hinseki*), and a Safety Control Manager (*anseki*)—collectively known as the "three key regulatory roles" (*sanyaku*). However, only the position of Marketing Director had a legal basis under the PMD Act, while the position of Quality Assurance Manager was provided by the GQP Ordinance[8] and that of Safety Control Manager by the GVP Ordinance.[9] With the 2025 Amendments, the appointment of a Quality Assurance Manager and Safety Control Manager is legally obligated under the PMD Act,[10] and they are subject to change orders.[11]

## 2.2 Enhancing Stable Supply Systems for Prescription Drugs

In recent years, shortages in the supply of prescription drugs have become a social issue in Japan, and it is still fresh in our memory that there were times when it was difficult to obtain drugs such as acetaminophen, used as an antipyretic and analgesic, and the MR vaccine. Currently, it is said that about 20% of prescription drugs are subject to restricted shipment or shipment suspension, and a supply shortage, mainly for generic drugs,

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6 Article 72-8 of the PMD Act as amended by the 2025 Amendments, not yet in force (the "**2025 PMD Act**").

7 Japanese House of Representatives, *Minutes of the Committee on Health, Labour and Welfare*, Statement by Director of the Pharmaceutical Safety Bureau, April 4, 2025, at page 6.

8 MHLW Ordinance on Standards for Quality Control of Pharmaceuticals, Quasi-Drugs, Cosmetics, and Regenerative Medicine Products.

9 MHLW Ordinance on Standards for Post-Marketing Safety Management of Pharmaceuticals, Quasi-Drugs, Cosmetics, and Regenerative Medicine Products.

10 Article 17-6 of the 2025 PMD Act.

11 Article 73 of the 2025 PMD Act.

has continued for several years. This shortage is believed to have arisen from a combination of several factors, including the inappropriate manufacturing by generic drug manufacturers mentioned above, importing difficulties due to manufacturing issues overseas, and increased demand due to the spread of infectious diseases, etc. In light of these circumstances, regulations have been introduced at multiple stages, from routine measures to those taken when supply instability occurs, as follows:

**(a) Routine Measures — Appointment of Specific Pharmaceutical Supply Control Manager and Preparation of SOPs (Effective by May 2027)**

As a routine measure, pharmaceuticals that require the establishment of a stable supply system are defined as "Specific Pharmaceuticals" (*tokutei-iyakuhin*), and marketing authorization holders for those pharmaceuticals are obligated to appoint a Specific Pharmaceutical Supply Control Manager.[12] Specific Pharmaceuticals include prescription pharmaceuticals, but do not include OTC drugs requiring guidance (*yo-shido-iyakuhin*) or over-the-counter (OTC) pharmaceuticals.[13] Specific Pharmaceutical Supply Control Managers are also subject to change orders, in the same manner as Quality Assurance Managers and Safety Control Managers.[14]

In addition, an Ordinance of the MHLW will separately provide for compliance matters to ensure a stable supply system.[15] Although the content is still under consideration and not yet finalized, it is expected to include preparation of SOPs for stable supply. Since these matters require action by marketing authorization holders, attention should be paid to the future MHLW ordinances.

**(b) Measures from Routine Measures to Measures Taken Upon Occurrence of Supply Instability — Reporting and Notification of Supply Status and Collection of Reports (Effective by May 2027)**

As a measure for the transition period from routine measures to those taken upon occurrence of supply instability, marketing authorization holders for specific pharmaceuticals are obligated to report to the Minister of Health, Labour and Welfare in advance when they intend to restrict or suspend shipments of specific pharmaceuticals and to notify the Minister once they have done so.[16] In addition, when the Minister of Health, Labour and Welfare needs to confirm the supply status of specific pharmaceuticals in question or their alternative drugs, the Minister may collect reports from marketing authorization holders and other related parties involved in the supply of those pharmaceuticals.[17]

**(c) Measures When Supply Instability Occurs — Facilitating Access to Alternative Overseas Drugs (Effective on May 1, 2026)**

When domestically approved pharmaceuticals cannot sufficiently meet demand, priority approval review can be granted for alternative overseas drugs that have the same active ingredients, dosage, administration, efficacy, and effects as those pharmaceuticals.[18] In addition, for alternative overseas drugs approved in this way, special provisions may be established, such as permitting foreign language labeling on containers and

12 Article 18-2-2 of the 2025 PMD Act.
13 Article 2, paragraph 17 of the 2025 PMD Act.
14 Article 73 of the 2025 PMD Act.
15 Article18-2-3 of the 2025 PMD Act.
16 Articles 18-3 and 18-4 of the 2025 PMD Act.
17 Article 18-5 of the 2025 PMD Act.
18 Article 14, paragraphs 9 and 10 of the 2025 PMD Act. Similar provisions have also been added for medical devices and regenerative medicine products.

packaging.[19]

**(d) Monitoring Supply and Demand Using Dispensing Data from Electronic Prescription Management Services (Effective on November 20, 2025)**

The reporting and notification by marketing authorization holders described in (b) above is a system for monitoring the supply status upstream in the pharmaceutical supply chain. On the other hand, monitoring the supply and demand status downstream, such as supply and demand by medical institutions, is also important to ensure stable supply. In this regard, the Minister of Health, Labour and Welfare is newly authorized to investigate and analyze dispensing data from electronic prescription management services and other sources to monitor the supply and demand status of specific pharmaceuticals.[20]

**(e) Establishment of Medium-Risk Category for Partial Change Approval and Creation of New Category for Specific Minor Changes (Effective by May 2028)**

To make a change to approved items of pharmaceuticals, a notification to the Minister of Health, Labour and Welfare was sufficient for minor changes, but for other types of changes, a partial change approval application had to be submitted and go through a review process by the regulatory authorities. In contrast, in Europe and the United States, in addition to prior approval and post-change notification—which correspond to these two Japanese categories of partial change approval and minor change notification—there are systems for "medium-risk" changes and minimum annual reporting, allowing for more rapid changes according to the level of risk.[21] In the 2025 Amendments, new categories have been established to harmonize with international standards, enabling changes and improvements to manufacturing methods, etc. in line with Europe and the United States.

Specifically, for "medium-risk" changes, a decision on approval is to be made within three months from the date of receipt of a partial change approval application.[22] While the specific approval items that fall under medium-risk changes will be separately defined by MHLW ordinances, current examples include the addition of manufacturing sites, partial removal of confirmation tests, changes due to revisions of foreign pharmacopoeias, and extensions of shelf life based on actual measurement data.[23]

In addition, for minor changes that have little impact on quality and are designated by future ordinances as "specific minor changes," instead of submitting notifications for each minor change, marketing authorization holders can report those changes to the Minister of Health, Labour and Welfare annually and receive confirmation that they are specific minor changes.[24]

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19 Article 80, paragraph 8.
20 Article 38-7 of the Medical Care Act as amended by the 2025 Amendments, not yet in force.
21 4th Expert Committee on the Ideal Pharmaceutical Regulations for Strengthening Drug Discovery Capabilities and Ensuring Stable Supply (October 13, 2023) Document 1 (MHLW, Pharmaceutical Affairs Division, Office of Pharmaceutical Review and Management: '*On the Ideal Approach to Pharmaceutical Review Related to Drug Manufacturing Methods, etc.*'), page 3.
22 Article 14, paragraph 15 of the 2025 PMD Act. Similar provisions have also been added for medical devices and regenerative medicine products.
23 See supra note 7, at page 7, Statement by Director of the Pharmaceutical Safety Bureau.
24 Article 14, paragraph 20 of the 2025 PMD Act.

**(f) Establishment of Generic Drug Manufacturing Infrastructure Development Fund (Effective on November 20, 2025)**

One of the causes of pharmaceutical supply shortages is said to be the decline in production efficiency due to "small-lot, multi-product manufacturing" in the generic drug industry. Therefore, to promote structural reform in the generic drug industry, a fund for the development of generic drug manufacturing infrastructure has been established to promote collaboration and reorganization among companies.[25] Specifically, the fund will subsidize capital investment for productivity improvement accompanying product integration and expenses for business reorganization. The fund is scheduled to provide intensive support for a limited period of five years.

## 2.3 Creating Environment to Accelerate Drug Discovery

In response to changes in the drug discovery environment in recent years, and to address the issues of drug lag and drug loss that have been recognized for some time, the following amendments have been made:

**(a) Amendments to Conditional Approval System (Effective on May 1, 2026)**

The conditional approval system was originally established based on a notification from the MHLW as the conditional early approval system, and was codified by the 2019 Amendments. Under this system, if it is difficult to conduct Phase III clinical trials (confirmatory trials) due to reasons such as a small number of participants, it allows applications for approval based on data up to Phase II clinical trials (exploratory trials), omitting Phase III clinical trials.[26] However, since there were no provisions for revocation of approval and the requirements were limited, the system has never actually been used.[27]

In the 2025 Amendments, the requirement of difficulty in conducting Phase III clinical trials has been abolished, and provisions for revocation of approval have been newly introduced, aiming to make conditional approval more widely applicable.[28] Under the 2025 PMD Act, for pharmaceuticals with high medical necessity, if clinical usefulness can be reasonably predicted and significant adverse effects are not reasonably expected, conditional approval will be granted.

**(b) Establishment of Innovative Pharmaceuticals Practical Application Support Fund (Effective on November 20, 2025)**

To promote the development of innovative pharmaceuticals in Japan, the Innovative Pharmaceuticals Practical Application Support Fund has been established.[29] In addition to subsidies for equipment investment, which are lacking in "drug discovery clusters," the fund can also provide subsidies for programs related to the development of manufacturing personnel, based on the needs of cluster operators.[30]

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25 Supplementary Provision, Article 27 of the Act on National Institutes of Biomedical Innovation, Health and Nutrition, not yet in force (the "**2025 NIBN Act**").
26 Article 14, paragraph 5 of the PMD Act.
27 See supra note 7, at page 8, Statement by Director of the Pharmaceutical Safety Bureau.
28 Articles 14-2-2 and 74-2 of the 2025 PMD Act.
29 Supplementary Provision, Article 20 of the 2025 NIBN Act.
30 Japanese House of Representatives, *Minutes of the Committee on Health, Labour and Welfare*, Statement by Minister of Health, Labour and Welfare, April 9, 2025, at page 31.

## 2.4 Strengthening Pharmacy Functions to Ensure Proper Access to Medicines

### (a) Partial Outsourcing of Dispensing Services (Unit Dose Packaging) (Effective by May 2027)

In response to increasing medical demand, and to enable pharmacists at pharmacy to focus more on patient-facing services by improving the efficiency of product-related services, the 2025 Amendments made it possible to outsource part of dispensing services. Specifically, when it is necessary for a pharmacy to improve the quality of medication guidance, dispensing services designated by the MHLW ordinance as particularly standardized ("designated dispensing services") may be outsourced to another operator of the pharmacy.[31] At present, designated dispensing services are expected to be limited to unit dose packaging.[32]

### (b) OTC Drugs Handover at Stores Without On-Site Pharmacists (Effective by May 2027)

Under the current law, pharmacies or stores operated by store-based distributors are required to have a pharmacist or a registered sales person stationed on-site.[33] However, with the spread of online communication tools, it is now possible for pharmacists to provide appropriate remote management, making it desirable to improve access to OTC drugs. Therefore, under the 2025 Amendments, even a person other than a pharmacy operator or pharmaceutical retail seller may, by registering as a registered handover store, receive delegation from a pharmacy operator or pharmaceutical retail seller to handover OTC drugs.[34] Pharmacy operators or pharmaceutical retail sellers must have a handover manager who is a pharmacist or registered sales person of OTC drugs manage these handovers.[35]

### (c) Reform of Pharmaceutical Sales Methods

#### (i) Codification of "Over-the-Counter Sales (Reibai)" Regulations (Effective by May 2027)

In addition to prescription drugs, other medical drugs (e.g., Japanese herbal medicines and antipyretic-analgesics) should also be, in principle, sold based on a prescription. However, "over-the-counter sales (*reibai*)," where sales are allowed without a prescription only in unavoidable cases, have not been restricted.[36] Recently, due to the decrease in medical visits during the COVID-19 pandemic, over-the-counter sales of medical drugs have rapidly expanded; moreover, some pharmacies have begun selling medical drugs routinely without prescriptions, as well as advertising inappropriately. Therefore, it was deemed necessary to clarify the regulation of over-the-counter sales under the PMD Act.[37] Under the 2025 PMD Act, it has been clarified that pharmacy-only drugs must not be sold to individuals without a prescription unless there is a legitimate reason. Sales are permitted only in cases specified by the MHLW ordinance as unavoidable.[38]

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31 Article 9-5 of the 2025 PMD Act.
32 Japanese House of Representatives, *Minutes of the Committee on Health, Labour and Welfare*, Statement by expert witness, April 8, 2025, at page 4.
33 MHLW Ordinance on the Operational Framework for Pharmacies, Store-Based Distributors, and Household Distributors.
34 Article 29-5 of the 2025 PMD Act.
35 Article 29-6 of the 2025 PMD Act.
36 MHLW notice "*Handling of Pharmacy-Only Pharmaceuticals*" issued on Mar. 18, 2014 (Yakushoku-hatsu No. 0318-4); MHLW notice "*Reiteration of Sales Methods for Non-prescription Medical Drugs*" issued on Aug. 5, 2022 (Yakusei-hatsu No. 0805-23).
37 7th Meeting on the Pharmaceutical Sales System (August 4, 2023), Reference Material 2 (MHLW, Pharmaceutical and Environmental Health Bureau, General Affairs Division: "*Reference Materials for Each Discussion Topic*") pages 9–10.
38 Article 36-3, paragraph 2 of the 2025 PMD Act.

### (ii) Pharmaceuticals with Potential for Abuse (Effective on May 1, 2026)

In recent years, OTC drug overdoses by young people have become a major social issue in Japan. To prevent abuse of pharmaceuticals, new regulations have been introduced for pharmaceuticals with potential for abuse, including restrictions on bulk purchases and obligations to provide information at the time of sale.

Under the 2025 PMD Act, the Minister of Health, Labour and Welfare designates as "designated abuse-prevention pharmaceuticals (*shitei-ranyo-boshi-iyakuhin*)" those pharmaceuticals that, if abused, may cause stimulation or depression of the central nervous system or hallucinations, and for which preventive measures are deemed necessary. Pharmacies or stores selling such pharmaceuticals are obligated, through pharmacists or registered sales persons of OTC drugs, to confirm the purchaser's usage status of other pharmaceuticals, etc. and provide necessary information as provided by ministerial ordinance.[39] In addition, for sales exceeding specified quantities (bulk purchases) or sales to persons below a certain age (young purchasers), pharmacists or registered sales persons of OTC drugs are obligated to provide information through face-to-face consultations, including online consultations.[40] Furthermore, when displaying designated abuse-prevention pharmaceuticals in pharmacies or stores, they must be displayed in accordance with the methods specified by ministerial ordinance.[41]

### (iii) Online Medication Counseling for OTC Drugs Requiring Guidance (Effective on May 1, 2026)

Under the current PMD Act, medication counseling for prescription drugs may be provided online;[42] however, for OTC drugs requiring guidance (*yo-shido-iyakuhin*), face-to-face consultation is required.[43] In the 2025 Amendments, it is now possible for pharmacists to provide online medication counseling for OTC drugs requiring guidance, at their discretion.[44] However, for those "designated OTC drugs requiring guidance (*tokutei-yo-shido-iyakuhin*)" which are specified by the Minister of Health, Labour and Welfare as requiring face-to-face sales, face-to-face medication counseling remains necessary.[45]

## 3. Comments and Outlook

The timing of enforcement of the amendments under the 2025 PMD Act varies widely—from those to be enforced within this year (2025) to those up to three years later. Amendments to be enforced within 2025 include the establishment of funds and requests for cooperation in the event of supply instability, which are amendments that do not entail legal obligations. In addition, matters for which relatively early measures are desirable, such as measures against overdoses by minors, will be enforced by May 1, 2026. On the other hand, amendments that require changes to governance structures within companies are given a two-year grace period after promulgation. Furthermore, the amendment of the system for partial change approval will be enforced last, within three years of promulgation.

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39 Article 36-11, paragraphs 1 and 2 of the 2025 PMD Act.
40 Article 36-11, paragraph 3 of the 2025 PMD Act.
41 Article 57-2, paragraph 4 of the 2025 PMD Act. According to the draft ministerial ordinance announced in October 2025, it is provided that designated abuse-prevention pharmaceuticals must be displayed within a designated display section and within 7 meters of a pharmacist or equivalent personnel. Additionally, the regulations on the structure and equipment of pharmacies and similar establishments are to be revised, requiring measures to prevent prospective purchasers of pharmaceuticals from entering within 1.2 meters of the display equipment.
42 Article 9-4 of the current PMD Act.
43 Article 4, paragraph 5, item 3 of the current PMD Act.
44 Article 4, paragraph 5, item 3 of the 2025 PMD Act.
45 Article 36-5, paragraph 3 of the 2025 PMD Act.

Many of the revised items specify that detailed requirements will be set forth in ordinances issued by the MHLW. For the amendments scheduled to take effect on May 1, 2026, the draft ordinance is currently open for public comment until November 1, 2025, and is expected to be officially promulgated in late November 2025. It will be important to continue monitoring the status of upcoming ordinances and related guidelines issued by the MHLW.



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