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Challenges in Generic Drug Supply

1. Introduction

(1) Generic drugs

Over the past 15 years, the proportion of generic drugs used in Japan has increased from around 35% to around 80%,[1] making it an indispensable component of our medical care today. Because the efficacy and safety of generic drugs have already been verified through its original brand-name drugs ("brand-name drugs"), generics can be generally developed in a fraction of the time and at a fraction of the cost compared to the original drugs.[2]

The cost of our medication, excluding copayments, is covered by public health insurance funded through insurance premiums and taxes. Therefore, reducing drug prices helps lower the burden of insurance premiums and taxes, ultimately contributing to the reduction of costs for health insurance societies and the national government. In Japan, where the issue of rising national healthcare costs due to a declining birthrate and aging population is becoming increasingly serious, it is an urgent priority to reduce the burden of insurance premiums and taxes. Accordingly, the government is implementing policies to further promote the use and spread of generic drugs.[3]

(2) Supply situation of generic drugs

Unfortunately, in reality, a serious situation has arisen in which the stable supply of generic drugs cannot be ensured. According to the *Report of the Study Group on the Industrial Structure to Ensure Stable Supply of Generic Drugs, etc.* (May 22, 2024) ("Industrial Structure Study Group Report") published in May 2024 by the Study Group on the Industrial Structure to Ensure Stable Supply of Generic Drugs, etc., as of May 2024, 3,906 pharmaceutical products, representing 23% of all approved drugs, are subject to shipment suspension or restricted supply.[4] Of which, 379 are brand-name drugs (approximately 10%), while 2,589 are generic drugs (approximately 66%), indicating that the current supply instability is primarily centered around generic drugs.[5]

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[1] Report of the Study Group on the Industrial Structure for Realization of Stable Supply of Generic Drugs, etc. (Summary Version) p.1

[2] As of the 2024 NHI drug price revision, the pricing rule for newly listed generic drugs is set at 50% of the price of the corresponding brand-name drug (for oral medications with more than seven new generic versions, the price is set at 40% of the original drug's price. For biosimilars, the price is set at 70% of the corresponding original drug's price.). ("Standards for Drug Price Calculation," Director of the Health Insurance Bureau, Ministry of Health, Labour and Welfare, (HIB Notification No. 0214-1), dated February 14, 2024) Chapter 2, Part 2, 1(a)(b), Central Social Insurance Medical Council's Drug Pricing Subcommittee (225th meeting) Material - 1 Reference 1: "Current Drug Price Standard System (Overview)," p.18)

[3] Promotion of Use of Generic Drugs and Biosimilars, Ministry of Health, Labour and Welfare

[4] Adjustment of shipment volume by restricting new orders or volume per order. (Footnote 2 on p.3 of the "Study Group Report on Rapid and Stable Supply of Pharmaceuticals" discussed below)

[5] Industrial Structure Study Group Report, p.3-4

According to the Industrial Structure Study Group Report, this issue was triggered by a series of violations of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960; hereinafter, "PMD Act") by generic drug companies. As a result, shipment suspensions were imposed on products from the violating companies. The incident began in December 2020, when an ingredient of a sleep aid was found in an antifungal drug manufactured and sold by Kobayashi Kako Co. Ltd. At that time, the company delivered the product to 237 medical institutions and pharmacies across 39 prefectures. Following the confirmation of the incident, reports on health issues were made by 245 people, making it a significant social issue.[6] The company was subjected to on-site inspections by the Ministry of Health, Labour and Welfare (MHLW), Fukui Prefecture, and the Pharmaceuticals and Medical Devices Agency (PMDA) on suspicion of violating the PMD Act. As a result, Fukui Prefecture issued a business suspension order for 116 days and a business improvement order, while the MHLW imposed an approval revocation and a business improvement order.[7] This kicked off a series of administrative actions, and by April 2024, 21 companies had been subjected to administrative dispositions such as business suspension orders and business improvement orders, etc. for violations of the PMD Act. It has been pointed out that insufficient governance and training within these companies, an excessive focus on prioritizing shipments, and imbalanced staffing led to management shortcomings in manufacturing and quality control, as well as compliance violations.[8]

Once the products of these violating companies are suspended, demand shifts to other manufacturers that produce drugs with the same compositional standards. The manufacturers experiencing a sudden influx of orders consequently restrict their shipments to avoid exhausting their inventories. This, in turn, results in a situation where the number of products under limited shipment became several times higher than that of the products initially suspended from shipment.[9]

2. The Nature of the Problem

While the immediate cause of the current issues surrounding generic drug supply lies in shipment suspensions by companies found to be in violation of regulations, the *Report by the Expert Panel on Comprehensive Measures to Achieve Rapid and Stable Supply of Pharmaceuticals* (June 6, 2023; "Study Group Report on Rapid and Stable Supply of Pharmaceuticals") points out that these violations stem from deeper structural challenges within generic drug companies, the industry, and the broader market as described below.[10]

(1) Issues with industrial structure

In general, generic drug companies tend to have smaller sales volumes than pharmaceutical companies that develop the brand-name drugs. Among roughly 190 companies, the top eight account for 50% of the generic drug market by volume, with the remaining 185 companies sharing the other half. This indicates that many companies handle only a small number of products and have limited supply volumes.[11] While numerous companies produce and market products containing the same active ingredients and standards, generic drug companies are legally obligated to maintain a stable supply for a minimum of five years following NHI drug price listing. They must continue supplying these products, even at small volumes, so long as there remains a medical necessity.[12] Therefore, it is not easy for these companies to withdraw from the market for items that they manufacture and sell.

In addition, due to distribution practices in which products are discounted to gain market share, and the difficulty of differentiating products by factors other than price, intense price competition tends to recur, resulting in an early decline in the prices (delivery prices) of generic drugs. To compensate for lower profits derived from lower prices, etc., companies will launch a newly listed product if the patent

[6] Meeting of Stakeholders on Measures to Ensure Stable Supply of Prescription Drugs (6th Meeting) Material 2-1, p.1
[7] p.2 of the above, p.3 of Industrial Structure Study Group Report
[8] Industrial Structure Study Group Report, p.3
[9] p.4 of the above
[10] Study Group Report on Rapid and Stable Supply of Pharmaceuticals, p.3-6
[11] p.4 of the above
[12] "Regarding the Stable Supply of Generic Drugs" Director of the Health Policy Bureau, Ministry of Health, Labour and Welfare (HPB Notification No. 0310003), dated March 10, 2006

for the brand-name drug has expired, resulting in an inefficient production structure of small-lot, multi-product production.[13]

(2) Issues under the NHI Drug Price Standard

In principle, the NHI drug prices provided to patients are revised to reflect prevailing market prices. As previously noted, the delivery prices of generic drugs tend to fall quickly because of distribution practices and the nature of the products, which results in an early decrease of their NHI drug prices. This decline in NHI drug prices is said to be putting financial pressure on generic drug companies, causing them to hesitate in investing in production facilities that support stable supply, as well as in small-lot, multi-product production resulting from the introduction of newly listed drugs.[14]

Additionally, systems such as minimum NHI drug prices, re-evaluation of unprofitable products, and essential medicines have been introduced to support NHI drug prices. However, due to stringent eligibility criteria, the number of generic drugs covered by these measures remains limited.[15]

(3) Supply chain issues

In Japan, to secure profitability, generic drug manufacturers heavily depend on countries such as China, India, and South Korea for lower-cost active pharmaceutical ingredients ("APIs") and raw materials, with approximately half of generic drugs using imported APIs.[16] This, in addition to the risk of supply disruptions due to circumstances in these countries, increases the risk associated with recent exchange rate fluctuations and price increases.[17]

The risk of supply instability caused by breaks in the supply chain primarily requires pharmaceutical companies supplying pharmaceuticals to implement countermeasures in the form of business continuity plans (BCPs). While the causes of this risk are varied, institutional and structural factors such as the difficulty of passing on costs due to fixed official prices mean that a single company may find it challenging to adequately manage the risk. Therefore, from the standpoint of healthcare security, the involvement of the public sector is considered necessary.[18]

3. Background of Government Measures

Considering the vulnerabilities that generic drugs face in terms of quality and stable supply, the government has been considering countermeasures.

While fundamentally addressing the challenges related to drug supply instability, the MHLW formulated a "Roadmap for the Appropriate Use of Generic Drugs Based on Securing Stable Supply"[19] in September 2024 to organize efforts for the proper utilization of generic drugs. The roadmap sets a numerical target of achieving a generic drug volume share of 80% or more in all prefectures by the end of FY 2029. To reach this goal, it outlines specific initiatives divided into two categories: "Efforts to Ensure Stable Supply and Gain Public Trust" and "Efforts to Achieve the New Target." To further promote the use and dissemination of generic drugs, the approach outlined not only sets numerical targets and initiatives to achieve them but also emphasizes

[13] Study Group Report on Rapid and Stable Supply of Pharmaceuticals, p.6
[14] p.6 of the above
[15] Specific examples of the shortcomings of these systems include the following: there are dosage form classifications for which no minimum NHI drug price has been set; re-evaluation of unprofitable products (system under which the amount calculated by the cost accounting method is used as the NHI drug price in certain circumstances, such as when the cost has risen significantly) is conducted once every two years and as a result it takes time before increased costs are reflected in NHI drug prices; and that the essential medicine system (system under which the NHI drug price is maintained before the drug becomes unprofitable, with respect to drugs which have a long history of clinical use and which have been designated as being medically highly necessary) is limited to items for which at least 25 years have passed since the listing of the NHI drug price (p.7 of the above; "Expert Panel on Comprehensive Measures to Achieve Rapid and Stable Supply of Pharmaceuticals" (10th meeting) Material 1, "Regarding the Stable Supply of Drugs (2)" p.7-20).
[16] Study Group on the Industrial Structure for Realization of a Stable Supply of Generic Drugs (6th Meeting), Material 3, p.8, approximately 60% of APIs for generic drugs in Japan are imported.
[17] Study Group Report on Rapid and Stable Supply of Pharmaceuticals, p.7
[18] p.8 of the above
[19] "Roadmap for the Appropriate Use of Generic Drugs Based on Securing Stable Supply," Ministry of Health, Labour and Welfare, September 30, 2024

efforts to ensure quality and stable supply, thereby addressing the structural issues surrounding the generic drug supply problem.[20]

The government's policy direction has been materialized through four key initiatives set out in the Industrial Structure Study Group Report: (1) ensuring robust manufacturing and quality control systems, (2) securing stable supply capacity, (3) building a sustainable industrial structure, and (4) promoting collaboration and cooperation among companies. We will take a closer look at each of these items below.

(1) Ensuring robust manufacturing and quality control systems

"Ensuring robust manufacturing and quality control systems" is intended to restore trust in generic drugs and prevent a recurrence of supply instability. This initiative is based on the understanding that thorough manufacturing and quality control are fundamental prerequisites for maintaining a stable supply of quality-assured generic drugs, and considers the current situation in which violations of the PMD Act related to quality control have triggered recent supply disruptions.

Specifically, the need to (a) conduct thorough self-inspections, (b) strengthen governance, and (c) strengthen and improve pharmaceutical oversight are pointed out. For example, as for (c) strengthen and improve pharmaceutical oversight, since FY2023, initiatives have been implemented in which the prefectural governments and the MHLW, in cooperation, conduct unannounced joint on-site inspections by PMDA and prefectural governments at manufacturing facilities identified as relatively high-risk.[21]

Reflecting this trend toward strengthening and improving pharmaceutical oversight, the revised PMD Act, enacted in May 2025 and discussed later, includes measures to streamline Good Manufacturing Practice (GMP) compliance inspections and to reinforce oversight. Specifically, under the revised act, the regular GMP conformity investigation, which had previously been required once every five years, can now be conducted at varying frequencies within a three-year period based on an assessment of each manufacturing site's non-compliance risk. In addition, for inspections by manufacturing process category, even at manufacturing sites under the jurisdiction of prefectural governments, the national government (PMDA) may now conduct inspections jointly with such prefectural governments when deemed necessary.[22]

(2) Securing stable supply capacity

The objective of "securing stable supply capacity" is to establish the following systems to ensure a stable supply of quality-assured pharmaceuticals.

(a) A system to ensure a stable supply of pharmaceuticals at company level; and
(b) A system in which the industry as a whole has the capacity to increase production as needed.

The Industrial Structure Study Group Report recommends, regarding (a), to establish a framework for organizing and enforcing the measures and requirements expected of companies to ensure stable supply, including the appointment of personnel responsible for supply stability and the development of organizational structures, and regarding (b), to consider an institutional framework for a management system that ensures the stable supply of pharmaceuticals, etc. by enabling responsive measures to fluctuations through continuous monitoring of supply and demand conditions during normal times.[23]

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[20]The following are given as specific measures. (1) As efforts to ensure stable supply and public trust, (i) efforts to ensure quality: implementation of unannounced joint on-site inspections by PMDA and prefectural governments, implementation by generic drug manufacturers of self-inspections promoted by industry associations, talent development programs aimed at fostering a culture of quality, such as external trainings and HR evaluations focusing on quality control; (ii) efforts to ensure stable supply: establishment of systems for reporting supply instabilities and supply status, publication of information related to stability of supply by generic drug companies, review of the legal framework of management systems related to ensuring stable supply, etc. (2) As efforts to achieve the new targets, (i) efforts to improve the usage environment: to promote targeted use, provide generic drug replacement rate information based on both volume and monetary value, and promote patient awareness of benefits through the cost difference notification program, etc.; (ii) efforts related to matters under the health insurance system: revision of insurance coverage in the case where a patient chooses to use an off-patent brand drug despite a generic option being available and introduction of selective treatment mechanism to promote the manufacturing industry's conversion from a business model reliant on such off-patent brand drugs to a R&D model with strong drug discovery capabilities.

[21]Industrial Structure Study Group Report p.11-13

[22]Summary Materials on the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 37 of 2025) (the "2025 Amendment Summary"), p.9

[23]Industrial Structure Study Group Report p.14-18

The revised PMD Act and the revised Medical Care Act enacted in May 2025 made statutory the obligation to appoint a Supply System Manager for prescription drugs with respect to (a), and with respect to (b), the obligation to notify when shipments are limited or supply is suspended, to collect reports when supply is unstable, and to request necessary cooperation such as increased production. Furthermore, regarding (b), it is notable that data from electronic prescription management services, such as dispensing data, is utilized to monitor supply and demand conditions.[24]

These legislative changes can be seen as having addressed certain challenges pointed out in the Industrial Structure Study Group Report, specifically, the lack of legal guarantees for companies' systems to ensure stable supply, and the absence of an institutional framework to implement responsive measures to fluctuate in pharmaceutical supply and demand during normal times.

(3) Building a sustainable industrial structure

"Building a sustainable industrial structure" aims to solve structural problems in the industry as a whole. Specific measures are being considered from two major perspectives: (a) improve production efficiency by optimizing small-lot, multi-product production, and (b) ideal pricing and distribution to create a virtuous cycle of stable profits and investment.

(a) Measures to improve production efficiency by optimizing small-lot, multi-product production

The Industrial Structure Study Group Report includes recommendations such as simplifying pharmaceutical regulatory procedures for manufacturing changes, clarifying and streamlining the process for supply suspension and NHI drug price removal when one product among consolidated listed products is withdrawn from the market,[25] and streamlining the principle of satisfaction of all standards.[26]

In relation to this, the Industrial Structure Study Group Report noted that, as product consolidation among companies accelerates to improve production efficiency, information such as production volumes, prices, and delivery destinations will likely be shared among companies. However, since such exchanges raise concerns about potential violations of the Anti-Monopoly Act, the report pointed out the need to clarify, through coordination with the Japan Fair Trade Commission ("JFTC"), the appropriate methods for legally exchanging information under normal circumstances, and to ensure that generic drug companies are properly informed of these guidelines. In this regard, on February 17, 2025, the MHLW and the JFTC jointly published the *Casebook under the Antimonopoly Act for Industrial Structure Reform to Ensure Stable Supply of Generic Drugs*.[27] This publication provides a certain degree of guidance for generic drug companies to exchange information for product consolidation without violating the Anti-Monopoly Act.

In addition, under the revised PMD Act enacted in May 2025, certain changes in manufacturing of pharmaceuticals that have minimal impact on product quality are now subject to approval within a specified period (approximately 40 days), while insignificant changes with little effect on quality no longer require individual notifications but can instead be reported collectively to the Minister of Health, Labour and Welfare once a year.[28] As such, this revision can be seen as a step toward streamlining part of the regulatory process.[29]

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[24] 2025 Amendment Summary p.3

[25] The principle of satisfaction all standards is the principle that when listing a generic drug in the NHI drug price standards, application should be made upon satisfying all the same standards as the original drug which became the standard formulation. Exceptionally, standards which are not necessarily medically required may be excluded from the scope of satisfaction upon separate consultation with the MHLW ("Satisfaction of Necessary Standards of Generic Drugs," Notification of the Health Policy Bureau No. 0310001 dated March 10, 2006). It is recommended that since low-demand standards may cause generic drugs to be unprofitable, after five years have passed since listing as required for stable supply, then, based on status of clinical use, the principle should be streamlined to allow suspension of supply or NHI drug price removal for items, even if only a part of the standards are satisfied, where satisfying all standards may not be necessary in light of medical requirements.

[26] Industrial Structure Study Group Report p.19-21

[27] (February 17, 2025) Formulation of "Casebook under the Antimonopoly Act for Industrial Structure Reform to Ensure Stable Supply of Generic Drugs," Japan Fair Trade Commission

[28] 2025 Amendment Summary p.9

[29] Other than those stated in the main text, after the publication of the Industrial Structure Study Group Report, measures have been taken to clarify and simplify the processes for supply suspension and NHI drug price removal through the issuance of a circular notice ("Supply Suspension and NHI Drug Price Removal for Prescription Drugs" (Notification No. 0807-1 of the Director of the Health

(b) Ideal pricing and distribution to create a virtuous cycle of stable profits and investment

The Industrial Structure Study Group Report recommends the establishment of a mechanism to publicize company information such as manufacturing capacity, production plans, and production records, and the use of evaluation results based on such publicized information, under the basic idea that companies that can provide a stable supply of quality-assured generic drugs should be evaluated in the market and consequently gain an advantage.[30] As for the former, in March 2024, the *Guidelines on the Publication of Information Related to the Stable Supply of Generic Drugs* were formulated to increase transparency among companies capable of ensuring a stable supply and to make it easier for medical institutions to select products from such companies.[31] Under these guidelines, each company publishes information about its stable supply system and related matters on its website, with the corresponding URLs listed on the MHLW's website.[32]

The Industrial Structure Study Group Report also includes recommendations regarding the role and framework of "authorized generics (AGs)."[33] Although AGs are not clearly defined, they are generally understood to be generic products that are identical to the brand-name drug not only in active ingredients, but also in APIs, additives, and manufacturing process, etc. Since they are manufactured using the same formulation as the brand-name drug, AGs often gain market share due to the assurance of equivalence. On the other hand, (i) in many cases, brand-name drug companies receive licensing fees from the marketing authorization holder of the AG, resulting in a dependence on off-patent brand drugs developed in a different form, (ii) the uncertainty over whether AGs will be listed on the NHI drug price list even after obtaining approval from the Minister of Health, Labour and Welfare has negatively impacted generic drug companies, making them hesitant to enter the market for pharmaceuticals that require substantial capital investment, such as biosimilars, and (iii) if AGs are not released, generic drug companies alone will be unable to ensure an adequate supply of generic drugs, leading to concerns over maintaining a stable supply. Taking these factors into consideration, it is advisable to review and clarify the future positioning of AGs.[34]

Furthermore, in order to ensure that generic drugs are distributed at appropriate prices and to help stabilize NHI drug pricing, it was pointed out that, based on the observations made in the Study Group Report on Rapid and Stable Supply of Pharmaceuticals[35] and the discussions held at the Conference on the Improvement of Prescription Drug Distribution, discussions should be accelerated to promote compliance with the revised *Guidelines for the Improvement of Commercial Transaction Practices of Ethical Drugs for Manufacturers, Wholesalers, and Medical Institutions/Pharmacies* ("Distribution Improvement Guidelines"),[36] which were updated in March 2024. In addition, steps should be taken

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Policy Bureau, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Ministry of Health, Labour and Welfare, and Notification No. 0807-2 of the Director of Health Insurance Bureau, Medical Affairs Division, Ministry of Health, Labour and Welfare, to Representatives of Prescription Drug Marketing Authorization Holder dated August 7, 2024).

[30] Industrial Structure Study Group Report p.21-23

[31] Formulation of "Guidelines on the Publication of Information Related to the Stable Supply of Generic Drugs" (Notification No. 0329-7 of the Director of the Health Policy Bureau, Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Ministry of Health, Labour and Welfare, dated March 29, 2024)

[32] mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iryou/kouhatu-iyaku/02_00001.html

[33] Industrial Structure Study Group Report p.23, footnote 23

[34] Industrial Structure Study Group Report p.23

[35] The revision was prompted by the indication in the Study Group Report on Rapid and Stable Supply of Pharmaceuticals that all parties involved in the distribution chain, including manufacturers, wholesalers medical institutions providing services covered by health insurance, and health insurance-covered pharmacies, should comply with the Distribution Improvement Guidelines in pharmaceutical transactions, seek to remedy trading practices unique to pharmaceutical industry, excessive drug price differentials, and the uneven distribution of drug price differentials, as well as establish an environment conducive to appropriate distribution transactions (*Guidelines for the Improvement of Commercial Transaction Practices of Ethical Drugs for Manufacturers, Wholesalers, and Medical Institutions/Pharmacies* (amended on March 1, 2024), p.2-3).

[36] The March 1, 2024 revised version stated that essential drugs, stability ensured drugs, re-evaluated unprofitable products, etc. should not be based on the traditional total value, but based on individual unit price negotiations (negotiations to determine transaction price for each individual product with a business partner, based on costs necessary for stable supply arising from regional differences and individual transaction terms, unaffected by the prices of other drugs), that negotiations should be conducted in compliance with the Distribution Improvement Guidelines in case of utilizing price negotiation services, and in principle no changes should be made to the agreed price within the fiscal year, and incorporated content regarding returns and handling procedures for single-company distribution.

to identify excessive or uneven price differentials and to rectify business practices unique to the pharmaceutical industry, thereby fostering an environment for appropriate distribution transactions.[37]

(4) Promoting collaboration and cooperation among companies

On "Promoting collaboration and cooperation among companies," the report recommended that, drawing on examples of industry restructuring in other sectors, the government consider measures to support initiatives that foster such collaboration. This recommendation reflects two key considerations: (i) addressing structural challenges in the industry requires significant investment to establish robust manufacturing and quality control systems and ensure stable supply structures, and (ii) for individual companies to improve production efficiency and profitability by optimizing product lineups and expanding market share, building systems that enable large-scale production and quality control could be an effective approach.[38]

The Industrial Structure Study Group Report also noted that, while information exchanges related to product consolidation, collaboration, and corporate integration could, in some cases, potentially violate the Anti-Monopoly Act, vague concerns about such violations should not hinder proactive consideration of these initiatives. To address this, the report recommended that the MHLW prepare and disseminate a collection of case examples illustrating forms of inter-company collaboration that can be conducted safely within the scope of the current laws pertaining to generic drug companies. The report also suggested establishing a consultation desk to address concerns related to the Anti-Monopoly Act and to provide procedural assistance for companies seeking guidance from the JFTC.[39] Building on these recommendations, in February 2025, as noted in 3.(3)(a) above, the MHLW and the JFTC jointly published the *Casebook under the Antimonopoly Act for Industrial Structure Reform to Ensure Stable Supply of Generic Drugs*. In addition, the MHLW set up a consultation desk to handle inquiries and provide advice on the Anti-Monopoly Act issues arising from collaboration or cooperation among generic drug companies or between specific products.[40] Moving forward, it is expected that product integration, collaboration and cooperation among companies, and business restructuring will be promoted through utilizing such casebook and consultation services.

4. Legislative Changes Addressing the Issue

Considering the causes of issues outlined above and the background of government measures, the Act Partially Amending the PMD Act[41] was enacted on May 14, 2025. The purpose of the recent revisions is to take necessary measures from four perspectives: (a) strengthen the assurance of quality and safety of pharmaceuticals, (b) strengthen the stable supply system of prescription drugs, (c) improve the environment to enhance active drug discovery, and (d) strengthen pharmacy functions for the appropriate provision of pharmaceuticals to the public.[42] The following explains the contents of the revisions based on the perspectives of (a) and (b), which are important in relation to the issue surrounding the supply of generic drugs.[43]

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[37] Industrial Structure Study Group Report p.23-24
[38] Industrial Structure Study Group Report p.25-26
[39] Industrial Structure Study Group Report p.26-27
[40] Consultation desk for matters related to the Anti-Monopoly Act in connection with the structural reform of the generic drug industry, Ministry of Health, Labour and Welfare
[41] Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 37 of 2025). The Medical Care Act, Narcotics and Psychotropics Control Act, Pharmacists Act, and the Act on the National Institutes of Biomedical Innovation, Health and Nutrition are also subject to amendment in addition to the PMD Act.
[42] 2025 Amendment Summary p.1
[43] In addition to those stated in the main text, the following provisions have been enacted as law through the recent amendments to the PMD Act and other acts:

- Expansion of application of the conditional early approval system (c)
- Promotion of formulation of development plans for pediatric pharmaceuticals (c)
- Creation of the Support Fund for the Commercialization of Innovative Pharmaceuticals (c)
- Over-the-counter drug sales under the remote supervision of pharmacists, etc., partial outsourcing of pharmacy dispensing operations (d)
- Review of the sale classifications of drugs and their sale methods (d)

While these measures are not considered to be directly related to the issue of generic drug supply, they affect pharmaceuticals in general, generic drugs included, and it is necessary to pay attention to their enforcement schedule, etc.

(a) Strengthen the assurance of quality and safety of pharmaceuticals[44]

Ensuring the thorough implementation of manufacturing and quality control management is a fundamental prerequisite for the continuous and stable supply of quality-assured generic drugs. The following measures have been enacted as law to fulfill these assumptions.

(i) Streamlining GMP conformity investigations and strengthening supervision;
(ii) Order to replace responsible executives in charge of pharmaceutical affairs at marketing authorization holders, etc., in cases of legal or regulatory violations; and
(iii) Enactment of the obligation to appoint a Quality Assurance Manager and Safety Management Manager for pharmaceuticals at marketing authorization holders.

(i) Streamlining GMP conformity investigations and strengthening supervision.[45]

First, as mentioned in 3.(1), regular GMP conformity investigations can now be conducted at varying frequencies within a three-year period based on an assessment of each manufacturing site's non-compliance risk. In addition, for inspections by manufacturing process category, even at manufacturing sites under the jurisdiction of prefectural governments, the national government (PMDA) may now conduct inspections jointly with such prefectural governments when deemed necessary.

(ii) Order for replacement of responsible executives in charge of pharmaceutical affairs at marketing authorization holders, etc. in cases of legal or regulatory violations.[46]

Measures have also been taken to enhance governance. Recent administrative disposition cases have confirmed the involvement of responsible executives.[47] Despite the fact that the conduct of business by such executive was considered to hinder the assurance of the quality and safety of pharmaceuticals, etc., the regulations under the PMD Act prior to its revision were limited to internal governance measures within companies, such as the obligation of the marketing directors, etc. to express their opinions to the marketing authorization holder, etc. As a result, the system was insufficient in adequately addressing illegal acts led by the responsible executives.[48] Accordingly, under the recent revision, when a violation of pharmaceutical-related laws and regulations has occurred due to the actions of a responsible executive, and it is determined that improvement in business operations necessary to prevent the occurrence or spread of harm to public health cannot be expected unless the responsible executive is replaced, the Minister of Health, Labour and Welfare may order the marketing authorization holder or manufacturer of pharmaceuticals, etc. to replace the responsible executive.

(iii) Appointment of a Quality Assurance Manager and the Safety Management Manager for pharmaceuticals at marketing authorization holders.[49]

Furthermore, the appointment of the Quality Assurance Manager and Safety Management Manager, which until now was based on the Good Quality Practice and Good Vigilance Practice ordinances, has become a legal obligation under the PMD Act. Like responsible executives, these managers are now also subject to replacement orders by the Minister of Health, Labour, and Welfare.

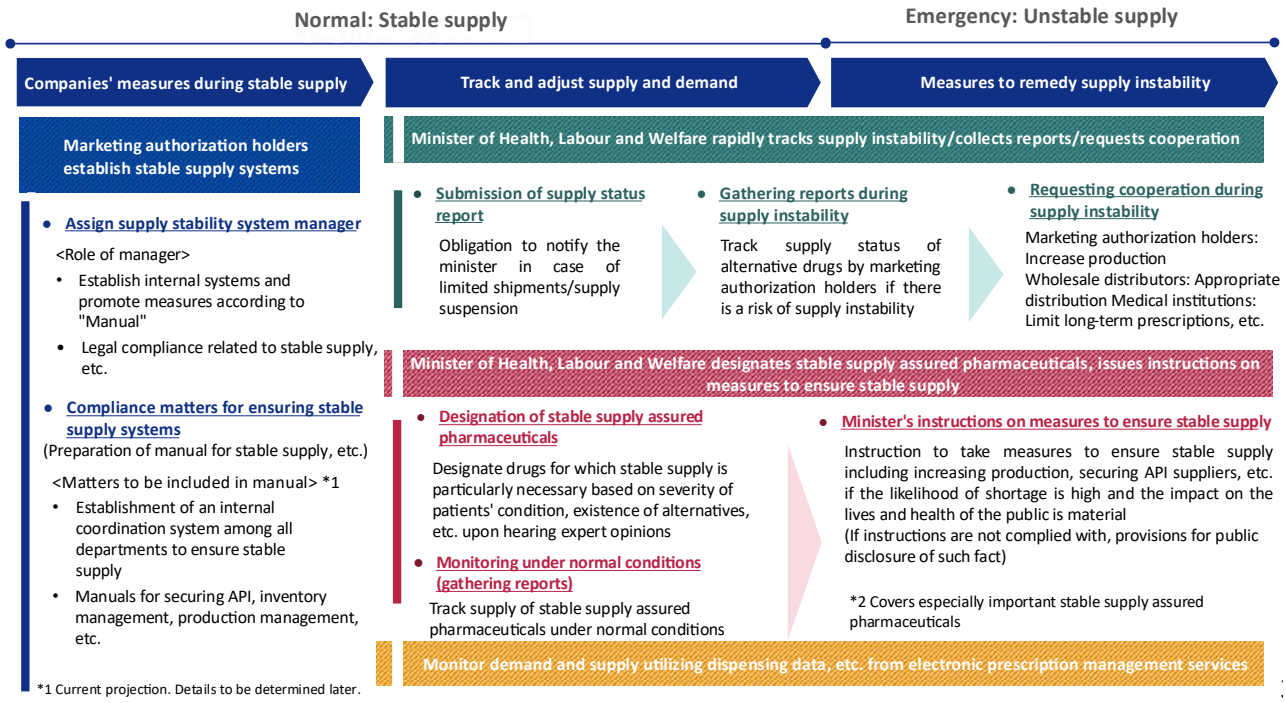
(b) Strengthen the stable supply system of prescription drugs

A. Establishment of a stable supply system for prescription drugs/ reports, requests, and instructions to ensure stable supply

As mentioned in 3.(2) above, the Industrial Structure Study Group Report recommends establishing a framework that organizes and enforces the measures and requirements expected of companies to ensure

[44] In addition to those stated in the main text, amendments related to this item also include provisions requiring marketing authorization holders of certain pharmaceuticals to create and implement plans for collecting information related to side effects.
[45] 2025 Amendment Summary p.9
[46] 2025 Amendment Summary p.2
[47] The term "responsible executive" refers to an executive whose scope of duties, as determined by the company's allocation of responsibilities among its officers, includes operations related to pharmaceutical laws and regulations (duties that must be performed in compliance with such laws and regulations). This includes the representative director and directors in charge of pharmaceutical-related operations.
[48] Summary regarding Amendments to the Pharmaceutical Affairs Act and other systems (Pharmaceuticals and Medical Devices Systems Subcommittee of the Health Science Council, January 10, 2025) p.2
[49] 2025 Amendment Summary p.2

stable supply, including the appointment of personnel responsible for supply stability, and to consider an institutional framework for a management system that ensures the stable supply of pharmaceuticals, etc. by enabling responsive measures to fluctuations through continuous monitoring of supply and demand conditions during normal times. In light of these recommendations, the current revision includes measures to (i) develop a stable supply system for marketing authorization holders of prescription drugs, (ii) establish provisions to enable the Minister of Health, Labor and Welfare to promptly identify supply instability and to make the necessary requests and instructions for a stable supply, and (iii) monitor the on-site supply and demand conditions by utilizing dispensing data, etc. from electronic prescription management services.[50] The overall picture is as follows.



(2025 Amendment Summary; excerpt & partially modified from p.3)

B. Establishment of a generic drug manufacturing infrastructure development fund

Furthermore, under the recent revision, a new Generic Drug Manufacturing Infrastructure Development Fund ("Fund") has been established.[51] In light of the current situation in which generic drug companies are experiencing a decline in production efficiency due to small-lot, multi-product production, etc., the Fund aims to encourage inter-company collaboration, cooperation, and restructuring. The Fund is meant to review and take necessary measures for approximately three years after the enforcement of the revision, but at present, companies submit to the Fund a plan outlining item integration and business restructuring to ensure a stable supply of generic drugs. This plan includes details such as annual capital investment, business objectives, and estimated expenses. The Fund then forwards the plan to the MHLW, which—after consulting with the JFTC as needed—determines whether to approve it. Once approved, the company becomes eligible for support from the Fund. Specific support is expected to include subsidies for equipment and facility costs aimed at improving productivity associated with item integration, as well as subsidies for the cost of coordination among firms for item integration and business restructuring.[52]

[50] 2025 Amendment Summary p.3
[51] With the amendment of the Act on the National Institutes of Biomedical Innovation, Health and Nutrition, provision of necessary funds and other support to manufacturers and distributors of generic drugs eligible for the system, and incidental operations have been added to the operations of the National Institutes of Biomedical Innovation, Health and Nutrition. It is provided that the Fund may be established for the purpose of covering the costs of these operations (Promulgation of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices p.18-21).
[52] 2025 Amendment Summary p.4

C. Streamlining of pharmaceutical procedures at the time of change of manufacturing method

Where streamlining of procedures related to pharmaceutical affairs is considered necessary to integrate items and improve production efficiency, the recent revision of the PMD Act has achieved the streamlining of procedures when changing manufacturing methods of pharmaceutical products. As mentioned in 3.(3)(a) above, changes that have minimal impact on product quality are now subject to approval within a specified period (approximately 40 days), while insignificant changes with little effect on quality no longer require individual notifications but can instead be reported collectively to the Minister of Health, Labour and Welfare once a year.[53]

5. Future Outlook

As we have seen, the recent revision to the PMD Act, etc. can be regarded as implementing a wide range of measures addressing each of the key initiatives outlined in the Industrial Structure Study Group Report: (1) ensuring robust manufacturing and quality control systems, (2) securing stable supply capacity, (3) building a sustainable industrial structure, and (4) promoting collaboration and cooperation among companies. However, this revision is not the final step. After its enforcement, it will be essential to closely monitor whether the supply issues surrounding generic drugs are truly being resolved, whether businesses are properly establishing stable supply systems, and whether the newly introduced obligations are being duly observed. The government is expected to conduct appropriate follow-up,[54] while we in the private sector must also continue to observe and assess the actual effectiveness of these measures.

In addition, the revised provisions are scheduled to be enforced in phases. For example the order to change responsible executives (4.(a)(ii)) and the obligation to establish a Supply System Manager (4.(b)(A)) will be enforced within two years of promulgation, and the streamlining of procedures when changing manufacturing methods for pharmaceutical products (4.(b)(C)) will be enforced within three years of promulgation.[55] Although a certain period of preparation is necessary, the on-site environment regarding the quality, safety, and stable supply of pharmaceuticals is serious, and it is undeniable that a certain amount of doubt remains as to whether we are fully grasping the voices of the field,[56] which are calling for efforts to improve the current situation as much as possible by implementing necessary revisions to laws and regulations as soon as possible.

In any case, it will be important for the government to continue to take flexible measures, not only to take rigid measures, but also to keep a close watch on the improvement of the generic drug supply problem in accordance with the situation surrounding enforcement, etc. while utilizing issuance of guidelines.

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[53] 2025 Amendment Summary p.9

[54] Minutes of the 9th Meeting of the Pharmaceuticals and Medical Devices Systems Subcommittee of the Health Science Council in FY 2024

[55] Promulgation of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

[56] Minutes of the Stakeholders' Meeting on Measures to Ensure Stable Supply of Prescription Drugs (20th Meeting), Ministry of Health, Labour and Welfare