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This issue covers the following topics:

ANTITRUST AND COMPETITION

Overview of Freelancer Protection Act

I. Introduction

On May 31, 2024, the government of Japan announced that the "Act on the Optimization etc. of Transactions Involving Specified Entrusted Enterprises" (the "**Act**"), approved in April 2023, will take effect on November 1, 2024, and released related cabinet orders, regulations, and guidelines. The Act's effectuation may subject entrusting enterprises, which entrust business to freelancers, to certain new obligations. Thus, before the Act's effective date, such entrusting enterprises should confirm what obligations are being imposed for which transactions, and consider what preparations need to be made to ensure their compliance with the Act. This newsletter provides a concise introduction to the provisions of the Act and their scope of application.

II. Purpose and Scope of Application of the Act

(i) Purpose

The Act was conceived in response to the growing diversification of work styles throughout Japan and is intended to create an environment that allows individuals to enjoy stable engagement in the businesses they undertake as enterprises, by (1) optimizing the transactions those individuals undertake as enterprises and (2) creating an employment environment for such transactions. The provisions of the Act concerning optimization of transactions introduce regulations in conformity with the Subcontract Act and are enforced primarily by the Japan Fair Trade Commission (the "**JFTC**") and the Small and Medium Enterprise Agency (the "**SMEA**"). In contrast, the provisions on creating an employment environment provide protections for freelancers similar to those for laborers, and are enforced primarily by the Ministry of Health, Labour and Welfare (the "**MHLW**").

(ii) Scope of Application

The Act applies to all transactions in which an enterprise "entrusts business" to an enterprise that does not "utilize employees". According to the guidelines concerning the Act, "utilizing employees" means employing laborers who are expected to work at least 20 prescribed working hours per week

and to be continuously employed for at least 31 days. "Entrusting business" means that an enterprise, for the benefit of its business, entrusts another enterprise to (1) manufacture goods (including processing), (2) create information-based products, or (3) provide services. Hereinafter, the entrusted enterprises who are covered by the Act are referred to simply as "freelancers".

III. Overview of Provisions on Optimization of Transactions

The provisions on the optimization of transactions are as detailed in (i) and (ii) below. These provisions introduce regulations in conformity with the Subcontract Act and are enforced primarily by the JFTC and the SMEA.

(i) Obligations imposed on Entrusting Enterprises

- When business is entrusted to a freelancer, the particulars of the entrusted services, remuneration amount, payment date(s), and other prescribed matters must be specified to the freelancer, as a general rule immediately, in writing or electronically (Article 3, Paragraph 1).

- Freelancers shall not be subjected to adverse treatment for having reported violations of the Act by their entrusting enterprises to the JFTC or the SMEA (Article 6, Paragraph 3).

(ii) Obligations imposed on Entrusting Enterprises Which "Utilize Employees"

The following provisions apply to entrusting enterprises which "utilize employees".

- As a general rule, the payment date for remuneration must be set within the shortest possible period, not to exceed 60 days counting from the date of receipt of the goods or services, and the remuneration must be paid by said date (Article 4, Paragraph 1, 5).

- In the case of any entrusted business which occurs over a period of time longer than the "period specified by cabinet order" (including where the entrustment of business continues beyond such period due to renewal of the agreement), there shall be no (1) refusal of receipt, (2) reduction of remuneration, (3) return of goods, (4) setting of a conspicuously low price, (5) coercion of purchase or use, (6) improper demand for economic gains, or (7) improper change of work contents or request for rework (Article 5). According to the cabinet order concerning the Act, the "period specified by cabinet order" with regard to this Article is one month.

(iii) Relationship to Anti-Monopoly Act and Subcontract Act

According to the guidelines concerning application of the Act, the Act shall have priority in principle with regard to any conduct that violates both the Act and the Anti-Monopoly Act. Likewise, the Act shall have priority in principle with regard to any conduct that violates both the Act and the Subcontract Act.

IV. Overview of Provisions concerning the Creation of an Employment Environment

The provisions concerning the creation of an employment environment are as detailed below. The following provisions provide protections for freelancers similar to those for laborers and are enforced primarily by the MHLW. In addition, all of the following provisions also apply to entrusting enterprises that "utilize employees".

- When information related to the recruitment of freelancers is provided in the form of advertisements or the like, (1) no false or misleading representations shall be made, and (2) the provided information must be kept accurate and up to date (Article 12).

- Measures shall be taken for creation of the systems necessary for the appropriate handling of consultations regarding harassment of freelancers (Article 14, Paragraph 1).

- In the case of any entrusted business which occurs over a period of time longer than the "period specified by cabinet order" (including where the entrustment of business continues beyond such period due to renewal of the agreement):

  ➢ necessary accommodation, if requested, must be granted to ensure that the freelancer can balance carrying out the entrusted business with childcare or other such activities (Article 13, Paragraph 1); and

  ➢ if the agreement for entrusted business is to be cancelled, as a rule, the freelancer must be notified at least 30 days in advance (Article 16, Paragraph 1).

  According to the cabinet order concerning the Act, the "period specified by cabinet order" with regard to Article 13, Paragraph 1 and Article 16, Paragraph 1 is six months.

V. Recommendations, Orders, Announcements, etc.

When an entrusting enterprise is found to have violated certain provisions, the JFTC or the Minister of Health, Labour and Welfare is entitled to issue a recommendation that such entrusting enterprise must take necessary remedial measures (Articles 8, 18). Further, when an entrusting enterprise subjected to such a recommendation has failed to take the measures of such recommendation without justifiable grounds, the JFTC or the Minister of Health, Labour and Welfare is entitled to order the entrusting enterprise to take the recommended measures and, if it gives such an order, is entitled to announce that it has done so (Articles 9, 19). Cases where such orders are breached will be subject to a fine of up to 500,000 yen (Article 24, Item (i)).

VI. Conclusion

As detailed above, entrusting enterprises involved in transactions with freelancers should confirm what obligations they will incur under the Act with respect to such transactions. This includes verifying such matters as whether the freelancers they engage are enterprises that do not "utilize employees", whether their transactions with those freelancers constitute "entrusting business", and the length of the period over which business will be entrusted to such freelancers. Even where such verification confirms the presence of transactions subject to the Act, entrusting enterprises which already have systems in place for compliance with the Subcontract Act may have fewer matters that need to be newly prepared to ensure compliance with the Act. In contrast, entrusting enterprises that are not subject to the Subcontract Act because they do not satisfy the stated capital requirements of said Subcontract Act, and that cannot be said to have such systems in place, may be faced with an urgent task to put such systems in place to ensure compliance with the Act. In light of the fact that the Act will take effect on November 1, 2024, it is desirable for entrusting enterprises that have or are planning to have dealings with freelancers to move forward with verification of the Act's potential application to them, and whether they need to take action for legal/regulatory compliance.

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PHARMACEUTICAL AND HEALTHCARE

Publication of Government Committee Report for Rebuilding the Generic Drug Industry in Japan

I. Introduction

On May 22, 2024, a report (the "**Report**") was published summarizing the discussions by the Review Committee on the Industrial Structure for the Realization of a Stable Supply of Generic Drugs at the Ministry of Health, Labour and Welfare (the "**MHLW**") (the "**Committee**"). The administrative action against generic drug companies in 2021 due to Good Manufacturing Practice ("**GMP**") issues led to concerns about the stable supply of generic drugs in Japan. The purpose of the Committee is to hold wide-ranging discussions on the ideal industrial structure and policies to rebuild the generic drug industry in Japan so as to ensure a stable supply of generic drugs. Experts in various fields with knowledge of the pharmaceutical industry have been appointed as members of the Committee. The author of this article, as an expert in the legal field, has also been appointed as a member of the Committee and has contributed to the discussions at each meeting and compilation of the discussions for the Report.

This issue presents an overview of the results of the discussions by the Committee, which are summarized in the Report.

II. Current Status and Issues in the Generic Drug Industry in Japan

The starting point for the Committee's discussions was to understand the current status of the generic drug industry and the issues it faces in achieving a stable supply of generic drugs. As described in Chapter 1 of the Report, the percentage of generic drugs in the overall use of pharmaceuticals in Japan has increased from approximately 35% to approximately 80% over the past 15 years. On the other hand, since 2021, there have been a series of violations of the Pharmaceuticals and Medical Devices Act by generic drug companies, and shipments of their products have been suspended, leading to a serious supply crisis of generic drugs that has continued for about three years.

In addition to the supply suspensions and the expansion of limited shipments triggered by the above-mentioned compliance issues, structural problems also contribute to continuing supply concerns. These include the repeated obtainment of new product approvals and NHI drug price listings to compensate for the combination of a decline in profitability of other products due to falling NHI drug prices therefor with the limited production capacity and production volume, especially for many relatively small and medium-sized companies. These factors have led to the expansion of small-volume, multi-product production, which in turn has led to further production-related inefficiencies. Another factor was that distribution practices and price competition after the NHI drug price listing accelerated the decline in profits, making it difficult to invest in manufacturing facilities and to secure and train human resources.

III. The Generic Drug Industry as It Should Be

In considering specific measures to resolve the various issues mentioned above, the Committee considered it important to clarify the aims of the generic drug industry. The Committee spent a substantial amount of time carefully discussing the ideal state of the generic drug industry, the results of which are shown in Chapter 2 of the Report. Specifically, it was decided that, as a natural prerequisite for the social responsibility of a pharmaceutical company, it is necessary to aim for the realization of the following three points to ensure a stable supply of quality-assured pharmaceutical products.

Ensure manufacturing and quality control systems	Manufacturing and quality control systems in place in all companies.
Ensure stable supply capacity	Each company must be able to maintain a stable supply of drugs, and the industry as a whole must have the capacity to increase production as needed.

Sustainable industrial structure	A virtuous cycle of profit and investment has been established and the industry is sustainable.

IV. Direction of Measures

The specific measures that were discussed in the Committee and ultimately proposed in the Report to resolve the various issues mentioned above cover a wide range of topics. These measures, summarized in Chapter 3 of the Report, are aligned with the above-mentioned ideal state of the generic drug industry. The Report also mentions the promotion of collaboration and cooperation among companies, from the viewpoint that there is a cost to the implementation of these measures, and that the establishment of production and quality control systems on a somewhat larger scale may be an effective option to improve production efficiency and profitability. An outline of these measures is as follows.

Ensure manufacturing and quality control systems	**Conducting thorough self-inspections** ✓ Prompt implementation of thorough self-inspections by all companies (use of outside expert organizations is also recommended) ✓ Publication of inspection results and reliable reporting to the competent prefectural governments and the MHLW
	Strengthening Governance ✓ Strengthening governance, including legal compliance ✓ Promoting human resource development, including fostering a quality culture ✓ Sharing of best practices mainly through industry associations
	Improvement of pharmaceutical regulatory oversight ✓ Implementation of unannounced on-site inspections of high-risk manufacturing sites in collaboration with prefectural governments and the PMDA ✓ Establishment of a cooperation system including prompt information sharing between the national and prefectural governments for pharmaceutical regulatory oversight
Ensure stable supply capacity	**Establishment of systems to ensure stable supply at individual companies** ✓ Confirmation of the organization and persons responsible for contributing to a stable supply, and the supply performance of each product after the NHI drug price listing ✓ Specifying measures that companies should be required to implement ✓ Transparency and clarification of responsibilities in inter-company outsourcing relationships
	Establishment of a management system to ensure a stable supply of drugs ✓ Examination of the institutional framework for a management system to ensure a stable supply of drugs (such as monitoring of supply and demand) with reference to the revised Infectious Disease Control Act and other existing systems ✓ Strengthening Supply chain resilience, including securing APIs and raw materials (including research and analysis with respect to same)
Sustainable industrial structure	**Improvement of production efficiency such as optimization of small-volume, multi-product production** ✓ Simplification of pharmaceutical regulatory procedures for changes in manufacturing process ✓ Clarification and simplification of the process for removing a product from the NHI drug price list for withdrawal of products from the market ✓ Rationalization of the identical product line-up policy between a brand drug and its generic drug

	✓ Arrangement of the relationship with the Antimonopoly Act concerning the adjustment of production volume and other collaborations between companies
	Prices and distribution that create a virtuous cycle of profit and investment ✓ Establishment of a mechanism for public disclosure of corporate information to make visible corporate efforts to ensure stable supply ✓ Utilization of corporate information in the NHI drug price system ✓ Study on the state of authorized generic drugs (AG) ✓ Compliance with revised distribution improvement guidelines and study of environmental improvements
Promote collaboration and cooperation among companies	**Improvement of production efficiency and profitability through collaboration and cooperation among companies** ✓ Increase in production capacity and scale of production per product through integration of products ✓ Promote efficiency through collaboration at various levels, including at the department level ✓ Promote industry restructuring through various models of corporate integration
	Measures to promote cooperation and collaboration among companies ✓ Consideration of measures to support corporate initiatives from various aspects such as financial measures
	Arrangement of the relationship with the Antimonopoly Act ✓ Prepare and disseminate casebooks and other materials on specific examples of legitimate business-to-business cooperation ✓ Establishment of a consultation service for antitrust concerns for the companies

The Committee also recommends that a five-year period of intensive reform should be set aside for the steady implementation of these measures, starting promptly with those that can be implemented, with prompt formulation of a roadmap and periodic follow-ups on the implementation status. In fact, some of the above-mentioned measures have already been implemented during the period of the Committee's discussions. In addition, generic drug companies are said to be actively considering various forms of collaboration and cooperation in response to the Committee's discussions.

V. Expectations for Stakeholders

The "Conclusion" section of the Report summarizes the Committee's discussions and outlines expectations for stakeholders in the generic drug industry. This includes the industry as a whole, led not only by individual generic drug companies, but also by industry associations and companies that are aware of their role as the core of the industry, together with involvement by financial institutions and investors, support by the government, and support by drug wholesalers, medical institutions, pharmacies, and other stakeholders. It is noteworthy that the Report also calls on the MHLW to consider the various measures that have been proposed through the discussions at the Committee, including the need for a new legislative framework, and to begin implementing them as soon as possible.

The publication of the Report is only a starting point. In order to realize the ideal state of the generic drug industry, it is important for all stakeholders to work together to intensively implement various measures in a short period of time. Based on the discussions at the Committee, the author of this article would also like to continue to contribute in various ways to help resolve issues in the generic drug industry and to help the industry make further progress.

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