(Attachment)

Guidelines for the Improvement of Commercial Transaction Practices of Ethical Drugs for Manufacturers, Wholesalers, and Medical Institutions/Pharmacies

I. Basic concept

1. Objectives

- In order to grasp appropriate customer purchase prices in the NHI Price Survey, it is necessary for the parties involved in distribution[1] to attempt to create a transparent customer purchase price (CPP), considering the official price specified by the NHI Price Standard in the public health insurance system. Under this principle, Ministry of Health and Welfare (the predecessor of the Ministry of Health, Labour and Welfare (MHLW)) established the "Conference for the Modernization of Commercial Transaction Practices of Ethical Drugs" in March 1983, formulated a model contract for the promotion of contract documents among the parties involved in distribution in 1987 as completed in the "Modernization of the Commercial Transaction Practices of Ethical Drugs and NHI Prices" in 1990, and targeted the continuous improvement of commercial transaction practices.
- Moreover, in June 2004, the "Council for the Improvement of Commercial Transaction Practices of Ethical Drugs" (RYUKAIKON) was started following the aforementioned conference, and an "Interim Report" was conducted in December 2004. In September 2007, the improvement of negative margin between CPP and wholesaler purchase price (WPP) etc., the resolution of continual delivery without price agreements, and the resolution of bundled transactions were requested in the "Urgent Proposal for the Improvement of the Commercial Transaction Practices of Ethical Drugs."
  In addition, the MHLW started a working group consisting of the parties involved in distribution under the RYUKAIKON and has addressed the improvement of commercial transaction practices in response to these requests.
- Moreover, in the "Proposal for the Promotion of the Improvement of the Commercial Transaction Practices of Ethical Drugs" (September 2015), various efforts were made, including the presentation of future matters to be addressed, such as the further promotion of unit price-based negotiation; however, considering the status of unit price-based transactions, etc., it is difficult to say that the situation is in line with the principles.
- In addition, considering that the surveys and revisions of NHI Prices will be conducted between the years of NHI Price Survey, which are conducted once every two years, it is necessary to promote the improvement of commercial transaction practices more than ever and to improve the survey environment.
- Therefore, although an improvement of commercial transaction practices has been promoted as an effort among the parties involved in distribution, in order to accelerate efforts toward improved commercial transaction practices under the initiative of the national government in the future, we will prepare the "Guidelines for the Improvement of the Commercial Transactions of Ethical Drugs for Manufacturers, Wholesalers, and Medical Institutions/Pharmacies" (hereinafter referred to as the "Guidelines") and will request compliance.

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[1] Marketing authorization holders of ethical drugs (manufacturers), pharmaceutical wholesalers (Oroshi), health insurance medical institutions, and health insurance pharmacies

- In addition, we will examine the handling of medical service fees, etc., by incorporating the purpose and content of the Guidelines into the "Scheme of Medical Reimbursement Fee Cuts for Low Rates on Price Agreement," and will implement comprehensive measures, including the enforcement of the policy in the health insurance system.
- The improvement of commercial transaction practices should be promoted in order to ensure the stability of distribution functions in an integrated manner by the parties involved in distribution in the future, and efforts should be made to secure fairness in the payment of distribution costs, etc., among the involved parties, as well as appropriate distribution costs.
- The MHLW will discuss the increase in drugs requiring special control,[2] conversion from the long-listed drugs to generic drugs, and changes in distribution modalities due to developments in ICT, etc., at the RYUKAIKON, and will make necessary efforts, such as the revision of the Guidelines for the improvement of commercial transaction practices.

2. Matters to be considered in the relationship between manufacturers and pharmaceutical wholesalers

(1) Concept of WPP negotiations

- In order to promote early conclusion and unit price-based contracts, to resolve negative margins between CPP and WPP,[3] net WPP based on the presentation of an appropriate primary WPP, considering the concluded price (CPP) level in downstream transactions between wholesalers and health insurance medical institutions/health insurance pharmacies, should be established.
- As for rebates, wholesale functions should be evaluated appropriately considering distribution costs. Regarding allowances that modify the WPP, dispositions reflecting the WPP should be conducted, and the administration standards should be clarified by contract.[4]

(2) New barcode labelling on pharmaceutical products, including information on changes by pharmaceutical unit/package

- From the viewpoints of medical care safety (prevention of misunderstandings), securing traceability (recalls, etc.), promoting streamlined distribution, and preventing the distribution of counterfeit products, a new barcode labelling on pharmaceutical products that includes information on changes by pharmaceutical unit/package will be required as of April 2021; however, it is desirable to accelerate the use of the new display for products that are widely available in significant quantities, as much as possible.

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[2] So-called "specialty drugs"

[3] Negative spread: Status in which the delivery price is lower than the WPP

[4] The "Guidelines Concerning Distribution and Business Practices" (secretariat of the Japan Fair Trade Commission, July 11, 1991) indicates that although "the granting of rebates, in and of itself, will not immediately become problematic with respect to the *Act on Prohibition of Private Monopolization and Maintenance of Fair Trade* (i.e., the "Antimonopoly Act")," it is possible that "the method of granting rebates may limit the business activity of clients

and thus become problematic with respect to the Antimonopoly Act," and further that "it is desirable to clarify the standards for granting rebates and to present such standards to the client."

3. Matters to be considered in the relationship between wholesalers and health insurance medical institutions/health insurance pharmacies

(1) Promotion of early conclusion and unit price-based contracts

- ○ Considering the purpose of the "Scheme of Medical Reimbursement Fee Cuts for Low Rates on Price Agreement," it is desirable to conclude a unit price-based contract on all items, in principle; however, the proportion of unit price-based contracts should be increased, at least from the previous fiscal year. Moreover, in a contract, a memorandum of agreement concerning the delivery of items should be used.
- ○ From the stage of price negotiation, the value of individual drugs should be considered.

(2) Improvement of frequent price negotiations

- ○ As frequent price negotiations obstruct steady supply and the mission of wholesalers, and increase the burden on the buyer side, it is desirable to conclude longer-term contracts, such as yearly contracts, enabling a focus on essential operations such as maintaining steady supply, without increasing the frequency of negotiations, considering the purpose of the "Scheme of Medical Reimbursement Fee Cuts for Low Rates on Price Agreement," except in cases in which variations in drug values occur during the period.

(3) Negotiations for excessive discounts, ignoring drug values

- ○ A negotiation for an excessive discount that ignores the value of the drug, such as one using a benchmark without proper consideration of the business conditions, is an action that is incompatible with the existing NHI Price Scheme listing by brand, which reflects the values of individual drugs.
- ○ From this viewpoint, negotiation for discounts that ignore the value of individual drugs and negotiations[5] for discounts that do not consider distribution costs at all, which may affect the steady supply of drugs and the management situation of wholesalers, should be avoided.
  As the setting of a delivery price based on drug value, as shown above, is affected by the setting of the WPP, price negotiations should proceed in a manner that is integrated with the wholesaler purchase price negotiation shown in 2(1).

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[5] A negotiation for a discount not considering distribution costs at all indicates a negotiation that ignores the setting of price in consideration of the distribution cost included in the NHI Price and the range of adjustment (2% of the NHI Price before revision) for the steady distribution of drugs considered in the NHI Price Revision (except for special reasons, such as discounts based on quantity, etc.).
In the cost calculation method, the distribution cost such as the mean rate in the previous three years of the field survey of the pharmaceutical industry is included.

4. Matters to be considered in common among the parties involved in distribution

(1) Handling of returned items

○ From the viewpoint of: maintaining a steady supply of drugs of ensured quality, the business influences of an increase in obsolete inventory and disposal cost, and the prevention of the distribution of counterfeit items, contracts should be concluded with reference to the model contract, including the handling of returned items, as was proposed in the interim report by the RYUKAIKON (2004) to decide the return policy, in advance, among the parties involved in distribution.

(2) Compliance with the fair competition code

○ Fair and proper transactions should be conducted in compliance with the "fair competition code concerning limitations on the provision of premiums for marketing authorization holders of ethical drugs" and the "fair competition code concerning limitations on the provision of premiums for wholesalers of ethical drugs," based on the *Act against Unjustifiable Premiums and Misleading Representations* (Act No. 134 of 1962).

(3) Concept of commercial transaction practices by product category

○ It is desirable for the parties involved in distribution to improve commercial transaction practices based on the characteristics of each category of products, such as drugs requiring special control, long-listed drugs, and generic drugs.

5. Promotion of the streamlining of distribution and the securing of safety

○ If increases in the cost of frequent delivery and emergency delivery obstruct a steady supply, a contract should be concluded among the involved parties.

○ It is desirable for wholesalers to promote distribution efficiency via joint delivery, for drugs for which the distribution cost is relatively high considering NHI Price, such as for infusion preparations and delivery to remote areas.

○ Based on the final summary of the "investigative commission concerning the modality of measures and policies for the prevention of the distribution of counterfeit ethical drug items," as it is necessary to resolve the issues concerning returned items, obsolete inventory, and recall costs in the trade of drugs in Japan, to prevent the incorporation of counterfeit items in association with an increase in expensive drugs in the drug distribution process, further efforts should be made among the parties involved in distribution under a series of supply chains.

II. Involvement of the MHLW

(1) Consultation with the MHLW

○ Price negotiations under the new NHI Prices after NHI Price Revisions will be conducted according to the Guidelines established in FY2018; however, a contact point has been established at the Economic Affairs Division, Health Policy Bureau, MHLW, to assist with cases in which negotiations among the parties involved in distribution has become deadlocked, and for when there is no chance of improvement.

○ The MHLW will summarize the consultation details according to each item of the Guidelines for the improvement of commercial transaction practices and will publish such details on the websites of the RYUKAIKON and the MHLW, etc., so as to facilitate compliance with the Guidelines for the improvement of commercial transaction practices through the visualization of important matters.

○ Regarding matters that affect the steady distribution of drugs, such as the long-term and wide-ranging

repetition of similar issues following disclosure, the required measures should be taken, including conducting hearings and guidance, along with reporting to the RYUKAIKON.

(2) Confirmation of the status of compliance with the Guidelines for the improvement of commercial transaction practices

○ The status, etc., of unit price-based contracts will be reported to the RYUKAIKON as well as to the Central Social Insurance Medical Council.

(3) Implementation of measures for promoting the improvement of commercial transaction practices

○ The MHLW will take necessary measures, such as a review of the model contract form, the collection and analysis of the data required for promoting the improvement of commercial transaction practices, and reporting to the RYUKAIKON.

III. Date of the application of the Guidelines for the improvement of commercial transaction practices, etc.

○ These Guidelines for the improvement of commercial transaction practices will be applicable from April 1, 2018.

○ The Guidelines for the improvement of commercial transaction practices should be reviewed as necessary, according to the confirmation of the status of compliance with the Guidelines, via the RYUKAIKON, etc.