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Basic Policy for Fundamental Reform of the Drug Pricing System

(Source:「Council on Economic and Fiscal Policy 」&「Central Social Insurance Medical Council 」)

This basic policy was announced on December 20, 2016, and was compiled and agreed upon by the four concerned ministers. On December 21, 2016, this policy was reported to and accepted by government advisory bodies “Council on Economic and Fiscal Policy” for the Cabinet and “Central Social Insurance Medical Council” for the Ministry of Health, Labour and Welfare. Detailed discussions are underway, targeting the finalization at the end of this year.

Basic Policy for Fundamental Reform of the Drug Pricing System

Of late, innovative and high-priced pharmaceutical products have been launched; however, the current drug pricing system is not flexible enough to manipulate such pharmaceutical products. Concerns have been raised about the possible influence on the public burden and the financial administration of medical insurance.

From the standpoint of accommodating both a “sustainable universal healthcare system" and the “promotion of innovation,” as well as achieving a “decrease in the public burden” and “improvement of the medical quality” that benefits people, we will, with a PDCA cycle in mind, work on the following activities to achieve a fundamental reform of the drug pricing system.

1. Fundamental Reform of the Drug Pricing System

(1) In order to respond to changes in the situation after the listing of drug prices under the National Health Insurance (NHI) scheme and to promptly respond to market expansion beyond a certain scale due to changes such as addition of indications, we will review drug prices four (4) times a year, making the best use of opportunities for new drug listings.

(2) To ensure timely reflection of the actual market prices in the NHI drug prices (Reimbursement Prices) and to control the public burden, a drug price survey of all listed drugs will be undertaken every year. A revision of the drug prices will be conducted based on its results.

Thus, in addition to the drug price survey that is currently conducted every two (2) years, a drug price survey of major distributors, etc. will be undertaken even during the years when the

regular two-yearly surveys are conducted, and a revision of the NHI drug prices of products with large discrepancies between the NHI prices and the actual market prices will be conducted (see Note).
(Note) Concrete contents shall be finalized within the next year.
In addition, with respect to the drug price survey, the accuracy of the survey results, the method of survey, and other aspects of survey will be re-examined, and the drug price survey itself will be revisited based on its results. The concrete shape of the survey shall be finalized within the next year.

(3) For accelerating R&D of new innovative drugs, a premium pricing system for the promotion of new drug development and the elimination/resolution of off-label use will be reviewed on a zero basis. In addition, an appropriate value appraisal of truly effective pharmaceutical products and the evaluation of innovation will be undertaken through the introduction of Health Technology Assessment (HTA), covering a price increase rule for highly cost-effective pharmaceutical products and promotion of R&D investment.
In this regard, toward the actual introduction of the HTA, the concerned organization and the system, with a third-party perspective, and its implementation plan will be deliberated based on expert knowledge, and the concrete shape of the scheme shall be finalized within the next year.

2. Reform and Future Efforts

(1) The accuracy and transparency of the drug pricing system should be ensured. In particular, while paying attention to highly confidential information of pharmaceutical companies, clarification of the grounds of drug pricing rules and improvement in the transparency of the drug pricing process will be examined, and then finalized.
With respect to especially high-priced pharmaceutical products, etc., an improvement to the adjustment rule with reference to foreign drug prices will be discussed by acquiring accurate information on foreign prices in consideration of the differences in systems among various countries, and will be finalized accordingly.

(2) A timely survey concerning the business management status of the relevant stakeholders to be affected by the reform of the drug pricing system will be conducted. Based on its result, actions as deemed necessary will be considered.

(3) For the Japanese pharmaceutical industry to transform a business model that relies on long-term listed drugs into an industrial structure with higher drug development capabilities, an expansion of policies and approaches to support R&D of innovative biopharmaceuticals and biosimilars will be considered. Furthermore, support to venture companies and promotion of competition in the generic drug market will be deliberated, and then finalized.

(4) To ensure stable distribution of pharmaceutical products while taking business conditions into consideration, improvements in distribution, promotion of efficient distribution, and appropriate measures for the profit structure accompanying the change in market environment will be espoused. Particularly, in order to promote appropriate price formation, effective measures to encourage price transactions on a product-by-product basis and an early settlement of negotiation will be discussed and then finalized.

(5) With respect to the new medical technology which has been assessed and established, a proper scheme or measures for prompt provision of service to people will be discussed based on cost-effectiveness and then finalized.