-Provisional Translation by JGA-
Industry-related extract from *Basic Policy on Economic and Fiscal Management and Reform 2017*
（Cabinet-published draft on 2nd June,2017) Chapter 3. 3. (1) Social Security. ⑦, page 33-35

Note: For this purpose, the description on 'dispensing fee' in this chapter was deleted in this translation.

(7) A fundamental reform of the drug pricing system, and proper use of pharmaceutical products, etc.

Based on the Basic Policy for Fundamental Reform of the Drug Pricing System (December 20, 2016), efforts will be made for a fundamental reform of the drug pricing system, such as measures to respond to market expansion due to an addition of indications, conduct of a drug price survey/revision every year, a zero-based fundamental re-examination of premium pricing system for the promotion of new drug development and the elimination/resolution of off-label use, and real introduction of Health Technology Assessment (HTA). These efforts aim to accommodate both a "sustainable universal healthcare system" and the "promotion of innovation," and achieve a "decrease in the public burden" and "improvement of the medical quality" that benefit the people.

In this regard, if market expansion is greater beyond a certain scale than estimated market size at the initial listing of the drug price a system shall be established to ensure prompt reduction of the price, referring to re-calculation based on the market expansion. A drug price survey of all listed drugs will be undertaken every year, and the revision of the drug prices based on its result shall be intended to reduce public burden. The premium pricing system for the promotion of new drug development and the elimination/resolution of off-label use shall promote innovative new drug research and development (R&D) and reduce public burden, such as by limiting the target to innovative pharmaceutical products. An evidence-based drug pricing system, incorporating HTA, will be established. In this regard, the transparent organization and system with a perspective of third party, and its implementation plan will be deliberated based on expert knowledge, and the concrete shape of the scheme shall be finalized within this year. Drug price will be determined based on innovativeness and usefulness, etc., to promote investment on new drug

development. New drugs with less innovativeness and usefulness, etc. compared to similar drugs will be clearly distinguished from the innovative new drugs in terms of pricing, and these drug prices will be further reduced. Appraising innovative new drugs and at the same time reducing the prices of long-term listed drugs shall transform the business model of the Japanese pharmaceutical industry, which relies on long-term listed drugs, into an industrial structure with higher drug development capabilities.

Taking note of the responsibility of stable supply of pharmaceutical products and sound development of the generic medicine industry, convergence of price-band for generic drugs will be discussed and finalized. In addition, an expansion of the scope of publication of the drug price survey will be studied, while paying attention to the confidential information of individual companies and influence on the business of wholesalers. To ensure stable distribution of pharmaceutical products and at the same time taking business conditions into consideration, improvement in distribution, promotion of efficient distribution, and appropriate measures for the profit structure accompanying the change of market environment will be taken.

These efforts will be promoted through making their processes transparent. And from the viewpoint of creating highly competitive industry, “Comprehensive Strategy for Strengthening Pharmaceutical Industry” will be reviewed.
For proper use of drugs, promotion of refill prescription for patients with stable conditions, based on a physician’s instruction, will be discussed to support the avoidance of remaining drugs. Additionally, measures for duplicate medications and multiple medications, in cooperation with insurers, will be promoted while grounding on the respective role of physicians and pharmacists. Measures for appropriate prescribing including the issue of duplicate medications and multiple medications for lifestyle-related diseases of the elderly and the preparation of the guideline will be examined on the basis of results of surveys in and outside Japan. Moreover, an efficient and effective use of pharmaceutical products will be promoted through the R&D of companion diagnostic agents. so that medications will be provided to patients who will have at most benefits from the given drugs.

The target volume share of generics is set at 80% by the end of September 2020. To attain this target as early as possible, further measures for promotion of generic use will be deliberated. In parallel with the expansion of approaches to support R&D of biopharmaceuticals and biosimilars, the cost saving amounts from use of biosimilars and share in value of biosimilars will be published, and the number of biosimilars (on a molecule basis) shall be doubled by the end of the fiscal year 2020.

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