Japan 2018: Updates on Drug Pricing

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Japan’s population remains roughly flat recently and has entered on the decreasing phase. It is projected, by year 2060; the total population will drop below 90 million while the aging population ratio will exceed 40%.

Sources: Ministry of Internal Affairs and Communications National Census and Population Estimates(*1), National Institute of Population and Social Security Research Future Population Projections for Japan (January 2012 estimate): Moderate-range Projects for Births and Deaths (Each year’s population is as of October 1)

Historical Changes in Social Security Related Costs and General Expenditures

(Based on original budget)
Yearly medical and pharmaceutical expenditures of NHI

Health expenditures of NHI and pharmaceuticals

- Medical expenditures
- Pharmaceutical expenditures

Trillion Yen

- 1993: 24T Yen
- 1994: 6.9T Yen
- 2001: 28.5%
- 2013: 40.1T Yen

Ratio of drug expenditures (%)

- 1993: 22.1%
- 2001: 40.1T Yen
Who shoulders the cost?

- In addition to ‘Abenomics’;
- Public?
- Patients?
- Employers?
- Practitioners?
- Industries?
The government makes efforts for enhancing efficiency and promoting institutional reforms, under the benchmark where the recent trend of social security expenditures shall be sustained until FY2018, considering the achievements of the three years of economic revitalization and reforms under the Abe Cabinet, which include the trend over the past 3 years that the essential increase of social security expenditures was approximately equivalent to the level caused by population aging (approximately 1.5 trillion yen in 3 years), the future economic situation and price movements, etc.
Examples of Reform

Take actions to optimize medical costs such as reduction of regional gap in medical costs by half.

To promote health and disease prevention, establish a database, enhance incentives, promote health management, and disseminate best practices nationwide.

Consider financial incentives to strengthen the functions of nursing care insurers.

Conduct a full reform of the National Health Insurance drug price system pursuant to the “Basic Policy on complete reform of the National Health Insurance drug price system”.

For the drug prescription fees, properly evaluate the tasks with goods and consider an evaluation system that focuses on tasks that include people. Aim to achieve a generic drugs usage ratio of 80% by September 2020.

For medical services provided at the terminal stage, disseminate information and raise awareness, establish collaboration between people concerned, develop human resources, and disseminate advanced case examples nationwide.

Consider revising the public assistance system and the self-reliance of the needy.
Basic Policy on complete reform of the National Health Insurance drug price system (summary)

Realizing “the reduction of the burden on the people” and “the improvement of the quality of the medical care” by balancing “Sustainability of Universal Health Insurance System” with “Promoting innovation”

Adequate response to the market expansion after listing the drug price list

To respond promptly to the market expansion of a drug due to the additional efficacy, the government will revise drug prices by using the opportunities of listing new drugs (4 times a year).

Drugs price survey and revision between the revisions every two years

A drug price survey on all drugs is conducted every year and, depending on the results, the government will revise drug prices which have large divergences of the prices between list prices and market prices.

Evaluation of innovation (Review of the Price Maintenance Premium, Establishment of the cost-effectiveness pricing system)

To promote innovative new drug development, the government will review the pricing system for the promotion of new drug development and the elimination/resolution of off-label use zero-based fundamentally.

The government will establish a drug pricing system reflecting the evaluation of cost-effectiveness, including raising the price if a drug has high cost-effectiveness (considering how to establish the system, including the creation of an organization and framework)

Measures in addition to the reform

- Ensuring an accuracy and transparency of drug pricing
- Improvement of Foreign Price Adjustment
- Swift understanding of stakeholders’ condition and response
- Prompt provision of new medical technology
- Transformation of the business models of the drug industry that depend on long-listed drugs, to an industrial structure that has a high capability of discovering innovative drugs
- Enhancing supporting measures for the research and development of biopharmaceuticals and biosimilar pharmaceuticals
- Support for venture business, promotion of competition of generic drug companies in the market
- Improvement of the efficiency of distribution structure to secure stable distribution of drugs and drug distribution and appropriate measures for the revenue structure in line with market environments, etc.
**Discussion about radical reform of the drug pricing system**

Based on the "Basic Policy on complete reform of the National Health Insurance drug price system" (December 20, 2016), the Special Committee on Drug Prices under the Chuikyo has been discussing since Jan. 2017, with holding the industry hearing for 3 times.

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan. 11</td>
<td>Response to the market expansion of a drug due to the additional efficacy</td>
</tr>
<tr>
<td>Jan. 25</td>
<td>Foreign average price adjustment</td>
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<tr>
<td>Feb. 8</td>
<td>Drug price survey</td>
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<tr>
<td>Feb. 22</td>
<td>Accuracy and transparency of drug pricing system (Similar drug comparison system)</td>
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<tr>
<td>Mar. 25</td>
<td>Drug price survey and revision of the middle year</td>
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<td>Mar. 29</td>
<td>Drug price survey</td>
</tr>
<tr>
<td>Apr. 12</td>
<td>Accuracy and transparency of drug pricing system (Cost accounting system)</td>
</tr>
<tr>
<td>Apr. 26</td>
<td>Pricing generic drugs</td>
</tr>
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<td>May 17</td>
<td>Industry hearing</td>
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<tr>
<td>May 31</td>
<td>Pricing long-listed drugs</td>
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<tr>
<td>Jun. 14</td>
<td>Price Maintenance Premium</td>
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<tr>
<td>Jun. 28</td>
<td>Evaluation of innovation</td>
</tr>
<tr>
<td>Jul. 26</td>
<td>Summary of the discussion part 1</td>
</tr>
<tr>
<td>Aug. 9</td>
<td>Summary of the discussion part 2</td>
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<tr>
<td>Sep. 13</td>
<td>Industry hearing</td>
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<tr>
<td>Oct. 27</td>
<td>Other items</td>
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<tr>
<td>Nov. 22</td>
<td>Showing the draft</td>
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<tr>
<td>Nov. 29</td>
<td>Industry hearing</td>
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<tr>
<td>Dec. 13</td>
<td>Showing the revised draft</td>
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</table>
Present system

Generally, reimbursement drug prices are revised (reduced) based on market prices every two years.

If applied Price Maintenance Premium, the revision of price of the drug is suspended till listing generic drugs or for 15 years.

*Requirements for application
[about companies] Responding to requests from MHLW for developing drugs
[about items] The divergence of the prices between list price and market price is below the average of all drugs

Problem

Practically, PMP is applied to all drugs if a company meets the requirement about companies. Therefore, even non-innovative drugs can maintain the prices.
Due to the requirement of the divergence of the prices, a company set the drug’s wholesale price high, and market price remains high.
The Review of Price Maintenance Premium
(The requirements about items and companies)

**Requirement about items**

**Present**
- Other drugs

**After review**
- Drugs applied innovation premium or value premium
- Drugs applied supplemental profit
- Orphan drugs, public recruitment drugs
- Drugs which have new clinically mechanism (limited to innovative or valuable drugs in accordance with standards)

**Requirement about companies**

**Present**
- A company engaged in the development of a new drug(s) upon request by the MHLW or application for public recruitment (Except the company which does not respond to the request properly)
- A company conducting R&D activities for the development of new drugs that could truly contribute to the improvement of medical care quality (among companies which has not been requested to develop a new drug(s))

**After review**
- A) Achievements and efforts for developing innovative drugs
- B) Achievements and efforts for eliminating drug-lag
- C) Developing new drugs as the world’s first approval
**Requirement about items**

To promote R&D investment by evaluating innovation of truly valuable drugs, application of PMP will be limited to truly innovative and valuable drugs as follows.

<table>
<thead>
<tr>
<th>Scope</th>
<th>Applicable drugs</th>
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<tbody>
<tr>
<td>New drugs which have no generic drugs*</td>
<td>Orphan drugs</td>
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<tr>
<td>Public recruitment drugs</td>
<td>Public recruitment drugs</td>
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<tr>
<td>Premium applied</td>
<td>Innovation premium, Value premium I, II</td>
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<td></td>
<td>Supplemental profit</td>
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<td>Premium for the verification of true clinical value</td>
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</tbody>
</table>

* Within 15 years after listing of the drug if no generic drugs have not been listed, Drugs which have new clinically mechanism (limited to innovative or valuable drugs) and drugs listed within 3 year after listing new drugs which the PMP applied(only 2\(^{nd}\) and 3\(^{rd}\) drugs)

In addition, the requirement of items about divergence of the prices between list price and market price will be abandoned because;
That requirement doesn’t necessarily evaluate innovation and value Companies set the wholesale price high, consequently market prices remain high.
[Requirement about companies (Company indicator)]
To eliminate/resolve non-approved drugs and off-label use, the company which does not respond to the request about development of the new drug from MHLW properly will be excluded from application continuously.

For the incentive of companies of further innovative drug development and drug-lag resolution, the government will introduce indicators consisted of A) innovative drug development, B) Measures about drug-lag, C) the world’s first approval. The premium applied will vary depending on these indicators.

While medical venture companies have limited achievement and future planning, they are expected to play important roles about innovative drug development, therefore they will be evaluated regardless of their company indicators.
### [Company indicator]

<table>
<thead>
<tr>
<th>Elements</th>
<th>Class</th>
<th>I</th>
<th>II</th>
<th>III</th>
</tr>
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<tbody>
<tr>
<td>A-1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Number of clinical trial in Japan (including multinational clinical trials with Japan) (after Phase II)</td>
<td>Upper 25%</td>
<td>4pt</td>
<td>Middle 50%</td>
<td>2pt</td>
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<tr>
<td>A-2</td>
<td></td>
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<tr>
<td>Number of new listed drugs (component) (Past 5 years)</td>
<td>Upper 25%</td>
<td>4pt</td>
<td>Middle 50%</td>
<td>2pt</td>
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<tr>
<td>B-1</td>
<td></td>
<td></td>
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<tr>
<td>Public recruitment drugs (launching development) (Past 5 years) (Except B-2)</td>
<td>2pt / 1 product</td>
<td></td>
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<tr>
<td>B-2</td>
<td></td>
<td></td>
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<tr>
<td>Public recruitment drugs (approved) (Past 5 years)</td>
<td>2pt / 1 product</td>
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<td>C</td>
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<tr>
<td>World’s first approval drug (Past 5 years)</td>
<td>2pt / product</td>
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</table>

### [Classification]

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>Range</td>
<td>Upper 25%</td>
<td>Others</td>
<td>Minimum</td>
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<tr>
<td>Rate</td>
<td>1.0</td>
<td>0.9</td>
<td>0.8</td>
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</tbody>
</table>

### [About medical venture companies]

Companies which meet definition as follows are classified into category II

- Less than 300 employees or less than 300 million yen
- The other corporation does not have shares or investment of more than 1/2 of the total number of shares or total investment
- A plurality of corporations do not have shares or investment of 2/3 or more of the total number of shares or total investment
- There is only one ingredient to which PMP was applied and in the previous business year (the past five years) in which the drug was approved, no profit for the current year has been posted or profit for the year has been recorded but there is no business revenue
The Review of Price Maintenance Premium (Overview)

Features of PMP

- Radical reform for efficient and effective system to promote innovative drugs
- Considering institutionalization

Requirement about items

Judge by the innovativeness and value of the drugs

Orphan drugs, Public recruitment drugs, premium applied drugs, drugs which have new clinically mechanism etc.

Price

- Drug price of new drugs that are not covered by this premium

Class I
Class II
Class III

Company Indicator

Premium

- Reduction due to the prevailing market price of the original drug

Listing of a new drug

Market launch of generic drugs or 15 years from the listing

*The limitation of the premium is set depending on the divergence ratio.
What happens next?

<Macro>
To what extend will the increase of social security expenditures be allowed?

- To be discussed toward next HONEBUTO (Jun.)

<Micro>
• Health Technology Assessment
• Drug price revision between the revisions every two years
  (The range of revision based on the survey conducted every year) ...
What is the TRUE solution of balancing innovation and sustainability?