Recent Trend of Generic Medicines Market
In Japan

Joint 22\textsuperscript{nd} EGA and 19\textsuperscript{th} IGBA Annual Conference

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Itsuro Yoshida
President of Japan Generic Medicines Association

JGA : Japan Generic Medicines Association

- **Founded**: 1965
- **Members**: 41 companies, 11 affiliate members (as of 2016/4)
- **President**: Itsuro Yoshida (since 2013)
  (President of Towa Pharmaceutical Co., Ltd.)

JGA is the sole association in Japan which consists of Marketing Authorization Holders of generic medicines.

JGA aims to contribute to the advancement of public health and welfare by supplying stably generic medicines with high quality and with reasonable price as well as to forwarding the common benefit of the members.

Transition of Population

Population growth and forecast

Total population: 128.1 million in 2010
Total population: 126.6 million in 2015
65 years old and over: 34 million in 2015
65 years old and over: 39 million in 2040


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Future Population Structure in Japan
Population Rate of 65 Years Old and Over

Japan is now on the way to the full-fledged aging society.

Source) National Institute of Population and Social Security Research
Breakdown of National Medical Expenditure by Age Group (FY2013)

The age group of 65 years old and over consumed 57.7% of total medical expenditure.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Expenditure (Trillion JPY)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-14 years old</td>
<td>2.45</td>
<td>6.1</td>
</tr>
<tr>
<td>15-44 years old</td>
<td>5.20</td>
<td>13.0</td>
</tr>
<tr>
<td>45-64 years old</td>
<td>9.30</td>
<td>23.2</td>
</tr>
<tr>
<td>65 years old and over</td>
<td>23.11</td>
<td>57.7</td>
</tr>
<tr>
<td>Total</td>
<td>40.06</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: The Ministry of Health, Labour and Welfare

Prediction of National Medical Expenditure

The national medical expenditure is estimated to become about 61 trillion JPY in FY2025.

Medical Expenditure (trillion JPY)

Estimation ca.61

10 years later estimation (in FY2025)
ca.61 trillion JPY
= 550 billion USD
= 470 billion EUR

Current expenditure (in FY2015)
45.7 trillion JPY
= 415 billion USD
= 351 billion EUR

Exchange Rate
1 USD = 110 JPY
1 EUR = 130 JPY

Source: The Ministry of Health, Labour and Welfare
The MHLW issued “Action program for Promotion of Generic Medicine Use” in October 2007.

The MHLW issued “Roadmap toward Further Promotion of Generic Medicine Use” in April 2013, with new target aiming at share of 60% or above by the end of FY2017.

The target volume share of generics has been revised from 60% or above by the end of FY2017 to 70% or above by mid-2017 as a step toward achieving 80% or above, and it is planned to attain the target goal of 80% or above at the earliest date possible between FY2018 and 2020. A detailed time-table for attaining 80% or above shall be finally set through evaluation of actual progress in volume share of generics by mid-2017.

New Targeted Volume Share

- **Step1**: 70% or above by mid-2017
- **Step2**: 80% or above at the earliest date possible between FY2018 and 2020.
The Ministry of Health, Labour and Welfare estimates that increasing the use of generics from nearly 47% volume share in FY2013 to 80% by FY2020 would save 1.3 trillion JPY.

1) Generic volume share from Sept.2005 to Sept.2015 are based on biennial drug price-volume market survey by the Government.

2) The Ministry of Health, Labour and Welfare estimates that increasing the use of generics from nearly 47% volume share in FY2013 to 80% by FY2020 would save 1.3 trillion JPY.

Source) The Ministry of Health, Labour and Welfare

Average Volume Share of Generics October 2013 - September 2014

Overview of NHI-related Approaches for Promotion of Generic Use

**Medical Fees**
- Additional fee in Inpatients and Outpatients Services which use of generics over a certain ratio to pharmaceuticals replaceable by generics
- Additional fee for INN Prescribing

**Dispensing Fees**
- Additional fee which dispense of generics over a certain ratio to pharmaceuticals replaceable by generics
- Fee for providing generic information to patients (Providing generic information has become one of the essential elements for obtaining a pharmacy care fee)

**Basic Rule for NHI Medical Services**
Prioritizing use of generics has been stipulated and guided.

**Change of Prescription Form**
Prescription form has been changed to facilitate substitution to generics.

**Substitution to Generics at Pharmacies**
Not only substitution of generics of the same strength and formulation as the reference innovator but also of different strengths and formulations (except for external drugs) is allowable.

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**Generic Penetration by Entry Year**

![Generic Penetration Graph](image)

Source: IMS MIDAS, Standard Units.

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Recent Trend of Volume Share of Generics

Volume Share of Generics (%) (Quarterly surveyed)

Source: JGA & IMS Japan

Pricing of Initial Entry Generics

Initial generic prices fixed to the % of innovator medicine price

In case of oral formulation

<table>
<thead>
<tr>
<th>Application Fiscal Year</th>
<th>% of innovator medicine price</th>
<th>In case number of GE entry exceeds 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY1993</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>FY1994–1995</td>
<td>90%</td>
<td></td>
</tr>
<tr>
<td>FY1996–2003</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>FY2004–2011</td>
<td>70%</td>
<td></td>
</tr>
<tr>
<td>FY2012–2013</td>
<td>70%</td>
<td>60%</td>
</tr>
<tr>
<td>FY2014–2015</td>
<td>60%</td>
<td>50%</td>
</tr>
<tr>
<td>FY2016</td>
<td>50%</td>
<td>40%</td>
</tr>
</tbody>
</table>

Initial generics prices have been lowered.
Targeted Volume Share of Generic Medicines
(by number of tablets)

October 2007 – March 2013
Action Program

FY 2012 (Actual Share 40%)
43.5 billion Tablets

FY 2018-2020 (Targeted Share 80%)
100 billion Tablets

July 2015 - March 2021
Sharp Increase of Target Volume Share

Mid-2017 (Targeted Share 70%)
84 billion Tablets

Basic Policy on Economic and Fiscal Management and Reform
2015 (30th June 2015)

April 2013 - March 2018
Roadmap

FY 2012 (Actual Share 40%)
43.5 billion Tablets

End of FY 2017 (Targeted Share 60%)
72 billion Tablets

Targeted Volume Share of Generic Medicines
(by number of tablets)

July 2015 - March 2021
Sharp Increase of Target Volume Share

Mid-2017 (Targeted Share 70%)
84 billion Tablets

Basic Policy on Economic and Fiscal Management and Reform
2015 (30th June 2015)

April 2013 - March 2018
Roadmap

FY 2012 (Actual Share 40%)
43.5 billion Tablets

End of FY 2017 (Targeted Share 60%)
72 billion Tablets

Status of Production Capacity and Capital Investment of Generic companies

Billion Tablets

Targeted volume by number of tablets

2014 (52%)
56.5 billion Tablets

2012 (40%)
43.5 billion Tablets

2018-2020 (80%)
100 billion Tablets

2017 (70%)
84 billion Tablets

Capital Investment Amount: Total 321.6 billion JPY
Loans payable: Total 200.7 billion JPY
Summary

1. The expanding of generic medicine use is firmly positioned as a contribution tool to the sustainable national health insurance scheme for the coming aging society.

2. Generic companies are required to develop their production capacity and APIs procurement in response to sharp increase in demand of generics. The capital investment for increase of production capacity to meet 80% volume share has been in progress.

3. Sharply growing generic market carries with growing competition and downward pressure of prices. Efficient and tough shape of industrial structure will be requested not only for generic companies, but also for innovators in total.
Summary

4. Further measures for promoting generic medicine may be limited by the era of 80% generic volume share.

5. The demand to individual generic company in such era is to transform its company structure adapted to the environment of rapid growth based on the promotion of generic medicine use into that required for sustainable growth after rapid growth stage.

Thank you very much for your kind attention