Overview of generics policy and penetration in Japan

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BACKGROUND
• The Ministry of Health, Labor and Welfare (MHLW) in Japan reported that the national health expenditure in 2013 exceeded over 40 trillion yen (293 billion euro) for the first time in history.1
• The government implemented various measures to control the increase of the national health expenditure through healthcare policies and the biennial revision of the National Health Insurance (NHI) medical fee schedule.

The NHI medical fee schedule is the reimbursement method for all healthcare services in Japan and is revised every two years. The reimbursement is set by points (one point is 10 yen).
• Japan being a low generic adoption market, one critical cost-containment measure was to increase generic uptake to generate savings to fund innovative medicines and control the healthcare expenditure.
• The Ministry of Finance predicted that if the generic penetration increased from 60% to 80%, 700 billion yen (5.2 billion euro) could be saved by 2020.

OBJECTIVES
• The objective of this research was to provide an overview of policies implemented in Japan and the revision of the NHI medical fee schedule to boost generics uptake, and to assess the impact of these measures.

METHODS
• Information on generics uptake and policies were retrieved from the Japanese authority website, Japan Generic Medicines Association website and grey literature. The revisions of the NHI medical fee schedule which encourage generic uptake were identified from the NHI medical fee schedule list.

RESULTS
Overview of health policies to boost generic uptake:
• Generics health policies have been implemented in Japan since 2002:
  • National Health Insurance (NHI) medical fee schedule introduced financial incentives to prescribe generic drugs for medical service providers in 2002: (Table 1). Since then, various financial incentives to promote generic use by medical service providers have been implemented in the revision of the NHI medical fee schedule by changing reimbursement points of healthcare services as described in Table 1.
  • In 2003, Japan introduced the peri-diem payment system (PDPs) with a diagnosis-related groups (DRG) rearranged grouping system called the diagnostic procedure combination (DPC). The DPC system provided better incentives for using generics. It was expanded to 21% of general hospitals (55% of hospital beds) in 2014.
  • In 2007, the ministry of health, labor and welfare (MHLW) put in place an action plan to encourage generic drug use based on five objectives:
    1. Keeping stable, the distribution of generics
    2. Ensuring good manufacturing practices and quality of generics
    3. Providing generics information
    4. Creating a positive environment for generics
    5. Promoting generics use by changes in the NHI system and fee schedule
  • In 2013, the MHLW developed a roadmap for generics uptake, setting a target penetration rate of 60% by the end of fiscal year 2017, enhancing an action plan which was implemented in 2007. A new indicator was introduced to achieve a generic uptake rate that is comparable internationally.
  • In 2014, more aggressive financial incentives in the NHI medical fee schedule were introduced, setting up a generic volume threshold for pharmacies. In addition, a financial incentive was introduced to the DPC system by creating a threshold for generic use that is over 60%.
  • In 2015, the target year defined in the roadmap 2013 was changed to the end of fiscal year 2016 by the council on Economic and Fiscal Policy to accelerate the generic penetration rate.

Assessment of the impact of measures:
The recent policies allowed a fast uptake of generics in Japan, especially in the recent years.
• The generic market share continuously increased from 32.5% (September 2005), 34.9% (September 2007), 35.8% (September 2009), 39.9% (September 2011), and 46.9% (September 2013) to 51.3% (September 2014) (Figure 1).
• Generic penetration increased by 7.0% between September 2011 and September 2013 while increase was by 2.4% between September 2005 and September 2007.2 Generic uptake increased by 4.4% between 2013 and 2014.4 (Figure 1)

Table 1. Highlights of health policy and healthcare system , and revision of medical fee schedule related to generics

<table>
<thead>
<tr>
<th>Year</th>
<th>Health Policy and revision of the NHI medical fee schedule</th>
<th>The NHI medical fee schedule - revisions of reimbursement</th>
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<tr>
<td>2002</td>
<td>- New indicator: Financial incentive to pharmacies was introduced adding extra points (4 points) when generic use was more than 55% of all prescriptions.</td>
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<td></td>
<td>- Inpatient and outpatient pharmacies were paid (one point is 10 yen) additional points (4 points) for each prescription of generic medicines.</td>
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<td>- Japan being a low generic adoption market, one critical cost-containment measure was to increase generic uptake to generate savings to fund innovative medicines and control the healthcare expenditure.</td>
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<tr>
<td>2003</td>
<td>- Revised the NHI medical fee schedule - adding extra points (5 points) when generic use was over 55% of all prescriptions.</td>
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<td></td>
<td>- Japan being a low generic adoption market, one critical cost-containment measure was to increase generic uptake to generate savings to fund innovative medicines and control the healthcare expenditure.</td>
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<tr>
<td>2008</td>
<td>- Revised the NHI medical fee schedule - adding extra points (4 points) when generic use was over 60%.</td>
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CONCLUSIONS
• The recent health policy measures to increase generics penetration confirm this as a priority for policy decision makers in Japan. Following recent aggressive policies, the Japanese generic market will soon match other developed countries.

Figure 1. Rate of generic penetration from Sep. 2009 to Sep. 2017

References:

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