Future Perspective and Policy Implications for Generics and Biosimilars

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3 Point Objectives:

1. How the reforms are shaping-up the Japanese GE industry?
2. What regulatory changes to anticipate?
3. Where will be GE after 2020?
GE Penetration: Past Drivers Played, New Targets Achievable

**Actual vs. Projected**

- **GE Penetration by Volume (New Method Calculation) %**
- **Source: MHLW, CRECON R&C**

- **Sep-05**: 32.5%
- **Sep-07**: 34.9%
- **Sep-09**: 35.8%
- **Sep-11**: 39.9%
- **Sep-13**: 46.9%
- **YE 2016**: 60.0%
- **YE 2017**: 80%
- **YE 2018**: 80%
- **2019-2020**: Target 80%

- **GE price band continues**
- **LL price bands made stringent**

- **3 price bands of GE**
- **3 price rules for LL**

- **GE supporting Rx-format & other measures**
- **Incentive system to PH* for GE introduced**
- **Further rise in incentives to PH for dispensing GE & guidance fee**
- **Change in Rx-format**

Generic reforms in Japan is a continuous effort and a learning process with multiple measures introduced in past.
Japanese GE Companies played in a broad range of financial measures; however as the pressure points pushing industry towards ~commodity, the financial dispersity among GE companies likely to be narrower.

- Difference between NP-Margins and COGS-margins of have shrieked by .93PP* and 4.2PP respectively and likely to drop further.
- It is notable however that similar difference for R&D as % of revenue has increased by 2.2PP.
- Nichi-Iko stands lower on NP-margins – it aims to ‘restructure its distribution system’, with priority on establishing Brand Awareness by 2020.

* Percentage point(s)
Japan GE Companies: Change in Dynamics

- Q1 → Traditional GE Market and largest.
  Traditionally more profitable, long-term opportunity
- Q3 → Future GE market with high growth
  Opportunity is near-term but low profitable
- Q2 → not feasible
- Q1→Q4→Q3 → Normal evolution
- Q1→Q3 → Complete Δ in business model

JP GE industry is – a group of three distinctly ‘isolated markets’. All generic companies position themselves into two broad market segments and distribution channels

For Generics, Marketing/Branding capabilities in GP/Dispensing pharma market, and distribution capabilities into DPC/large hospitals segment will determine success.
- GE-penetration varies significantly among the prefecture (from 73.3% in Okinawa to 51.3% in Tokushima; ~22PP).
- While not determined – but social-economic factors viz. average income, age spread, and intensity of GE-companies promotional efforts could be attributed such difference.
- While reason could be many – the variation suggest a likely upside in overall GE-penetration rate with likely areas to focus upon (by GE companies in particular).
## Listed Drugs: Pricing Regulations

### GE Drugs

<table>
<thead>
<tr>
<th>Group</th>
<th>GE price as % of brand</th>
<th>New Price</th>
<th>GE Name @ NHI Listing</th>
<th>Pricing Likely in Future</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>&lt;30%</td>
<td>GE in the same bracket will receive uniform price</td>
<td>GE name with no brand name (e.g., atorvastatin calcium hydrate tablets)</td>
<td>All groups may be dissolved under one group with same price for all GE?</td>
</tr>
<tr>
<td>II</td>
<td>30%-50%</td>
<td>NHI price - which is the Wt. Avg. price</td>
<td>GE name + brand name (e.g., atorvastatin calcium hydrate tablets &quot;Sawai&quot;)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>&gt;50%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Long Listed Drugs

<table>
<thead>
<tr>
<th>GE replacement rate after 5 years of GE listing ( Earlier)</th>
<th>GE replacement rate after 5 years of GE listing (2016 Onwards)</th>
<th>Future Direction</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20%</td>
<td>&lt;30%</td>
<td>A harsher and homogeneous pricing method could be introduced to all long-listed drugs?</td>
</tr>
<tr>
<td>20% to 40%</td>
<td>30% to 50%</td>
<td>Such regulatory change may be unfriendly to AG</td>
</tr>
<tr>
<td>40% to 60%</td>
<td>50% to 70%</td>
<td></td>
</tr>
</tbody>
</table>

### Pricing Likely in Future
- All groups may be dissolved under one group with same price for all GE?

### Future Direction
- A harsher and homogeneous pricing method could be introduced to all long-listed drugs?
- Such regulatory change may be unfriendly to AG

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Pricing regulations are becoming stricter for all listed drugs in general
GE Pricing Directions: One ‘Yakka’ likely?

Following 80% GE target achievement:

- LLPs
  - GE Price Band I (AGs)
  - GE Price Band II
  - GE Price Band III
  - ~ 2018-2020 <4-bands

- Branded GEs
  - Commodity GEs
  - 2018-20 ~ 2-bands

- 2022 + 1-Price

Major changes in Industry will start surfacing after the 80% GE penetration target achieved by 2020:

- Narrowing GE pricing bands: eventually in direction of reaching towards ‘two’ price bands only?
- Two broader class of GEs: Branded GEs and Commodity GEs (or Generic GEs)?
- Pressure will mount on local GE companies – call to adopt strategies to mitigate pressure if not already done
  - API/Intermediate cost cutting measures
  - Achieving efficient distribution systems
  - Value added products or services through partnering
  - Consolidation activities to spur
Value contribution from LL drugs is on fall and will continue to do so in coming years:
1. Growing GE penetration
2. Continuous price cuts
3. Growing contribution from new drugs

While GE penetration set to reach ~80%, the industry growth backed by R&D and new products

Top three of the Japan generic companies will improve their contribution in the growing GE space

- 50% of Japan GE market is expected to be constituted by these three companies alone by 2020
- Sawai is likely to exhibit maximum growth followed by Nichi-Iko and Towa
- Nichi-Iko low margin business and Towa’s distribution efficiencies are challenge – but both companies are likely to overcome individual challenges and succeed
Parallel distribution poses several limitations and under evolving scenario, new candidates may evolve. Possibilities may include:

- Non-purchasing model may evolve for Pharmacy and GP markets
  - FFS* – paid to PWS** depending on quantity ordered, account managed etc.
- PWS may resister themselves as manufacturer (import finished good and repackage)

Pricing pressure likely to bring ‘manufacturing area’ under intense exploration to cut cost – though challenges remains

- Quality issues
- 100% finished vs. repacked
- Local manufacturing to local repacking
- Long term reliability

* Fee for service  ** Pharmaceutical Wholesalers
Japanese regulators have shown openness to biosimilars (BS)– ahead to USA on regulatory pathway

Biosimilars are going to play as vital catalyst for industry:
  o Total biologics market has already crossed ¥800b mark and the pipelines are full of new candidates
  o Estimated ~¥300b+ opportunity will open up in next 3 years and ~¥600b+ opportunity to open in next ~7 years.

Mixed response for biosimilars so far: Encouraging uptake of Filgrastim BS (~50% vol share) and Lantus BS (~9% within 2 months of launch); while very slow uptake on Remicade BS (~1% by vol)

Success determinants for future
  I. CT Data Japan vs. Foreign (‘Made in Japan’ vs. ‘Tested in Japan’)
  II. Role of Health Economics to be prominent
      e.g. Onco vs. others – different game plan
  III. HP vs. GP
  IV. Manufacturing ‘Brand’ vs. Manufacturing ‘Ability’
SUMMARY:

– Reforms are continuous efforts and a learning process in Japan – they have played well in enhancing GE-penetration successfully
– New GE targets are achievable – we are going to see more stringent pricing regulations
– The ‘window’ of GE and LLP pricing band will be narrowed down ‘significantly’
– Following 80% target achievement – GE manufacturer may come under pressure to sustain bottom-line margins – new catalyst will be required
– Distribution system may come forward with novel, value-added services, catering to the needs of GE-companies in particular
– Success in biosimilars field will remain challenging and will vary from case to case – however, availability of Japanese data, pharmaco-economics support, hospitals use ratio and marketing muscle will drive the penetration
– The major Japanese GE players will continue to ‘march forward’ as winners