

# Generics in Japan

## The Largest Untapped Market For Generics and Biosimilars

### Table of Contents

#### 1. Introduction to the Japanese Pharmaceutical Market

This chapter highlights the key players, the innovators, generic companies, pharmacy chains, and wholesalers and positions them in the Japanese Pharma market. It describes the key aspects of regulatory systems in Japan and explains how change to the regulatory system is unfolding. Various regulatory bodies and their functions are discussed.

- 1.1 Overview of the Japanese Pharma market
- 1.2 Government and non-government organizations controlling the healthcare sector in Japan
  - 1.2.1 **Koro-sho**: Ministry of Health Labor and Welfare; deciding authority for all healthcare policies
  - 1.2.2 **Chui-kyo**: Central Social Medical Insurance; deciding authority for reimbursement policy
  - 1.2.3 PMDA: Pharmaceuticals and Medical Devices Agency ; evaluates quality, efficacy and safety of drugs
  - 1.2.4 **Ishi-kai**: Japan Medical Association; strongest barrier to generic penetration
  - 1.2.5 JPMA: Japan Pharmaceutical Manufacturers Association; strong supporter of industry development
  - 1.2.6 JGPMA: Japan Generic Pharmaceutical Manufacturers Association: spreading awareness about generics
  - 1.2.7 JPA: Japan Pharmaceuticals Association: contributes to improvement of national health and welfare
- 1.3 Improving regulatory scenario will bolster generic uptake
  - 1.3.1 5 year clinical trial activation plan on track to match international standards
  - 1.3.2 Changes in approval system to reduce approval time
  - 1.3.3 High safety bar for approval of generic drugs
  - 1.3.4 Draft guidelines for Biosimilars : a new growth driver for generic firms in the pipeline
  - 1.3.5 Outsourcing of manufacturing process
  - 1.3.6 Free pricing remains a distant dream in Japan
  - 1.3.7 Price cuts continue to create a hole in the pocket for pharma companies



- 1.4 Introduction to key players and their positioning in Japan pharma market
  - 1.4.1 Challenges for innovators in the domestic market and the way forward
  - 1.4.2 Reasons for historical low penetration for generics and future growth prospects
  - 1.4.3 Separation of prescribing and dispensing activities gives dispensing power to pharmacy chains
  - 1.4.4 Oligopolistic distribution channel controlled by wholesalers

## **2. High cost of Healthcare - 8% of GDP - prompts government to reform the system**

**Health insurance structures in Japan and how they have led to the cost cutting initiatives discussed in this chapter. How increasing generic uptake emerged as a key direction for the government.**

- 2.1 Universal health insurance, increased financial burden for government
- 2.2 Drugs cost: significantly contributes to total healthcare expenditure
- 2.3 DPC – Diagnosis Procedure Combination, limits medical expenditure by hospitals
- 2.4 Impact of reforms

## **3. Why has Generic Penetration Been Low?**

**Description of the key factors that contribute to poor generic uptake in Japan:**

- 1) Low margins received by doctors and pharmacies from generic drugs;**
- 2) Imbalance in bargaining power of different interest groups;**
- 3) Poor management of product quality by generic companies and inability to provide sustained supply;**
- 4) Psychological barriers encountered in breaching doctors' and patients' perceptions of generics as inferior.**

- 3.1 Change in government approach to generic drug promotion
  - 3.1.1 Decreasing trend of Yakka-Sa: difference in reimbursement price from the price to dispensing pharmacies
  - 3.1.2 Special price cuts: threat to companies with higher exposure to “long listed products”
  - 3.1.3 Margin pressure on pharma chains leads to resistance to generic uptake
  - 3.1.4 Wholesalers avoid generics owing to low profitability
  - 3.1.5 Lack of interest from physicians in promoting generics
  - 3.1.6 NHI price cuts affect generic drugs too
- 3.2 Vested interests of key bodies like the *Ishi-Kai* dampens generic uptake
- 3.3 Multiple patent extensions help innovators to increase drug patent life
- 3.4 Stringent quality standards create entry barrier
  - 3.4.1 Re-examination system: similar to data exclusivity in west

3.5 Insufficient information provided to doctors by generic drug companies

3.5.1 Medical representatives: key to increase market share in safety conscious market

3.6 Sense of inferiority towards generics among patients creates psychological barrier

#### **4. Reforms, Implemented on April 2008 and Other Proposals Will Have Both Near-term and Long-term Impact on the Industry**

**April 2008 saw a number of Japanese healthcare reforms coming into force. This chapter highlights how they are likely to promote the overall use of generics and whether they will help to achieve the ambitious government target of expanding the generic market from the current ~17% (by volume) to ~30% (by volume) by 2012. The new reforms are broadly focused towards meeting two goals: *increase the use of generics* and, at the same time, *foster innovation*. They can be categorized into two parts – first, those which will impact the market in the short term (within 1-2 years), and second those which will play out in the long run (after >2 years)**

4.1 Near term impacts of reforms

4.1.1 NHI biennial price cuts – continuously decreasing ‘Yakka-Sa’ can be a good sign for generic drugs

4.1.2 Patient co-prescription can be increased to lower government’s healthcare burden

4.1.3 Reversal of ‘Check-Box’ in Rx format: positive for generics

4.1.4 DPC expansion will open up the hospital market for generics

4.1.5 Incentives for pharmacist to dispense generics

4.2 Long term Impacts of reforms

4.2.1 Freedom to stock one generic brand: proposed reform that should increase generic uptake

4.2.2 DPC for out patients will further enhance generic sales

4.2.3 Change in pharmacy education system: a step in right direction

4.3 Reforms which will protect the interest of innovator pharma companies

4.3.1 Short term: drug lag to decrease

4.3.2 Long term: possibility of removing price cuts during patent life

4.4 Government is determined to increase public awareness about generics

## 5. Japan Generics – Today & Tomorrow

**This chapter describes the current landscape of generic market and projections. Strategies adopted by different sets of companies to gain the ground in different segments are illustrated. The relative strengths of different generic players and the future of different market segments (and thus players) are discussed. The strategic rationale behind the acquisition of Ranbaxy by Daiichi Sankyo is discussed as a case study.**

- 5.1 Companies with focus on GP/dispensing pharma need a different strategy from those focusing on DPC hospitals
- 5.2 Key Japan Pharma companies and their positioning
  - 5.2.1 Towa – A GP and small-hospital-focused company
  - 5.2.2 Nippon Chemiphar - a good blend of branded and wholesaler oriented generic business model
  - 5.2.3 Sawai - dispensing pharmacy market focus will boost sales in near term
  - 5.2.4 Nichi Iko - wholesaler route and focus on DPC market will help to capture benefits of generic growth
  - 5.2.5 Takeda – 20% of domestic sales (¥155b) coming from patent-expired products
  - 5.2.6 Astellas - 40% of domestic sales (¥222b) coming from patent-expired products
  - 5.2.7 Daiichi Sankyo - 70% of domestic sales (¥360b) coming from patent-expired products
  - 5.2.8 Eisai - 23% of domestic sales (¥75b) coming from patent-expired products
  - 5.2.9 Mitsubishi Tanabe - 75% of domestic sales (¥320b) coming from patent-expired products
  - 5.2.10 Chugai - 20% of domestic sales (¥77b) coming from patent-expired products
  - 5.2.11 Shionogi - 50% of domestic sales (¥88b) coming from patent-expired products
  - 5.2.12 Dainippon Sumitomo - 45% of domestic sales (¥110b) coming from patent-expired products
  - 5.2.13 Kyowa Hakko - 27% of domestic sales (¥120b) coming from patent-expired products
  - 5.2.14 Kyorin - 33% of domestic sales (¥29b) coming from patent-expired products
- 5.3 Relative comparison tables for Japanese generic companies
- 5.4 Case Study: Daiichi Sankyo – the rationale of the Ranbaxy acquisition deal
- 5.5 Outlook of the future Japanese generic landscape