# Pharmaceutical Supply Chain in Japan

## Periodic Drug Price Revisions by National Health Insurance Increase Competition and Squeeze Profit Margins



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## GBI Research Report Guidance

The report focuses on the current scenario of the pharmaceutical supply chain in Japan and outlines various models that are currently followed in the industry. The report also analyzes some case studies to identify the best practices in the industry.

- Chapter three gives an overall picture of pharmaceutical supply chain management in Japan and describes the various distribution channels and their evolution.
- Chapter four provides an insight into the legal and regulatory landscape, focusing on laws and regulations that must be followed to obtain marketing, manufacturing and distribution licenses for drugs in Japan.
- Chapter five provides a detailed overview of the risks that can prevent effective and efficient supply chain management.
- Chapter six discusses the pressures driving change in the pharmaceutical supply chain industry.
- Chapter seven discusses the drivers and barriers surrounding the supply chain industry in Japan.
- Chapter eight examines some of the leading wholesale distributors, as well as their market share, business models and strategic scenarios.

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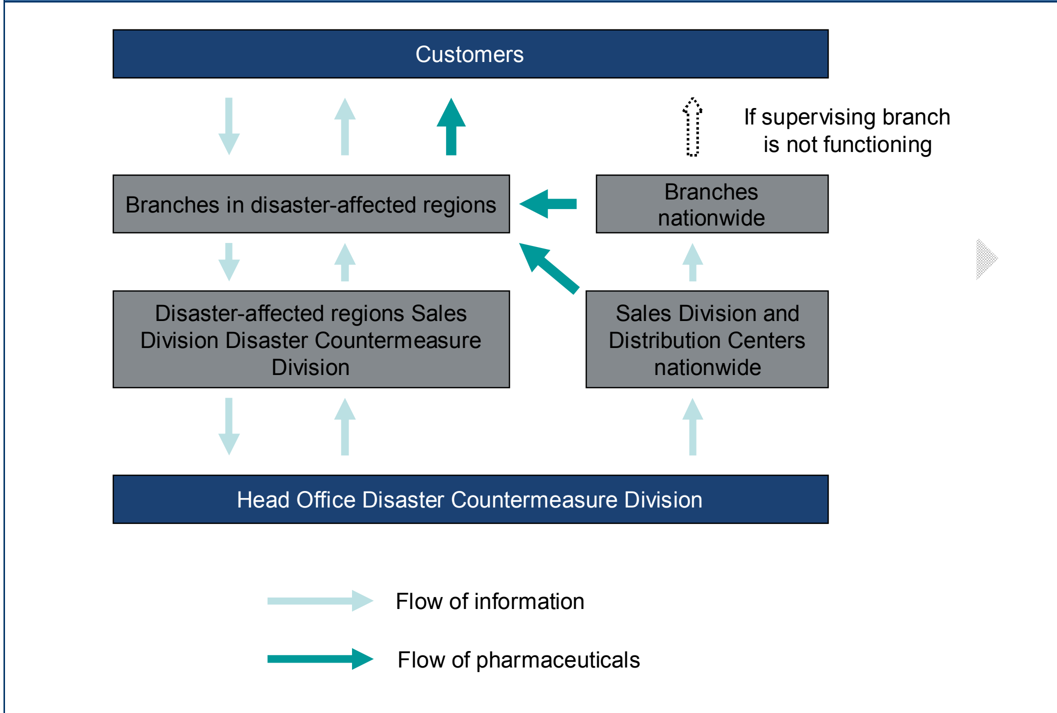
# Pharmaceutical Supply Chain in Japan - Executive Summary

### Business Continuity Planning Enhancements for Disaster Management

*The number of pharmaceutical wholesalers in Japan has fallen by XX% over the last decade*

The east Japan earthquake and nuclear power plant accident of March 2011 highlighted issues in the country's supply chain. Although only marginally affected in comparison with other Japanese industries, production activity in some manufacturer locations became stagnant due to the restricted power supply and damage to distribution centers. Industry leaders have reformulated their supply chain strategies in response to these catastrophes.

**Pharmaceutical Supply Chain in Japan, Suzuken Group, Supply System at Times of Disaster, 2011**




Source: Company website

As part of its Business Continuity Plan (BCP), Suzuken has upgraded its disaster countermeasure system, formulated guidelines to ensure the supply of pharmaceuticals at times of major disaster and implemented regular drills. The company is striving to construct a cooperative relationship with hospitals and pharmacies so that products can be delivered through nationwide branches if supervising branches are not functioning.

The company's headquarters have been constructed in line with earthquake resistance criteria and have a private generator for use during electrical power failure.

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## 2 Introduction

*The top four wholesalers, namely Medipal Holdings, Alfresa Holdings, Suzuken and Toho Holdings, accounted for XX% of the overall pharmaceutical distribution market in 2011 and generated a total of JPY XX trillion ($XX billion) in 2011*

The Japanese pharmaceutical market was worth $XX billion in 2010, second only to that of the US. It has certain characteristics that make it unique and attractive for international companies. The market is dominated by branded products as Japanese citizens consider quality, not cost, to be the most important factor in making decisions related to healthcare (DDB, 2009). Generic drugs account for only XX% of the pharmaceutical industry. Pressures such as an aging population, drug price revisions, patent expiries and drug lags have compelled industry leaders to rationalize their sourcing and distribution and increase operational efficiency in order to become quicker and reduce costs.

GBI Research's analysis shows that supply chain participants in Japan still follow a traditional route, whereby drugs manufactured by pharmaceutical companies are distributed solely through wholesalers to patients via retailers. The top four wholesalers, namely Medipal Holdings, Alfresa Holdings, Suzuken and Toho Holdings, accounted for XX% of the overall pharmaceutical distribution market in 2011 and generated a total of JPYXX trillion ($XX billion) in 2011.

Healthcare in Japan is primarily paid for by the National Health Service (NHS) and administered by the Ministry of Health, Labour and Welfare (MHLW). Drug prices are fixed and controlled by the government. However, the price at which the manufacturer sells the drug to the wholesaler depends on negotiations between both parties. Similarly, pharmacy margins depend on negotiations between the wholesaler and pharmacy. All key players in the supply chain suffered losses due to revisions to National Health Insurance (NHI) drug prices in 2010 which meant they had to compromise on profit margins.

The Pharmaceutical Affairs Law (PAL) regulates the manufacture, marketing and distribution of pharmaceutical drugs and medical devices in Japan. Foreign manufacturers find it difficult to establish themselves because of the rules and regulations established by PAL in the country. This has led to significant M&A activity in the Japanese pharmaceutical industry. The key regulators in Japan are the MHLW and the Pharmaceuticals and Medical Devices Agency (PDMA).

The Japanese pharmaceutical supply chain is growing because of factors such as globalization, free trade agreements with various countries, growing demand for secure packaging and increasing M&A activities.

### 3.3.2 Wholesaler

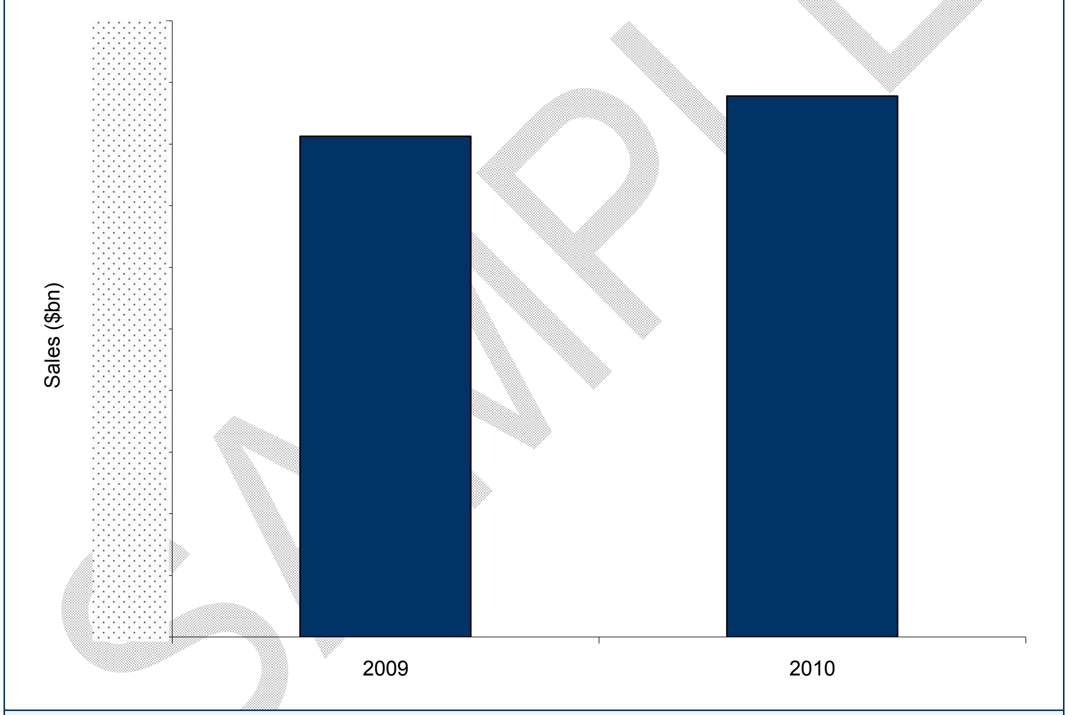
Japan's drug wholesalers purchase pharmaceuticals from manufacturers for sale to medical institutions such as pharmacies, hospitals, clinics, and other customers. In addition to logistics, wholesalers have the following important functions:

- Provision of drug information
- Customer support
- Product promotions
- Price negotiations

As of April 1, 2012, the Federation of Japan Pharmaceutical Wholesalers Association (JPWA) consists of XX member drug wholesalers (JPWA, 2011). The pharmaceutical distribution (wholesale) industry is concentrated into large four groups and has seen repeated reorganization and restructuring since the 1990s. The industry is an oligopoly, with the top four companies representing XX% of the Japanese pharmaceutical distribution market.

*As of April 1, 2012, the Federation of Japan Pharmaceutical Wholesalers Association (JPWA) consists of XX member drug wholesalers*

**Figure 3: Pharmaceutical Supply Chain in Japan, Market Size of Pharmaceutical Wholesalers and Distributors, $bn, 2009 and 2010**






Source: GBI Research; annual reports of the 30 major companies in the Japanese Pharmaceutical Wholesale Association (as of March 31, each year)

As shown in the above figure, the pharmaceutical wholesale and distribution market grew at a rate of XX% between the fiscal year ended 2009 and the fiscal year ended 2010 to reach $XX billion, based on the sales of XX major companies. This slow growth was due to negative influence from NHI drug price revisions and the subsequent expansion of generic drugs.

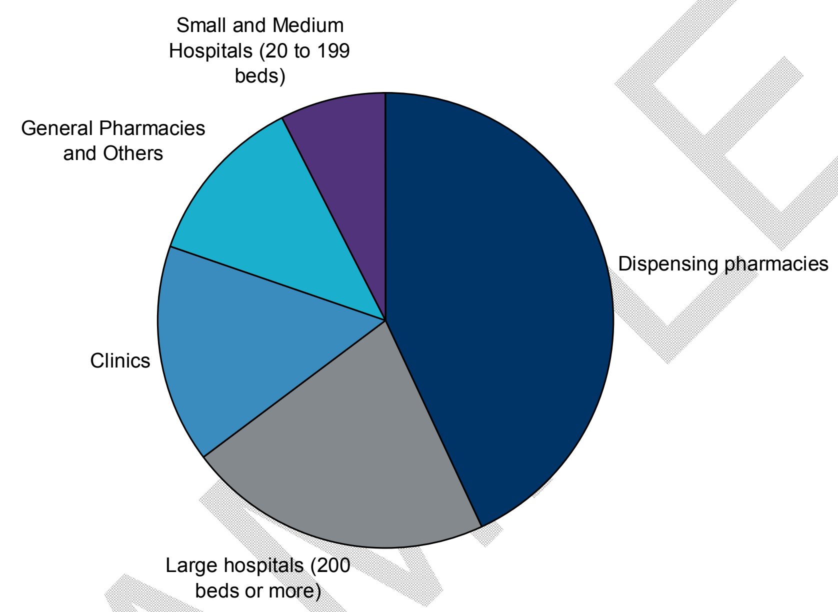
#### *3.3.2.1 Wholesaler Customers*

Drugs are bought from wholesalers by five types of medical institutions:

- Dispensing pharmacies
- General pharmacies
- Large hospitals
- Small and medium hospitals
- Clinics

A breakdown is given in the following figure:

**Figure 4: Pharmaceutical Supply Chain in Japan, Pharmaceutical Sales by Facility (%), 2010**




Source: GBI Research; annual reports of leading six companies in the pharmaceutical distribution (wholesale) business

Dispensing pharmacies account for XX% in terms of sales, followed by large hospitals with XX% and clinics with XX%.

# 9 Pharmaceutical Supply Chain in Japan – Appendix

## 9.1 Market Definitions

- Supply chain management companies comprise organizations involved in the labeling, packaging, warehousing, distribution and destruction of pharmaceutical products.

## 9.2 Abbreviations

**3PL:** Third-Party Logistics

**ALC:** Area Logistics Center

**API:** Active Pharmaceutical Ingredient

**AR:** Assist Representative

**ASEAN:** Association of Southeastern Nations

**BCP:** Business Continuity Plan

**CEPA:** Comprehensive Economic Partnership Agreement

**CMO:** Contract Manufacturing Organization

**CSIMC:** Central Social Insurance Medical Council

**DPC:** Diagnosis Procedure Combination

**DPO:** Days of Payables Outstanding

**DSO:** Days of Sale Outstanding

**DTH:** Direct-to-Hospital

**DTP:** Direct-to-Pharmacy

**EAN:** International Article Number

**EHI:** Employees' Health Insurance

**FDA:** Food and Drug Administration

**FLC:** Front Logistics Center

**GDP:** Good Distribution Practices

**GPMSP:** Good Post-Marketing Surveillance Practice

**GPSP:** Good Post-marketing Study Practice

**GTIN:** Global Trade Item Number

**GVP:** Good Vigilance Practice

**HRI:** Human Readable Interpretation

**ICH:** International Conference on Harmonisation

**JFMDA:** Japanese Federation of Medical Device Associations

**JPWA:** Japan Pharmaceutical Wholesalers Association

**MHLW:** Ministry of Health, Labour and Welfare

**MS:** Marketing Specialist

**NDDR:** New Drug Discovery Research

**NHI:** National Health Insurance

**NHS:** National Health Service

**OTC:** Over-the-Counter

**PAL:** Pharmaceutical Affairs Law

**PDMA:** Pharmaceuticals and Medical Devices Agency

**RFID:** Radio Frequency Identification

## 9.3 Bibliography


- Barnes K (2008). Japan's Contract Manufacturing Awakening. Outsourcing-Pharma.com. Available from: http://www.outsourcing-pharma.com/Contract-Manufacturing/Japan-s-contract-manufacturing-awakening. [Accessed May 16, 2012].
- Central Social Insurance Medical Council (2008). Report on the Survey Regarding the Status of Generic Medicine Usage. Available from: http://www.mhlw.go.jp/shingi/2008/07/dl/s0709-7i.pdf. [Accessed May 21, 2012].
- Cronin R (2008). RFID versus Barcode. PharmTech.com. Available from: http://www.pharmtech.com/pharmtech/IT/RFID-versus-Barcode/ArticleStandard/Article/detail/564670. [Accessed May 16, 2012].
- DDB Worldwide Communications Group Inc. (2009). Health is Wealth. Available from: http://www.ddb.com/ddb_health/pdf/yellowpapers/DDB_YP_Health_April09.pdf [Accessed June 6, 2012].
- Institute for Safe Medication Practices Canada (2008). Pharmaceutical Bar Coding to Improve Patient Safety Options for Technical Standards in the Canadian Environment. Available from: http://www.ismp-canada.org/download/PharmaceuticalBarCodingtoImprovePatientSafety-ISMPCanadaJan08.pdf.
- Iizuka T. (2007). Experts' agency problems: evidence from the prescription drug market in Japan. RAND Journal of Economics,Forthcoming. Available at SSRN: http://ssrn.com/abstract=949668 [Accessed June 5, 2012].
- Japan Pharmaceutical Manufacturers Association (JPMA, 2012). Pharmaceutical Administration and Regulations in Japan. Available from: http://www.jpma.or.jp/english/parj/pdf/2012.pdf. [Accessed June 7, 2012].
- Japanese Pharmaceutical Wholesalers Association (2011). JPWA Guidebook 2010-2011. Available from: http://www.jpwa.or.jp/jpwa/index-e.html. [Accessed May 4, 2012].
- Kaneko T, et al (2007). RFID Solutions for the Medical and Pharmaceutical Industries. Hitachi Review Vol. 56 (Sept 2007) 83.
- Lundborg et al (2002). Health Professionals' and Consumers' Views on the Role of the Pharmacy Personnel and the Pharmacy Service in Hanoi, Vietnam – A Qualitative Study. Journal of Clinical Pharmacy and Therapeutics; 27: 273-80.
- Maurer P (2008). Loving the Japan Pharma Market. Pharma Japan; 2117 Available from: http://www.ifpw.com/documents/FOCUS2011/Focus%20031011.pdf [Accessed May 17, 2012].
- Ministry of Foreign Affairs of Japan (2012). Free Trade Agreement (FTA) and Economic Partnership Agreement (EPA). Available from: http://www.mofa.go.jp/policy/economy/fta/. [Accessed May 24, 2012].
- Mizuho Corporate Bank, Ltd. (2011). Japan Industry Outlook/36. Available from: http://www.mizuhocbk.com/fin_info/industry/pdf/1036_07.pdf. [Accessed May 4, 2012].
- Ministry of Health, Labour and Welfare (2007). New vision for the pharmaceutical industry. Available from: http://www.mhlw.go.jp/bunya/iryou/shinkou/dl/01_0001.pdf. [Accessed May 25, 2012].
- Ohtaki S, et al (2003). Doctor–patient communication: a comparison of the USA and Japan. Family Practice; 20: 276–282.
- Pharma Japan (2011). Focus Vol. 18, No. 5, Japanese Wholesalers Struggle with Pricing System. Available from: http://www.ifpw.com/documents/FOCUS2011/Focus%20031011.pdf. [Accessed May 22, 2012].

- Pharmaceuticals and Medical Devices Agency (2011). Application for Accreditation of Foreign Manufacturers. Available from: www.pmda.go.jp/english/service/pdf/application.pdf [Accessed May 29, 2012].
- Pharmaceutical Security Institute (2012). Counterfeit incident trends. Available from: http://www.psi-inc.org/incidentTrends.cfm [Accessed June 4, 2012].
- Tang J (2008). The Role of Pharmacists in Asia and Africa. Available from: http://www.farmfak.uu.se/farm/samfarm-web/DiplomaWork/HT08_JanetT_apotekarens_roll_i_fyra_lander.pdf [Accessed May 23, 2012].
- World Health Organization (2010). Pharmaceutical Administration and Regulation in Japan. Available from: http://apps.who.int/medicinedocs/documents/s18577en/s18577en.pdf. [Accessed June 1, 2012].


## 9.4 Research Methodology

GBI Research's dedicated research and analysis teams consist of experienced professionals with a pedigree in marketing, market research, consulting backgrounds in the medical devices industry, and advanced statistical expertise.

GBI Research adheres to the codes of practice of the Market Research Society (www.mrs.org.uk) and the Strategic and Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised. The following research methodology is followed for all databases and reports.

### 9.4.1 Coverage

The objective of updating GBI Research's coverage is to ensure that it represents the most up-to-date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

GBI Research aims to cover all major news events and deals in the medical industry, updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research's expert panel (see below).

### 9.4.2 Secondary Research

Secondary research was carried out on internal and external sources to obtain qualitative and quantitative information in the report.

The secondary research sources that are referred to in this report include but are not limited to:

- Company websites, annual reports, financial reports, investor presentations and SEC Securities and Exchanges Commission filings.
- Industry trade journals, scientific journals and other technical literature.
- Relevant patent and regulatory databases.
- National government documents, statistical databases and market reports.
- News articles, press releases and webcasts specific to the companies operating in the market.

### 9.4.3 Primary Research

GBI Research conducts hundreds of primary interviews each year with industry participants and commentators in order to validate its data and analysis. A typical research interview fulfills the following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive landscape, future outlook, etc.
- Helps in validating and strengthening the secondary research findings; and
- Further develops the analysis team's expertise and market understanding.
- Primary research involves email correspondence and telephone interviews, as well as face-to-face interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers and national sales managers;
- Hospital stores, laboratories, pharmacies, distributors and paramedics;
- Outside experts: investment bankers, valuation experts, research analysts specializing in specific medical equipment markets; and
- Key Opinion Leaders: physicians and surgeons specializing in different therapeutic areas corresponding to different kinds of pharmaceutical drugs.

### 9.4.4 Expert Panel Validation

GBI Research uses a panel of experts to cross-verify its databases and forecasts.

GBI Research's expert panel comprises marketing managers, product specialists, international sales managers from medical device companies, academics from research universities, KOLs from hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment and supplies.

Historic data and forecasts are relayed to GBI Research's expert panel for feedback, and adjusted in accordance with their feedback.



## 9.6 Disclaimer