

**Summer Training at
Sun Pharmaceuticals Industries Ltd.**

Study of Generic Market for Japan (Generic Companies' Portfolio and Profitability) and suggest a viable Business Model for Japan Market

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**MBA-Pharmaceutical Management (MBA-PM)
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CERTIFICATE

is is to certify that **Ms. Shalini Attkan** has undergone her summer training in
Pharmaceuticals limited, Mumbai from 3rd April, 2014 to 4th June ,
2014. Her approach to the study has been scientific and analytical.

The summer training is partial fulfilment of the course requirement

Wish her success in all her future endeavours.


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TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Ms. Shalini Attkan** of Indian Institute of Health Management Research, Jaipur has undergone her summer project in Sun Pharmaceutical Industries Ltd, in **Business Development Department** from **April 03, 2014 to June 04, 2014**. Her project title was **“Study of Generic Market (Companies' Portfolio and Profitability) and Suggest a Viable Business Model for Japan Market”**

She has completed the project to the satisfaction of her project guide and the organization

We wish her success in all future endeavors.

for **SUN PHARMACEUTICAL INDUSTRIES LTD.**

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Acknowledgement

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Executive summary

The project was done to study the generic market of Japan (generic companies' portfolio and profitability) and suggest a viable business model.

The study was based on primary and secondary data. It was descriptive analytical type of study. The data was collected from the industry professionals, IMS database, companies' annual report and public domain data available on internet. Duration was two months.

The study was done on 27 generic base companies in Japan and business model was studied. The data collected for each company was sorted and compiled and analysis was done on the basis of their product line, target therapy areas, their financial positions, their research and development plans and pipelines and distribution system.

On the basis of the above information, the top products, brands and generics were identified.

For further analysis, SWOT analysis and comparative analysis was done.

This study provides an insight about the Japan market, its pharmaceutical market, position of generics in Japan and generic companies. It also gives an outline about how the business is done by these companies and what is their current position in market.

The types of business models identified on the basis of this analysis were found to be of 3 types, organic growth, co-development and alliance with foreign major pharma companies.

The viable model for company turns out to have alliance with local companies and start with its core competencies and strength in therapy areas. The manufacturing can be either done in-house or may be done on contract manufacturing or out licensing can be done. The partners will be helpful in distribution and marketing. Thus the resources of partners can be utilized in making a position in the market. Since only generics will be the product type, new drug delivery methods and combination can be explored as per the demographic demand.

Introduction

Japan overview

Japan is world's 3rd largest economy after USA and China.

Gross domestic product (GDP) for the year 2012 at official exchange rate was \$5.9 trillion.

Service sector dominates the GDP with a contribution of 71.4% followed by industrial production (27.5%) and Agriculture (1.2%). Japan spends 9.3% of the total GDP as health expenditures.

The total population of the country is 127 Million with a growth rate of -0.07% in 2012 & Life expectancy at birth is 83 years. The largest portion of the total population is covered by people of 25-54 years of age. Of the total population, 67% populations are living in urban areas of the country.

Major cities by population are:

- TOKYO (capital) 36.507 million;
- Osaka-Kobe 11.325 million;
- Nagoya 3.257 million;
- Fukuoka-Kitakyushu 2.809 million

Literature review

Health Care System in Japan

People in Japan have the longest life expectancy in world. All residents of Japan are required by the law to have health insurance coverage. Patient accepts responsibility for 30% of healthcare costs while the government pays the remaining 70%. Payment for personal medical services is offered through a universal health care insurance system that provides relative equality of access, with fees set by a government committee. Health insurance is, in general, mandatory for residents of Japan, though there is no penalty on individuals who choose not to comply, and around 10% of the population does not enroll. People without insurance through employers can participate in a National Health Insurance Programme administered by local governments. Patients are free to select physicians or facilities of their choice and cannot be denied coverage. Hospitals, by law, must run as non-profit and be managed by physicians. For-profit corporations are not allowed to own or operate hospitals. Clinics must be owned and operated by physicians.^[5]

Japanese Pharmaceutical Market

World's second-largest pharmaceutical market, JPY9,547 billion (US \$100.5 billion). (IMS data for 2012)

Japan leads the Asia Pacific pharma market with 65% market share. Generic market account approx. 10% of total market and is worth US \$9.7 billion. Japan's generic-drug market is expected to expand by about 8% a year and reach ¥1.3 trillion yen (\$13.2 billion) in 2017. (Nikkei report July 2013)

While there is large scope in Japan, the road is not that easy because of stringent regulatory requirements and high quality and cosmetic standards. Generic pharma companies have to meet JP requirements both for APIs as well as Formulations

Generic definition in Japan

Generics should have the same active ingredients, dosage, administration route, and indications, as those of approved drugs in Japan. They should Have the same quality, efficacy, bio equivalency (generally, it is not required for intravenous injection), expiry period and safety compared with original drug. Also have the same line up with original drug (packaging) and assure stable supply and submitted after re-examination period of original drug.

ANDA Filling

ANDA filling can be done twice in a year, February and august. It takes around 17 months to enter into NHI price list. After ANDA filling, once manufacturing of 3 validation batch is done, application of GMP inspection is done. After GMP inspection and PMDA review in form of questions is done, application for raw data review is submitted. It takes around 2 months to get approval after raw data review is complete. If the approval is done, application for NHI price is submitted, till this time 1 year has passed. It takes more 4-5 months to get NHI price.

Regulatory bodies

Two Authorities are involved in the Application Review

- Ministry of Health, Labor, and Welfare (MHLW)
- Pharmaceutical and Medical Devices Agency (PMDA)

The MHLW is in charge of pharmaceutical regulatory affairs in Japan and regulated by Pharmaceutical Affairs Law (PAL, 1943)

Organization and Functions of MHLW

- 1) Pharmaceutical and Food Safety Bureau (PFSB): Clinical studies, approval reviews and post-marketing safety measures.
- 2) Health Policy Bureau: Promotion of R&D, production and distribution
- 3) National Institute of Health Sciences (NIHS): Evaluation center for the reviews required for approval to manufacture or import drugs

Pharmaceutical and Medical Devices Agency (PMDA)

It was established on April 1, 2004, as an independent administrative organization conducting the reviews. The PMDA consists of 13 departments under which the Office of OTC and Generics is also there.

[1]

Marketing Approval

Marketing approval and licenses are required in order to market drugs in Japan, and obtained from the Ministry of the MHLW or prefectural governor.

The following requirement must be met for this purpose

- The applicant is marketing authorization holder
- The manufacturing site has been accredited as a manufacturer by MHWL.
- The products name, ingredients, contents, dosage and administration, indication or efficacy etc are appropriate (high quality standards)
- GMP compliance of the product as designated by ministerial ordinances
- Companies are required to appoint general marketing compliance officers and to have them ensure compliance with the quality control standards.
- Marketing business license: Importers of drugs who import drug on commercial basis are required to obtain a marketing business license.

Approval for Generic Drugs

When the active ingredients, dosage, administration route, and indications are the same as those of approved drugs in Japan

Application procedures remain the same as for new drugs

A review by the PMDA is undertaken; after reviews on drug equivalence and compliance approval is granted.

Review for Generic Drugs

- 1) Equivalency Reviews: PMDA investigates if the ingredients and their contents, dosage and administration and indication etc. of the applied product are equivalent to those of existing products
- 2) Compliance Inspection: Paper based compliance inspection carried out by PMDA office of confirmatory audits based on the background data
- 3) Dossiers compliance inspection (Raw data review)^[3]

Hurdles for Generics in Japan

- Multiple patent extensions (for one or multiple patents)
- Re-examination System, which has similar functions of Data Exclusivity
- Pharmaceutical Regulation, which in general forbids generic application with only off –patent indications
- JGPMA has requested Allow generic application with only off-patent indications with no condition.
- Insufficient information provided for medical professions by generic drug companies. (Japanese law does not regard labeling information for generic drugs and is considered as innovator property)

According to the Road Map to Promote the Usage of Generic Drugs announced by MHLW in 2013, the target share (unit base) of generic products will be reached 60% by the end of March 2018.

Pricing system

In the past, generic drugs have been entered in the NHI Drug Price List once every 2 years, but the entry has been made once a year from 1994 and twice a year since 2008 (entries in May and November from 2009). The NHI pricing is done by following principles:

1. When the brand drug is already entered in the list and a generic drug identical to the brand drug is entered for the first time, the price of the generic drug is obtained by multiplying the brand drug price by a factor of 0.7. The factor is 0.6 for oral preparations, in the case that more than 10 brands are already on the market. When both the brand and generic drugs are already entered, the price of the newly entered generic drug is the same as the lowest of the generic prices.
2. When there are many brands with the same standard, i.e., when the number of products already entered and to be entered exceeds 20, the price of the generic drug to be entered is obtained by multiplying the lowest among all products entered by a factor of 0.9. A special formula was introduced for biosimilar products. A premium (maximally 10/100 of the standard) is added to the standard price depending on qualitative and quantitative data obtained from clinical trials.

According to NHI price revision in 2014, the NHI price of generic product will be 60% of the innovator's. In case of oral dosage forms, the NHI price will be 50% of the innovator's if there are more than 10 products listed.

Requirements

MHLW/PMDA has listed some requirements for generic companies. They have some key points which companies need to fulfill.

- 1) Development
 - a. Triplicate analysis at all ACC stability station for API and FP
 - b. Storage condition for stability 40 ± 1 °C / $75 \pm 5\%$ RH, 6 month
 - c. Strict compliance to Japanese Pharmacopoeia (JP)
 - d. High standard quality and cosmetic compliance (Zero critical defects, <0.65% major defects and <2.5% minor defects)
 - e. Same shelf life and storage condition as innovator product
- 2) Steady delivery
 - a. Delivery to wholesaler: 1 day
 - b. Never "Out of stock"
 - c. Clarification of the supplier information (FAX No., TEL No. etc.)
 - d. Preparation of the same strength as the innovator
- 3) Suitable quality
 - a. Practice of long-term stability test, stability test of unpackaged products etc.

- b. Survey of literature regarding generic
- c. Regular practice of dissolution equivalency test with innovator
- 4) Information to customer
 - a. Updation in PMDA system: within 3 week after changing packaging insert
 - b. Distribution of information to customer within 1 month after changing packaging insert
 - c. MR control/training
 - d. Printing of bar-code: action according to the notice(June 29, 2012)

Reexamination and Reevaluation

Re-examination

Marketers must perform post-marketing surveys on new drugs to reconfirm the safety and efficacy of drug by reexamination by the MHLW.

It is obliged only for a given period (4-10 years, normally 6 years) after the marketing approval of New Drugs. No approval of generic drugs before the end of Re-examination period is done, even in case of no patent infringement.

This system's function is similar to Data Exclusivity.

Re-evaluation

All drugs, including those that have completed re-examination must undergo re-evaluation to recheck their efficacy, safety, and quality in accordance with progress in medical and pharmaceutical sciences.

Rationale

This study will be beneficial to the company as company is targeting an entry in Japan market. Japan is a complex market where generics are not considered a drug of choice Therefore a study depicting the business model of generic companies of Japan will help sun pharma to form strategy to successfully place itself in Japan market.

Objectives

- To study the business model of the generic companies in Japan
- To suggest a viable business model for Japan

Methodology

Study design – descriptive analytical study on 27 generic companies of Japan

Source of data – primary and secondary data collected by

- Industry professionals
- IMS Dataview 7

- Annual reports of companies
- Sun Japan team
- Internet

Data analysis plan - data was compiled and analyzed quantitatively.

Duration – 2 months

Analysis

Data collected was compiled together, sorted on the basis of the companies' name. The public domain information i.e. corporate profile, history, financial details (if available), their distribution system was studied and compiled as a report. The products brand or generics or combinations, were categorized on the basis of therapy area they target. Top 10 brand and generic products were listed out. On the basis of this information available SWOT analysis and comparative analysis was done.

Findings

The research was done on following 27 generic companies of Japan. The companies are listed on the basis of their sales in 2013^[2] (highest to lowest).

1. Meiji Seika Pharma Co., Ltd.
2. Mochida Pharmaceutical Co., Ltd.
3. Nichi-Iko Pharmaceutical Co., Ltd.
4. Kaken Pharmaceutical Co., Ltd.
5. Sanwa Kagaku Kenkyusho Co., Ltd.
6. Sawai Pharmaceutical Co., Ltd.
7. Nippon Kayaku Co., Ltd.
8. Fuso Pharmaceutical Industries Ltd.
9. ASKA Pharmaceutical Co., Ltd.
10. Elmed Eisai Co., Ltd.
11. Nipro Pharma Corporation
12. Nippon Chemiphar Co., Ltd.
13. Yoshindo Inc.
14. Nihon Generic Co., Ltd.
15. Mitsubishi Tanabe Pharma Corporation
16. Maruishi Pharmaceutical Co., Ltd.
17. Fuji Pharmaceutical Co., Ltd.
18. Daiichi Sankyo Espha.
19. Mylan Pharmaceutical Co., Ltd.
20. Sandoz Japan
21. Kyowa Pharmaceutical Industries Co., Ltd.
22. Showa Kako Corporation

23. Kyorin Remedio
24. Iwaki Seiyaku Co., Ltd.
25. Towa Pharmaceutical Co., Ltd.
26. Ohara Pharmaceutical Co., Ltd.
27. Kobayashi Pharmaceutical Co., Ltd.

Meiji Seika Pharma Co., Ltd

Meiji Seika Pharma Co., Ltd was found to have the highest sales in 2013(IMS data). It is a part of Meiji Seika Holdings Co., Ltd. Meiji Seika has around 12% share in total sales of Meiji Seika holding co., Ltd.

Meiji Co., Ltd the other part of Meiji Seika Holdings makes food products and supplements.

Meiji Seika Pharma has business of ethical pharmaceuticals, agricultural chemicals and veterinary products.

They have good number of products and their specialty is in anti infective drugs (antibiotics) and neurology. The brand to generic ratio was found to be 60:40.

Their distribution system is very well developed and has relations with many overseas companies.

Meiji Seika focuses their R&D mainly on infectious diseases and central nervous system disorders.

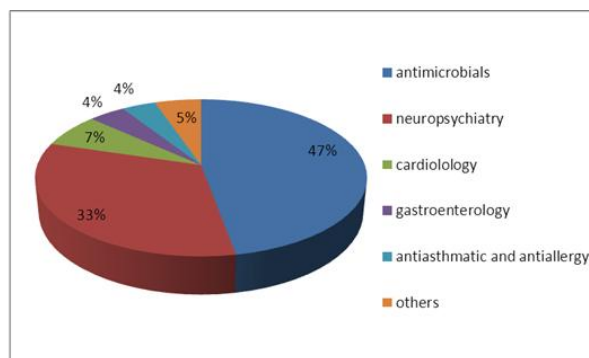


Fig no.1: sales wise segmentation of products of Meiji Seika pharma

They are also working in developing new chemical entities and also generic drugs including anticancer drugs and biologics.

There are four research and development center in Japan.

They have 9 products under phase I clinical trials. These products are reported to have antimicrobial and antipsychotic activity. They have 810 medical representatives.

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Amlodipine M-Sk	48,920	Hypertension	Meiact	152,909	Antibiotic
Vancomycin Meiji S	40,660	Antibiotic	Reflex	136,756	Depression
Donepezil Hcl Meij	29,869	Depression	Depromel	40,192	Depression
Rabeprazole M-Sk	15,686	Gastritis	Fosmicin	28,365	Antibiotic
Meropenem Meiji	15,473	Antibiotic	Meilax	26,515	Anxiety
Paroxetine M-Sk	13,527	Depression	Vicillin Sx	23,831	Antibiotic
Clarithromy.Meiji	9,124	Antibiotic	Orapenem	18,771	Antibiotic
Olopatadin.Hcl Mei	8,372	Allergy	Isodine	18,137	Antiseptic
Edaravone Meiji	8,008	Depression	Ebastel	15,540	Allergy
Nafamostat Meiji S	7,063	Blood Coagulation	Omegacin	11,283	Antibiotic

Table no.1: Top 10 Generic and Brand products of Meiji seika pharma

SWOT Analysis

Strengths

Good number of antimicrobials and neuropsychiatric products
R&D well developed
Well developed distribution system

Weakness

Products are limited to acute therapy
Limited cancer related products

Opportunity

Very rich R&D pipeline
Biologics and oncology may prove to be the next target segment

Threats

Women health and pediatrics not targeted

Fig no 2: SWOT Analysis of Meiji Seika Pharma

Mochida Pharmaceutical Co., Ltd

Mochida pharmaceutical is one of the oldest organizations. It was established in 1913.

They have shown consistent growth in past years with around 10% net income. It spends around 14% of income in research and development.

The brand to generic ratio was found to be 80:20.

Mochida specializes in cardiology. Another categories on they are focused is gynaecology and neuropsychiatry and haematology. Mochida Pharmaceutical's product development pipelines offer lineups that will greatly enhance their major specialties: cardiovascular medicine, obstetrics and gynecology, dermatology, emergency medicine, and psychiatry. They have 720 medical representatives.

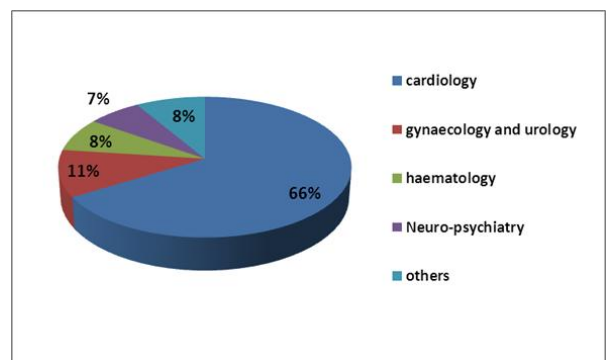


Fig no. 3: sales wise segmentation of products of Mochida

Top products

(sales in thousands of USD)

Generic		Sales	Indication	Brand	Sales	Indication
Heparin	Moch	23,370	Blood Coagulation	Epadel	400,669	Huntington's Disease
Magnesium Oxid.	Moc		Mineral	Atelec		Hypertension
		11,724	Supplement		122,514	
Thrombin	Moch	9,622	Blood Coagulation	Dinagest	80,704	Contraceptive
Voglibose Od Qq		4,252	Diabetes	Lexapro	37,010	Depression
Donepez.Hcl Od Moc		3,169	Depression	Arasena A	22,552	Viral Infection
Pioglitazone Mochi		2,322	Diabetes	Besofen	20,540	Skin Care
Filgrastim Bs Moch			Blood Loss During	Miraclid		Hypercholesterolemia
		1,727	Surgery		18,424	
Chorionic Gon Moch		1,681	Infertility	Fastic	15,975	Diabetes
Novo Prota.Sulf.Mo		1,510	Heparin Overdose	Florid	12,551	Fungal Infection
Dopamine Hcl Mochi		1,273	Psychosis	Grandaxin	12,548	Anxiety

Table no. 2: Top 10 Generic and Brand products of Mochida seiyaku

SWOT Analysis

Strength

- Huge number of cardiovascular drugs

Weakness

- Therapies focus on degenerative disorders and not acute or chronic

Opportunities

- R&D focus on neuropsychiatry, another major category

Threats

- No specific drugs for women healthcare, children and oncology

Nichi-Iko Pharmaceutical Co., Ltd

Nichi-iko was established in 1965 as Nihon Iyakuin Kogyo Co., Ltd was renamed after merger in 2005. It has shown growth in last 2 years, the net sales have gone high even after price revision.

The brand to generic ratio was found to be 24:76.

Nichi-iko has a large product line with differentiation. Its products are equally distributed in acute and chronic therapy. They cover major therapeutic area with generic available in all

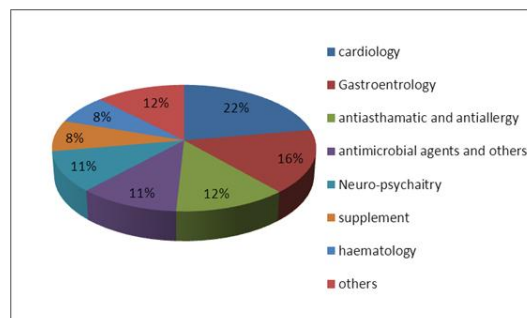


Fig no. 5: sales wise segmentation of products of Nichi-iko

types of dosage form and strengths. They cover oral dosage form, parenteral and topical dosage forms. Good numbers of injectables.

Nichi-iko is working on anti cancer and biologics. Nichi-iko has a well developed distribution system, with 3 distribution centers across Japan. There are around 266 Sales and marketing representatives.

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Limaprost Alfade.N	39,647	Platelet Aggregation	Besofthen	24,423	Skin Care
Omeprazole Nichiik	18,258	Peptic Ulcer	Pravalon	21,460	Hypercholesterolemia
Lansoprazole Nichi	17,764	Peptic Ulcer	Tryptanol	7,732	Depression
Amlodipine Nichiik	17,603	Hypertension	Fesin	6,455	Supplement
Pranlukast Nichiik	17,034	Asthma	Sefmazon	5,802	Antibiotic
Nifedipine Nichiik	16,948	Hypertension	Proarisin	4,771	Inflammation
			Teiyaku		
Donepezil Hcl Nich	16,115	Depression	Cefotax	3,801	Antibiotic
Edaravone Nichiiko	13,181	Depression	Betahistine	3,422	Vertigo
			Me.Nic		
Icosapen.Ethyl Nic	11,998	Hypertriglyceridemia	Dezolam	3,254	Depression
Cilostazol Nichiik	11,730	Congestive Heart Failure	Periactin	3,187	Allergy

Table no 3: Top 10 Generic and Brand products of Nichi-iko

SWOT Analysis

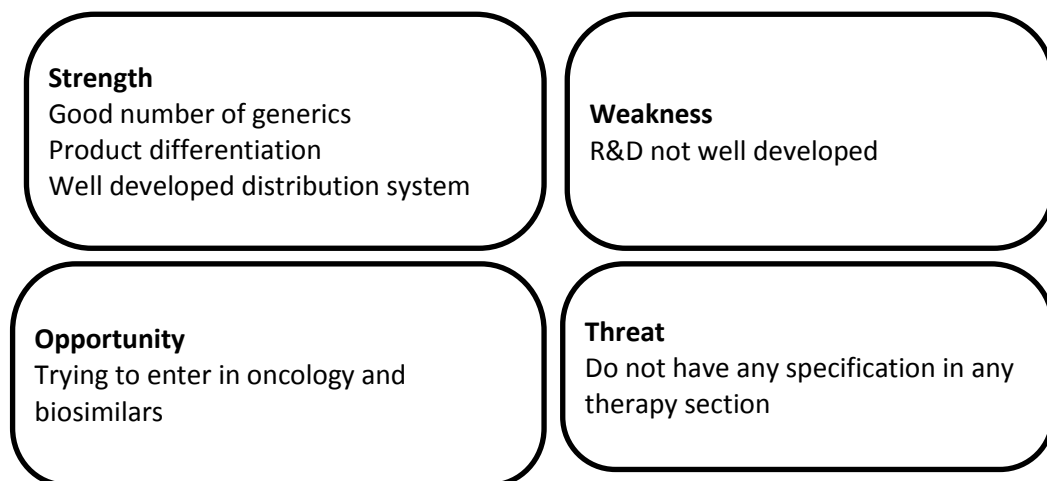


Fig no 6: SWOT analysis of Nichi-iko

Kaken Pharmaceutical Co., Ltd

Kaken pharmaceutical co. ltd started their full scale production of antibiotics in 1948. Now they have business of ethical pharmaceutical drugs, agrochemicals and also renting estate. Pharmaceutical drugs are the major business i.e. 92% of total sales.

The brand to generic ratio was found to be 74:26.

Kaken focuses on acute therapies like inflammation, pain, muscular skeletal pain, allergy, etc. The chronic condition which they target is osteoarthritis, rheumatoid arthritis and gout. The dosage form is also limited to oral dosage forms and topical forms. It has expanded in other sections recently. Kaken's R&D is totally focused on inflammation and pain section. The products in pipeline are related to same category.

There are around 750 sales and medical representatives.

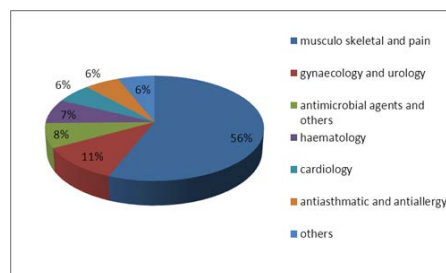


Fig no 7: sales wise segmentation of products of Kaken

Top products

(sales in thousands of USD)

Generic		Sales	Indication	Brand	Sales	Indication
Amlodipine	Kakn	10,819	Hypertension	Artz	298,015	Osteoarthritis
Loxoprofen	Na	8,274	Inflammation	Adofeed	55,329	Inflammation
Kake						
Pranlukast	Kaken	5,030	Asthma	Procylin	44,717	Hypertension
Rabeprazole	Na	4,928	Gastritis	Lipidil	39,379	Dyslipidemia
Kak						
Rebamipide	Kaken	3,659	Gastritis	Fiblast	33,944	Skin Infection
Donepezil Hcl	Kake	3,072	Depression	Empynase	31,067	Proteolytic Enzyme
Levofloxacin	Kaken	2,987	Antibiotic	Ebrantil	17,646	Hypertension
Itraconazole	Kaken	2,383	Fungal Infection	Ropion	10,452	Inflammation
Latanoprost	Kaken	2,312	Glaucoma	Clexane	10,443	Blood Coagulation
Kinex	Kakn	1,680	Diabetes	Cytotec	10,058	Gastritis

Table no 4: Top 10 Generic and Brand products of Kaken

SWOT Analysis

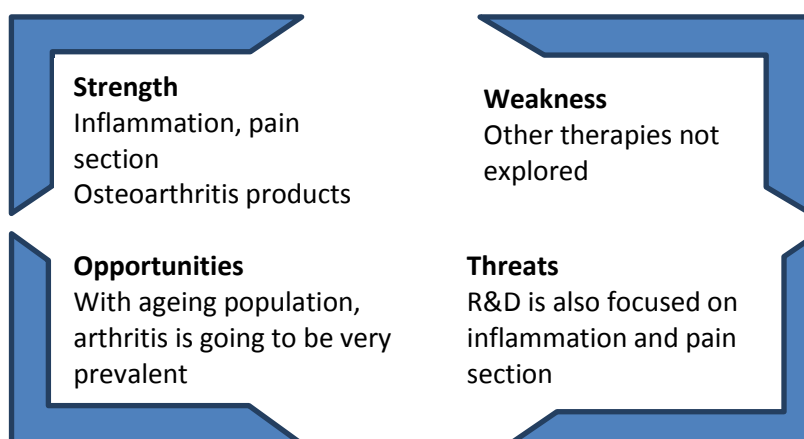


Fig no 8 SWOT analysis of Kaken

Sanwa Kagaku Kenkyusho Co., Ltd

Sanwa Kagaku Kenkyusho Co., Ltd was established in 1953. It has various business activities like R&D, manufacturing and marketing of pharmaceuticals, diagnostics, medical and nursing care nutritionals and healthcare products and contract manufacturing of pharmaceuticals.

The brand to generic ratio was found to be 44:56.

Sanwa Kagaku Kenkyusho has two types of products pharmaceutical products and diagnostic kits. Diagnostic kits include test kits for glucose, pregnancy, protein and other blood tests.

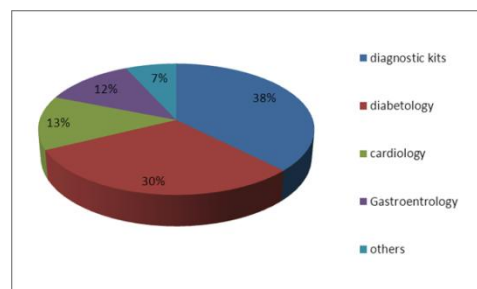


Fig no 9 sales wise segmentation of products of Sanwa

In Pharmaceutical products, diabetes and cardiology is the major segment. Diabetes mellitus remains the focus of Sanwa. R&D is based on diabetes only. The R&D pipeline has products for diabetes and conditions related to it such as diabetes neuropathy.

It has 475 medical representatives.

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Lansoprazole Od Sa	15,485	Gastritis	Glucose, Blood Tests	234,140	Test Kit
Nifelantern Cr	7,379	Hypertension	Seibule	178,858	Diabetes
Glimepiride Sanwa	6,493	Diabetes	Argamate	57,169	Laxative
Calc. Carbonate San	4,587	Supplement	Carnaculin	38,590	Hypertension
Pranlukast Dk	2,637	Asthma	Diart	25,983	Diuretic
Loxoprofen Na Sanw	2,336	Inflammation	Diamox	5,434	Glaucoma
Alendronate Sanken	1,494	Osteoporosis	Clearview In.Ab	5,010	Pregnancy Test Kit
Losartan Potas.Dk	1,393	Hypertension	Touchron	4,722	Inflammation
Quetiapine Sanwa	1,289	Depression	Ebrantil	3,787	Hypertension
Mexirate Sanken	1,079	Depression	Vasolator	3,595	Angina

Table no 5 Top 10 Generic and Brand products of Sanwa

SWOT Analysis

Strength

Diagnostic kits
Diabetes mellitus

Weakness

R&D is also based on diabetes only

Opportunity

New products in major therapy sections like cardiology and neuropsychiatry
Products specifically for osteoporosis and gout

Threat

Not a public company
Oncology and women health are growing sector

Fig no 10
SWOT analysis of Sanwa

Sawai Pharmaceutical Co. Ltd

Sawai Pharmaceutical Co., Ltd was established in 1929. They have around 620 products, one of the largest product lines.

The brand to generic ratio was found to be 24:76.

Sawai pharmaceutical produces products covering all therapeutic areas, Cardiovascular, Gastro-intestinal, Blood / body fluid, Other metabolic, Antibiotics, Central nervous system, Antiallergics, Chemotherapeutics, Vitamins, Anti-cancer, etc.

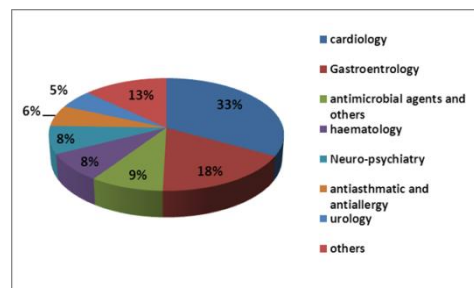


Fig no 11 sale wise segmentation of products of Sawai

The products are available in oral, injectable and topical dosage form. They also produce inhalational liquids.

They launched maximum no. of products in last two years.

Sawai has a very well developed and functioning R&D. They have launched 15 new products in 2013.

In the year 2013, Sawai was the only company to market RISEDRONATE Na tablets 17.5mg, which are used to treat osteoporosis.

Sawai also supplies 30 types of orally disintegrating (OD) tablets, which can be administered without water. This is the biggest range of OD products in the Japanese generic drug industry.

In the year 2013, their R&D expenditure was the highest in the Japanese generic drug manufacturing industry at 4,551 million. During the three-year period covered by their medium-term plan, they plan to spend 17,300 million on R&D. They have the highest supply capacity with 5 manufacturing plants. They have 9 branches and 11 sales offices in Japan. The number of medical representatives is also high, 400.

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Atorvastatin Sawa	48,449	Hypercholesterolemia	Gasrick	19,626	Gastritis
Tamsulosin Hcl Saw	23,312	Enlarged Prostate	Limarmone	17,966	Platelet Aggregation
Lansoprazole Sawai	21,778	Gastritis	Atanaal	10,818	Hypertension
Voglibose Sawai	19,518	Diabetes	Omepron	9,837	Gastritis
Amlodipine Sawa	16,549	Hypertension	Methycool	6,736	Supplement
Pravastatin Na Saw	14,771	Hypertension	Allozym	6,062	Gout
Cilnidipine Sawai	12,379	Hypertension	Sennoside	5,483	Laxative
Icosapen.Ethyl Saw	9,509	Hypertriglyceridemia	Nicarpin	5,199	Hypertension
Rabeprazole Na Saw	9,434	Gastritis	Cardonan	3,992	Hypertension
Carvedilol Sawai	8,757	Hypertension	Itorat	3,603	Antibiotic

Table no 6 Top 10 Generic and Brand products of Sawai

SWOT Analysis

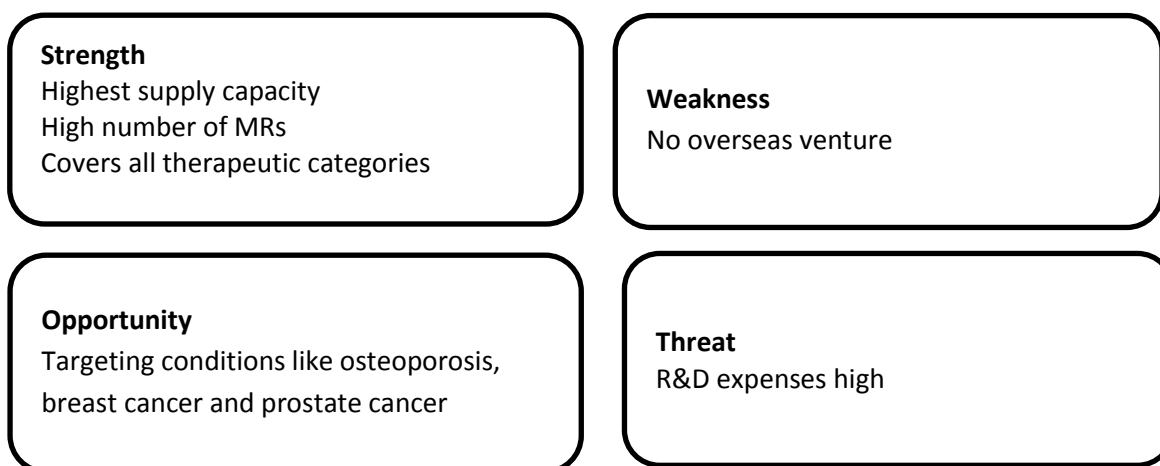


Fig no 12 SWOT analysis of Sawai

Nippon Kayaku Co. Ltd

Nippon Kayaku was founded in 1916 as Nippon Kayaku Seizo Co., Ltd. it changed its name after acquiring 2 companies in 1945 as Nippon Kayaku Co., Ltd.

In 1943, Yamakawa Seiyaku was merged into Nippon Kayaku Co., Ltd. and pharmaceutical business was launched. Nippon Kayaku has been producing and selling cancer-related pharmaceuticals such as anti-cancer drugs, including bleomycin, drugs used to ease pain caused by cancers and generic drugs, which have been widely discussed recently as its main products. Nippon Kayaku maintains a staff of more than 400 MRs (medical representatives), of who approximate 100 are cancer specialist MRs. The brand to generic ratio was found to be 35:65.

Nippon Kayaku focuses on chronic therapy. It has large numbers of antineoplastic products, and they lay focus on prostate cancer, breast cancer and lung cancer among others. They also have antineoplastic antibiotics.

The products are present in variety of dosage forms such as injectable, capsules, tablets, powders and even topical preparations for other therapy products.

Nippon Kayaku has been expanding its product line in oncology segment. The new products launched in 2011 and 2012 are also from the same segment. Highest grosser products are from the same category.

They have tried to expand product mix by introducing products targeting neuropsychiatry, cardiology, antimicrobials, etc. They introduced BCG vaccine.

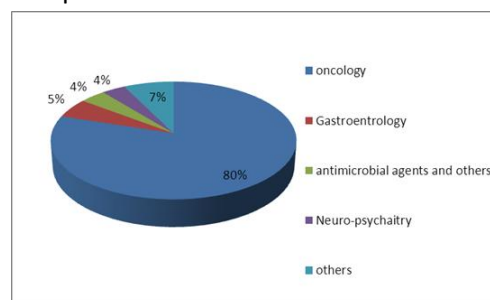


Fig no 13 sales wise segmentation of Nippon Kayaku

Nippon Kayaku has been conducting full-scale research and development of a polymeric micelle anti-cancer drug.

The polymeric micelle anti-cancer drug comprises chain polymers in which hydrophilic polyethylene glycol (A) and a polyamino acid processed to exhibit hydrophobic property (B) are aggregated to form nanoparticles while encapsulating the anti-cancer drug.

Although the molecular weight of the chain polymers is in the order of tens of thousands, the molecular weight increases to a few million when they are aggregated. In water, the aggregated polymers appear as a spherical aggregate with a diameter of 20-100 nm.

Top Products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Paclitaxel Nk	82,052	Oncology	Odyne	28,724	Oncology
Carboplatin Yamaka	44,914	Oncology	Randa	21,483	Oncology
Bicalutamide Nk	41,679	Oncology	Saligren	14,415	Auto Immune Disease
Epirubicin Hcl Yam	15,654	Oncology	Fareston	14,170	Oncology
Granisetron Nk	15,140	Emesis Or Vomiting	Millisrol	9,566	Angina
Levofolinate Nk	10,249	Oncology	Calsed	9,492	Oncology
Anastrozole Nk	7,676	Oncology	Lastet	8,157	Oncology
Gemcitabine Nk	6,099	Oncology	Pinorubin	7,622	Oncology
Sennoside Yamakawa	4,356	Laxative	Oncovin	6,417	Oncology
Doxorubici.Hcl Nk	3,282	Oncology	Immunobladder Yama	6,364	Vaccine

Table no 7 Top 10 Generic and Brand products of Nippon Kayaku

SWOT analysis

Strengths

Largest number of cancer related products
Products include anticancer, antibiotic and analgesics
Injectable generics
Distribution within Japan is very good

Weakness

Less penetration in other therapy segments
Generics form present only in cancer related products

Opportunities

Cancer is one of the national health problem in Japan, thus cancer related products will be in demand.
Have expanded in vaccines, cardiology and neuropsychiatry

Threats

Generic market is expanding in Japan; Nippon Kayaku does not have generics products in any other segment.
R&D expenses is high

Fig no 14 SWOT analysis of Nippon Kayaku

Fuso Pharmaceutical Industries Ltd

Fuso was established in 1957. The brand to generic ratio was found to be 52:48.

Fuso pharmaceutical has large number of supplements. Supplements include mineral supplements, vitamins, amino acids, etc. Anti allergy product like pollen which is a new therapy for treating allergy is high grosser. Products are available in oral and injectable dosage form.

Fuso is trying to expand and differentiate in different therapy sections like cardiology and neuropsychiatry. They have 332 medical representatives.

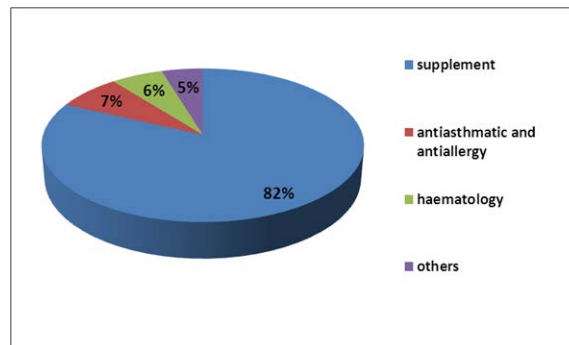


Fig no 15 sales wise segmentation of products of Fuso

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Sod Chloride Fuyk	92,950	Blood And Body Fluid	Kindaly	169,984	Mineral Supplement
Heparin Fuyk	10,611	Blood Coagulation	Cernilton	25,907	Allergy
Glucose Fuso	7,547	Blood And Body Fluid	Minihepa	8,275	Blood Coagulation
Water For Inj.Fuso	7,266	Injections	I Stat Cartr.	4,115	Blood Test Kit
Sennoside Fuso	5,368	Laxative	Replas	2,293	Mineral Supplement
Biotin Fuso	2,879	Supplement	Caltan	2,732	Mineral Supplement
Vitamin C Fuso	2,320	Supplement	Rocain	1,894	Arrhythmia
Sph.Carbon.Ads.Fuso	1,585	Drug Overdose	Berabu	1,185	Blood Coagulation
Lactoringer Fuso	1,578	Blood And Body Fluid	Artfed	886	Mineral Supplement
Xylitol Fuso	969	Supplement	Methycobide	849	Mineral Supplement

Table no 8 Top 10 Generic and Brand products of Fuso

SWOT Analysis

Strength
Supplements
Anti Allergy products

Weakness
R&D not developed

Opportunity
New products in chronic therapy products
NDAs filed for a drug on the pain of neuralgia occurring after the cure of herpes zoster and intraoral patch.

Threat
Chronic conditions are upcoming market

Fig no 16 SWOT analysis of Fuso

ASKA Pharmaceutical Co. Ltd

ASKA pharmaceutical co. ltd was formed in 2005 after merger of two companies i.e. Teikoku Hormone Mfg. Research Laboratory Co., Ltd. and Grelan Pharmaceutical Co., Ltd.

It has business of manufacturing, sale and import/export, etc. of pharmaceuticals, veterinary medicines, quasi-drugs, foods, and medical devices.

The brand to generic ratio was found to be 57:43.

ASKA has a large number of products related to women health. They have number of products related to infertility and contraceptive. They also have original products related to gastric ulcers and hyperlipidemias.

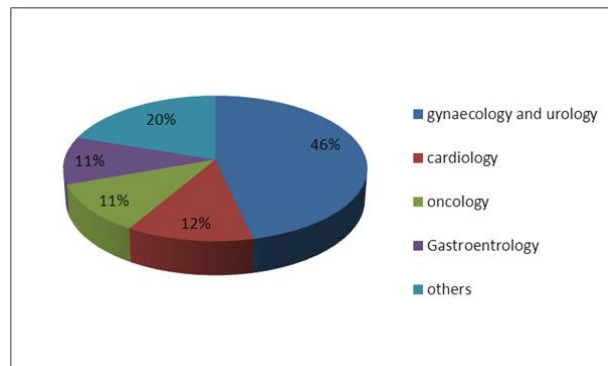


Fig no 17 sale wise segmentation of products of ASKA

They have products only in oral dosage form and transdermal patches. They have distributed their products in major sections, and they target both acute and chronic therapies. Their focus remains on women health and degenerative disorders.

There are around 290 medical representatives.

ASKA pharmaceuticals have many original drugs to their credit. R&D plays a very important role in making ASKA pharmaceuticals a reputed name. ASKA also promote joint development with Japanese as well as other overseas companies. Anticancer and infertility medication is under development.

Top products

(sales in thousands of USD)

Brand	Sales	Indication	Generic	Sales	Indication
Thyradin S	48,298	Hyperthyroidism	Bicalutamide Aska	27,804	Prostate Cancer
Lipidil	19,037	Dyslipidaemia	Amlodipine Aska Se	24,161	Hypertension
Prostal	18,634	Contraceptive	Rabeprazole Na Aa	10,592	Gastritis
Altat	15,066	Peptic Ulcer	Hmg Aska Seiyaku	8,724	Menopause
Gonapure	7,581	Menopause	Osteluc Aska Seiya	2,249	Arthritis
Luteonin	7,298	Uncomplicated Premature Labour	Rebamipide Aska Se	1,879	Gastritis
Warkmin	7,244	Vitamin D Supplement	Loratadine Aa	1,717	Allergies
Norlevo	6,926	Contraceptive	Losartan Potas.Aa	1,707	Hypertension
Ramian	6,474	Hypercholesterolemia	Parotin Aska	1,544	Depression
Menoaid Combi	5,160	Menopause	Mesalazine Aska Se	1,425	Inflammatory Bowel Syndrome

Table no 9 top 10 Brand and generic products of ASKA

SWOT Analysis

Strength

Innovative products (well developed R&D)
Distribution in major therapy sections
Large no. of women health products

Weakness

R&D is limited to core strength of companies
Distributions system may not be well developed
Dosage forms very limited

Opportunities

Trying to enter in less common therapies like prostate cancer, migraine.
New infertility and cancer product under development

Threats

New drug delivery systems are gaining popularity, and ASKA focuses only on oral dosage form
No pediatric products

Fig no 18 SWOT analysis of ASKA

Elmed Eisai Co. Ltd

Elmed Eisai is a part of Eisai Co. Ltd. it is the generic maker. The business is manufacturing and marketing of pharmaceutical drugs, over-the-counter drugs and Pharmaceuticals Production Systems.

The brand to generic ratio was found to be 10:90.

Cardiology, antiasthmatic and antiallergy drugs remain core competency of Eisai. Apart from these neuropsychiatry is another category in which Eisai has competency. It has full explored these chronic sections. The dosage forms are limited to oral dosage form and transdermal patches only. Acute therapy sections like peptic ulcer and gastric ulcers are also targeted.

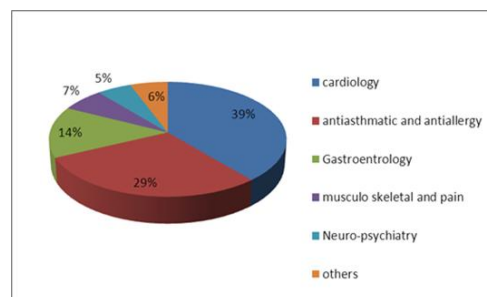


Fig no 19 sale wise segmentation of products of Elmed Eisai

Elmed Eisai is a R&D based company. It has huge R&D pipeline.

The products are targeted in oncology, neurology and cardiology. There are many R&D center across Japan as well as across world. Medical representatives – 40

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Atorvastatin Ee	48,080	Hypercholesterolemia	Blostar M	9,522	Peptic Ulcer
Fexofenadi.Hcl Ee	43,911	Allergy	Menilet	8,614	Angina
Amlodipine Emec	37,923	Hypertension	Liduc M	2,634	Hypercholesterolemia
Pranlukast Emec	35,246	Asthma	Lipola M	1,478	Hypercholesterolemia
Rebamipide Emec	27,666	Gastritis	Mucobulin	500	Respiratory Diseases
Loxoprofen Emec	11,805	Inflammation	Telbans Ds	446	Asthma
Felbinac Eisa	6,145	Inflammation	Porosave	334	Vitamin D Supplement

Isosorbi.Dinit.Eme	4,012	Angina
Glimepiride Emec	3,343	Diabetes
Epalrestat Emec	3,255	Diabetes

Table no 10 Top 10 Generic and Brand products of Elmed Eisai

SWOT Analysis

Strength

Huge R&D product pipeline
Neurology and cardiology

Weakness

Less penetration in other sections
Other dosage forms not explored

Opportunities

Good number of oncology drugs in pipeline

Threats

R&D expenses are high
Degenerative disorders remains focus
Women health or male healthcare problems not targeted at all.

Fig no 20 SWOT analysis of Elmed Eisai

Nipro Pharma Corporation

Nipro Pharma Corporation is a part of Nipro Corporation. Nipro Corporation has business of medical equipment, pharmaceutical and glass related. Nipro Pharma Corporation has business of Generic Drugs, Pharmaceutical Kit Products and Contract Manufacturing Services.

The brand to generic ratio was found to be 25:75.

Nipro Pharma's product includes generic products and diagnostic kits.

Their generic products cover acute therapy sections. However they lay emphasis on neuropsychiatry products also.

The products are available in oral, injectable and topical dosage form. They have also introduced half dose tablets, orally dissolving tablets.

Diagnostic kits include glucose tests, blood tests, urine test and pregnancy test kits. Other pharmaceutical kits include prefilled syringes, half dose kits, double bag kits (liquid/powder and liquid/liquid), and pre mixed bag solution.

They contract manufacture for more than 60 companies. Nipro Pharma's sales organization consists of nine bases and ten branch offices throughout Japan.

There are 196 medical representatives in Nipro Pharma's workforce.

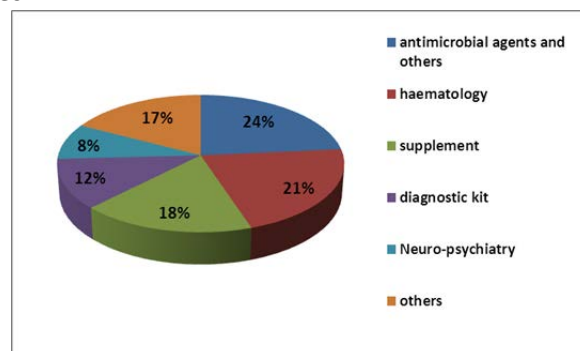


Fig no 21 sale wise segmentation of products of Nipro Pharma

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Sod.Chl.Iso.Nipro	27,982	Blood And Body Fluid	Glucose, Blood Tests	28,335	Test Kit
Heparin Na Dial.Ni	14,325	Anticoagulant	Lympack	27,511	Mineral Supplement
Cefmetazole Na Nip	11,374	Antibiotic	Wystal	11,683	Antibiotic
Cefotiam Hcl Nipro	11,139	Antibiotic	Sefmazon	8,092	Antibiotic
Edaravone Np	7,967	Depression	Clidamacin	1,674	Antibiotic
Dalteparin Na Nipr	7,106	Anticoagulant	Hishiphagen C	1,529	Mineral Supplement
Donepezil Hcl Nipr	5,699	Depression	Hitocobamin-M	1,480	Supplement
Amlodipine Np	4,748	Hypertension	Solyugen	1,310	Mineral Supplement
Meropenem Np	4,435	Antibiotic	Solyugen	1,250	Mineral Supplement
Rebamipide Np	4,331	Peptic Ulcer	Hisinalc #3	1,133	Mineral Supplement

Table no 11 Top 10 Generic and Brand products of Nipro Pharma

SWOT Analysis

Strength

Large manufacturing capacity
Injectable
Pharmaceutical kits

Weakness

Focus is on acute therapy in spite of having large manufacturing capacity
Fewer products related to women health or oncology or cardiology.

Opportunity

New drug delivery forms
Injectable kits and test kits

Threat

Does not have products in chronic therapy
Women health and oncology are growing sectors

Fig no 22 SWOT analysis of Nipro Pharma

Nippon Chemiphar Co. Ltd

Chemiphar was formerly known as Hitachi Chemical Co., Ltd. it was set up in 1950. In 1970, Company changed name to Nippon Chemiphar Co., Ltd. the business is Manufacture, sale, import and export of ethical pharmaceuticals and diagnostic agents and healthcare business.

The brand to generic ratio was found to be 26:74.

Nippon Chemiphar has one of the largest generic product line ups. The products cover major therapeutic categories. Both acute and chronic therapies are equally targeted. The products are available in oral, injectable and topical dosage form.

Chemiphar aims to develop at least 15 generics in a year.

Medical representatives – 263

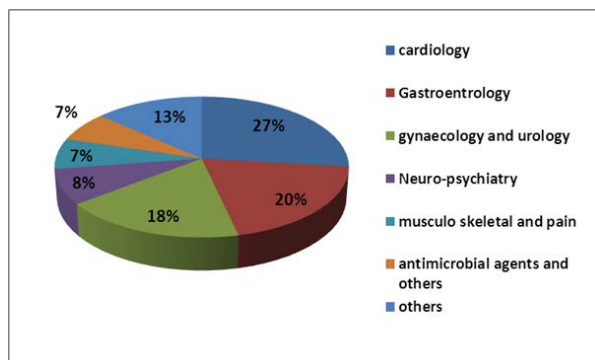


Fig no 23 sale wise segmentation of products of Nippon Chemiphar

Top products

(sales in thousands of USD)

Brand	Sales	Indication	Brand	Sales	Indication
Amlodipine Chemiph	29,305	Hypertension	Uralyt	26,933	pH Regulation And Digitalis Overdose
Lansoprazole Chemi	17,742	Gastritis	Zeflopto	13,177	Platelet Aggregation
Rabeprazole Na Che	13,495	Gastritis	Soleton	10,627	Inflammation
Donepezil Hcl Chem	12,082	Depression	Alyprost	4,877	Erectile Dysfunction
Pravastatin Na Che	11,671	Hypercholesterolemia	Picillibacta	\$4,123	Antibiotic
Voglibose Chemipha	10,010	Diabetes	Tiepenem	\$3,640	Antibiotic
Cilostazol Chemiph	5,503	Congestive Heart Failure	Raynanon	2,967	Inflammation
Famotidine Chemiph	4,874	Gastritis	Calvan	2,545	Hypertension
Bicalutamide Chemi	4,024	Prostate Cancer	Itorat	2,036	Fungal Infection
Rebamipide Chemiph	3,666	Gastritis	Kinegluco	1,904	Diabetes

Table no 12 Top 10 Generic and Brand products of Nippon Chemiphar

SWOT Analysis

Strength

One of largest generic product line up

Weakness

New drug delivery systems not explored

Opportunities

15 new generics will provide them a position above the other generic companies
Healthcare products

Threats

SG &A expenses and operating income is high
R&D expenses remain same

Fig no 24 SWOT analysis of Nippon Chemiphar

Yoshindo Inc.

Yoshindo is one of the first companies in Japan to begin manufacturing generic medicines. It began operations in 1954 and was formally established in 1962

The business is manufacturing and selling prescription drug.

The brand to generic ratio was found to be 63:37.

Yoshindo is an active pharmaceutical ingredient manufacturing company. It also does contract manufacturing. The active ingredient ranges from amino acid, mineral supplements, vitamins and mineral supplements, etc.

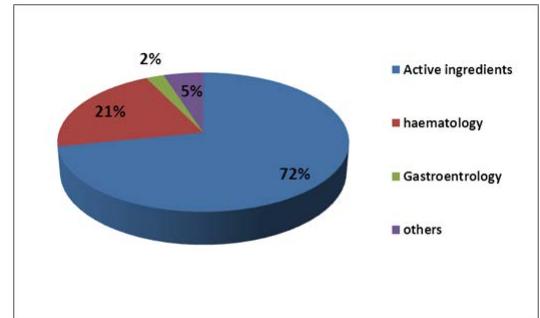


Fig no 25 sale wise segmentation of products of Yoshindo

They have products for blood and body fluid and gastroenterology. They also have few products in cardiovascular, neuropsychiatry and antibiotics.

The products are available in oral, injectable and topical dosage form, but mostly powders and granules.

Top Products

(sales in thousands of USD)

Generic		Sales	Indication	Brand	Sales	Indication
Heparin	Yosh	22,671	Blood Coagulation	Baifiru	42,237	Mineral Supplement
Tranexamic Ac	Yosh	2,601		Solita T	25,544	Mineral Supplement
Rabeprazole Na	Yd	1,890	Gastritis	Pn Twin	16,184	Mineral Supplement
Tansonin	Yoshindo	1,734	Supplement	Twinpal	12,208	Mineral Supplement
Mannitol	Yoshindo	1,296	Supplement	Lowhepa	11,386	Blood coagulation
Donepezil Hcl	Yosh	1,266	Depression	Solita T	9,167	Mineral Supplement
Amlodipine	Yd	1,170	Hypertension	Neoamiyu	8,969	Mineral Supplement
Loxoprofen Na	Yosh	440	Inflammation	Coahibitor	8,900	Blood coagulation
Mecobalamin	Yoshin	437	Supplement	Bicarbon	4,964	Mineral Supplement
Dramamine	Yoshindo	422	Emesis Vomiting	Or Elemenmic	6,452	Mineral Supplement

Table no 13 Top 10 Generic and Brand products of Yoshindo

SWOT Analysis

Strength

APIs
Contract manufacturing

Weakness

Not a public company

Opportunity

It established a Joint Venture (YL Biologics) for biosimilar business with Lupin (April 23, 2014). It executed LOI for Contract base manufacturing of biopharmaceuticals with Eisai.

Threat

Joint ventures only with Japanese companies

Fig no 26 SWOT analysis of Yoshindo

Nihon Generic Co. Ltd

Nihon generic co. ltd is a subsidiary of non pharmaceutical company. The business is manufacturing and selling ethical pharmaceutical drugs. Generics are the main business. The brand to generic ratio was found to be 17:83.

Nihon has one of the largest numbers of generic. They have differentiated their products in major therapeutic categories. The products are available in oral, injectable and topical dosage form.

They have maximum number of new products in last 2 year. They have expanded in new therapeutic conditions.

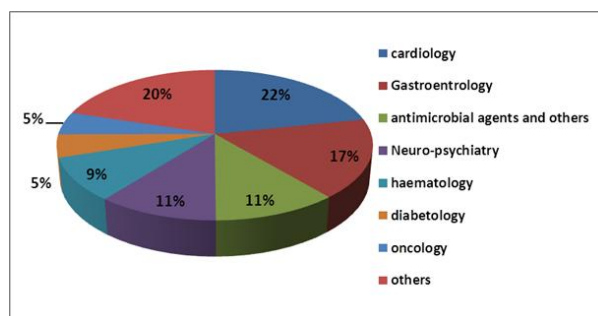


Fig no 27 sale wise segmentation of products of Nihon Generic

Top Products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Amlodipine N.Gener	13,566	Hypertension	Limarmone	10,764	Platelet Aggregation
Rabeprazole Na Jg	8,418	Gastritis	Tathion	5,052	Supplement
Donepezil Hcl Jg	6,286	Depression	Omepron	2,644	Gastritis
Bicalutamide Jg	5,955	Prostate Cancer	Alenapion	2,336	Allergy
Lansoprazole Jg	5,060	Gastritis	Cefspan	1,632	Bacterial Infection
Atorvastatin Jg	4,092	Hypercholesterolemia	Sedekopan	1,217	Insomnia
Voglibose N.Generi	3,632	Diabetes	Asasurfan	1,213	Urinary Tract Infection
Loxoprofen Na N.Ge	3,433	Inflammation	Anginal	1,171	Platelet Aggregation
Ursodeoxyc.Acid N.	3,258	Supplement	Azucurenin S	1,148	Skin Care
Ciclosporin N.Gene	3,034	Immunosuppressant	Alflosin	901	Prostate Cancer

Table no 14 Top 10 Generic and Brand products of Nihon Generic

SWOT Analysis

Strength

Large number of generics

Weakness

No specialization in any therapy

Opportunity

Expanding in new therapies sections

Threats

Product differentiation in many therapies

Fig no 28 SWOT analysis of Nihon Generic

Mitsubishi Tanabe Pharma Corporation

Mitsubishi Tanabe Pharma Corporation is generic maker subsidiary of Mitsubishi Tanabe.

The brand to generic ratio was found to be 42:58.

Tanabe pharmaceuticals target blood and body fluid products and supplements along with neuropsychiatry and cardiology.

Their drug allopurinol for gout is the highest grosser. The products are available in oral, injectable and topical dosage form. Tanabe has a very rich R&D pipeline. The new products are for diabetes, neurology, hematology, allergy, asthma, biologics and vaccines.

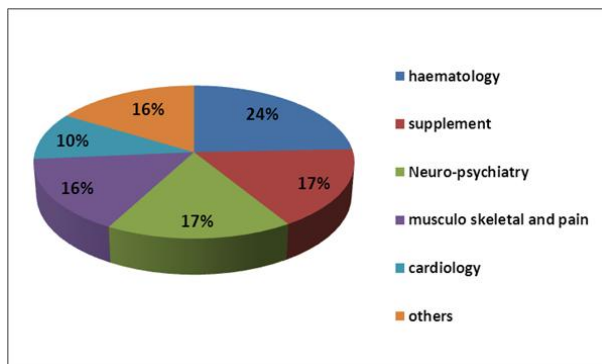


Fig no 29 sales wise segmentation of products of Tanabe

They have two head offices. They have 16 sales offices across Japan and 4 research centers. They have 120 medical representatives.

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Donepezil Hcl Tana	13,074	Depression	Alositol	23,650	Gout
Aspara-Ca	11,753	Supplement	Asverin	18,881	Inflammation
Aspara H.Tanabe	9,056	Supplement	Adona	11,482	Bleeding disorders
Amlodipine H.Tanab	5,220	Hypertension	Pa	\$3,686	Analgesic
Quetiapine H.Tanab	4,799	Depression	Rafuront	3,533	Muscle relaxant
Rebamipide H.Tanab	3,423	Gastritis	Hibon	3,529	Supplement
Pravastatin Na H.T	3,029	Hypercholesterolemia	Alegysal	2,925	Allergy
Pioglitazone Tanab	1,965	Diabetes	Mucotron	2,558	Respiratory Diseases
Paroxetine Tanabe	1,887	Depression	Gurufamin C	1,682	Supplement
Clarithromy.H.Tana	1,676	Antibiotic	Nikoranmart	1,651	Hypertension

Table no 15 Top 10 Generic and Brand products of Tanabe

SWOT Analysis

Strength

Rich R&D pipeline
Good network, distribution system

Weakness

R&D expenses have reduced

Opportunity

New products in every major field
Biologics and vaccines

Threat

No products in Oncology

Fig no 30 SWOT analysis of Tanabe

Maruishi Pharmaceutical Co. Ltd

Maruishi pharmaceutical co. ltd was founded in 1888 and incorporated in 1936.

The business is marketing and selling pharmaceutical products. The brand to generic ratio was found to be 68:32.

Maruishi has maximum number of injectable. These products are anesthetics and preoperative drugs. Other than these antiseptic and disinfectants are major products.

The products are available in injectable form and topical formulations. Some oral dosage forms are also available.

New products are also of same category.

They found to have 93 medical representatives.

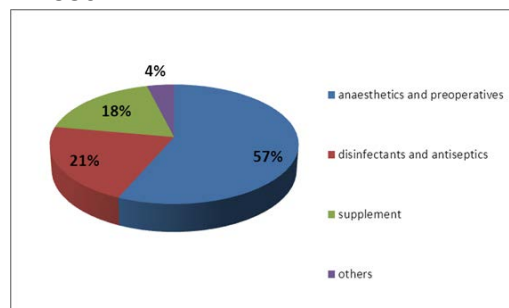


Fig no 31 sales wise segmentation of products of Maruishi

Top Products

Generic	Sales	Indication	Brand	Sales	Indication
Propofol Maruishi	25634.927	Hypnotic	Magmitt	26837.267	Mineral Supplement
Glycerin Maruishi	4197.518	Skin Care	Sevofrane	22791.073	General Anaesthetic
Flumazenil F Marui	2192.935	Bzd Poisoning	Precedex	20455.698	Sedative
Codeine Phos.Marui	827.817	Opioid Analgesic	Welpas	14618.911	Disinfectant
Mepivacaine Hcl Np	742.15	Anaesthetic	Maskin	10677.718	Disinfectant
Lidocaine Maruishi	686.654	Anaesthetic	Horizon	3591.64	Anxiety
Sorbitol Maruishi	307.044	Skin Care	Popscaine	3506.788	Anaesthetic
Zinc Oxide Maru	291.419	Skin Care	Maskin	2491	Antiseptic
Acrinol Maruishi	163.128	Antiseptic	Sosegon	1992.283	Opioid Analgesic
Dihy.Code.Phos.Mri	162.059	Opioid Analgesic	Delux C M	1139	Mineral Supplement

Table no 16 Top 10 Generic and Brand products of Maruishi

SWOT Analysis

Strength

Injectable anesthetics

Weakness

No therapy specific drugs

Opportunities

New products targeting neuropsychiatry

Threats

No target patients
No therapy targeted

Fig no 32 SWOT analysis of Maruishi

Fuji Pharmaceutical Co. Ltd

Fuji Pharma was established in 1965. They offer services like medical care for women, in vitro diagnostics, acute medical care products and curative medicine (injection agents), information regarding pharmaceuticals and health. Their core competency lies in Research and development, manufacture, and marketing in selected disease domains, Passionate about quality of products, people, and management, Hard- working employees and partners.

The brand to generic ratio was found to be 63:37.

Fuji pharma is working on women health care products and diagnostics. It has launched new products in the year 2012. It has expanded in the field of CNS drugs, CVS drugs and Oncology. The products are available in oral, injectable and topical dosage form.

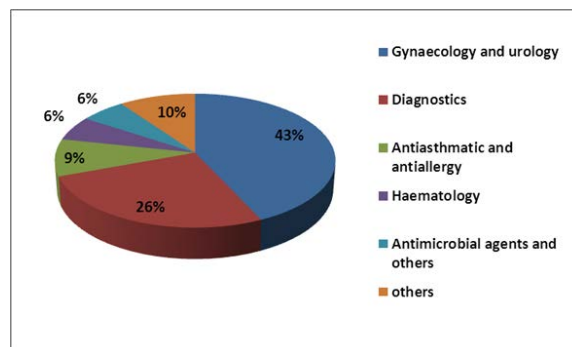


Fig no 33 sales wise segmentation of products of Fuji Pharma

Medical representatives = 180

Top Products

(sales in thousands of USD)

Generic	Sales	Category	Brand	Sales	Category
Limaprost Alfade.F	3,468	Hypertriglyceridemia	Lunabell Haigo	28,173	Women Health
Glucagon Fuji	2,646	Diabetes	Oypalomin	24,104	Diagnostic
Flumazenil Fuji	2,289	Benzodiazepine Poisoning	Folyrmon P	11,037	Women Health
Fluconazole Fuji	2,279	Fungal Infection	Ilopaque	6,316	Diagnostic
Heparin Fuji	2,237	Blood Coagulation	Solcort	5,862	Allergy
Nafarelin Fuji	2,146	Women Health	Sol Melcort	5,725	Allergy
Progesterone Fuji	2,065	Women Health	Buserecur	3,415	Women Health
Chorionic Gonadotrophin Fuji	1,537	Women Health	Favoir	2,705	Women Health
Betamethasone Fuji	1,407	Allergy	Labellefile	2,256	Women Health
Teicoplanin Fuji	1,401	Oncology	Alyprost	2,094	Erectile Dysfunction

Table no 17 Top 10 Generic and Brand products of Fuji Pharma

SWOT Analysis

Strength

Diagnostics and contrast media
Women health care products
Injectable

Weakness

Focusing only in acute therapy

Opportunity

New drug delivery system approach
Hormonal therapies for women

Threats

Chronic therapies not touched
Neuropsychiatry and cardiology products are few

Fig no 34 SWOT analysis of Fuji Pharma

Daiichi Sankyo Espha

Daiichi Sankyo Espha is the generic maker company of Daiichi Sankyo Company Ltd.

The brand to generic ratio was found to be 46:54.

Daiichi has good number of products in chronic therapies like neuropsychiatry and cardiology.

Its products range in many major categories. Dosage forms explored are only oral dosage form. It has also tried topical dosage form. Few products in major sections like oncology.

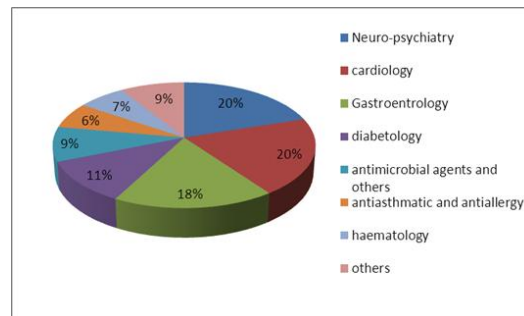


Fig no 35 sales wise segmentation of products of Daiichi

Prostate cancer, enlarged prostate and benign prostate hypertrophy are specifically targeted. Daiichi has a very rich R&D pipeline. It has many products in oncology and cardiovascular therapy sections under phase I, II & III trials. Apart from these major therapy sections, other acute conditions are also targeted by Daiichi. It also joined with other organizations in R&D. there are 70 medical representatives.

Top Products

(sales in thousands of USD)

Generic		Sales	Indication	Brand	Sales	Indication
Donepezil	Daic	14,827	Depression	Pantosin	25,211	Vitamin B5 Supplement
Amlodipine	Daic	8,636	Hypertension	Artrofone	19,189	Inflammation
Atorvastatin	Daic	7,066	Hypercholesterolemia	Neuer	5,178	Gastritis
Pioglitazone	Daic	6,681	Diabetes	S.M.	4,763	Mineral Supplement
Losartan	Daic	4,011	Hypertension	Hyamine	2,008	Antiseptic
Edaravone	Dsep	2,938	Brain Ischemia	Sinlestal	1,995	Hypercholesterolemia
Captopril		2,671	Hyprertension	Kazmarin	340	Enlarged Prostate
Zolpidem	Daic	2,556	Depression	Rimapurinol	208	Gout
Quetiapine	Daic	2,544	Depression	Silvinol	206	Angina
Paroxetine	Daic	2,181	Depression	Homerlight	126	Muscle Relaxant

Table no 18 Top 10 Generic and Brand products of Daiichi

SWOT Analysis

Strengths

Very rich R&D pipeline
Neuropsychiatry and cardiology products
Male healthcare problems like prostate cancer, enlargement and hypertrophy specifically targeted

Weakness

Very few products related to women health and oncology
Acute therapies not targeted

Opportunities

With many products under pipeline, Daiichi has great opportunities in terms of original products

Threats

High R&D expenses

Fig no 36 SWOT analysis of Daiichi

Mylan Pharmaceutical Co. Ltd

Mylan pharmaceutical co. ltd is the Japanese subsidiary of Mylan. It was established in 2008.

The business is manufacturing, selling and import of generics.

The brand to generic ratio was found to be 15:85.

Mylan has a large product differentiation. Their products cover majorly all therapeutic areas. Their focus is similar in acute as well as chronic therapies. Gastroenterology and antibiotic products are top products. In gastroenterology, products cover conditions like gastritis, poisoning, gastric ulcer, peptic ulcer, etc.

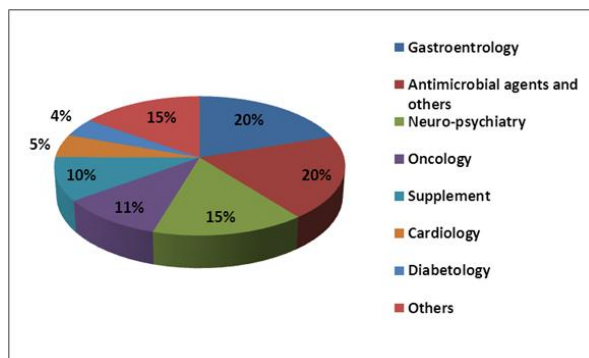


Fig no 37 sale wise segmentation of products of Mylan

The products are available in variety of formulations, oral, injectable and topical formulations.

Medical representatives = 155

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Sph. Carbon. Ads. Myl	10,367	Poisoning	Adelavin	3,772	Supplement
Ciclosporin Myla	4,880	Immunosuppressant	Calforte	2,480	Supplement
Vancomycin Myla	3,855	Bacterial Infection	Amsulmylan	2,479	Bacterial Infection
Fluconazole Myla	3,811	Bacterial Infection	Pre Dopa	2,252	Anxiety
Bicalutamide Myla	3,772	Prostate Cancer	Forsenid	2,196	Laxative
Omeprazole Myla	2,957	Gastritis	Deribadex	1,421	Blood Coagulation
Sod Chloride Myla	2,578	Supplement	He.L.Myl		
Methotrexate Myla	2,408	Oncology	Escain	1,035	Anesthetic
Amlodipine Myla	2,375	Hypertension	Negmin	1,024	Skin Care
Nateglinide Mylan	2,128	Diabetes	Narcarcin	1,016	Gout
			Thiola	864	Urinary tract infection

Table no 19 Top 10 Generic and Brand products of Mylan

SWOT Analysis

Strength

Vast product differentiation
Good distribution system within and outside Japan
Variety of dosage form available

Weakness

Not a market leader in any category

Opportunity

Entering into women healthcare products and ophthalmic products

Threat

Market is growing fast, n Mylan does not have product which is a market leader or highest grosser in any category

Fig no 38 SWOT analysis of Mylan

Sandoz Japan

Sandoz Japan is Japanese subsidiary of Sandoz, a Novartis company. Sandoz is the world leader in generic industry. They have over 1000 product mix. In Japan, the brand to generic ratio was found to be 26:74.

Sandoz has done product differentiation in almost all the major therapeutic segments.

In Japan, Sandoz is known for its antibiotics and oncology products. The products are available in oral dosage form, injectable and topical form.

The new products are for conditions like glaucoma, osteoporosis and gastric ulcer. New products for neuropsychiatry, oncology and antibiotics are also launched.

Medical representatives – 103

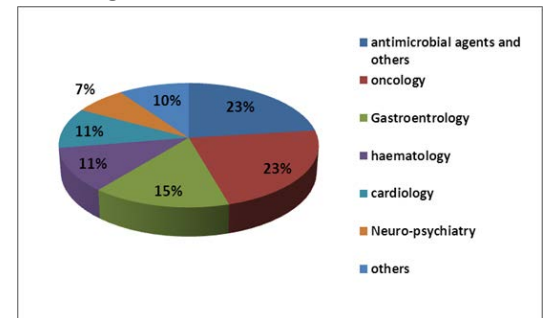


Fig no 39 sales wise segmentation of products of Sandoz

Top Products

(sales in thousands of USD)

Generic		Sales	Indication	Brand	Sales	Indication
Cefepime	Novt	7,943	Antibiotic	Sennaride	2,850	Stimulant Laxatives
Atorvastatin	Novt	7,325	Hypercholesterolemia	Seniran	2,613	Depression
Amlodipine	Novt	5,810	Hypertension	Rimactan	2,351	Tuberculosis
Somatropin Bs	Sand	5,055	Replacement Therapy Of Growth Hormone	Servambutol	1,904	Tuberculosis
Etoposide	Novt	4,755	Oncology	Mevalact	1,869	Hypercholesterolemia
Ceftriaxone	Roch	3,561	Antibiotic	Uteron	1,612	Tocolytic
Paclitaxel	Novt	3,224	Oncology	Talotren	1,414	Asthma
Famotidine	Novt	2,257	Peptic Ulcer	Sanmel	903	Antacid
Gemcitabine	Novt	2,252	Oncology	Alcenol	621	Hypertension
Docetaxel	Novt	2,153	Oncology	Well Bi	367	Hypertension

Table no 20 Top 10 Generic and brand products of Sandoz

SWOT Analysis

Strength

Product differentiation in major therapeutic segments
Generic products

Weakness

No over the counter, healthcare and skin care products

Opportunity

New products are targeting specific conditions.
Biosimilars

Threats

Dietary supplements and OTC markets are growing

Fig no 40 SWOT analysis of Sandoz

Kyowa Pharmaceutical Industries Co. Ltd

Kyowa pharmaceutical industries co. ltd was established in 1954. Now it is a part of Lupin group. It has another subsidiary I'rom pharma. The brand to generic ratio was found to be 41:59.

Kyowa has major products related to neuropsychiatry. The conditions include depression, psychosis, schizophrenia, Parkinson's disease, etc. The products are available in oral and topical dosage form. Kyowa has expanded in cardiology and antimicrobials also; the newly launched products belong to these categories. The target customers of kyowa are elderlies.

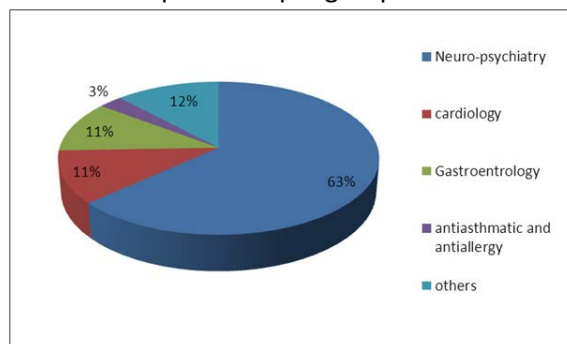


Fig no 41 sales wise segmentation of products of Kyowa

Medical representatives – 78

Top Products

(sales in thousands of USD)

Generic		Sales	Indication	Brand	Sales	Indication
Quetiapine	Lupi	5,689	Depression	Mestinon	1,990	Myasthenia Gravis
Risperidone	Lupi	4,500	Psychosis	Undepr	1,811	Depression
Flunitrazepam	Amel	3,944	Insomnia	Excemide	1,591	Epilepsy
Omeprazole	Amel	3,915	Gastritis	Eparose	1,590	Huntington's Disease
Sulpiride	Lupi	2,481	Schizophrenia	Calfina	1,297	Supplement
Valproic Acid	Lupi	2,356	Epilepsy	Akiriden	1,125	Parkinson's Disease
Amlodipine	Lupi	2,325	Hypertension	Halrack	897	Insomnia
Pravastatin Na	Ame	1,925	Hypercholesterolemia	Kashilon Amel	866	Inflammation
Donepezil	Lupi	1,772	Depression	Myorelark Amel	731	Muscle Relaxant
Carbamazepine	Amel	1,430	Depression	Triphedion	726	Parkinson's Disease

Table no 21 Top 10 Generic and Brand products of Kyowa

SWOT Analysis

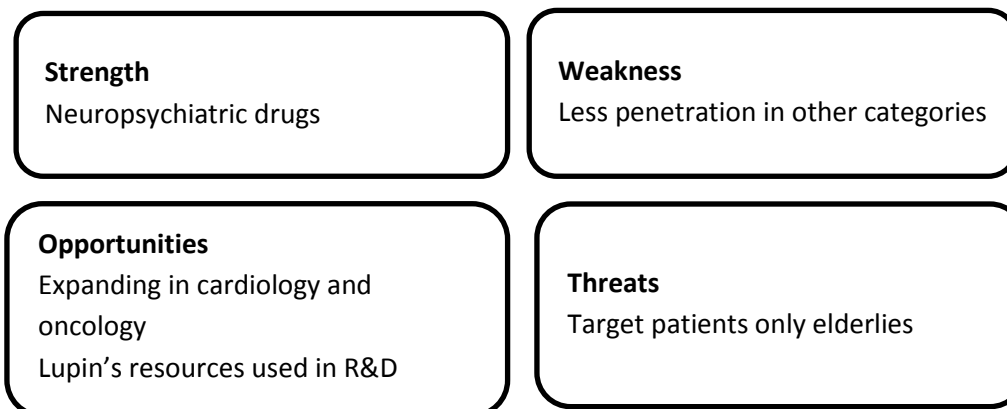


Fig no 42 SWOT analysis of Kyowa

Showa Kako Corporation

Showa Kako was founded in 1918 and was established as Showa Kako Corporation in 1932 after a joint venture. The business includes Functional material, Organic chemical, Inorganic chemical, Dye stuff and dyeing aids and pharmaceuticals.

The brand to generic ratio was found to be 85:15.

They have few pharmaceutical products.

Their products cover acute segments like musculo-skeletal pain and inflammation, allergy and asthma.

The products are majorly available in topical and oral dosage form.

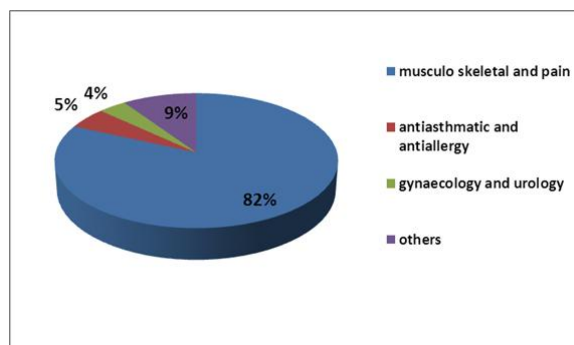


Fig no 43 sales wise segmentation of products of Showa

Top products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Allopurinol Show	1,980	Gout	Calonal	44,861	Fever And Mild Pain
Clemastine Show	244	Allergy	Aphtasolon	2,167	Allergy
Mecobalamin Showa	150	Supplement	Floures	1,670	Diagnostic
Circulin Show	109	Hypertension	P Magen	1,555	Mineral Supplement
Benzetho.Chl.Kys	54	Skin Care	Hinoporon	848	Mineral Supplement
Tetracycline Syk-	20	Bacterial Infection	Sateritt	405	Respiratory Diseases
Ambroxol Showa	Hcl 12	Respiratory Diseases	Azray	338	Skin Care
			Periofeel	239	Bacterial Infection
			Lausit	147	Inflammation
			Ora Bliss	94	Supplement
			Unipron	74	Inflammation

Table no 22 Top 10 Generic and Brand products of Showa

SWOT Analysis

Strength

Topical products
Pain and inflammation

Weakness

No products in chronic therapy
Distribution system is weak

Opportunity

New product in neuropsychiatry

Threat

Small business, pharmaceuticals are a small segment

Fig no 44 SWOT analysis of Showa

Kyorin Remedio

Kyorin Remedio is a part of Kyorin Holding Inc. The business is manufacturing and selling pharmaceutical drugs. The brand to report ratio was found to be 53:47.

Kyorin has products related to inflammation, muscle pain, arthritis, allergy and asthma. The products are available in oral, topical and injectable dosage forms. They have products for osteoporosis and prostate cancer. The new products are in major categories like cardiology, neurology and oncology.

They relatively have a good number of products in their pipeline. The products are related to asthma and allergy. Kyorin has joined with many companies in and outside Japan.

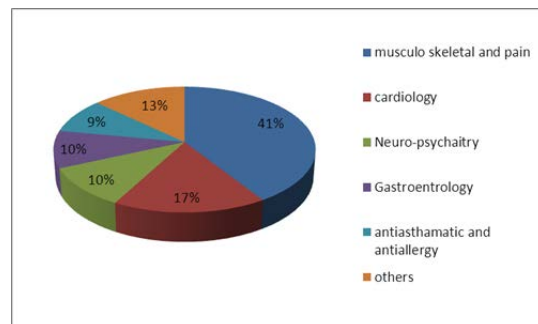


Fig no 45 sales wise segmentation of products of Kyorin

Medical representatives – 70

Top Products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Amlodipine K.Rimed	2566.877	Hypertension	Tohberick	15985.671	Inflammation
Rebamipide K.Rimed	2002.479	Gastritis	Minitro	2518.602	Angina
Donepezil Hcl Kyor	1865.139	Depression	Ne	889.088	Supplement
Edaravone Kyorin	1501.558	Brain Ischemia	Gasdock	430.303	Peptic Ulcer
Rabeprazole Na Kyo	1333.721	Gastritis	Lipovatul	409.2	Hypercholesterolemia
Allopurinol Kyor	1244.569	Gout	Alegain	313.257	Allergy
Olopatadin.Hcl K.R	1020.642	Allergy	Mitan B2	285.402	Supplement
Bicalutamide K.Rim	761.561	Enlarged Prostate	Hyal	268.615	Cataract
Fluticasone K.Rime	758.692	Allergy	Pharcoba	200.723	Supplement
Levofloxacin K.Rim	720.327	Bacterial Infection	Benzmarone	194.939	Gout

Table no 23 Top 10 Generic and Brand products of Kyorin Remedio

SWOT Analysis

Strength

Inflammation and allergy drugs
Joined hands with many big companies with rich R&D

Weakness

Limited products in major therapies

Opportunities

Specific products for conditions like prostate cancer

Threats

R&D pipeline has products for conditions like inflammation, allergy and asthma only

Fig no 46 SWOT analysis of Kyorin

Iwaki Seiyaku Co. Ltd

Iwaki Seiyaku Co., Ltd. was established in Sep 1948. The business is Manufacture and Sales of Ethical & Proprietary Drugs, Bulk Pharmaceutical Chemicals & Intermediates, Food Additives, Cosmetic Ingredients, Chemicals for Data Recording Paper, Intermediates for Dyes & Pigments, and Intermediates for Agricultural Chemicals.

The brand to generic ratio was found to be 67:33.

Iwaki has two types of products pharmaceutical drugs and OTC drugs.

Iwaki seiyaku has largest number of topical products. These products are topical disinfectants, antifungal agents, corticosteroid products, gargles, etc. it has covered all the topical dosage forms.

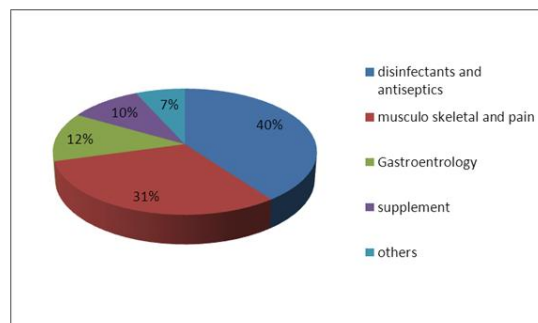


Fig no 47 sales wise segmentation of products of Iwaki

It also some oral dosage formulations like capsules, tablet, chewable tablets. Iwaki is mainly a generic company, so their R&D is also focused in same direction. They have many products to their credit.

Top Products

(sales in thousands of USD)

Generic	Sales	Category	Brand	Sales	Category
Maxacalcitol Iwaki	992	Supplement	Neojodin	4,516	Antiseptic
Lanoconazole Iwaki	970	Anti Fungal	Shinluck	3,781	Laxative
Tacrolimus Iwaki	587	Immunosupressant	Dermosol G	2,590	Antibiotic
Mometason.Furo.Iwa	506	Anti Inflammatory	Stibron	2,151	Anti Inflammatory
Clindamyc.Phos.Iwa	419	Antibiotic	Dermosol	1,522	Anti Allergy
Vitamin C Iwak	389	Supplement	Nitrazen	1,408	Anti Fungal
Diphenhydramin.Iwa	385	Anti Allergy	Paldes	1,270	Skin Disorders
Pyridoxal Iwaki	308	Supplement	Salex	1,126	Anti Allergy
Lysozyme Chlor.Iwa	293	Anti Allergy	Spirazon	894	Anti Allergy
Dexamethasone Iwak	289	Anti Inflammatory	Yupitel	824	Anti Allergy

Table no 24 Top 10 Generic and Brand products of Iwaki

SWOT Analysis

Strength

Topical products, disinfectants, antiseptic and skin care products

Weakness

Target only on acute and OTC
No chronic therapy products

Opportunity

OTC products are huge in demand

Threats

Major therapy sections like cvs and CNS not targeted

Fig no 48 SWOT analysis of Iwaki

Towa Pharmaceutical Co. Ltd

Towa pharmaceutical co., Ltd was established in 1951 and incorporated in 1957. The business is manufacture and sales of ethical drugs. The brand to generic ratio was found to be 13:87.

Towa pharmaceuticals have one of the largest generic product lines. The specialty therapy sections are cardiology, gastroenterology, neuropsychiatry and allergy.

The products are available in oral, injectable and topical dosage form.

New products cover the same therapy sections, along with few drugs in oncology and antimicrobial.

There are two distribution centers in east Japan and west Japan. Sales offices are there in 8 regions and total contributes to 58 branches all over Japan.

The large number of MRs (556) among Japanese generic manufacturers is the driving force of Towa.

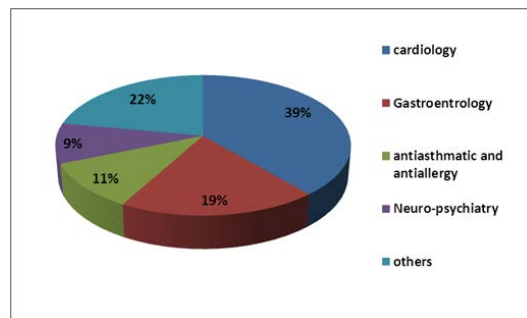


Fig no 49 sales wise segmentation of products of Towa

Top Products

Generic	Sales	Indication	Brand	Sales	Indication
Amlodipine Towa	6,859	Hypertension	Roumis	662	Supplement
Lansoprazole Towa	1,987	Gastritis	Nikoranmart	209	Hypertension
Carbocisteine Towa	1,434	Respiratory Diseases	Osagren	183	Platelet Aggregation
Atorvastatin Towa	1,104	Hypercholesterolemia	Tamslon	177	Enlarged Prostate
Omeprazole Towa	1,041	Gastritis	Towamin	166	Hypertension
Famotidine Towa	1,024	Gastritis	Antobron	156	Respiratory Diseases
Nifedipine Towa	910	Hypertension	Emeromin	141	Allergy
Pravastatin Sod.To	674	Hypercholesterolemia	Cilostazol Towa	140	Congestive Heart Failure
Rabeprazole Na Tow	659	Gastritis	Simvastatin Towa	134	Hypercholesterolemia
Donepezil Hcl Towa	637	Depression	Vanarl N	134	Supplement

Table no 25 Top 10 Generic and Brand products of Towa

SWOT Analysis

Strength

Largest number of generic
Great workforce of 556 MRs
Covers major therapy sections

Weakness

No group companies, does not have any
alliance or joint venture with any
company within Japan or overseas

Opportunity

Towa direct sales system
New products in oncology
RACTAB technology

Threat

Women health and pediatric products
are not targeted

Fig no 50 SWOT
analysis of Towa

Ohara Pharmaceutical Co., Ltd

Ohara pharmaceutical co., ltd was founded in 1957 and was established in 1964.

The brand to generic ratio was found to be 22:78.

Ohara pharmaceutical manufactures generics, APIs and orphan drugs.

The products cover major therapeutic sections like cardiology, gastroenterology and oncology. They also have products in neuropsychiatry and antimicrobials.

Orphan drugs are for leukemia, leukocytopenia, stem cell transplantation and Parkinson's disease.

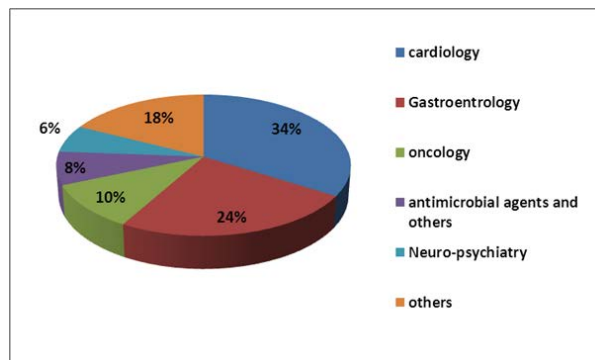


Fig no 51 sales wise segmentation of products of Ohara

Products are available in commonly used dosage forms i.e. oral, injectable and topical.

R&D is based on orphan drugs, cardiovascular and oncology.

Top Products

(sales in thousands of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Amlodipine Ohara	2,766	Hypertension	Supacal	1,273	Gastritis
Famotidine Ohara	2,416	Gastritis	Dopaston	1,204	Parkinson's Disease
Levofolinate Ohara	1,469	Oncology	Leucon	428	Supplement
Pravastatin Na Oha	924	Hypercholesterolemia	Pisulcin	422	Antibiotic
Rabeprazole Na Oha	912	Gastritis	Lobu	400	Inflammation
Donepezil Hcl Ohar	724	Depression	Litomerin	397	Tocolytic
Levofloxacin Ohara	593	Antibiotic	Leukerin	360	Oncology
Imidapril Hcl Ohar	497	Hypertension	Troxsin	261	Gastritis
Pioglitazone Ohara	489	Diabetes	Roxati	96	Gastritis
Epalrestat Ohara	432	Diabetes	Selspot	30	Inflammation

Table no 26 Top 10 Generic and Brand products of Ohara

SWOT Analysis

Strength

Orphan drugs, generic and API

Weakness

Not a public company

Opportunity

Oncology products

Threat

Women health not targeted

Fig no 52 SWOT analysis of Ohara

Kobayashi Pharmaceutical Co., Ltd.

Kobayashi pharmaceutical co., ltd was founded in 1919.

The brand to generic ratio was found to be 13:87.

Kobayashi has products like pharmaceuticals, air fresheners, oral hygiene products, body warmers and cooling sheets.

Kobayashi Kako's main products are related to inflammation, allergy, etc. Products are available in oral and topical dosage form.

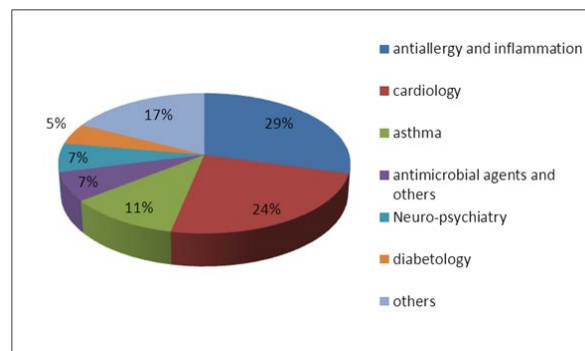


Fig no 53 sales wise segmentation of products of Kobayashi

They are trying to enter into oncology drugs. The recently launched products are from anti infective and oncology.

Their focus remains on OTC products, so they are exploring skin care and Chinese herbal drug.

Top Products

(sales in thousand of USD)

Generic	Sales	Indication	Brand	Sales	Indication
Fexofenadi.Hcl Kn	4,373	Allergy	Parkiston Combin.L	331	Parkinson's Diseases
Atorvastatin Kn	2,059	Hypercholesterolemia	Placode Combinatio	204	Allergy
Pranlukast	2,042	Asthma	Alkixa	119	Skin Infection
Kob.Kak					
Amlodipine Kn	853	Hypertension	Mucothio	104	Oncology
Tamsulosin Hcl Ek	573	Enlarged Prostate	Laxodate	104	Laxative
Olopatadin.Hcl	513	Allergy	Lypoaran	84	Diabetes
Mee					
Pantethine Kn	475	Supplement	Anetocaine	76	Anaesthetic
Voglibose	399	Diabetes	Vicclox	75	Viral Infection
Kob.Kako					
Flutamide	392	Prostate Cancer	Camotat	72	Hypertension
Kob.Kako					
Losartan K Kn	303	Hypertension	Merlactone	68	Diuretic

Table no 27 Top 10 Generic and Brand products of Kobayashi

SWOT Analysis

Strength

Products target every age group
Women and children targeted products

Weakness

No major products in chronic therapies
Target only acute therapy

Opportunities

OTC products like skin care products and Chinese herbal products will be in demand
Expanding in oncology with drugs targeting breast cancer and prostate cancer

Threats

R&D expenses are high

Fig no 54 SWOT analysis of Kobayashi

Research and Suggested Model

The research was done the basis of the information compiled as under. As the research was based only on generic companies of Japan, thus these companies were selected on the basis of their generic sales. It includes the IMS data sales for the year of 2013. The sales are then divided on the basis of brand and generic sales. Internal data which was taken into consideration was the total internal sales, net income and net income to total sales percent, number of medical representatives, number of employees and their main therapy areas.

Other factors which was taken into consideration was earnings before Income Tax i.e. EBIT and EBIT%, brand to generic ratio and main products sales in the year 2013.

Companies	IMS Sales	Brand sales	Generic sales	Internal Sales	Net Income	Net Income (%)	No Of Med Rep	No Of Employee	Main Therapy Sections
Meiji Seika	868.7	563.6	305	1337	76	5.68%	810	14819	Antimicrobials
Mochida	847.9	780.8	67	939	98	10.44%	720	1753	Cardiology
Nichi-Iko	710.6	181.4	529	954	52	5.46%	266	880	Cardiology
Kaken Seiyaku	674.3	613.8	61	936	97	10.33%	750	1649	Pain And Anti Inflammatory Agents
Sanwa Kagaku Kenkyusho	631.7	341.3	290	695			475	1507	Diagnostic Kits And Diabetes
Sawai Seiyaku	583	147.3	436	817	122	14.93%	400	1050	Cardiology
Nippon Kayaku	410.7	167.8	243	1600	167	10.44%	421	1806	Oncology
Fuso Yakuhin	376.3	240.4	136	490	19	3.88%	332	1370	Supplements
Aska Seiyaku	285	202.1	83	395	4	1.01%	290	888	Women Health
Elmed Eisai	283.7	23.53	260	6103	514	8.42%	40	10495	Cardiology
Nipro	263.5	73.52	190	2447	104	4.24%	196	2039	Antimicrobials
Nippon Chemiphar	247.5	78.8	169	318	18	5.66%	263	679	Cardiology
Yoshindo	213.5	172.3	41					526	API And Supplements
Nihon Generic	171.7	55.88	116					185	Cardiology
Tanabe Seiyaku	160.2	94.18	66	141	3	2.13%	120	180	Haematology
Maruishi Seiyaku	149.3	113.3	36	369			93	482	Anaesthetic And Preoperative Preparations
Fuji Pharma	147.1	104.5	43	243	23	9.36%	180	619	Diagnostic And Women Health
Daiichi Sankyo Espha	128.1	59.61	68	111			70	32000	Cardiology And Neuropsychiatry
Mylan Seiyaku	118.6	31.52	87	6909	624	9.03%	155	438	Gastroenterology
Sandoz Japan	94.69	27.66	67	9159			103	23000	Antimicrobials
Kyowa Yakuhin	73.89	30.57	43	125			78	425	Neuropsychiatry

Showa Kako	55.21	52.63	2.6					335	Pain And Anti Inflammatory Agents
Kyorin Remedio	44.66	24.33	20	124	6	4.84%	70	297	Pain And Anti Inflammatory Agents
Iwaki Seiyaku	32.35	25.82	6.5					266	Disinfectants And Antiseptics
Towa Yakuhin	31.51	5.212	26	561	63	11.23%	56	1830	Cardiology
Ohara Yakuhin	21.48	5.413	16	139				312	Cardiology
Kobayashi Kako	18.39	1.736	17	362				400	Anti Allergy And Inflammation

Basic model

Japanese market is a complex market. Generics were not considered a drug of choice, but with the rising health expenses Japan Government realized the importance of generic medicines. Japan pharmaceutical market is USD 100 Billion dollars (NHI Price base). The ethical drug market is around USD 89 billion and generic around USD 11 billion. They are now trying to promote generics among physicians, hospitals, pharmacists as well as patients. Many programmes have been developed to promote generics in Japan.

A company needs the local office, workforce, manufacturing and packaging facilities, distribution and marketing system for the basic functioning.

Generic companies of Japan are mostly subsidiaries of the innovator companies. Their business includes both generic and brand products. The products majorly constitute of brand i.e. the most commonly used ratio is 60:40. Generic ratio differs from 40-50%. Even the core generic companies like Nihon Generic, Elmed Eisai and Daiichi Sankyo Espha have 10-15% brand products.

Japan companies do business in three manner, organically, co-development and alliance with foreign major pharmaceutical companies.

For the most Japan companies, organic growth would be the most preferred business model. They grow on their strengths and core competencies. It was found, that the companies focus majorly on one therapy area. Their research and development is totally committed to that field only. They expand in field related to their competencies. Other than their core business the companies with good manufacturing ability also indulge in contract manufacturing. Many companies like Mylan, Towa, Meiji Seika, Sawai, Nippon Kayaku, Nipro Pharma and Iwaki have business model of organic growth.

Another business model is co-development. It is a very common and popular business model in Japan which pharmaceutical companies adopt. ANDA and commercialization is done by 2 companies for 1 product.

In this the leader takes the initiative and the contract has to be done before the application. Companies have their own brand name and obtain the NHI price at the same time. The development cost gets reduced and price revision would be done on each brand name.

Manufacturing is mostly done by the leader company and the products are sent to the partner companies for marketing and distribution. In this way the products are available in different markets together and marketing is done by both the companies. Companies like ASKA, Kyorin Remedio and Yoshindo have adopted this business model.

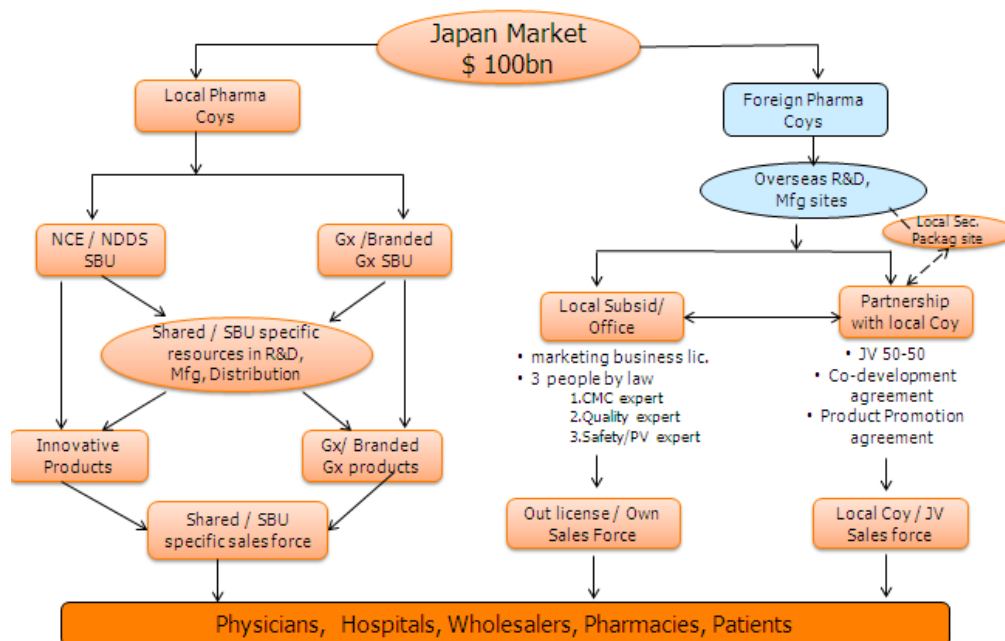
Alliance with foreign companies is relatively a new concept in Japan. There have been many joint ventures, mergers and acquisitions in last few years which have opened many opportunities for Japan companies to explore other market and foreign pharma companies to explore Japan market. Kyowa Yakuhin is now a part of Lupin group, which also has subsidiary company I'rom Pharmaceutical.

There have been joint ventures related to biosimilars and oncology products like Yoshindo has joint venture for biosimilars with Lupin. Many joint ventures include research and development regarding oncology products and there is extensive research in field of biologics and hormonal therapies for women.

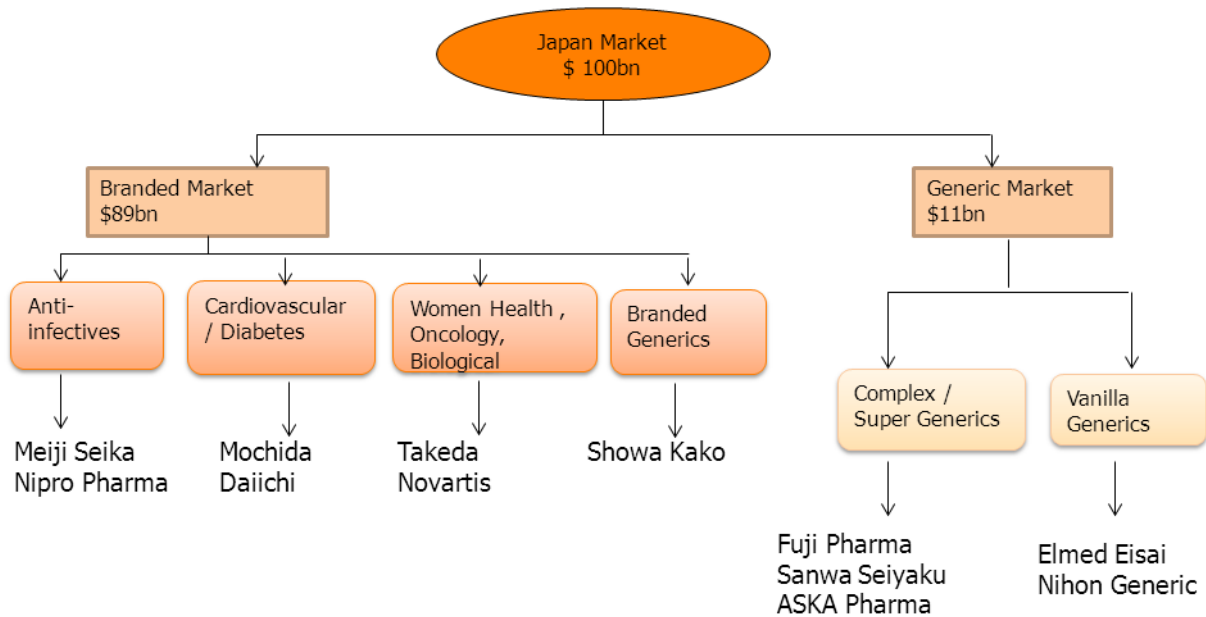
There business is mainly based on vanilla generics e.g. atorvastatin, enalapril, etc. very few companies have complex generics like glucagon, bicalutamide.

For overseas companies, penetration into generic market becomes difficult as they do not have the local office, workforce. The packaging is another major issue as the drugs need to match the standards. The distribution and marketing system needs to be very strong in a market like Japan. Thus overseas companies seek local companies for partnerships and alliances. Generating the local workforce and packaging facilities is the toughest part for the overseas companies. Partnerships with japan companies help them to grow with limited resources meanwhile they are working on developing their mark in the field.

1. Operating Model



2. Therapy/ business model



Suggested model

A company is targeting entry into Japan market. Being a competitive market where generic penetration is limited it is important to choose a sustainable business model.

A business model consists of four interlocking elements that, taken together, create and deliver value^[4]:

1. Customer value proposition (CVP)
2. Profit formula
3. Key resources
4. Key processes

Customer value proposition

Creating value for customers is very important in any business, and in business like pharmaceuticals it becomes altogether more crucial. Later it turns into the core competency or strength of the company. It includes

- Target Customers
- Job To Be Done
- Offerings

Thus as a pharmaceutical company who wants to enter into Japan market the target customers would be elderlies. Since the maximum population is of 25-54 years, the degenerative disorders or the chronic therapy is the biggest market. There are some therapy areas where there is less presence of generic drugs like dermatology. Therefore the job to be done would be to explore these therapy areas and offer

the best quality generics. Neuropsychiatry and oncology are other fields where the company can lay its focus on.

Profit model

The profit formula shows how you will make profits for the company while still providing value to the customer.

- Revenue model = price x volume
- Cost structure = Direct costs, indirect costs and economies of scale
- Margin model = Given the revenue and cost structure how much profit do the company make

Therefore for earning the maximum profit, a company should enter with a new product on the very first day i.e. the ANDA filling has to be done before anybody else does it for that product, so that it becomes the market leader. As there are competitors and substitutes available in the market, price erosion will be seen with time. But the market leader still enjoys the maximum market share even on maturity of the product.

Key resources

The key resources are assets such as the people, technology, products, facilities, equipment, channels, and brand required to deliver the value proposition to the targeted customer.

For an overseas company, generating these resources is the major challenge.

Setting up a local office and dedicated workforce is a difficult task. It takes time to build the suitable channels and brand, therefore partnership and alliances helps the company to understand the market and develop a suitable and successful system. The facilities and technology for the packaging is one of the major points of concern. The supply, distribution and marketing are the fields in which a partner company can help.

Key Processes

Successful companies have operational and managerial processes that allow them to deliver value in a way they can successfully repeat and increase in scale.

Key processes as well as rules, metrics, and norms, which make the profitable delivery of the customer value proposition repeatable and scalable. Might include:

- Processes: design, product development, sourcing, manufacturing, marketing, hiring and training, IT
- Rules and metrics: margin requirements for investment, credit terms, lead times, supplier terms
- Norms: opportunity size needed for investment, approach to customers and channels

Processes like design, manufacturing and marketing is the primary concern for the new pharmaceutical company. As there are very stringent rules regarding the formulations as well as active pharmaceutical

ingredients in Japan, so the products have to match the standards. The quantity to manufacture is also main decision as there is large amount of investment involved, therefore the quantity has to be carefully decided, as the company does not want to incur losses.

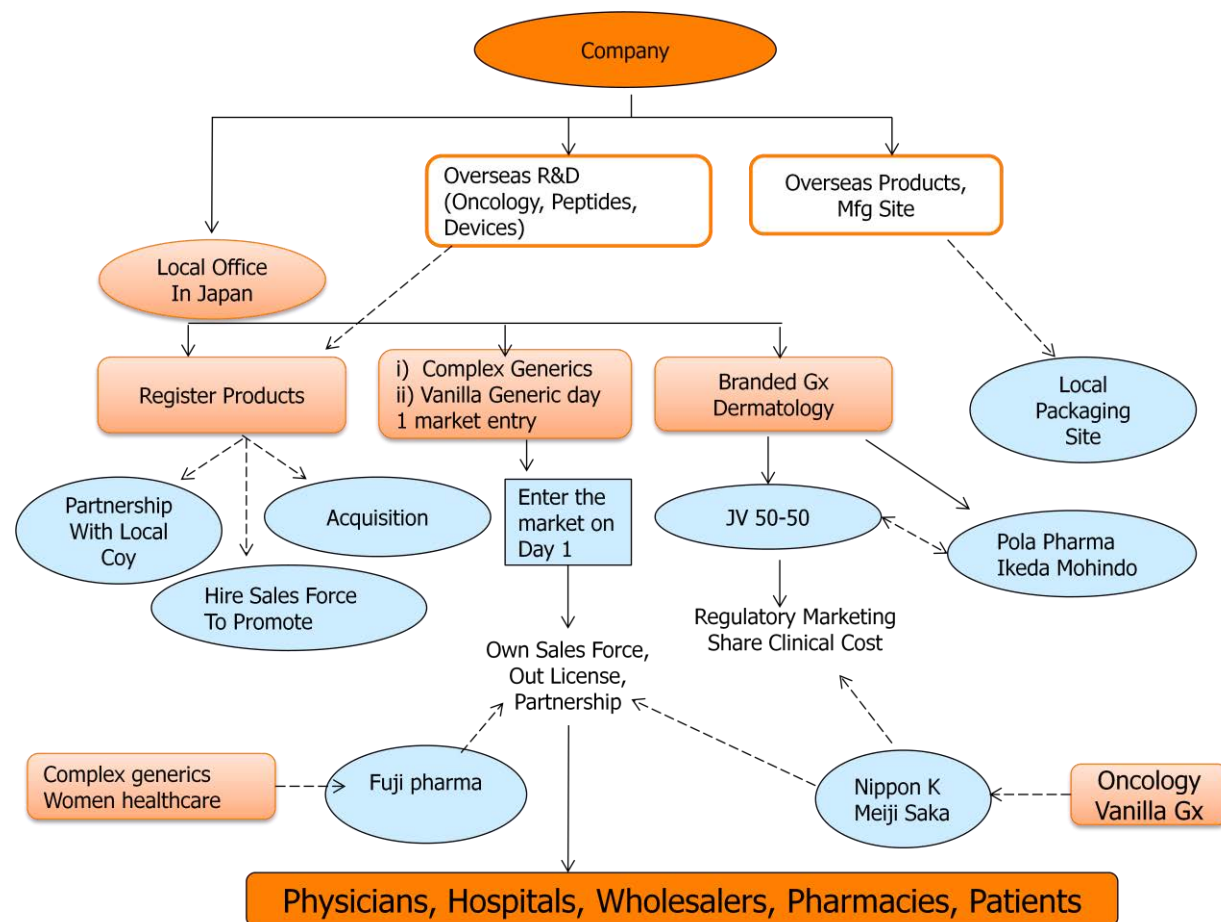
For pharmaceutical company, the growth depends upon the regular innovations in products, their product line and Research and development. For establishing a successful R&D, the company needs to focus on the existing trend in which the overt study is happening and also the future trends.

In Japan, extensive research is happening in field of oncology, hormonal therapies. The Japanese companies are spending huge amount of capital in developing the new products and conditions like osteoporosis, breast cancer, prostate cancer, gout or hyperuricemia. Future trends like biologics, biosimilars are also gaining focus. Therefore the company can either start with these conditions or join hands with the company that has well developed R&D facility and enter into co-development.

Complementary decisions

The company has to make sure that these four elements are consistent and complementary. For example it shouldn't have a high service CVP and then not invest in staff training and service processes.

Suggested model



Discussion and conclusion

If a company has to enter into Japan market, it has to form a perfect amalgamation of its core competencies, its available resources, the partnership or alliance and its products.

From the above findings, we can say that the therapy areas which are of high concern should be targeted. The target therapy area may be dermatology, oncology and neuropsychiatry. Dermatology accounts for 35% of total pharmaceutical sales in 2012, but generic dermatology products are very few. Products with new dosage form gain popularity very fast, so the concern should also be on new drug delivery approaches.

The company has to start with setting up the local office and understanding the market. The workforce and technology has to be developed and channels identified.

Entering the market on the first day with a new product, which may be vanilla generic and emerging as a market leader should be of prime focus. Only then the company can cash on the maturity of the product even after price erosion.

Complex generics are not very prevalent in the Japan market. Very few companies aim to make complex generics. So it can be a growing area

Even the small scale companies and relatively new companies have the workforce of around 40 medical representatives. Therefore a team of at least 50 medical representatives has to be developed.

The forming the supply and distribution system will take time. Partner can help in marketing and distribution. Out licensing can also be done in this case.

Research and development should be focused on existing and future trends and joining hands with the company which has rich R&D would be a profitable option.

Japan companies like Nichi-iko, Sawai, Nihon Generic, Nippon Chemiphar, etc have the big portfolio of generic products. They also have very strong research and development ability

Nihon Generic and Nippon Chemiphar has given the maximum products in last two years, apart from them Kyowa, Meiji Seika and Iwaki has the ability to bring the generics on day 1 in market

Players like Chemiphar, ASKA, Fuji Pharma and Kyowa have expertise to develop the complex products like peptides and biologics. Oncology is another therapy area where presence of these coys is visible

Women healthcare products is the strength of companies like Fuji Pharma and ASKA

Yoshindo, Sawai, and Meiji Seika has the strongest manufacturing and Research and development capability

Nippon Kayaku, Mochida, ASKA and Kyowa also has the rich research and development capability

Companies which have the ability to develop branded generic portfolio in dermatology are Iwaki, Mochida, Nipro and Sawai

Ethical considerations

Ethical aspects of the study have been addressed by implementing the following measures:

The data collected is related to the study only and is not used for any other purpose.

Texts belonging to other authors that have been used in any part of this study have been fully referenced.

The study was done as an intern in Sun Pharma, thus any confidential information has not been disclosed

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