Pharmaceuticals in Japan

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1. Competitive advantages of Japanese Pharma Industry (1) New Drug Research & Development

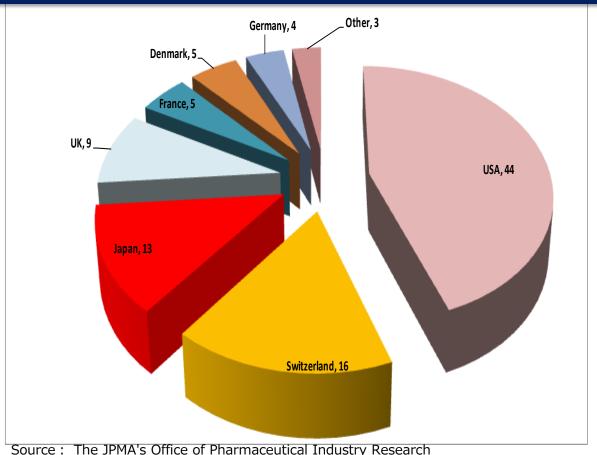
New Drug Research & Development Capability is one of the excellent competitive edges of Japanese pharmaceutical companies.

- The list of 100 top-selling pharmaceutical products world wide for 2010 included 13 products that were discovered and developed by Japanese companies. As shown in the next slide, by country, Japan is the third largest creator of new pharmaceutical products in the world after the U.S. and Switzerland.
- The top-selling Japan-originated products listed on slide 4 were discovered and developed by leading Japanese pharmaceutical companies. These products contribute to people's health in more than 60 countries throughout the world.
- The Japanese pharmaceutical industry is competitive in R&D capability. Japanese pharmaceutical companies have continued to increase their investments in R&D for the discovery and development of innovative new drugs every year, which represent more than 17% of total net sales.

1. Competitive advantages of Japanese Pharma Industry (1) New Drug Research & Development

Japan greatly contributes to improving the world's medical care through the development of new pharmaceutical products.

Japan is the third largest country providing global "Top 100" selling pharmaceutical products. (2010)



Source: The JPMA's Office of Pharmaceutical Industry Research Pharmaprojects, @2013 IMS Health. IMS World Review

1. Competitive advantages of Japanese Pharma Industry (1) New Drug Research & Development

Japan contributes to the world's medical care through the development of new pharmaceutical products.

Innovative new medicines created by leading Japanese companies and ranked in the global "Top 100" by sales (2011)

Brand Name	Generic Name (INN)	Developer (URL)	Indication	Amount of Sales (US\$ million)
Crestor	Rosuvastatin	Shionogi http://www.shionogi.co.jp/en/	High cholesterol	7,919
Abilify	Aripiprazole	Otsuka http://www.otsuka.co.jp/en/	Schizophrenia	5,318
Blopress/Amias/Kenzen	Candesartan	Takeda http://www.takeda.com/	Hypertension	4,307
Actos/Glustin	Pioglitazone	Takeda http://www.takeda.com/	Type 2 Diabetes	4,007
Olmetec/ Benicar	Olmesartan	Daiichi Sankyo http://www.daiichisankyo.com/	Hypertension	3,484
Pariet/AcipHex	Rabeprazole	Eisai http://www.eisai.com/	Gastro-intestinal	2,808
Leuplin/Enantone	Leuprorelin	Takeda http://www.takeda.com/	Prostate cancer	2,369
Aricept	Donepezil	Eisai http://www.eisai.com/	Alzheimer's disease	2,351
Prograf /advagraf /graceptor /astagraf XL	Tacrolimus	Astellas http://www.astellas.com/en/	Immunosuppression	2,000
Takepron/Prevacid/Ogast/Lans ox/Agopton	Lansoprazole	Takeda http://www.takeda.com/	Gastro-intestinal	1,606
Cravit/ Levaquin/ Tavanic	Levofloxacin	Daiichi Sankyo http://www.daiichisankyo.com/	Antibacterial	1,480
Vesicare	Solifenacin	Astellas http://www.astellas.com/en/	Overactive bladder	1,451

Source : Office of Pharmaceutical Industry Research (${\tt J}$ ${\tt P}$ ${\tt M}$ ${\tt A}$)

1. Competitive advantages of Japanese Pharma Industry (2) High Product Quality

High Product quality is another excellent competitive edge of the Japanese pharmaceutical companies.

- The Japanese pharmaceutical industry has a competitive advantage through its ability to manufacture high quality drug products, as well as high quality packaging technologies.
- In addition, products are manufactured to meet the specific needs of patients and healthcare providers
 - e.g., Printing product names on tablets to help prevent medication error
- With the world's highest level of quality control and quality assurance, the Japanese pharmaceutical industry seeks improved quality of pharmaceuticals around the world

Please visit the web-site for at video of one of the Japan's leading company's production facilities

http://www.jpma.or.jp/movie/movie.wmv

Japanese pharmaceutical companies provides innovative and high quality products to the global market.

- Japan pharma have 319 overseas subsidiaries and employ 65 thousand people in local markets as of 2011. 114 out of these overseas subsidiaries have manufacturing facilities.
- Japan pharma have their own local sales & marketing branches and/or have licensed out many products to local companies. In global markets, there are many of pharmaceutical products discovered and developed by Japanese companies.
- Japan pharma strive to satisfy unmet medical needs through
 R&D of innovative new drugs and expansion into global markets
- Japan pharma are reliable global business partners for providing high quality pharmaceutical products in a stable and reliable manner

The Japanese companies strive to create innovative new drugs to meet unmet medical needs

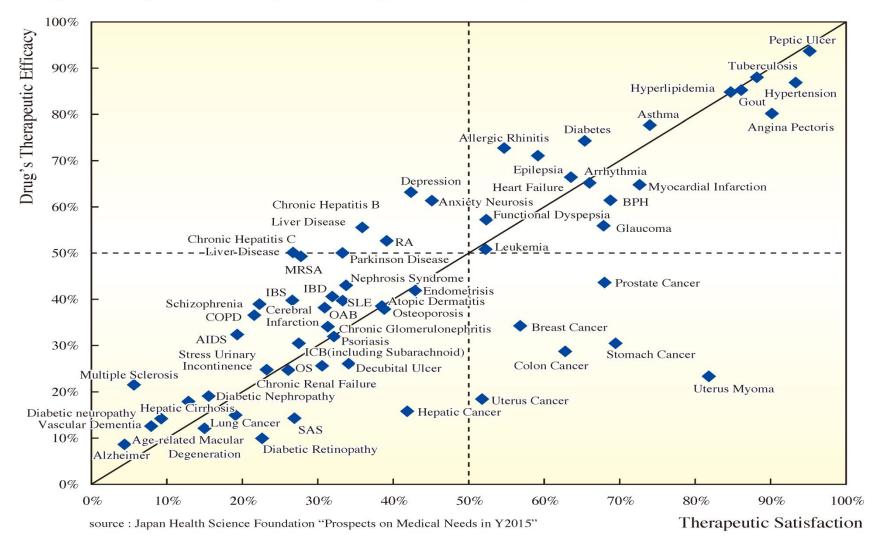
- There are still many unmet needs, such as diseases with no satisfactory treatments, as is shown on the next slide (slide 8). Japanese pharmaceutical companies play an important role in creating innovative new drugs to meet those unmet medical needs.
- In order to find solutions to these unmet medical needs, Japanese pharmaceutical companies are making use of a variety of strategies to create innovative new drugs both on their own and in collaborations and alliance with partners world wide, such as shown on slides 9 and 10.
- A number of Japanese companies have launched their own research funds to collaborate with outside researchers with promising innovative new drug seeds.

<Research Funds by Japanese companies>

- a³ (a-cube) (Astellas)
- FINDS (Shionogi)
- TaNeDS (Daiichi Sankyo)
- GHIT Fund (more information on the 2nd last slide) http://www.ghitfund.org/en/

Japanese companies are conducting R&D to realize innovative drugs that meet unmet medical needs, such as the disease areas plotted in the lower left part of this chart.

Drug's Therapeutic Efficacy vs. Therapeutic Satisfaction



Japanese pharmaceutical companies have realized numerous successful international alliances with partners around the world focused on innovative drug research. Below are a sample of some of the partnerships entered into in 2013 alone, with 2012 partnerships featured on the next slide.

October 2, 2013 (Takeda)

Partnership with Tri-Institutional Therapeutics Discovery Institute, Inc.

http://www.takeda.com/news/2013/20131002_6004.html

September 18, 2013 (Eisai)

Collaborate with Selvita S.A.

http://www.eisai.com/news/news201352.html

September 9, 2013 (Kyowa Kirin)

Establish Singapore Translational Research Laboratory

http://www.kyowa-kirin.com/news_releases/2013/pdf/e20130909_01.pdf

April 5, 2013 (Astellas)

Collaborate with Ambrx Inc.

http://www.astellas.com/en/corporate/news/detail/astellas-and-ambrx-initiate-co.html

•February 28, 2013 (Takeda)

Partnership with Resolve Therapeutics LLC.

http://www.takeda.com/news/2013/20130228 5671.html

January 8, 2013 (Eisai)

Agreement with Epizyme, Inc., and Roche Molecular Systems

http://www.eisai.com/news/news201303.html

January 8, 2013 (Daiichi-Sankyo)

Collaborate with Amplinmune

http://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/005132/20130108_421_E.pdf

Japanese pharmaceutical companies have realized numerous successful international alliances with partners around the world focused on innovative drug research. Below are a sample of some of the partnerships entered into in 2012 alone.

October 3, 2012 (Takeda)

Collaborate with Advinus initiate

http://www.takeda.com/news/2012/20121003_4000.html

September 12, 2012 (Eisai)

Partnership agreement with the Sabin vaccine institute to develop vaccines for Neglected Tropical Diseases

http://www.eisai.com/news/news201265.html

August 31, 2012 (Shionogi)

Memorandum signed with Danish Universities for collaboration in R&D

http://www.shionogi.co.jp/en/company/news/2012/pmrltj0000000wfd-att/e_120831.pdf

August 29, 2012 (Takeda)

Joint research agreement with BC Cancer Agency

http://www.takeda.com/news/2012/20120829_3993.html

August 15, 2012 (Eisai)

Opening of a new pilot antibody manufacturing plant

http://www.eisai.com/news/news201254.html

• July 17, 2012 (Chugai)

Opening of "Chugai Pharmabody Research Pte.Ltd." in Singapore

http://www.chugai-pharm.co.jp/hc/ss/english/news/detail/20120717110000.html

•June 12, 2012 (Astellas)

Collaborate with DNDi on new drug discovery research for the treatment of Neglected Tropical Diseases

http://www.astellas.com/en/corporate/news/pdf/20120612_eg.pdf

June 4. 2012 (Astellas)

Astellas and Drais Partner to develop second compound through Seldar

http://www.astellas.com/en/corporate/news/pdf/120604_1_Eg.pdf

•May 2, 2012 (Eisai)

Collaborate with UK based horizon discovery to identify and validate cancer targets

http://www.eisai.com/news/news201220.html

March 29, 2012 (Daiichi-Sankyo)

Collaborate with NGM to discover and develop innovative therapeutics for Diabetes

http://www.daiichisankyo.com/media investors/media relations/press releases/detail/005904/20120329 377 E2.pdf

2. Value Creations

(1) <u>Asia Partnership Conference of Pharmaceutical</u> Associations (APAC)

In 2012, 12 Asian pharmaceutical associations from 11 Asian economies formed a new alliance now known as APAC.

Mission and Goals;

"To expedite the launch of innovative medicines for the peoples in Asia".

APAC acts through expert working groups to create a platform for open innovation and regulatory convergence in Asia.

http://www.jpma.or.jp/english/media/130412.html

Please click the attachment on the right for the official report of the 2nd conference.

Official Minutes
The 2nd Asia Partnership Conference of Pharmaceutical Associations

The 2nd

Asia Partnership Conference of Pharmaceutical Associations

(APAC)

April 11-12, 2013

Tokyo, Japan



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2. Value Creations (2) Contribution to Global Health

JPMA and its individual membership companies acknowledge our role as a stakeholder and our responsibility to contribute to improving global health. JPMA has published a statement on Global Health. Please visit the JPMA website through the link below to learn more about our activities. http://www.jpma.or.jp/english/isuues/position/global health.html

GHIT Fund:

Leverage Japanese innovation to save lives in developing nations

Partners:

- Japanese government
- -Ministry of Health, Labor and Wealth and Ministry of Foreign Affairs
- Bill & Melinda Gates Foundation
- 5 Japanese Pharmaceutical Companies
- Astellas, Eisai, Shinogi, DaiichiSankyo, Takeda



3. For More Information

(1) Japan Pharmaceutical manufacturers Association

http://www.jpma.or.jp
http://www.jpma.or.jp/english/jpmaguide/2013/index.html

(2) List of the membership companies of JPMA,
70 companies including US/Europe multi-national companies
http://www.jpma.or.jp/english/about_us/member.html