



# **JAPAN**

## **Track A: Breakout Session**

### **U.S. Embassy, Tokyo**

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**Commercial Attaché**



**@DiscoverForums**

# Outline

- ❑ USG Activities
- ❑ Scene-setters for the Secretary
- ❑ Industry Subsector Overview

# U.S. Embassy, Tokyo: Activities & Highlights

November 2013: Letter--Commerce Secretary Pritzker to MHLW Minister

December 2013: Deputy Assistant Secretary Holly Vineyard-MHLW in Tokyo

February 2014: Principal Deputy Assistant Secretary John Andersen Meetings  
with MHLW in Tokyo

May 2014: Letter Commerce Secretary Pritzker to Chief Cabinet Secretary Suga

June 2014: Deputy Assistant Secretary Holly Vineyard-MHLW in Tokyo

June 2014: 5<sup>th</sup> Vaccine Policy Exchange (VPE) in Tokyo

September 2014: Deputy Assistant Secretary Holly Vineyard-MHLW in Tokyo  
Day-long Ad Hoc Dialogue on healthcare issues (post-EHI)

# U.S. Department of Commerce Visit to Japan

- ✓ October 19-24, 2014: Secretary Commerce Penny Pritzker  
Healthcare & Energy Business Development Mission to Japan and Korea

20 Companies, 12 in Healthcare Industry in Japan:  
Over two days of bilateral meetings and roundtables

Penny Pritzker, Secretary of Commerce



# Commercial Landscape

- Generates over 6.5% of the world economy, with a GDP of almost \$5 trillion.
- U.S.'s number 4 export market – \$200 billion.
- The largest source of FDI into the United States in 2013.
- The second-largest stock of FDI in the United States - over \$300 billion.
- U.S. companies hold over \$1 trillion in Japanese assets.
- Foreign buyers hold about 1/3<sup>rd</sup> of all shares listed on the Tokyo stock market, the vast majority being U.S. holders.
- Over 500,000 Americans are directly employed by the likes of Toyota, Suntory and Softbank -- U.S. companies in Japan directly employ over 300,000 Japanese, & U.S. companies make up fully one-third of all foreign companies in Japan.

# Japan's “Abenomics” and Economic Reforms in 2014

- Nickname for the multi-pronged economic program of Japanese prime minister Shinzō Abe.
- Abe’s program consists of “Three Arrows”
  - ✓ monetary,
  - ✓ fiscal, and
  - ✓ regulatory reform.
- Growth Strategy (released June 2014)
  - ✓ lowering the corporate tax from 35 to below 30 percent,
  - ✓ promoting a performance-based salary system, and
  - ✓ allowing an expansion of foreign workers in certain sectors of the economy
- Japan aims to achieve a balanced budget by fiscal year 2020.



# Abenomics Growth Strategy for Health Care

- Prime Minister Abe's growth strategy calls for promotion of the domestic pharmaceutical, medical device and biotechnology industries for additional investment and exports.
- Japanese version of America's National Institutes of Health will be inaugurated in 2015, while a "special economic zone" was designated in western Japan to enhance medical services by using information technology to build an efficient medical platform.
- Japan's new Pharmaceuticals and Medical Devices Law will take effect on November 25, 2014.
  - ✓ Independent chapter for "medical devices"
  - ✓ Expansion of third party certification system for high risk devices
  - ✓ Quality Management System (QMS) adherence to ISO13485
  - ✓ Introduction of conditional approval system for regenerative medical products

# Japan's Healthcare System

## - Major Characteristics

- **National Health Insurance (NHI) System (achieved in 1961) - most of the population is enrolled in some form of health insurance scheme and are thus required to pay insurance premiums**
- **Free Access - patients can freely choose doctors, clinics, hospitals (8,565 hospitals, 100,152 clinics and 68,474 dental clinics in 2012)**
- **Low Co-payment Rate - patient can receive necessary medical care for a small fee (patients are required to pay anywhere 10 and 30% of treatment fee)**
- **Constrained Healthcare Expenditure - spends about 8% of its GDP (U.S. 15%)**
- **Fee for service – reimbursed based on point system**

# Japan's Healthcare System

## - Rapidly Changing Healthcare Environment

- High life expectancy - male: 81.13 female: 87.99 (2014 est)
- Birth/Death rate – 8.07 birth and 9.38 death /1,000 population (2014 est)
- Population - 127,103,388 (2014 est.)
- Aging society - the elderly will make up a significant percentage of the total population (those over 65 are estimated to reached a record high of 25.0 percent in 2013 and is projected to reach approximately 33.4 percent in 2035).
- The second highest healthcare expenditure - total health expenditure was estimated at \$502.9 billion with per capita health spending at \$3,955 in 2013

# Healthcare Bilateral Cooperation

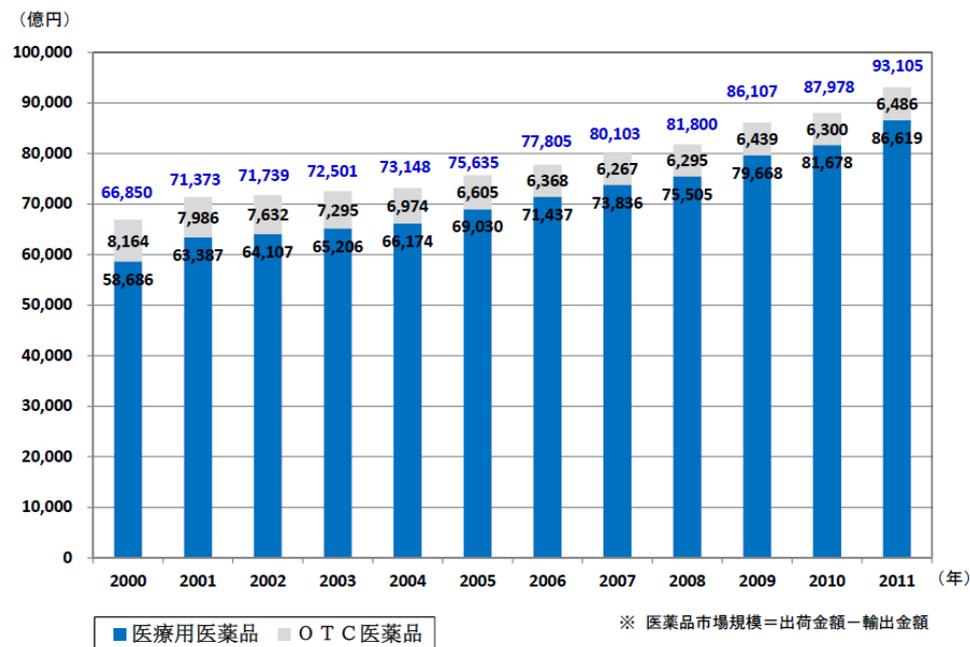
- The U.S. Department of Commerce (DOC) has chaired discussions with Japan's Ministry of Health, Labour and Welfare (MHLW) on regulatory and reimbursement issues for over 30 years
- In September 2014, an ad hoc meeting on healthcare issues was viewed as a resumption of the longstanding bilateral dialogue on this sector between USDOC and MHLW.
- Chaired by DAS for Asia Holly Vineyard on the U.S. side and by her counterparts at the Councilor level from MHLW, several issues of concern to industry related to Japan's pricing and regulatory systems were discussed.
- Newly appointed Minister Yasuhisa Shiozaki heads the MHLW as an apparent effort of Prime Minister Abe to emphasize labor and pension reform, as well as innovation in health industry.

## World's Second Largest Healthcare Market

- Japan has a rapidly-aging demographic profile, consisting of relatively prosperous seniors with increasing expectations for improved quality of life in their later years.
- Japanese market for pharmaceuticals and medical devices is large and established; The Japanese market for patented pharmaceuticals is the largest one outside of the United States, and is projected to remain so for at least a decade.
- Sophisticated medical devices, regenerative medicine and Health IT are sub-sectors that are particularly suited to meeting Japan's healthcare needs.

# Pharmaceuticals

- 2<sup>nd</sup> largest pharmaceutical market – after the US.
- Patented drugs comprise the vast majority of Japan's pharmaceutical market - representing more than 83% of the total.
- US market share is approximately 20%.
- Japan's pricing and reimbursement systems recognize the value of innovation.



## More Pharmaceutical Background

- Industry would like the price premium system that minimizes downward price revisions on new drugs during their patent periods (officially called the “Premium for the promotion of new drug creation and the resolution of un-approved indications”) to be made a regular part of the pricing system--it has been a success to date.
- According to surveys and press reports, foreign and Japanese companies are bringing much or all of their drug pipelines to Japan, and are committed to drug development in Japan simultaneously with drug development in the United States and Europe.
- Industry has increased clinical development staffs in Japan and are looking at Japan increasingly as a site for early drug development.

# Medical Devices

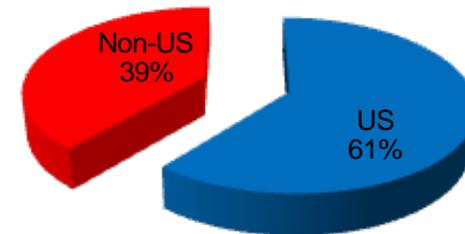
- **\$32 billion market – great opportunities for innovative US products**
- **Total imports of U.S. medical devices exceeded \$7.4 billion in 2010, a 23 percent market share - U.S. firms have achieved a much higher market share than the official statistics.**
- **Per capita spending is high, and the country is open to new and innovative medical technologies and treatment despite a strong emphasis placed on cost-containment.**
- **3<sup>rd</sup> largest importer of medical devices.**
- **Medical device purchasing in Japan is closely linked to the levels of national health insurance system reimbursement. However, it is by no means an easy country to penetrate**

# Medical Devices—Foreign Firm Dominance

- The market remains heavily dependent on imports, especially sophisticated medical technologies.
- Few domestic firms are “global” except for Terumo, Olympus, Toshiba, Nipro and aspiring smaller firms.
- According to the American Medical Devices and Diagnostics Manufacturers’ Association (AMDD), a trade association of Japanese operations of U.S. medical devices and diagnostics companies, approximately 60% of “new medical devices” approved in Japan were from its member companies.



US Market Share of New Medical Devices  
(2005 - 2010)



# Health Information Technology (IT)

- The market size of Health IT systems in Japan is roughly \$6.3 billion.
- The adoption of electronic medical records (to safely store and effectively retrieve and share patient information) is an important priority. Due to rapid demographic changes and hospital shortages, demand for home nursing care is expected to grow.
- Health IT is an emerging sector--promising areas for U.S. exporters include security/privacy, data integration, and cloud computing, although existing and potential barriers will need to be addressed in each of these areas.
- U.S. industry has identified several obstacles to widespread adoption of Health IT in Japan, which thereby also serve as impediments to U.S. Health IT exports. The key obstacles include lack of financial incentives for doctors and hospitals; a lack of coordination among Japanese ministries to collectively develop policies that promote adoption of Health IT; and challenges in enabling different systems to communicate with each other (often referred to by the industry term “interoperability”).

# Vaccine Policy – Vaccine Gap

	Japan	Australia	Korea, South	Singapore	Indonesia	Thailand	USA
Gross National Income / capita (US\$)	37,780	43,770	18,830	37,220	2,230	37,760	47,240
BCG (tuberculosis)	✓		✓	✓	✓	✓	
Diphtheria, Tetanus, Pertussis					✓	✓	
Diphtheris, Tetanus, Acellular Pertussis	✓	✓	✓	✓			✓
Oral Polio	✓			✓	✓	✓	
Inactivated Polio		✓	✓		✓		✓
Haemophilus influenzae type b	✓	✓					✓
Hepatitis B		✓	✓	✓	✓	✓	✓
Measles					✓	✓	
Measles, Rubella or combination	✓						
Measles, Mumps, Rubella		✓	✓	✓		✓	✓
Japanese Encephalitis Virus	✓		✓			✓	
Tetanus					✓		
Diphtheria, Tetanus	✓				✓		
Tetanus, Diphtheria			✓			✓	
Tetanus, Diphtheria, Acellular Pertussis				✓			✓
Pneumococcal conjugate		✓		✓			✓
Varicella		✓	✓				✓
Meningococcal C conjugate		✓					
Meningococcal A,C,W,Y conjugate						high risk	✓
Human Papillomavirus	✓	✓					✓
Rotavirus	✓	✓					✓
Hepatitis A		high risk					✓
Typhoid			high risk				
Influenza	✓	high risk	high risk	✓			✓

# Regenerative Medicine – New Growth Area

- Regenerative medicine and the clinical application of stem-cell related therapies has been an area targeted for development by the Government of Japan - Regenerative Medicine Promotion Act.

【Traditional Pathway of approval】



【New Pathway for regenerative medical products】



\* Probable benefit: Assumption of efficacy with small patient population.

\*\* Safety: Earlier detection and evaluation of adverse events.

# Challenges and Biennial Price Revisions in Conclusion

Japan's aging population, combined with a diminishing number of children has led to serious financial difficulties for Japan's medical system.



## Policies to cut healthcare spending

- Two key bodies responsible for drug and device pricing are the MHLW and the Central Social Insurance Council (Chuikyo). Chuikyo, the body that advises the MHLW, is made up of representatives from the medical community, insurers, and representatives of the “public interest.”
- Chuikyo deliberates Japan's reimbursement pricing policies for the following two-year period. In April 2014, Japan's Council on Economic and Fiscal Policy (CEFP) began considering a proposal to move from a biennial to an annual reimbursement cycle for medical devices and pharmaceuticals.

## Challenge of Annual Price Revisions-continues

- Ministry of Finance, which is looking for ways to reduce healthcare expenditures. In June 2014, the Cabinet made a formal decision to study the issue further.
- Specifically, the Cabinet called for a study to determine the appropriate frequency of reimbursement price revisions. This study has commenced this fall 2014.
- Industry is concerned about the administrative burden of collecting and submitting data annually.
- Industry is also concerned that an annual cycle will create greater uncertainty and lead to more frequent reimbursement cuts, which would conflict with Prime Minister Abe's policies to promote the development of a strong pharmaceutical and medical device industry in Japan.

**We look forward to working with DGM attendees and companies.**

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