

**Saturday, August 2<sup>nd</sup> 2014**

**Brazil-Japan Seminar on Pharmaceuticals and Medical Devices  
Regulations**



## **Building a New Partnership through Pharmaceuticals**



**Masafumi Nogimori**

**President, The Federation of Pharmaceutical Manufacturers'  
Associations of JAPAN (FPMAJ)**

**(Representative Director, Chairman of the Board,  
Astellas Pharma Inc.)**

# JAPAN's Pharmaceutical Industry

①	Number of Companies:	349
	• *Research-oriented Companies:	72
②	Number of Employees:	167,514
③	Pharmaceutical Market:	10,016 billion yen
④	Pharmaceutical Production:	6,977 billion yen
	• as a percentage of GDP:	1.48%
	• Prescription Drug Production:	6,263 billion yen

\*as of April 1<sup>st</sup> 2014

1 yen = 0.0218 R\$ = 0.0099 US\$ (as of July 1<sup>st</sup> 2014)

③ List Price    ④ Ex-factory Price with consumption tax

Source: ①,② : Statistics on Pharmaceutical and Medical Device Industry 2012; Ministry of Health, Labour and Welfare (MHLW)

③ : Japan Pharmaceutical Market in 2013; IMS Health

④ : Labour Force Survey 2012; Ministry of Internal Affairs and Communications (MIC)

# New Medicines from JAPAN

Number of Global  
"Top 100" selling  
Medicines (in 2013)

Country	Number of Medicines
USA	53
<b>JAPAN</b>	<b>10</b>
Switzerland	10
Germany	9
UK	6
France	4
Other	2

Innovative New  
Medicines from JAPAN

*INN	Developer	Indication
Olmesartan	Daiichi-Sankyo	Hypertension
Candesartan	Takeda	Hypertension
Leuprorelin	Takeda	Prostate Cancer
Tacrolimus	Astellas	Immunosuppression
Solifenacin	Astellas	Overactive Bladder
Rabeprazole	Eisai	Peptic Ulcer

# JAPAN's Innovation to Global Health

## Global Health Innovative Technology (GHIT) Fund

- Supporting development of vaccines and medicines for infectious diseases in the developing world
- Contributors :
  - Japanese Government (\*MHLW and \*\*MOFA)
  - Bill & Melinda Gates Foundation
  - 5 Japanese Pharmaceutical Companies  
(Astellas, Daiichi-Sankyo, Eisai, Shionogi, Takeda)

## Collaboration between BRAZIL and JAPAN

- Merck, Astellas, Farmanguinhos, and 3 other partners participate in Pediatric Praziquantel Consortium
- Eisai and \*\*\*FIOCRUZ are developing a medicine for cerebral malaria

\*MHLW: Ministry of Health, Labour and Welfare

\*\*MOFA : Ministry of Foreign Affairs

\*\*\*FIOCRUZ: Fundação Oswaldo Cruz

# JAPAN's Innovative Pipelines



**Alogliptin**  
(Diabetes Mellitus)  
**Brentuximab Vedotin**  
(Malignant Lymphoma)  
**Mifamurtide**  
(Osteosarcoma)



**Daiichi-Sankyo**

**Combination of  
Olmesartan, Amlodipine,  
and Hydrochlorothiazide**  
(Hypertension)

**Edoxaban**  
(Anticoagulant)



**Enzalutamide**  
(Prostate Cancer)  
**Mirabegron**  
(Overactive Bladder)



**Fentanyl**  
(Cancer Pain \*TDDS)  
**Oxybutynin**  
(Overactive Bladder \*TDDS)



**Eribulin**  
(Breast Cancer)

**GHIT Fund**

**(Global Health Innovative Technology Fund)**

\*TDDS : Transdermal Drug Delivery System

# Further Contribution to BRAZIL

## JAPAN's Pharmaceutical Companies' Proposal

## Clinical Trial, NDA, GMP

- ① **Acceleration of review process for Clinical Trial approval and \*NDA**
- ② **Clarification of the required Clinical Trial for NDA**
- ③ **Harmonization with \*\*ICH requirements for \*\*\*GMP**

\*NDA: New Drug Application

\*\*ICH: International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

\*\*\*GMP: Good Manufacturing Practice

# Further Contribution to BRAZIL

## JAPAN's Pharmaceutical Companies' Proposal

Compulsory License,  
Tariff/Tax, Traceability

- ④ **Not to extend the scope of Compulsory License for medicines**
- ⑤ **Reduction of Tariff rates and improvement of convoluted Tax system for medicines**
- ⑥ **Creation of Traceability environment for medicines**

# Further Contribution to BRAZIL

## JAPAN's Pharmaceutical Companies' Proposal

## Patent, Data, Trade Mark

- ⑦ ANVISA's pre-approval assessment of pharmaceutical Patent to be limited only to the assessment in the light of Public Health
- ⑧ Protection of Patent for second medical use and invention of crystal polymorph
- ⑨ Development of legal systems for Data Protection Period and Patent Term Restoration
- ⑩ Acceleration of examination process for Patent and Trade Mark registration



# *Muito Obrigado !*



**Building a New Partnership  
through Pharmaceuticals**



ご清聴いただき、ありがとうございました！