

JAPANESE INDUSTRY'S ACTIVITIES IN BRAZIL

2016 OCTOBER 4

JAPAN EXTERNAL TRADE ORGANIZATION (JETRO)

SAO PAULO OFFICE

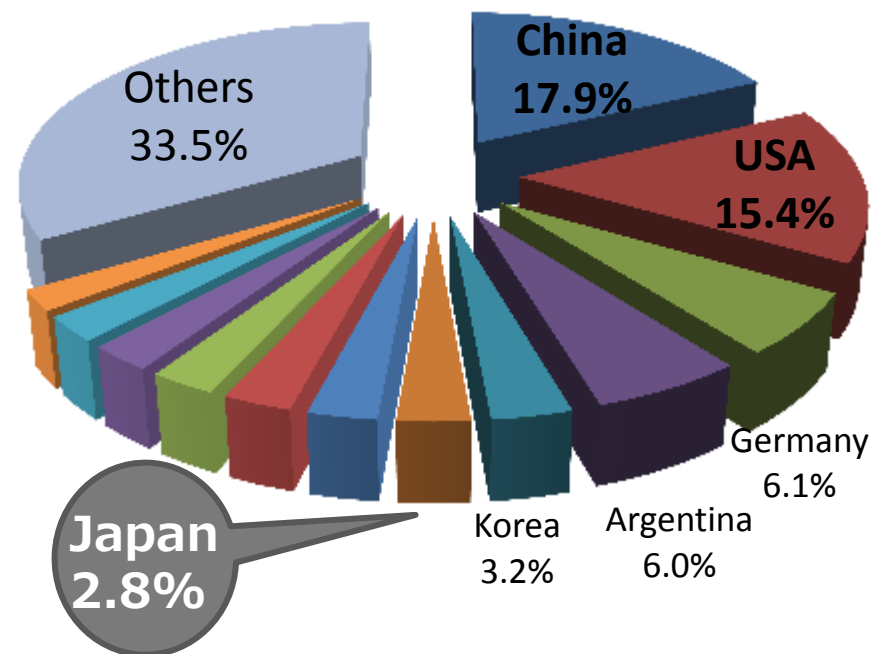
Brazil's Top Import Partners

(Units: US\$ FOB million)

	2014	2015		
	Value	Value	Share	Growth Rate
China	37,345	30,719	17.9%	△17.7%
USA	35,018	26,471	15.4%	△24.4%
Germany	13,838	10,380	6.1%	△25.0%
Argentina	14,143	10,285	6.0%	△27.3%
Korea	8,526	5,421	3.2%	△36.4%
Japan	5,901	4,877	2.8%	△17.4%
Italy	6,312	4,675	2.7%	△25.9%
Nigeria	9,495	4,633	2.7%	△51.2%
France	5,700	4,457	2.6%	△21.8%
Mexico	5,363	4,378	2.6%	△18.4%
India	6,640	4,290	2.5%	△35.4%
Spain	3,910	3,500	2.0%	△10.5%
Others	76,963	57,363	33.5%	△25.5%
Total	229,154	171,449	100.0%	△25.2%

Source : MDIC

The 5th largest exporter

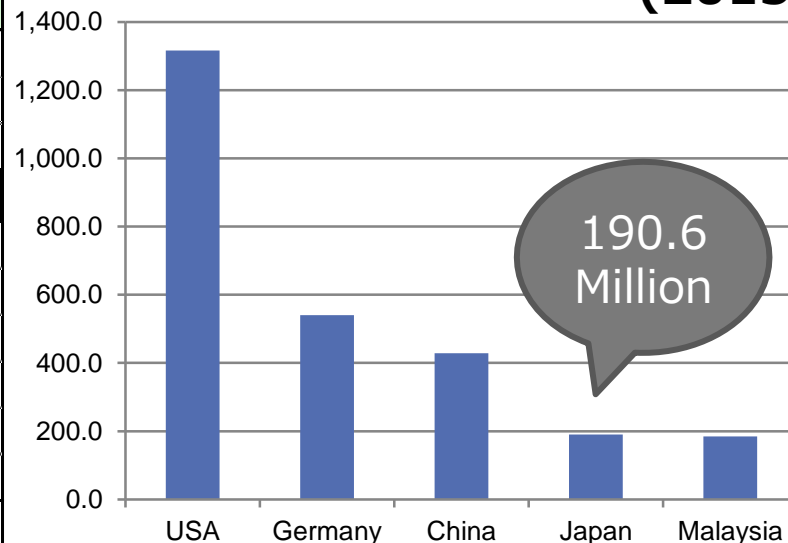


Medical device Imports by Country of Origin

(Units: US\$ FOB million)

	2013	2014	2015	
	Value	Value	Value	Share
USA	1,535	1,561	1,316	32.7%
Germany	727	678	541	13.4%
China	432	469	429	10.6%
Japan	242	239	191	4.7%
Malaysia	205	180	184	4.6%
Switzerland	184	186	140	3.5%
France	167	154	123	3.1%
Ireland	112	118	115	2.9%
Puerto Rico	93	97	108	2.7%
UK	119	105	88	2.2%
Others	1,085	989	794	19.7%
Total	4,901	4,776	4,029	100.0%

Imports by Country of Origin (2015)



Japan is the 4th largest exporter

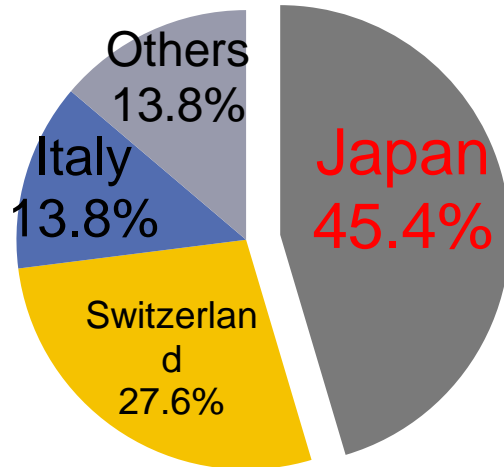
Medical device Imports from Japan

(Units: US\$ FOB million)

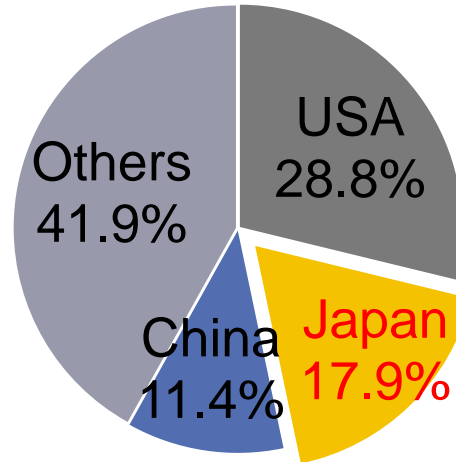
Description	2012	2013	2014	2015		Annual Average Growth Rate
	Value	Value	Value	Value	Share	
Instruments and appliances used in medical, surgical, dental or veterinary sciences	73.2	93.1	76.7	68.6	57.3%	Δ2.1%
Other diagnostic equipment	22.7	45.3	34.6	22.2	18.5%	Δ0.8%
Ultrasonic scanning apparatus	10.5	10.7	13.7	9.5	8.0%	Δ3.3%
Other syringes, needles, catheters, cannulae and the like	8.0	8.4	7.8	6.3	5.2%	Δ7.9%
Ophthalmic instruments and appliances	1.8	3.2	3.2	3.4	2.9%	23.7%
Dental drill engines	1.0	0.0	2.6	2.9	2.4%	42.0%
Apparatus based on the use of X-rays or of alpha, beta or gamma radiations	36.2	26.9	42.4	27.5	23.0%	Δ8.7%
Computed tomography apparatus	16.6	12.4	21.7	13.0	10.9%	Δ7.7%
For other uses	6.8	3.8	6.5	4.9	4.1%	Δ10.2%
Other, for medical, surgical or veterinary uses	5.3	5.2	7.4	4.2	3.5%	Δ7.5%
Photographic plates and film in the flat for X-ray	21.7	20.5	20.2	13.7	11.5%	Δ14.1%
Wadding, gauze, bandages and similar articles	2.3	4.5	4.8	5.9	4.9%	37.7%
Gauze, bandages, plaster	1.9	4.0	4.4	5.6	4.7%	43.4%
Total	140.1	148.9	150.0	119.7	100.0%	Δ5.1%

Medical device Imports from Japan(2015)

**Dental drill engines
(HS Code : 901841)**

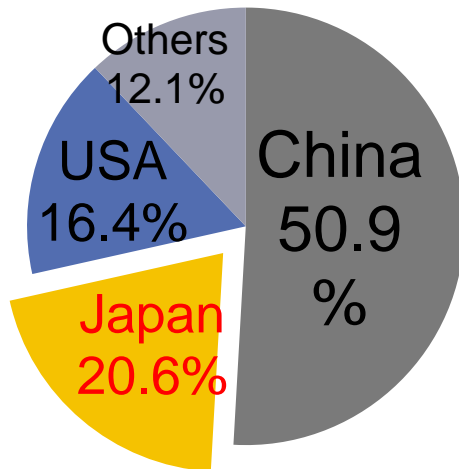


**Gauze, bandages, plaster and others
(HS Code : 300510)**

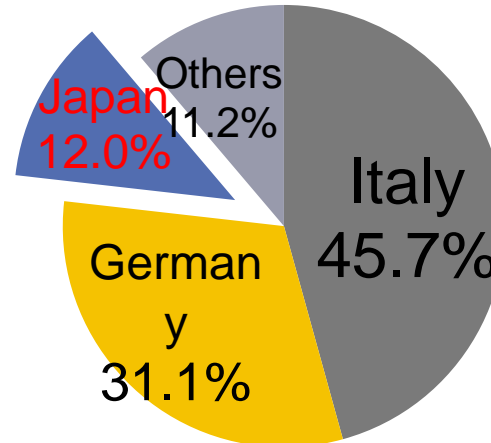


■ **13.1%(2014)→
17.9%(2015)
increased
market share**

CT (HS Code : 902212)



Artificial tooth (HS Code : 902121)



■ **9.5 %(2014)→
12.0%(2015)
increased
market share**

Foreign Direct Investment by Country

(Units: US\$ FOB million)

	2014	2015		
	Value	Value	Share	Growth Rate
Netherlands	8,791	11,573	20.0%	31.6%
USA	8,580	6,647	11.5%	△22.5%
Luxembourg	6,659	6,599	11.4%	△0.9%
Spain	5,962	6,570	11.3%	10.2%
Germany	1,574	3,453	6.0%	119.4%
Japan	3,780	2,878	5.0%	△23.9%
France	2,945	2,841	4.9%	△3.5%
Norway	554	2,445	4.2%	341.3%
Italy	868	1,720	3.0%	98.2%
UK	1,726	1,649	2.8%	△4.5%
Switzerland	1,973	1,126	1.9%	△42.9%
Chiles	1,273	1,024	1.8%	△19.6%
Belgium	347	989	1.7%	185.0%
Canada	912	978	1.7%	7.2%
Virgin Islands	772	764	1.3%	△1.0%
Mexico	125	573	1.0%	358.4%
Others	9,258	6,078	10.5%	△34.3%
Total	56,099	57,907	100.0%	3.2%

Japan is
the 6th
largest
investor

Note : Balance of payments basis, excluding reinvested earnings

Source : Central Bank (BC)

Foreign Direct Investment by Industry

(Units: US\$ FOB million)

	2014	2015		
	Value	Value	Share	Growth Rate
Agriculture, Livestock and Mining (and Others)	5,621	8,310	14.4%	47.8%
Extraction of petroleum and natural gas	2,158	4,595	7.9%	112.9%
Mining of metal ores	2,149	1,516	2.6%	△29.5%
Mining related services	771	1,414	2.4%	83.4%
Manufacturing (and Others)	16,922	20,967	36.2%	23.9%
Motor vehicles, trailers, bodies for motor vehicles	2,914	4,518	7.8%	55.0%
Chemicals	2,176	2,417	4.2%	11.1%
Food	1,547	2,321	4.0%	50.0%
Tobacco	41	2,184	3.8%	5526.8%
IT equipments, electronic products	1,528	1,122	1.9%	△26.6%
Machinery and equipment	814	1,087	1.9%	33.5%
Electrical and electronic equipment	1,020	1,019	1.8%	△0.1%
Services (and Others)	33,357	28,409	49.1%	△14.8%
Trade (excluding motor vehicles)	5,657	5,471	9.4%	△3.3%
Telecommunications	4,919	4,552	7.9%	△7.5%
Electricity, gas, and others	2,552	3,930	6.8%	54.0%
Real estate	1,641	2,150	3.7%	31.0%
Financial service and auxiliary activities	4,763	1,381	2.4%	△71.0%
Health	16	1,338	2.3%	8262.5%
IT services	1,188	1,005	1.7%	△15.4%
Selling or buying real estate	199	221	0.4%	11.1%
Total	56,099	57,907	100.0%	3.2%

■ January 2015, Brazil opened healthcare sector to private ownership

■ Allowing foreign companies to invest capital in private hospitals, health institutions

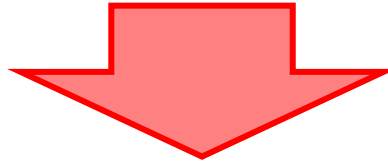
■ More investment opportunities

Note : Excluding reinvested earnings
Source : Central Bank (BC)

Japanese Medical device and Pharmaceutical Companies in Brazil

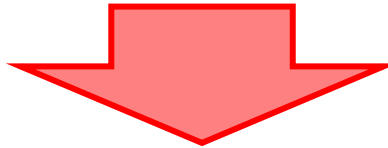
Prior to 1990~

Import through local distributors



Late 1990's~

Establish factories and local corporations expecting to expand market share in Brasil



2000~

Acquisition of local companies to expand production and sales network

Japanese Medical device Companies in Brazil

2010 and later~

Growing interest to expand sales in Brazil

Direct sales, following the Brazilian regulations

Business expansion through acquisition

Medium-sized companies starting to enter Brazilian market

Recently established :

2010 FUJIFILM DO BRASIL

2012 NIHON KOHDEN DO BRASIL

2012 OMRON ELETRÔNICA DO BRASIL

2014 3-D Matrix MEDICAL TECHNOLOGY

2014 Paramount Bed do Brasil

2016 ASAHI INTECC CO. LTD.

About one-third of the Japanese medical device companies entered Brazil after 2010

Japanese Pharmaceutical Companies in Brazil

Manaus Free Zone

- Farmaceutica do Hisamitsu Brasil

- Astellas Farma Brasil
- Eisai Laboratórios
- Otsuka Pharmaceutical
- Rohto Mentholatum



Sao Paulo

- Daiichi Sankyo Brasil
- Takeda Brasil

Rio Grande do Sul

- Takeda Brasil

Prior to 1990

New and generic drugs, medical consumables such as Salonpas, ointments

Further market expansion

2012 Takeda Brasil acquires Multilab

2014 Otsuka Pharmaceutical enters Health food sector through acquisition of Jasmine

2014 Sumitomo Dainippon Pharma and Daiichi Sankyo Brasil sign license agreement

Japan Brazil Joint Public-Private Sector Medical seminar

August 4, 2014 1st Brazil-Japan Joint Public-Private Sector Open Seminar on Regulations in Pharmaceuticals and Medical Devices (Rosa Rosarum, São Paulo)



Remarks by Prime Minister Abe at the 1st Seminar

September 10, 2015 2nd Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices (JETRO Headquarters, Tokyo)

October 4, 2016 3rd Brazil-Japan Seminar on Regulations on Pharmaceuticals and Medical Devices (Hotel Novotel Jaraguà, Sao Paulo)

2014 Bilateral meeting between Prime Minister Abe and then President Rousseff
Agreement to promote cooperation in the health and medical sector

1st Seminar – Presence of PM Abe, Dr. Barbano then Director President of ANVISA, 350 participants from government and public sector. Commitment to deepen cooperative relation between Japan and Brazil on medical devices and pharmaceuticals.



2015 Presence of Dr. Barbosa, Director President of ANVISA in Japan
Presentation of efforts in Brazil to expedite examination and to be more efficient. Expectation expressed towards ANVISA's initiative to reform. Confirmation was made for further bilateral cooperation.

Improvement on examination process

Efforts in Brazil since 2014

2014 Nov.	1. Revocation of the validity (1year) of the Operating Permit, Autorização de Funcionamento de empresa (AFE) required for manufacturing and sales activities.
	2. Extension of renewal term of the GMP Certificate (from 2 to a maximum of 4 years).
2015 Jan.	3. The GMP audit services performed by ANVISA can now be performed by a third party agency (ANVISA certified agency).
	4. GMP audit information held by foreign authorities can now be used by ANVISA.
	5. Extension of product registration period (from 5 to maximum of 10 years).
2016 Aug.	6. Flexibility in transfer of product registration in transactions

Results since 2015

- Great Improvement on Registration Time for Class I, II, III, IV products
- Transparency secured on examination

For a Better Business Environment

**Outstanding
Improvement!**

- Simplification of operating permit, Autorização de Funcionamento de empresa(AFE) re-registration procedure, required for acquisition and secondary investment.
- Greater interest in implementing 2.to 5. with the changes since 2014.
- Further expedition of customs clearance on imports
- Reduction in waiting time for GMP audits.

Japan-Brazil Public-private partnership

Japan-Brazil Cooperation in Preventive medicine

Early Cancer Detection Project in Brazil

- Improve quality of life for people in Brazil
- Reduce cancer medical cost in Brazil by early cancer detection

Colorectal cancer → other cancer screening projects !

High interest from the Brazilian side → pilot project in Brasilia



JICA

- Nikkei Hospital-based Public-Private Partnerships in Medical care cooperation

Nikkei Training Program: Directors and officials from 6 Nikkei Hospitals were invited to Japan

Activities of JETRO

Information

- Information on the ANVISA approval and registration system and publication of reports related to medical device market in Brazil and other Latin American countries.
- Information on changes in the system through daily news letter “Tsusho Koho (Business News)”.

Seminars

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

Supporting Efforts to Develop Business Environment

- Working together with Public-private sectors, participation in medical workshops

Individual Consultation

- Support to Japanese companies in considering investment or to expand investment.
- Consultation on the medical device market and on new changes in the system in Brazil.
- Support to companies by experts.

【Study Reports】

November 2015 Latest Trend in Medical Device Market in L. America

<https://www.jetro.go.jp/world/reports/2015/01/3c99cdea65145906.html>

March 2015 Overview of Approval and Registration System of ANVISA (Brazil's National Health Agency)

<https://www.jetro.go.jp/world/reports/2015/02/fcea1fc7565daddb.html>

October 2013 Medical Device Market in L. America

<https://www.jetro.go.jp/world/reports/2013/07001514.html>

March 2012 Brazil's Medical Device Market and Regulations

<https://www.jetro.go.jp/world/reports/2012/07000870.html>

ブラジル国家衛生監督庁
(ANVISA) の認証・登録制度の
概要

2015年3月
日本貿易振興機構（ジェトロ）
サンパウロ事務所

MUITO OBRIGADA !

[Disclaimer of Liability]

Responsibility for any decisions made based on or in relation to the information provided in this material shall rest solely on readers. Although JETRO strives to provide accurate information, JETRO will not be responsible for any loss or damages incurred by readers through the use of such information in any manner.