

**UK
TRADE &
INVESTMENT**



Brazil Health Seminar

Rt Hon Kenneth Clarke MP

**UK
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Brazil: An overview of the country and health sector

**John Doddrell
HM Consul General and UKTI Director**

Brazil: Country Profile



Flag of the Federative Republic of Brazil

Language:	Brazilian Portuguese
Currency:	Real (BRL)
Capital city:	Brasília
Population:	194 million (5th largest in the world)
Area:	8.5 Million km², 5 regions and 27 states



- Região Norte
- Região Nordeste
- Região Centro-Oeste
- Região Sudeste
- Região Sul

Striking Facts

RICH NATURAL RESOURCES

25% of world's agricultural land and 22% of world's fresh water

A WORLD LEADER IN PRODUCTS AND EXPORTS

- Largest producer of ethanol; 2nd largest producer of soya
- Largest exporter of meat, chicken and leather
- Largest producer and exporter of coffee, sugar cane and fruit juices

THE ENGINE ROOM OF THE LATIN AMERICAN ECONOMY

Brazil responsible for half of Latin America's GDP. São Paulo state economy alone represents more than Argentina and Chile combined

A FAST DEVELOPING PUBLIC & PRIVATE SECTOR HEALTH ECONOMY

- With a health economy predicted to be valued at \$85bn by 2015

Comparison UK



Indicator	UK	Brazil
Population	62 million	194 million
Land Mass	245,000 km ²	8,500,000 km ²
Real GDP (est. 2011)	\$2.43 trillion	\$2,48 trillion
GDP Per Capita (est. 2011)	\$39,000	\$13,000
Real GDP Growth (est. 2011)	1,1%	2,7%
Ease of Doing Business Index (2012)	7 th	130 th

Sources: *IMF; worldbank.org*

The Brazilian Health Sector

**Valued at \$85bn
by 2015**

**Universal
healthcare
system.
Significant
additional
investment**

**Buoyant medical
devices market
with a large
number of
imports**

**Bio-technology
parks rapidly
developing in Sao
Paulo state**

**Brazil produces
close to 1/6th of
world's
biotechnology
output**

**Brazilian industry
sees the UK as a
leader in bio-
technology and is
looking for British
partners**

British exports are growing



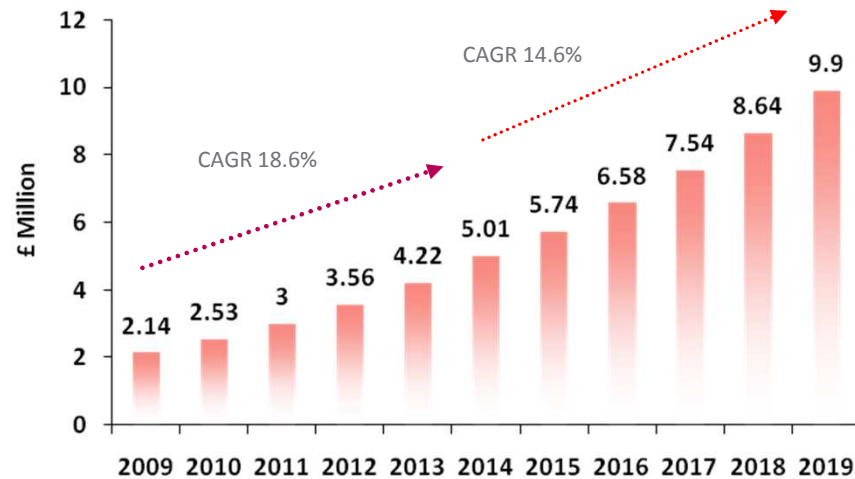
The bi-lateral health relationship is extremely strong with a strong desire on both sides to work closely together

Brazilian private and public sector hospitals are looking for British expertise and products

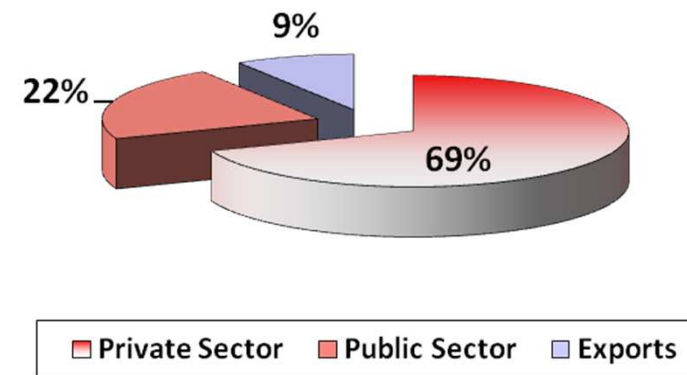
It is a complex market place and you will almost certainly need a local partner

Med tech market is growing

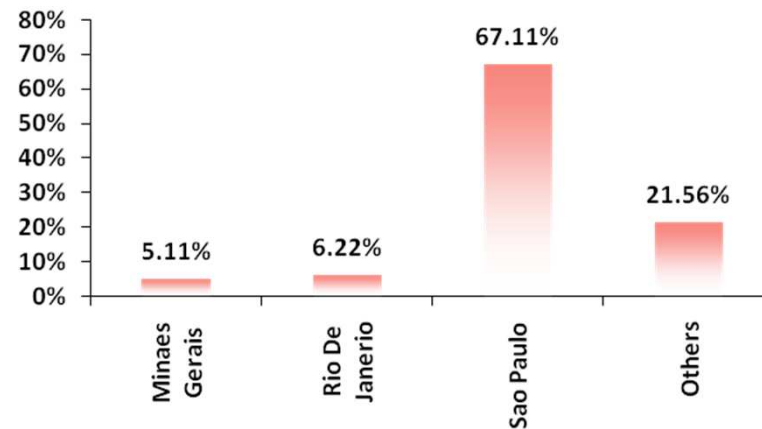
Value of Medical Devices Market⁶⁷



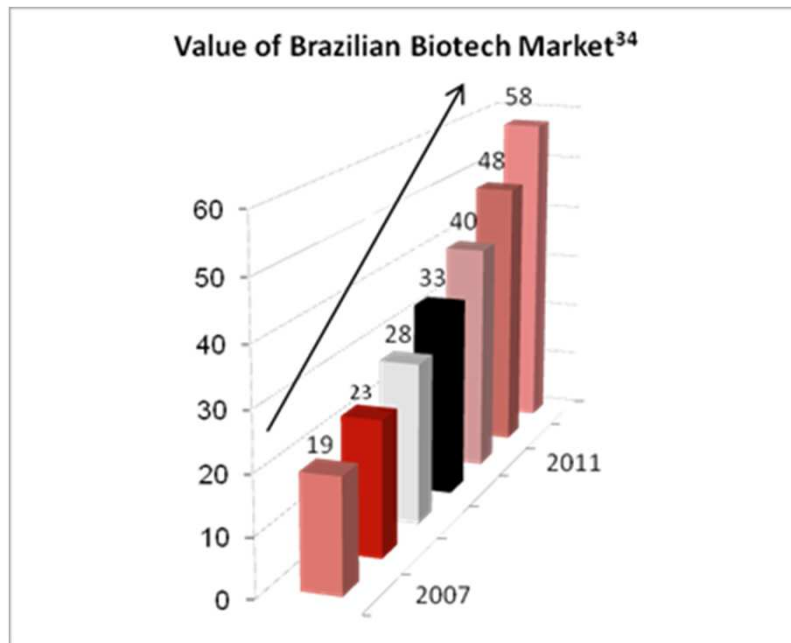
Sales by Sector⁷⁰



Medical Device Companies By State - Brazil⁶⁹



Brazilian biotech market growing



Governmental Support

National Policy for biotechnology providing important investment and tax incentives

Special governmental initiatives to encourage innovation

Fiscal incentives to stimulate biotechnology growth

State funding available for the top innovators

Health PPP

Federal, state and municipal governments investing billions of dollars in healthcare infrastructure projects

They are looking for international expertise in all areas, including hospital construction

Access to the market is through existing Brazilian PPP consortia keen to meet with British partners

12 PPP opportunities

São Paulo

5 new hospitals

São Paulo

*12 new
pharmaceutical
distribution
centres*

São Paulo

*1000 bed
hospital for care
for the elderly*

São Paulo

*Pharmaceutical
production plant*

Mato Grosso

*New paediatric/
maternity hospital*

Mato Grosso

*New multi
specialty
hospitals*

Federal district

4 new hospitals

Rio

*New multi
specialty
hospitals*

Salvador

*Construction of
infectious
diseases hospital*

Salvador

*New 300 bed
hospital*

Ceará

*Construction of
multi specialty
hospital*

Rondônia

New Hospital

PPP: Next steps

- Full report on all health opportunities in Brazil will be ready before the end of April
- **Will include details of :**
 - PPP models used in Brazil
 - How to access the market
 - Legal framework for foreign companies
 - Payment commitment by the state
 - How to link with existing Brazilian consortia
- PPP mission to Brazil on 20 May led by Ken Clarke

Not all good news...

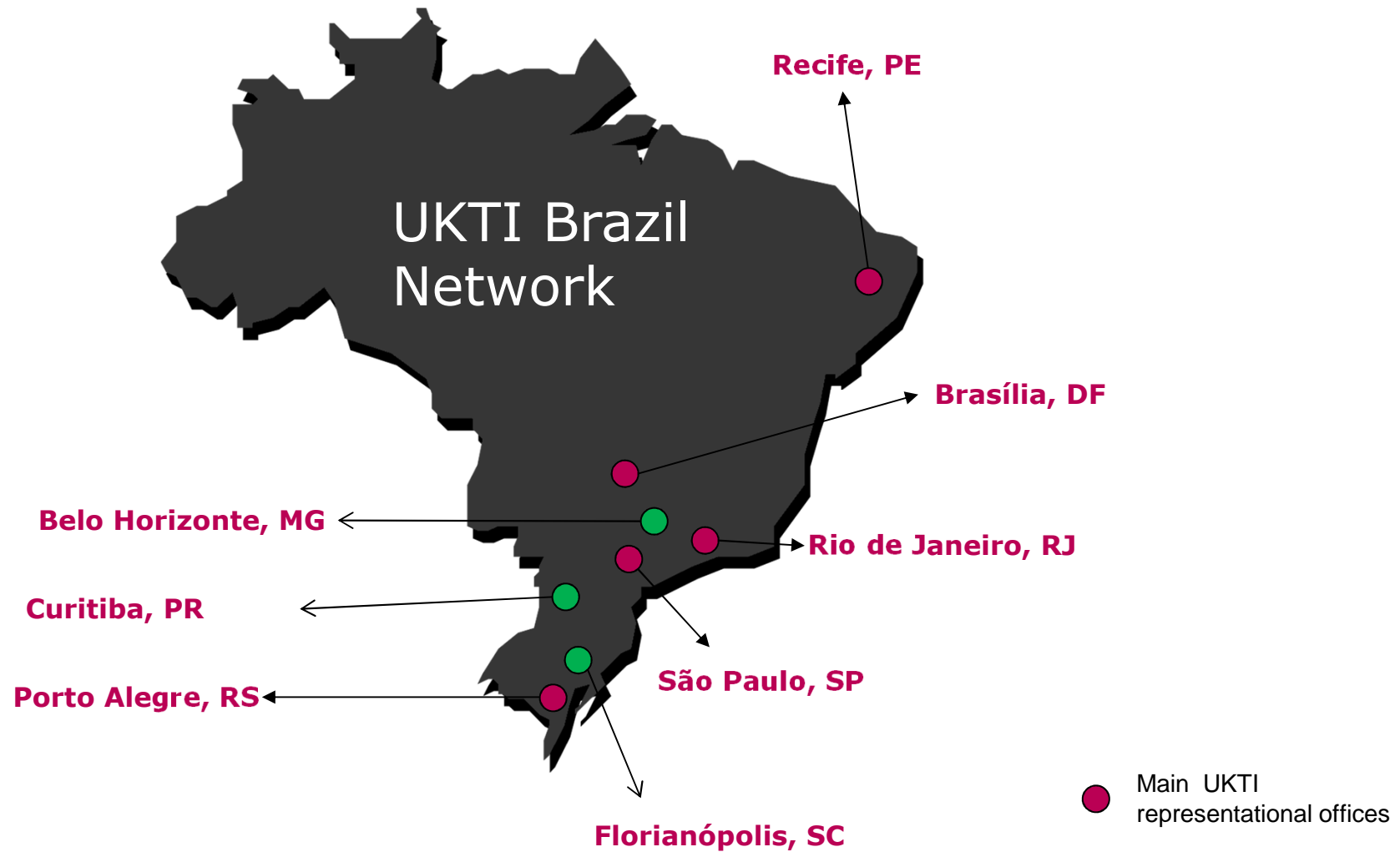
- **Complicated Tax System / High Import Duties**
- **Inflexible Employment Laws (*CLT*)**
- **Heavy Bureaucracy**
- **Infrastructure problems, not keeping pace with growth**
- **High cost of borrowing**
- **Bilateral Trade Agreements, particularly with other South American countries, create a potential competitive disadvantage for non-members**

How can UKTI help?

TRADE SERVICES

- Market analysis and **insightful** sector briefings
- Practical support setting up and attending **meetings in Brazil**
- Identification of **potential business partners**
- **Analysis** of market entry strategies
- **Advice** on local regulations, standards, business practices and culture
- **Assistance** with organisation of promotional events or seminars
- Marketing and PR services

UKTI Brazil Network



Contact



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Director Trade & Investment – Brazil**

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Health Sector in Brazil and the role of BNDES

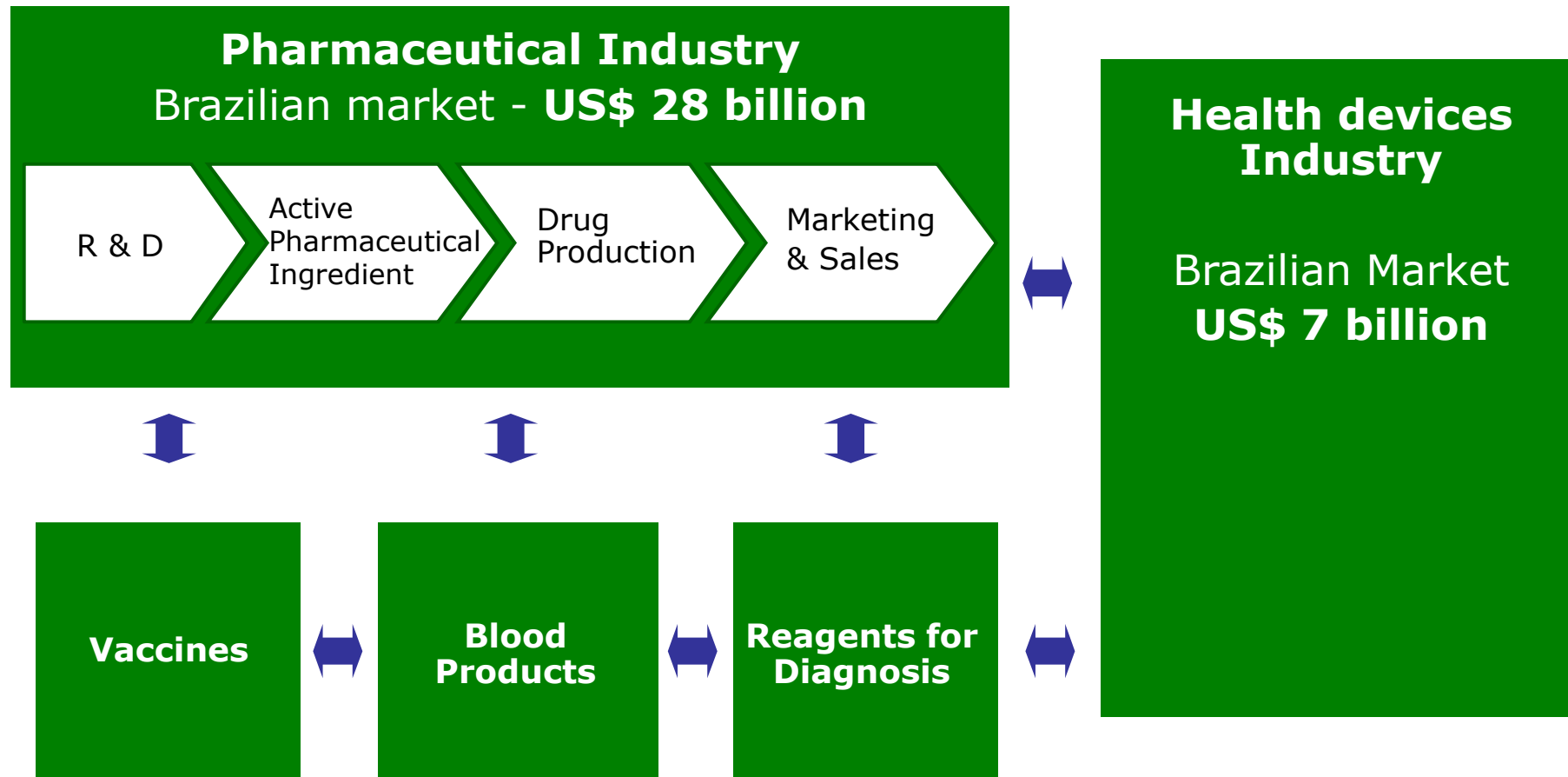
Jaime Gornsztejn
(jaime@bndes.gov.br)

- Health Sector in Brazil
- Public Policies
- Challenges and opportunities
- Public-Private Partnerships

- Health Industry in Brazil
- Public Policies
- Challenges and opportunities
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Health Industry in Brazil

Structure



Health Industry in Brazil

Dimensions



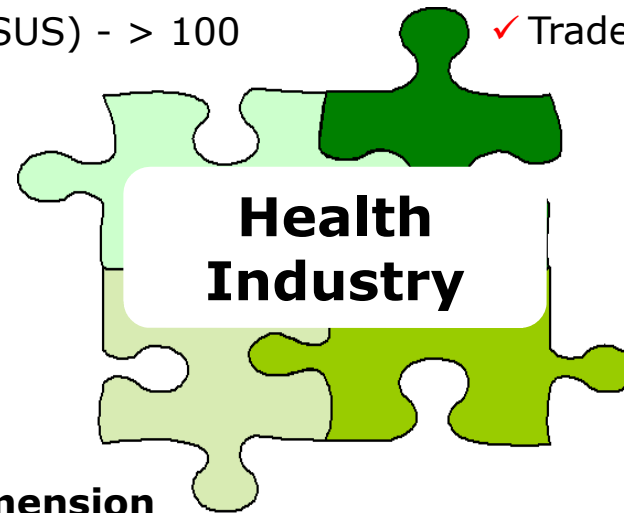
Potential to address social, technological, economical and political aspects together

Social Dimension

- ✓ Growing demand for health products and services
- ✓ Public Health System (SUS) - > 100 million people

Economical Dimension

- ✓ Health expenses - 8% of GDP
- ✓ Average Growth - 14% p.y. (2003 -2011)
- ✓ Trade deficit - US\$ 11 bi (2011)



Technological dimension

- ✓ R&D-based processes
- ✓ Development and spread of new technologies

Political Dimension

- ✓ Importance of governmental demand
- ✓ Industrial Policy - Health Industry as a strategic area

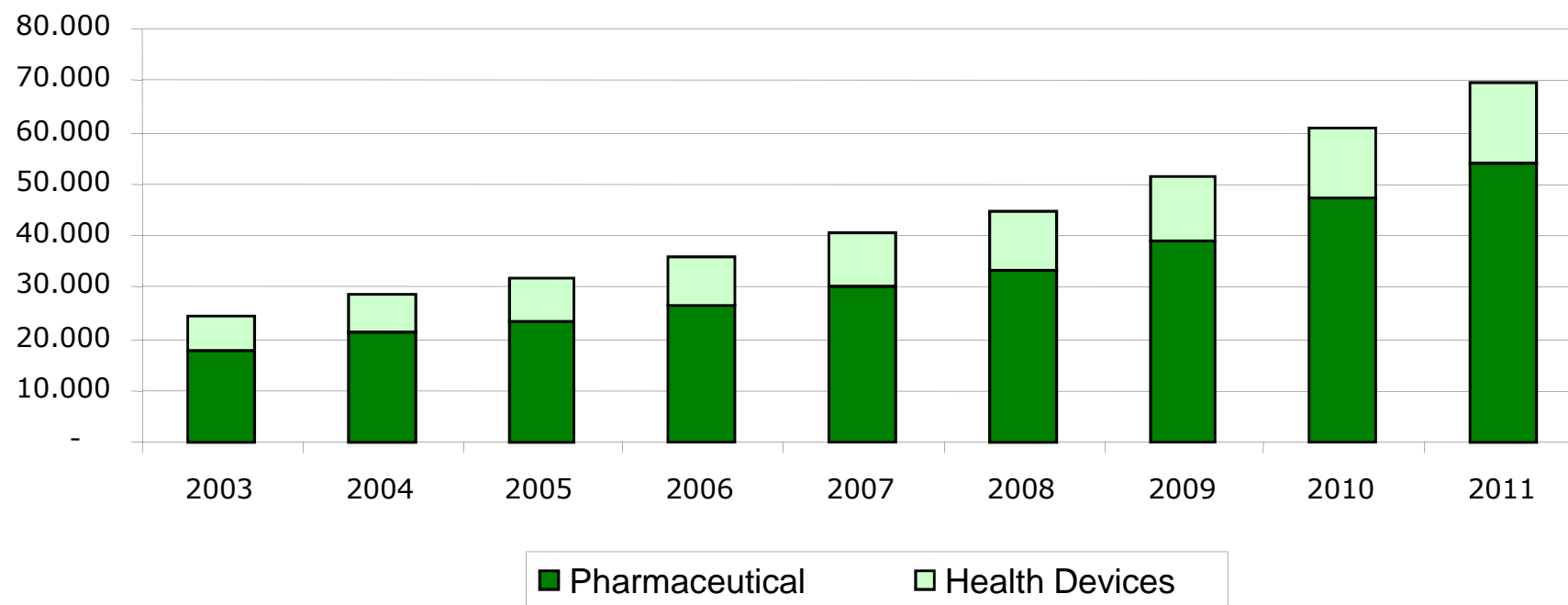
Health Industry in Brazil

Growing demand



▪ Average Growth (CAGR 2003-2011)

- Pharmaceutical market: 15% p.y.
- Health devices market: 11% p.y.



Public and private markets

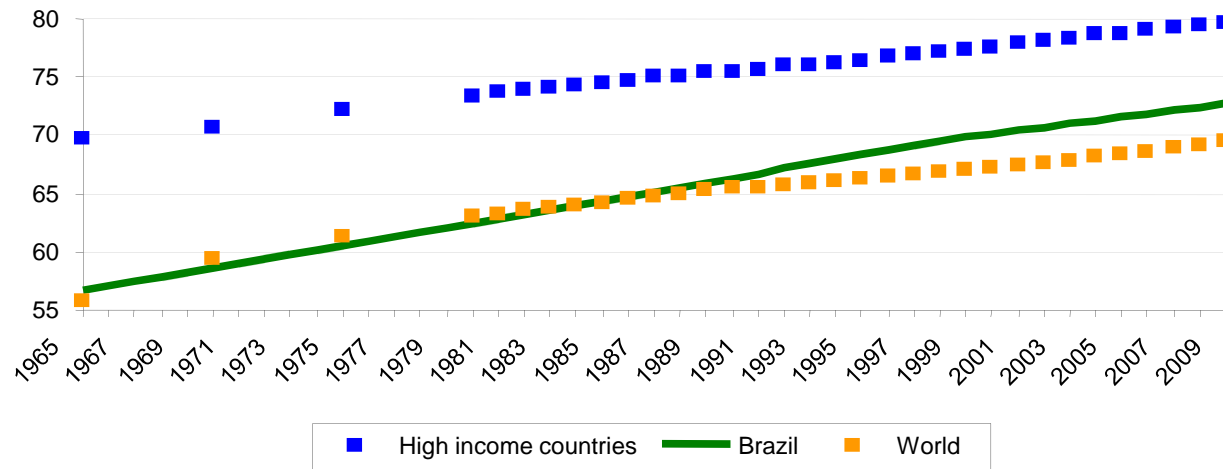
Source: IMS Health / Sindusfarma, ABIMO / IEMI, Ministério da Saúde

Health Industry in Brazil

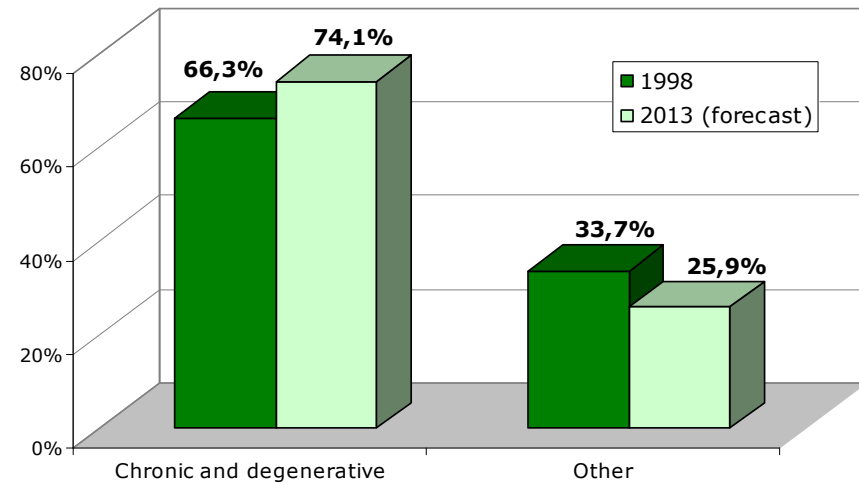
Growing demand



Higher life expectancy



Changes in epidemiological profile

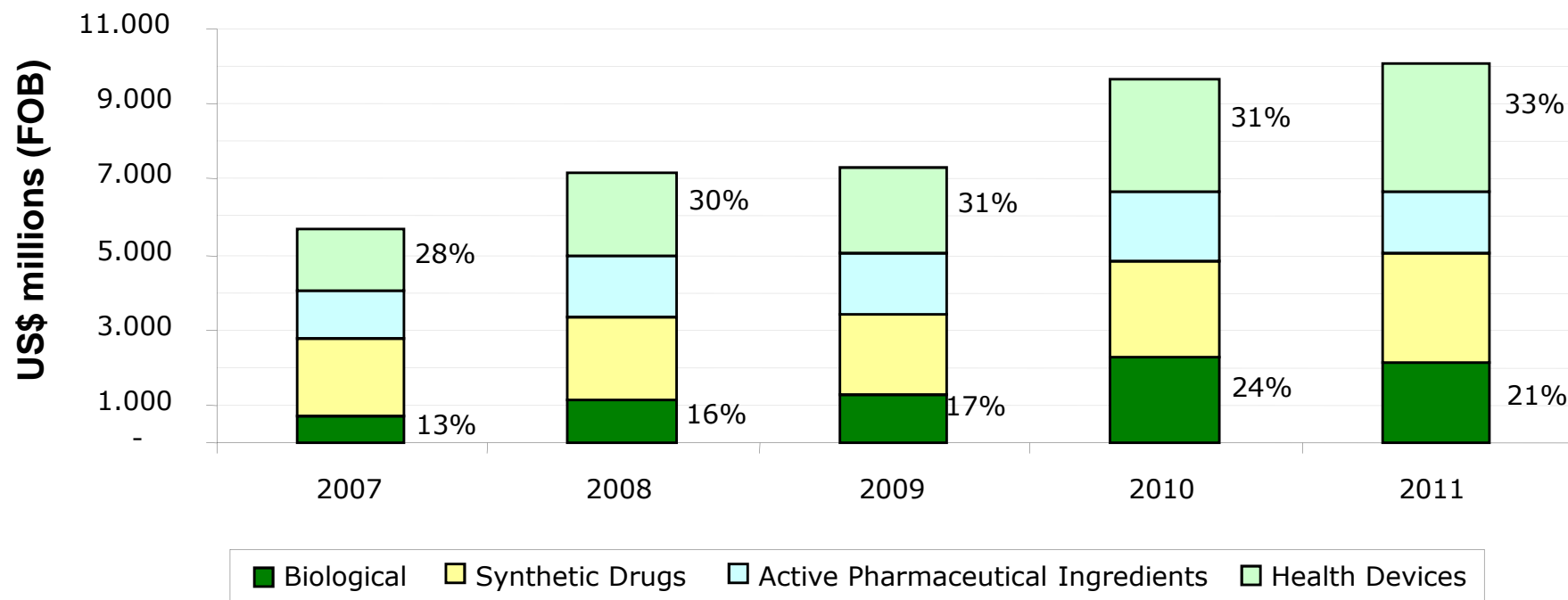


Health Industry in Brazil

Dependence on foreign products



Trade deficit



Source: SECEX, Abifina, IEMI / ABIMO

Health Industry in Brazil

Pharmaceutical Market

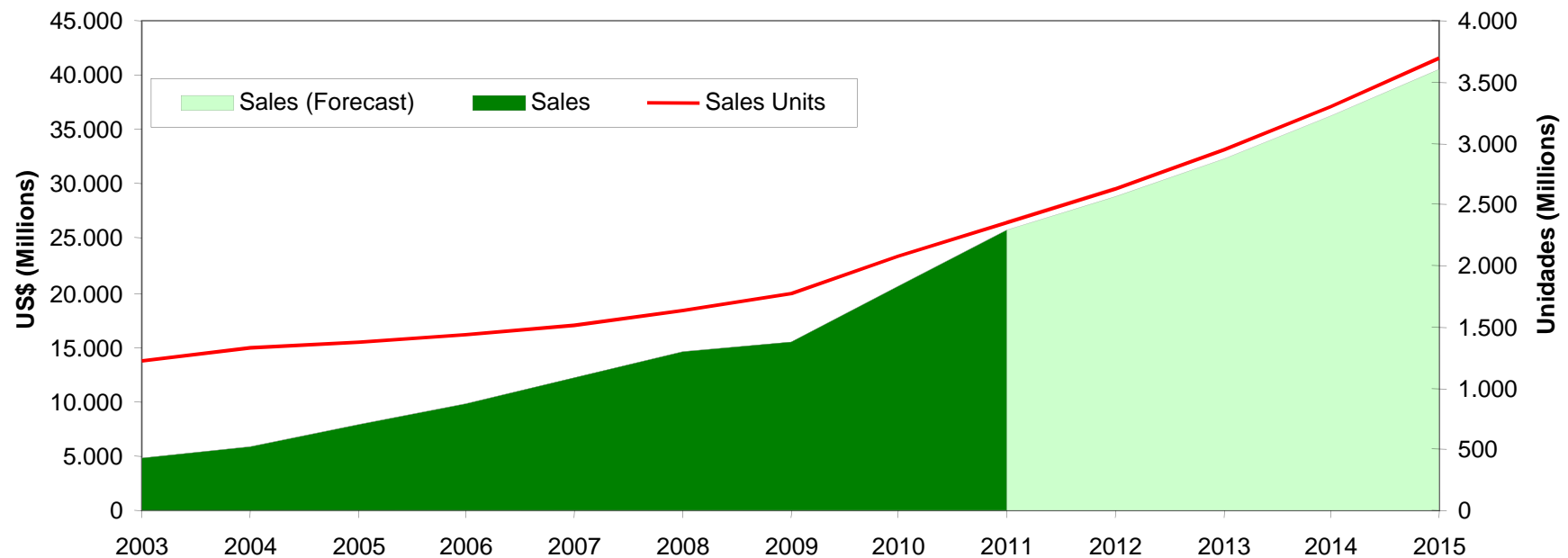


■ Sales - retailers

Average Growth (CAGR)

- US\$: 24% p.y.
- Qty: 9% p.y.

Historical data and forecast



Source: IMS Health / Sindusfarma

Health Industry in Brazil

Pharmaceutical Market



Ranking of Countries (evolution)

2005	2010	2015
1 United States	1 United States	1 United States
2 Japan	2 Japan	2 Japan
3 France	3 China	3 China
4 Germany	4 Germany	4 Germany
5 Italy	5 France	5 France
6 United Kingdom	6 Italy	6 Brazil
7 Spain	7 Brazil	7 Italy
8 Canada	8 Spain	8 India
9 China	9 Canada	9 Spain
10 Brazil	10 United Kingdom	10 Russia
11 Mexico	11 Russia	11 Canada
12 Australia	12 India	12 United Kingdom
13 South Korea	13 Australia	13 Venezuela
14 Turkey	14 Mexico	14 Turkey
15 India	15 South Korea	15 South Korea
16 Russia	16 Turkey	16 Australia
17 Netherlands	17 Poland	17 Mexico
18 Belgium	18 Netherlands	18 Argentina
19 Poland	19 Belgium	19 Poland
20 Greece	20 Greece	20 Belgium

Health Industry in Brazil

Pharmaceutical Market



Priority – Biotech

- Competitiveness
 - ✓ Products of high value and fast growing market
- Cost and availability of products for Public Health System (SUS)
 - ✓ 41% value of centralized purchasing
 - ✓ Lack of national production
- Technological dynamism => economic development
 - ✓ New technological path



Health Industry in Brazil

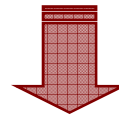
Medical Equipment Market



Brazilian Health Devices Market

US\$ 7 Billion

▪ Segments



Competitiveness varies according to the segment

- ✓ Brazilian Health Devices Industry is competitive in:
 - ✓ Odontology equipments, devices and services (Dentistry segment)
 - ✓ Neonatal incubators (Medical and hospital equipment segment)

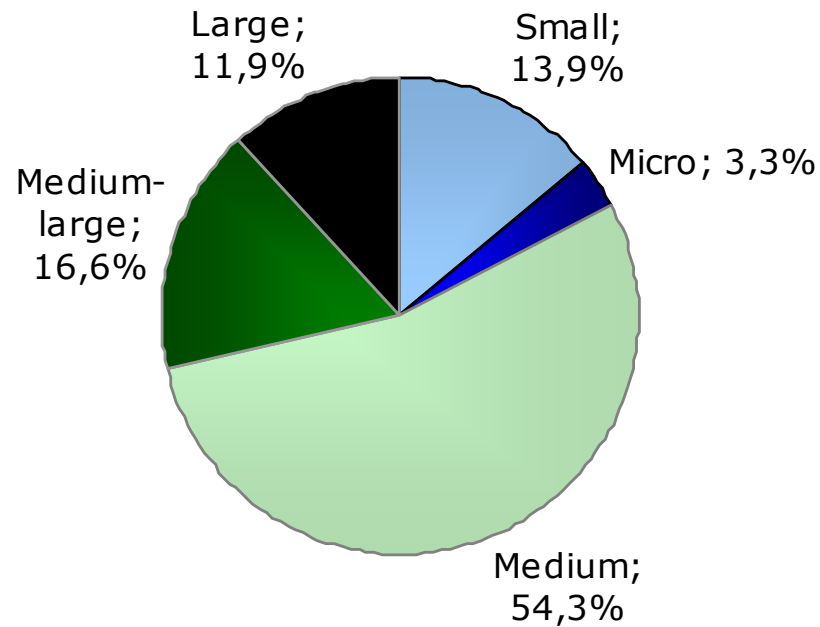
Health Industry in Brazil

Medical Equipment Market



Based on small and medium companies

- ✓ More than 500 companies



Health Industry in Brazil

Medical Equipment Market



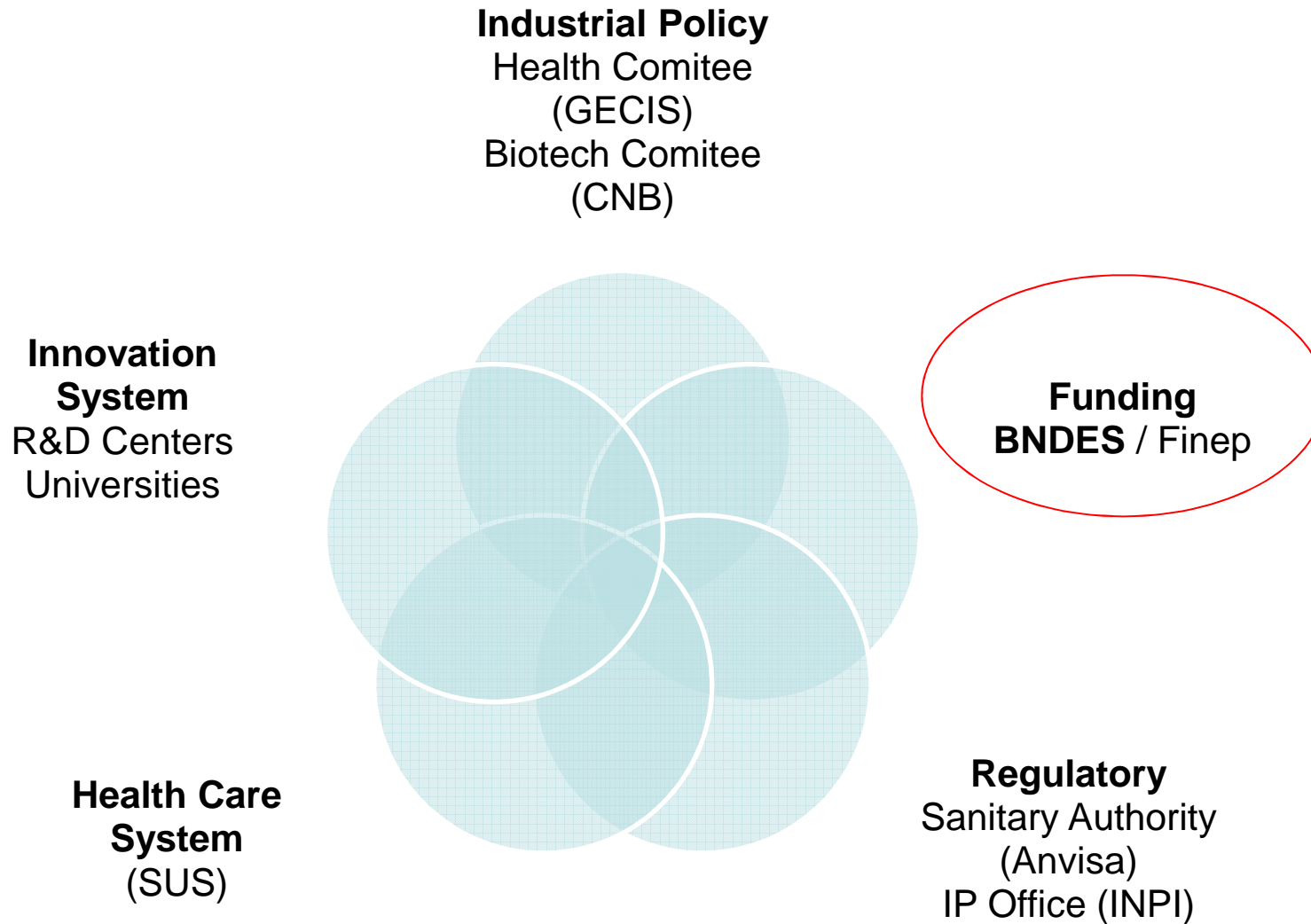
Drivers for change in the medical equipment industry

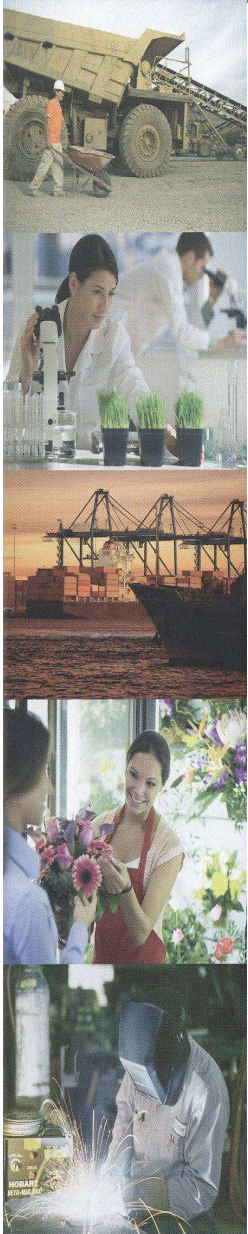
- ✓ Change in the demographic and epidemiological profile → increase in health demand
- ✓ Growing importance of diagnostics
- ✓ Trends integrated health care solutions
- ✓ Growing attraction of investments of foreign companies (Philips, GE, Siemens)

- Health Industry in Brazil
- Public Policies
- Challenges and opportunities
- Public-Private Partnerships

Public Policies

Institutional framework

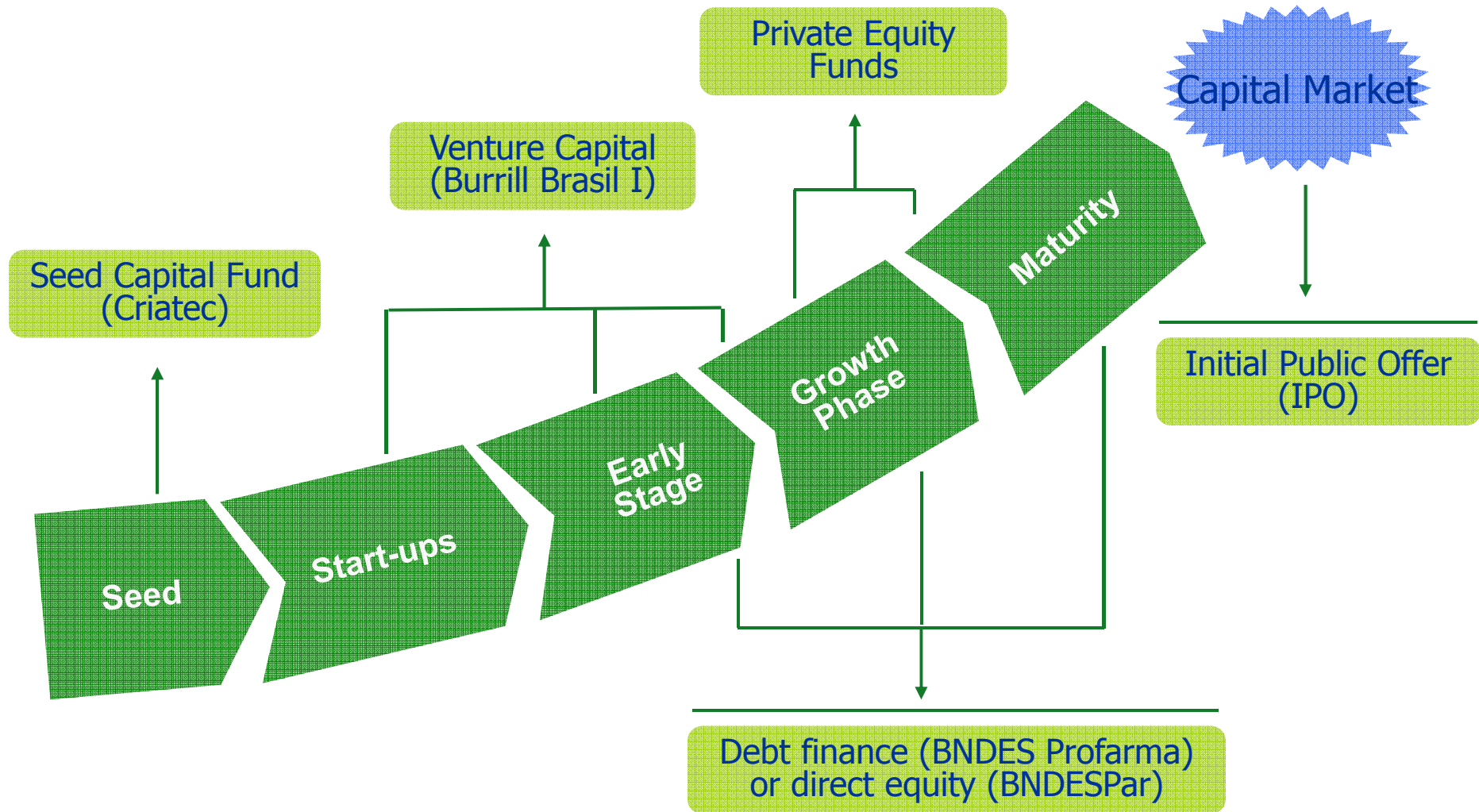




- Fully state-owned company under private law.
- Key instrument for implementation of Federal Government's industrial and infrastructure policies - broad presence on Brazilian economy.
- Provides long-term financing (the main provider) directly or by accredited financial agents.
- Provides equity investment directly or by funds.
- Emphasis on financing investment projects, but also supports exports, environmental and social projects.

Public Policies

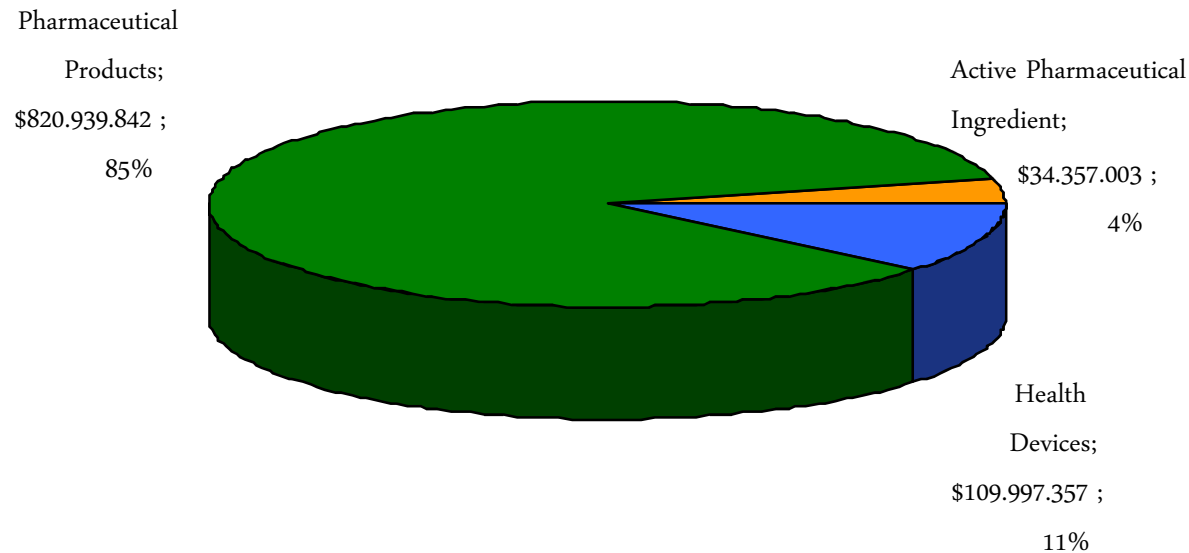
BNDES Financial Support Toolkit



BNDES PROFARMA

Portofolio – Activity

(contracted and approved projects)



Stock portfolio since 2004
Last update: February 2013
Exchange rate:
R\$ 1,95 / US\$ (19/02/2013)

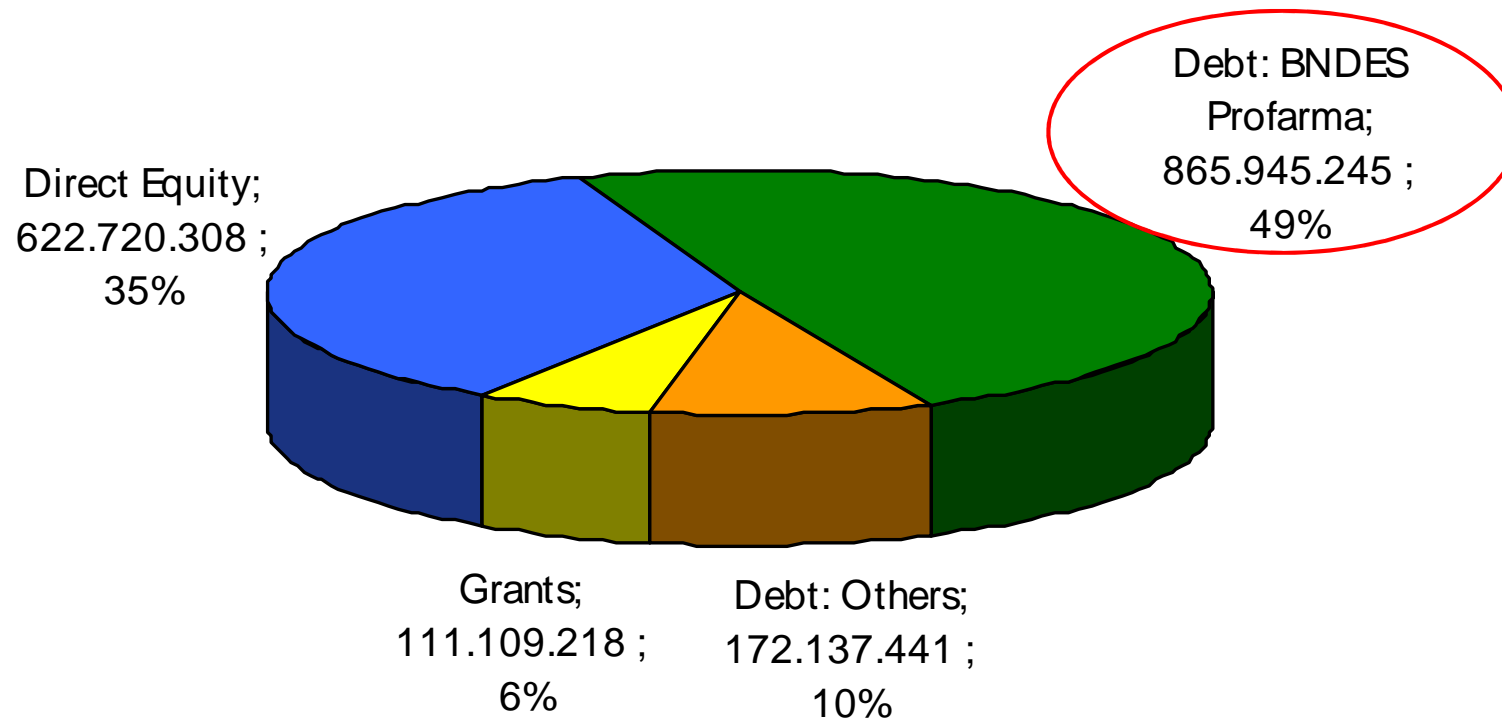
Public Policies

BNDES Financial Support – Health Industry



Portofolio – Instruments

(contracted and approved projects)

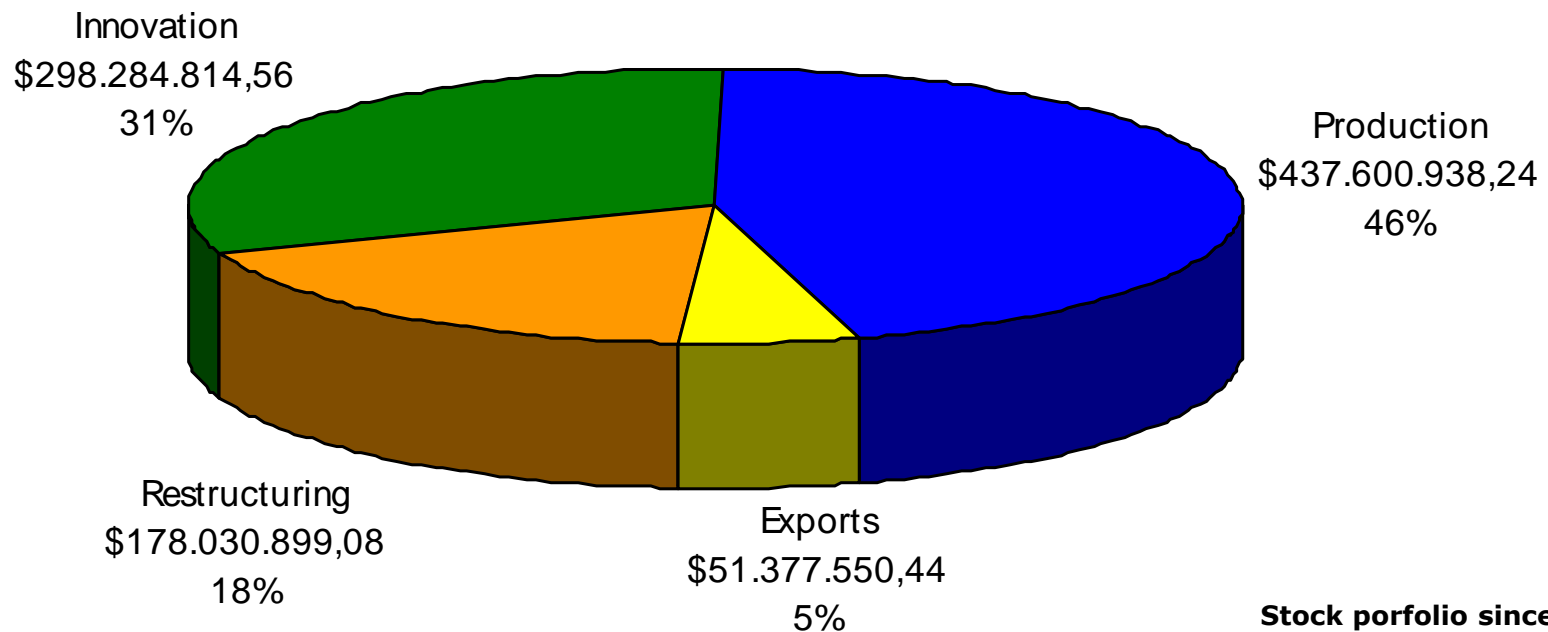


Stock portfolio since 2004
Last update: February 2013
Exchange rate:
R\$ 1,95 / US\$ (19/02/2013)

BNDES PROFARMA

Portofolio – Focus

(contracted and approved projects)



Stock portfolio since 2004
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Public Policies

Institutional framework



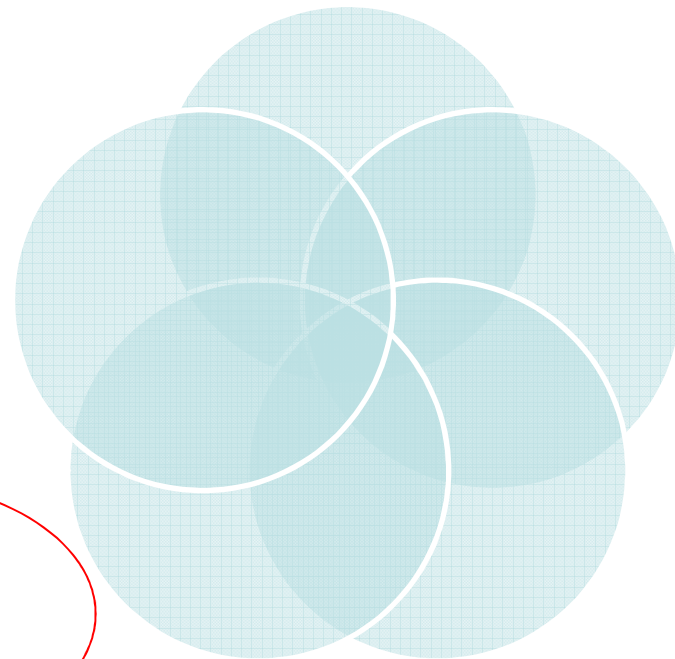
Industrial Policy
Health Comitee
(GECIS)
Biotech Comitee
(CNB)

**Innovation
System**
R&D Centers
Universities

Funding
BNDES / Finep

**Health Care
System
(SUS)**

Regulatory
Sanitary Authority
(Anvisa)
IP Office (INPI)



Public Policies

Governmental demand to induce development



Partnerships for Productive Development (PDP)

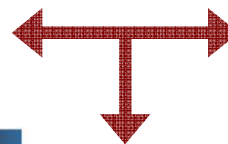
- ✓ Based on technology transfers from private companies to public laboratories
- ✓ Governmental demand: US\$ 2,8 billion
- ✓ Partnerships (formalized and in process) – 55
 - 47 drugs
 - 5 vaccines
 - 2 health devices
 - 1 R&D project



PRIVATE COMPANIES



PUBLIC LABORATORIES



MARKET

- Health Industry in Brazil
- Public Policies - the role of BNDES
- Challenges and opportunities
- Public-Private Partnerships

Increase investments in innovation and production

Pharmaceutical Industry

- ✓ Development of biosimilars (biotechnology platform) – focus on Brazilian companies

Health Devices Industry

- ✓ Increase competitiveness of Brazilian companies
- ✓ Attract investments on R&D of foreign companies to Brazil

**Promote health
industry
development**

**Broaden population
access to health
goods**

**Increase of
Brazilian
industry
competitiveness**

**Improvement in
local R&D chain**

**Catch-up in new
technological
platforms**

**Diversification of
strategic
products and
services**

- Health Industry in Brazil
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BH Basic Health Units



- Scope: construction, renovation, and management/operation of non-clinical services in the basic BH health network;
 - Works: reconstruction of 61 (sixty one) and construction of 19 (nineteen) new Health Centers; construction of 1 Central Sterile Material and 1 Diagnosis Support Unit;
 - Services: cleaning, building maintenance, maintenance of equipment and furniture, concierge, and surveillance.
- Estimated Amount of Investment: US\$ 206 million;
- BNDES/IFC studies in partnership;
- Notice and its attachments are awaiting publication to start the bidding process.



- Scope: Deploying of Network SERVICES BIOIMAGEM, hierarchical as the complexity of care, linked by resources of TELEMEDICINE AND INFORMATION SYSTEMS, covering the following tests:
 - conventional radiology
 - Mammography
 - computed tomography
 - magnetic resonance
- Adequacy of infrastructure of 27 units, and the construction of a central reports;
- BNDES/EBP studies in partnership;
- Ongoing studies: End of a diagnosis of the state of the network / early financial modeling.



Brazilian Chamber of Commerce in Great Britain

- Founded in 1942 to promote trade and investment between Brazil and UK
- Over 200 members in sectors such as oil & gas, energy, mining, financial services, information technology, defence & security, professional and legal services, among others
- Membership base includes major corporates and SMEs
- Information about the Brazilian market (newsletters, database)



Brazilian Chamber of Commerce in Great Britain

- Sample of recent and future events :
 - Briefing on the Brazilian Economy – Senior Economist – Bradesco Securities - October 2012
 - Networking Reception – December 2012
 - Infrastructure Roadshow, with Brazilian cabinet ministers - 1st March
 - Joint-Ventures Brazil-UK – 20th March
 - Annual Gala Dinner with guest speakers Ken Clarke MP, Sir Frank Chapman (BG-Group) and Rubens Ometto (Cosan and Raizen) – 14th May
 - Summer Networking
 - House of Commons Networking

www.brazilianchamber.org.uk



BNDES

*Brazilian
development bank*

Jaime Gornsztejn
(jaime@bndes.gov.br)

Medical Devices Environment in Brazil

London - UK
House of Commons
February 25th, 2013

Agenda



Associação Brasileira da Indústria
de Alta Tecnologia de Equipamentos,
Produtos e Suprimentos Médico-Hospitalares

www.abimed.org.br

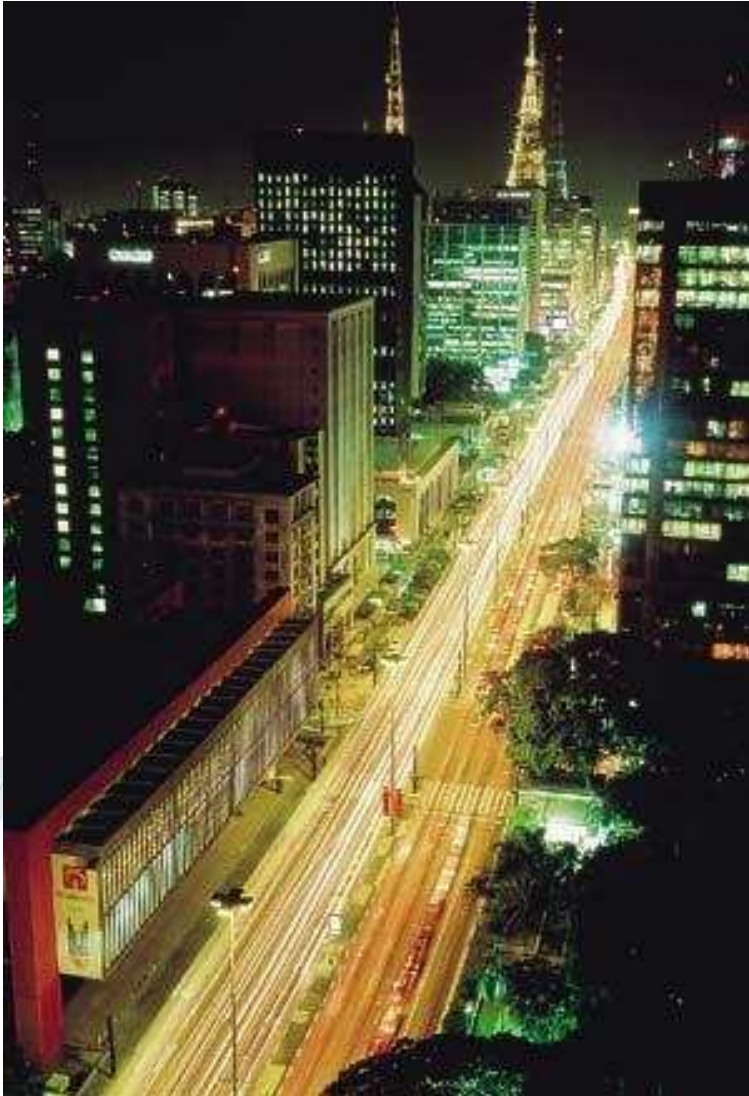
- ABIMED at a glance
- Socio-economical data of Brazil
- Brazil`s Healthcare Market
- Regulatory environment in Brazil
- Some useful tips



ABIMED

**Brazilian Association of High Technology
Industry for Medical Equipment, Products
and Supplies**

About the Association



- Founded on June 18th, 1996
- Non-profit, non-governmental organization
- 130 members

Institutional Guidelines



www.abimed.org.br

- **Vision**

- Become the most representative entity in the product segment of **ADVANCED MEDICAL TECHNOLOGY** in Brazil

- **Mission**

- Represent its members by defending their interests before governmental authorities and departments as well private entities both in Brazil and abroad, fostering the best solutions for the Health industry.

Institutional Guidelines

- **Values**

- ***Ethics***

- Fundamentals described in the ABIMED's Code of Ethics are complied in all processes of the Association, which is intended to be the paradigm of the ethical behavior of its members

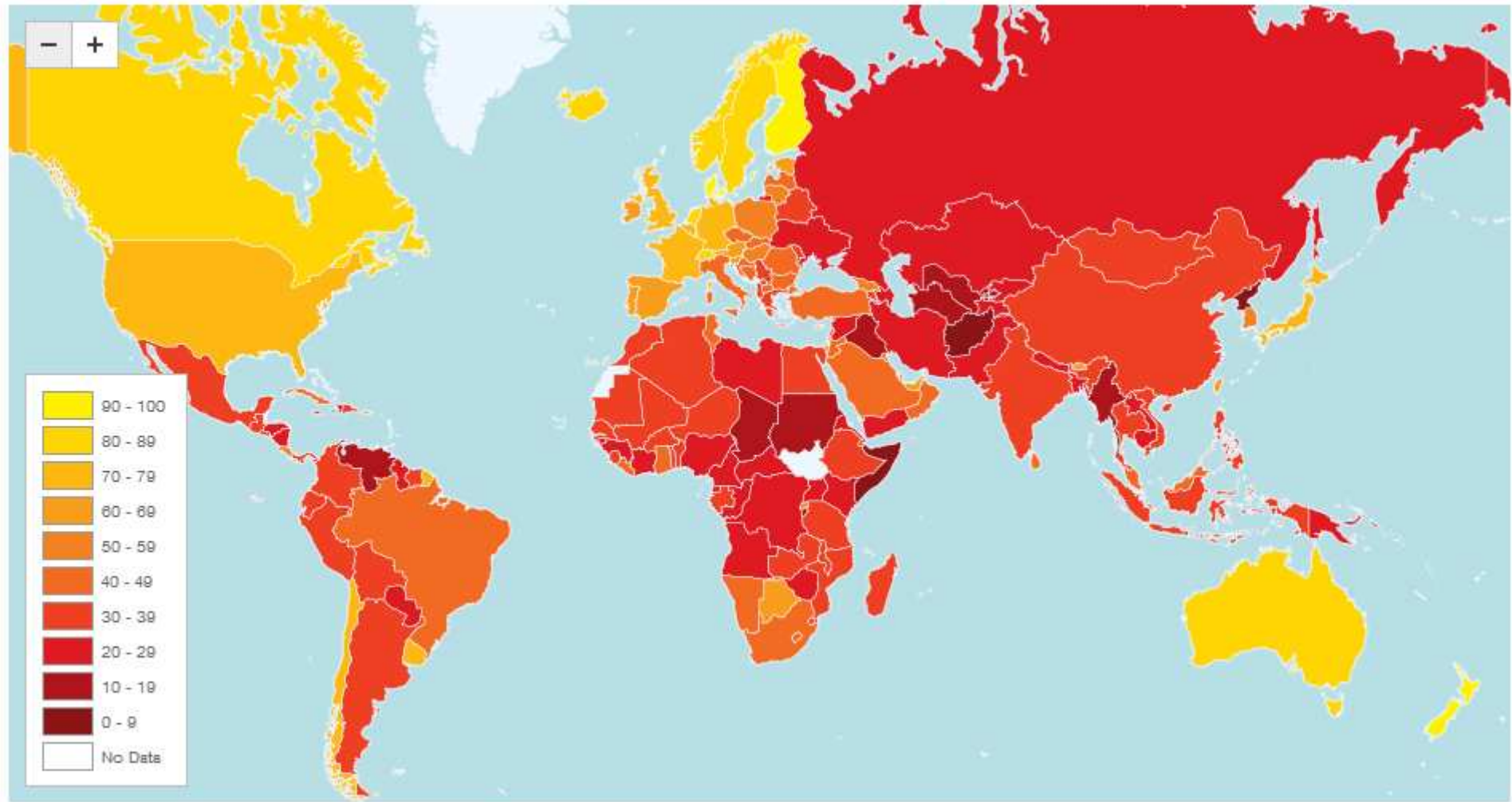
- ***Democratic Principles***

- Transparency in all management processes of the Association, allowing the effective participation of its members

- ***Market and Industry Knowledge***

- Command of the regulatory norms as well as of the market data, which are made available to the members and to other industry players as well.

Transparency Perception Index



How ABIMED works



www.abimed.org.br

- Internal Chambers
- Main Permanent Groups
- Ad Hoc Groups
- Outsourced services and consultants
- Interaction with international Associations
- Periodical Meetings with Government Authorities
- Training and seminars to associates

Strategic goals

1. Make the Association strong and reference of the Industry
 1. Influence demands in favor of the members
 2. Revert non favorable decisions
 3. Be relevant in the Health Industry and in the Brazilian economy
 4. Have credibility and transparency before authorities and its members

2. Consolidate the governance model and the management by outputs
 1. Assure the financial balance of the Association
 2. Assure the accomplishment of the agenda and of the projects
 3. Create a professional and compatible organization (Work and sector related groups,)

3. Encourage the adoption of Code of Ethics in all activities
 1. Revise and update the Code with the best practices
 2. Intensify the communication with the members
 3. Promote and divulge the Code of Ethics

4. Promote access to new technologies – Government and Health insurers
 1. interact with academic entities and medical societies

Socio-economical data of Brazil



Brazil – A country of contrasts

Economy

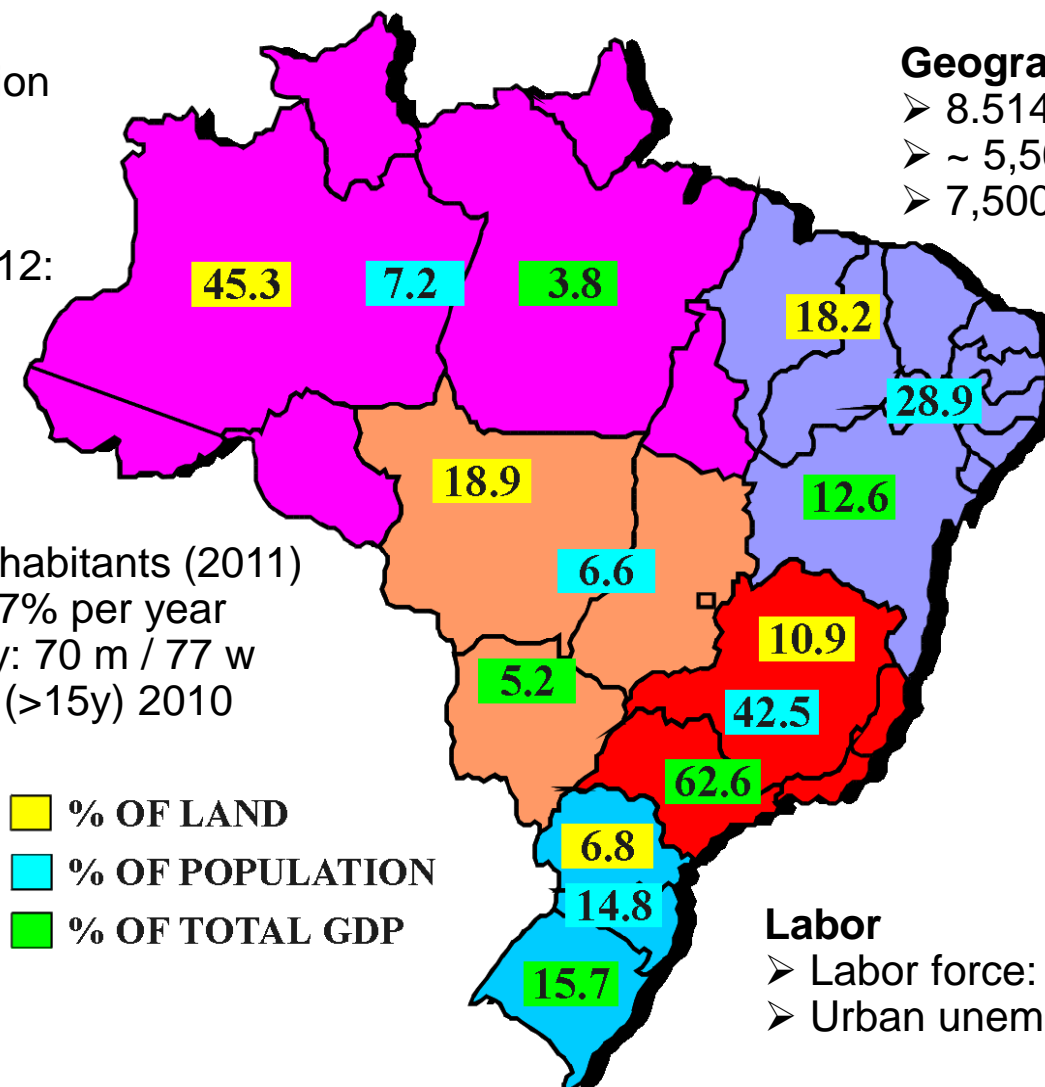
- GDP 2011: US\$ 2.475 Trillion
- GDP per capita (2011): US\$12,696
- Inflation rate 2011: 6.5%
- Basic interest rate Sept 2012: 7.25%
- GDP growth 2011: 2,7%

Population

- 194.9 million inhabitants (2011)
- Growth rate: 1,7% per year
- Life expectancy: 70 m / 77 w
- Illiteracy: 9.6% (>15y) 2010

Geography

- 8.514 million km²
- ~ 5,560 cities
- 7,500 km coastline



Labor

- Labor force: ~ 90 Million
- Urban unemployment: 7%

Current policies and tendencies



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- Plan “Bigger Brazil” – *Innovate to compete . Compete to grow*
 - Foster local innovation and technological development
 - Create and strengthen critical Brazilian competences
 - Increase intern and extern markets for Brazilian enterprises
 - Assure a *socially-including* and environmental sustainable growth
- Investment bubble – World Football Cup (2014) and Olympics Game (2016)
- Preference to local manufactured products and services in government procurement - Law 12.349/2010
 - Up to 25%
 - Decree 7.767/2012 – Preference for medical devices and materials (from 8% to 25%)
- Trend to regulatory and economical barriers
- Reduce trade balance deficit

Opportunities & Weaknesses



www.abimed.org.br

➤ Opportunities

- Dynamic and growing internal market
- Demography bonus
- Rise of a new middle class
- Pursuit of healthcare and life quality

➤ Weaknesses

- High tax burden
- Deficient infrastructure and logistics
- Lack of qualified labor
- Increase of health costs



Brazil's Healthcare Market

Healthcare Structure

- Brazilian Constitution states: “Access to healthcare is a right of the citizen and a duty of the State” (Art. 196). Additionally: “Health assistance is open to private enterprise” (Art. 199)
- Healthcare expenditure is about US\$ 200 billion a year, from which about 55% are private; approx. 25% out of pocket
- Ministry of Health is responsible for the execution of health policy. Under the Ministry of Health are:
 - SCTIE – Secretariat of Science, Technology and Strategic Materials
 - ANVISA - National Health Surveillance Agency → independent; power to regulate and control
 - SAS – Secretariat of Healthcare Assistance
 - ANS – National Agency of Supplemental Healthcare - regulates the private sector – HMOs (Health Medical Organizations)

Brazilian Healthcare segment



www.abimed.org.br

- 6,758 hospitals (70 % private)
- 464,094 hospital beds
- 247,350 healthcare services
- 18,080 laboratories
- 370,000 physicians
- 1,48 million nursing personnel
- 220,000 dentists
- ~ 80,000 drugstores

Sources: CNES, ANVISA

General Overview



www.abimed.org.br

Beds	SUS	Non SUS	Total
• Surgery	76,666	40,495	117,161
• General	84,245	31,671	115,916
• Psychiatry	38,764	11,693	50,457
• Pediatrics	48,273	10,900	59,173
• Obstetrics	22,700	5,894	28,594
• Other	50,629	14,427	65,056
• ICU	17,357	10,380	27,737
Total	338,634	125,460	464,094

Medical devices market



Associação Brasileira da Indústria
de Alta Tecnologia de Equipamentos,
Produtos e Suprimentos Médico-Hospitalares

www.abimed.org.br

- Total : US\$ 16.6 bi
 - 0.6% of Brazilian GNP
- Import: US\$7.7 bi
- Export: US\$1.5 bi
- 13,000 companies
- 120,000 employees



Regulatory Environment in Brazil

Product Registration

RDC 185/2001



Class I – LOW RISK

Non-invasive products, temporary use



Class II – MEDIUM RISK

Invasive products, short use



Class III – HIGH RISK

Surgical products, long term use



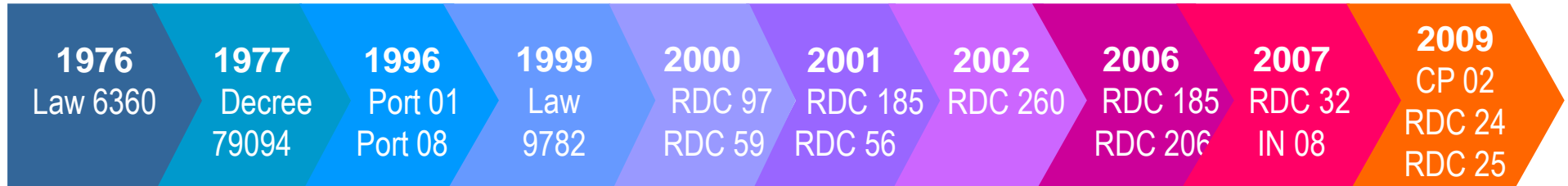
Class IV – MAXIMUM RISK

Surgical products, long term use,
direct contact with CNS, CS or
biologically absorbed

Regulatory history in Brazil



www.abimed.org.br



General Law of Sanitary Surveillance	1st Definition of Medical Devices ("Correlato")	1st Regulation for Medical Devices and IVD	Creation of ANVISA National Health Surveillance Agency	Family of MD's ----- Good Manufacturing Practices for MD's (starting locally) <i>Inspired in FDA 's 21CFR 820</i>	New MD registration process Essential requirements for MD safety and effectiveness <i>Inspired in MDD93/42 EEC</i>	Isenção de Registro de Correlato (revoked in May'09 by RDC 24)	Economical Data for MD's ----- New IVD registration process	New compulsory certification acc. IE 60601 INMETRO ----- List of IEC 60601-2-X standards applicable to compulsory certification	Post Market – Adverse events Draft ----- Cadaster – Simplification of classes I & II ----- International GMP inspection compulsory to Classes III & IV starting 2010
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Time to Market



	By Laws	AFE	GMP	Product Certification (*)	Product Registration or Inclusion
Class I	3 mo	8-10 mo		3 mo	6 mo
Class II	3 mo	8-10 mo		3 mo	6 mo
Class III	3 mo	8-10 mo	36-60 mo	3 mo	12 mo
Class IV	3 mo	8-10 mo	36-60 mo	3 mo	12 mo

(*) Can be done simultaneously to other phases

This journey may consume from 20 to 88 mo



Some useful tips

Some useful tips:

- Choose your business mode (direct, indirect or even both)
- Work with your lawyer in connection with a local one, especially in the event you choose an indirect business approach
- The selection of your business partner is of utmost importance to your success – Work hard and deeply on this selection
- Same for pricing
- Remember, Brazil is a very big country - chances are that a single dealer won't be a good idea
- Consider the segregation of registration ownership from a distribution contract
- In doing product registration be prepared to respond questions that you may think are not necessary - Be proactive as it will save time



Thank you and good luck in Brazil

Brazilian Health Seminar

London 25th February 2013



Our Experience in Brazil

Stephen Williams

Sales Director Intersurgical Ltd

Some Statistics

- Population 194m (July 2012) 2.74% of the world and the 5th largest.
- 67% 15 – 64 years of age
- Sao Paulo 18.8m, Rio 10.5m, Porto Alegre 3.7m
- 7500 hospitals, 4560 private, 2940 public.



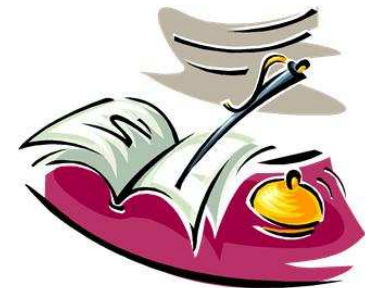
How we started...

- **First mistake** – in 2002 we were approached by a distributor to sell our products in Brazil who registered the products on our behalf.
- Always do your homework first !



Get registered yourself....

- In 2004 we realised that we could register our products locally in our own name by using a local Anvisa registration specialist – lawyer.
- As with most things in Brazil this process takes some time and is costly, but worth it as this gives you control on who you sell to in the market.



Then we started to move forward

- By 2005 we had registration of two product groups, filters and breathing systems and started to sell through our first distributor based in the south. This distributor then introduced us to another in Sao Paulo.
- Over the next five years we started to set up our distribution network. Not all distributors are able to import and some only act as local distributors.
- No one distributor can cover all Brazil.
- But beware, finding distributors can be a lottery!



Bureaucracy and Taxes

- Also be aware that the cost (tax) to import products into Brazil is about 100%, this is to help and protect local companies.
- However, as with Intersurgical, if all your competitors also import you are OK.
- To be successful in Brazil you have to be aware of the "*bureaucracy culture*" and understand the timing to get through all the stages.

Finding distributors

- In 2006 / 2007 we had our first stand with the British Pavilion at Hospitalar and employed a new Regional Manager based in Brazil – important.
- In 2007 we held our first distributor´s meeting in conjunction with the exhibition
- From 2008 - onwards we have had our own stand at Hospitalar ...

Hospitalar Sao Paulo Brazil



Moving onwards...

- During these formative years we chose further products to register and introduced more regional distributors.
- In 2011 we decided to get some help from the commercial dept at the Consulate in São Paulo / UKTI and we ordered a report about setting up ourselves in Brazil.
- We are now actively, but slowly moving forward with this plan to manufacture and sell locally and into Latin America

Setting up Intersurgical Brazil

- An important point to mention is the complexity of bureaucracy in all processes from registration at Anvisa to selling to the end user (hospitals) which adds a long time & costs to start doing business effectively in Brazil.
- Also there does seem to be lack of knowledge of the professionals in general who do the registrations, consultants, import forwarders, etc, which can cause delays and expensive penalties.

Interesting Information

- This documentary is interesting. The example (confectionary) is similar to healthcare because it also involves ANVISA
- <http://www.bbc.co.uk/news/business-18020623>

And Finally....

- I can say that Brazil is a high potential market for the healthcare business, being in the 10 top world economies not only for now, but thinking towards the future. But to be successful you have to be aware of the "*bureaucracy culture*" in Brazil and understand the timing required to get through all the stages.
- By 2014 Intersurgical hope to have a fully functioning local factory and sales operation in Brazil which will also act as our Latin America sales office selling without issue into the local Mercosur countries.



Many thanks for your attention

**UK
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Questions and answer session

Rt Hon Kenneth Clarke MP