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

MEDICAL DEVICES INDUSTRY VIEW

1st Brazil-Japan Seminar on Pharmaceuticals
and Medical Devices Regulations

São Paulo, August 2nd 2014

Agenda

- Overview Healthcare structure in Brazil
- Healthcare and Medical Devices Market
- Industrial policies in Brazil
- Main aspects of regulation

Healthcare Structure

- **Brazilian Constitution states:** “Access to healthcare is a right of the citizen and a duty of the State” (Art. 16). Additionally: “Health assistance is open to private enterprise” (Art. 199)
- **Ministry of Health is responsible for the execution of health policy. Under the Ministry of Health are, among others:**
 - ANVISA - National Health Surveillance Agency → independent; power to regulate and control
 - SCTIE – Secretariat of Science, Technology and Strategic Materials
 - SAS – Secretariat of Healthcare Assistance
 - ANS – National Agency of Supplemental Healthcare - regulates the private sector – HMOs (Health Medical Organizations)
 - CONITEC – National Commission for implementing new technologies at SUS

Brazilian Healthcare Figures

- 6,831 hospitals (70 % private, 21% munic., 8% state, 1% fed.)
- 506,336 hospital beds
- 272,422 healthcare services
- 20,020 laboratories
- 421,384 physicians
- 2,58 million other healthcare professionals
- 220,000 dentists
- 70,000 drugstores

A Country of Contrasts

Economy

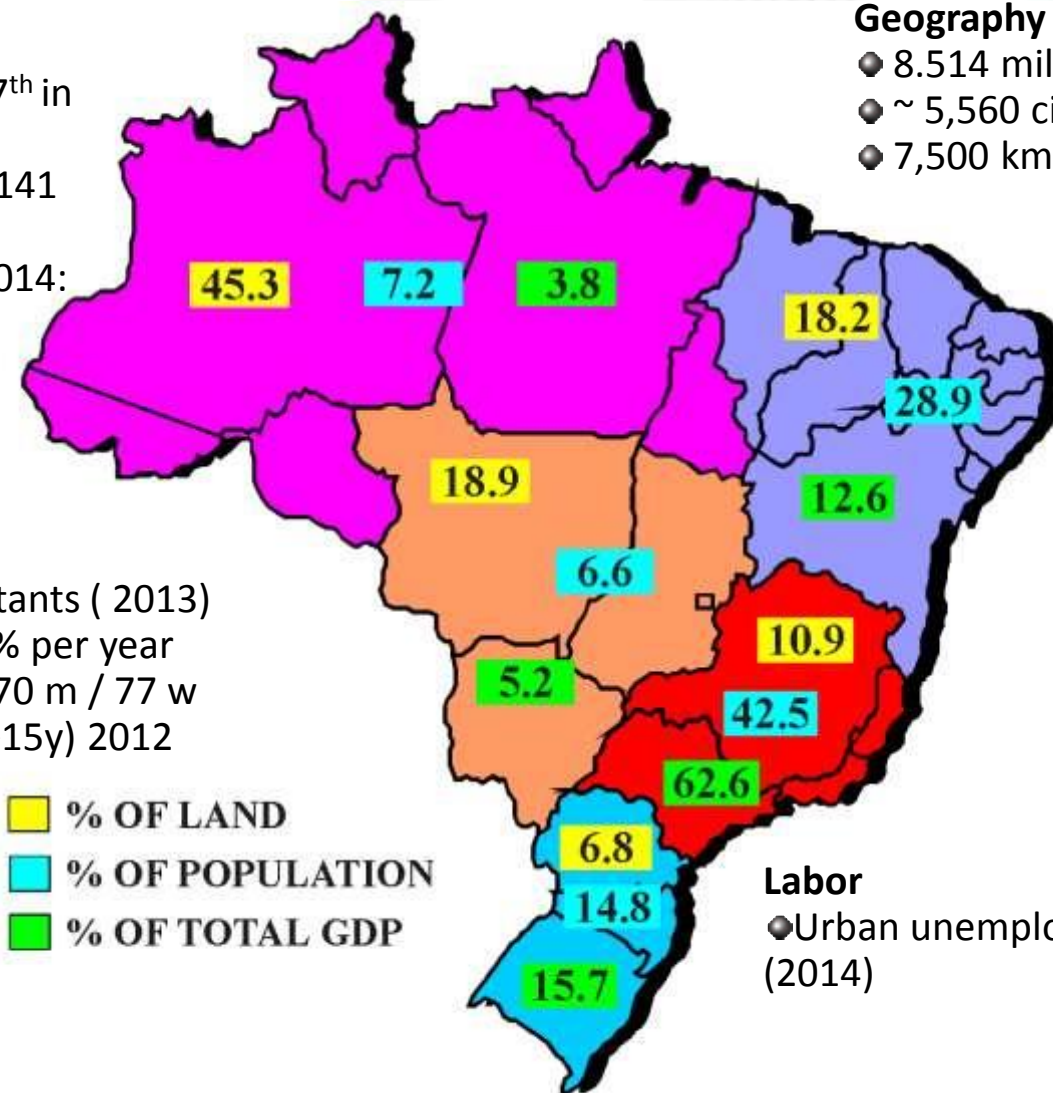
- ◆ GDP 2013: US\$ 2.240 Trillion (7th in the world)
- ◆ GDP per capita (2013): US\$11,141
- ◆ Inflation rate (2013): 5.91%
- ◆ SELIC -Basic interest rate Jul. 2014: 11.00%
- ◆ GDP growth (2013): 2.3%
- ◆ GDP growth exp 2014: 1.8%

Population

- ◆ 201.3 mil. inhabitants (2013)
- ◆ Growth rate: 1,7% per year
- ◆ Life expectancy: 70 m / 77 w
- ◆ Illiteracy: 8.7% (>15y) 2012

Geography

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



Labor

- ◆ Urban unemployment: 7,1% (2014)

Healthcare and Medical Devices Market



Healthcare Expenditures



Healthcare expenditures worldwide
10.4% of global GNP:US\$ 7 tri. (2010)

- ◆ ***59.2% covered by public services***
- ◆ ***40.8%, covered by private services***

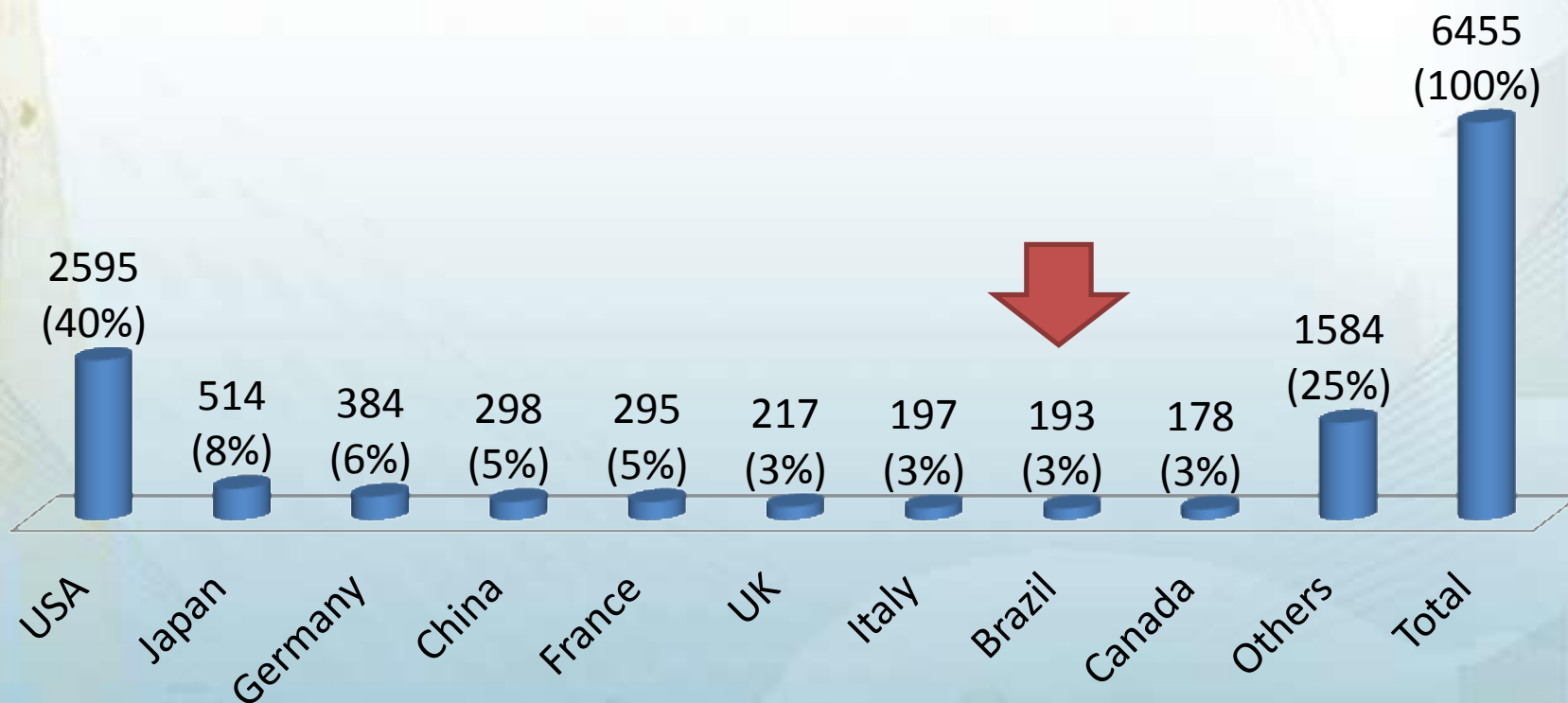


Brazilian Healthcare expenditures
9% of GNP : R\$ 339 bi. (2010)
(8th largest in the world)

- ◆ ***47% covered by public services***
- ◆ ***53% covered by private services***

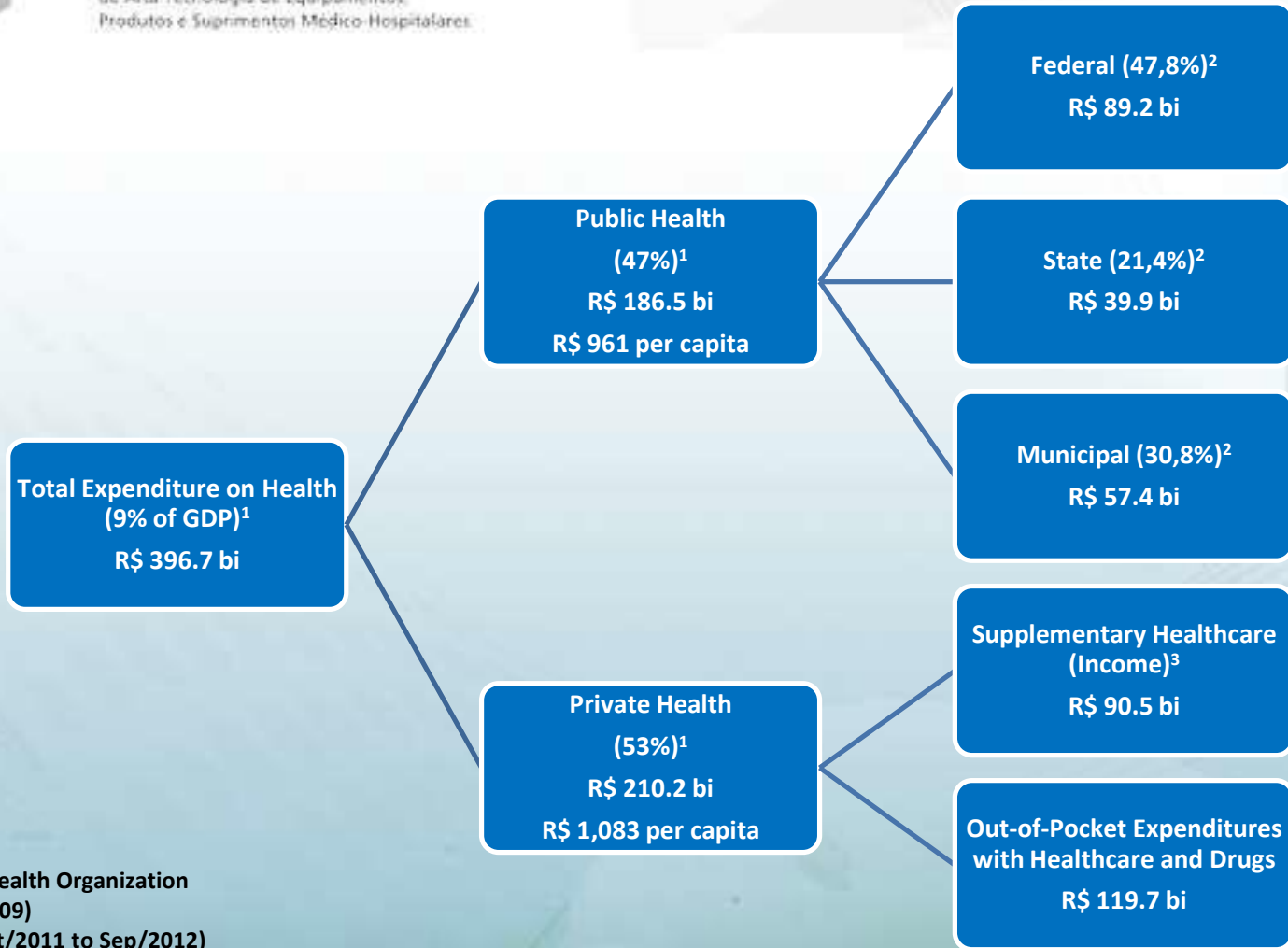
Healthcare Expenses (2010)

Billions of USD



Source: WHO

Healthcare expenditures distribution



¹ World Health Organization

² IBGE (2009)

³ ANS (Oct/2011 to Sep/2012)



Total market: US\$ 1 tri

- ◆ **US\$ 670 bi - Pharma**
- ◆ **US\$ 9 bi - Vaccines**
- ◆ **US\$ 25 bi - IVD – Invitro Diagnosis**
- ◆ **US\$ 300 bi – MD - Medical Devices (Brazil: US\$ 11bi)**

Opportunities & Challenges

● Opportunities

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

● Challenges

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

Brazilian MD market (2013)

- 13 K companies (majority small companies)
- 130 K employees
- Market: US\$ 11 bill.
- Taxes generated by MD: US\$2,4 bi
- Import: US\$ 4.5 bi
- Export: US\$ 700 mil
- Local production: US\$2.4bi

Medical Devices Export

● Main products

- Odontology: chairs, dental implants, consummables
- Neonatal incubators
- Catheters, suture needles
- Orthopaedic implants and articles
- Radiology

● Main destinations

- USA
- Argentina
- Mexico
- Colombia
- Venezuela
- Chile
- Belgium
- Germany
- Spain
- Paraguay

Industrial Policies in Brazil



“Brasil Maior” Plan

Innovate to compete . Compete to grow

- Foster local innovation and technological development
- Create and strengthen critical competences of Brazilian economy
- Increase internal and external markets for Brazilian companies
- Assure a socially-including and environmental sustainable growth

Brazilian Policies

- Foster local production and reduce the external dependence on Medical Devices
- Prioritize the clinical and pre-clinical research in the country
- Promote international cooperation for technology transfer
- Strengthen structure for R&D and innovation
- Use the purchasing power of government for strategic products for NHS
- Preference for domestic products and services in federal public tenders

Fostering the industrial policy

- Ministerial policies
 - PPB – Basic Productive Process
 - PDP – Partnership for Productive Development (Ord. 837/2012) – technology transfer x governmental procurement 5 years
 - Offset model – e.g.: Linear accelerators for radiotherapy
- Interface management among “Brasil Maior” Plan, GECIS and Sanitary Surveillance
 - Agreement 13/2013: ANVISA / MoH / MDIC –
- INOVA Saúde Plan – Focus on innovation
 - Funding by FINEP, BNDES & MoH
- Preference to locally manufactured products and services
 - Law 12.349/2010 – Decree 7767/2012 for MD

Health Technology Assessment & Policy Reimbursement Criteria

- **Law 12.401/2011**
 - Changes rules for therapeutical assistance and technology incorporation at SUS
 - Defines CONITEC as responsible for evaluating the technologies
 - Establishes 180 days as max. period for evaluation
 - Regulated by decree 7724/2012 and Ordinance 748/2012
- **Alignment with government policies**
 - Prioritizes strategic products

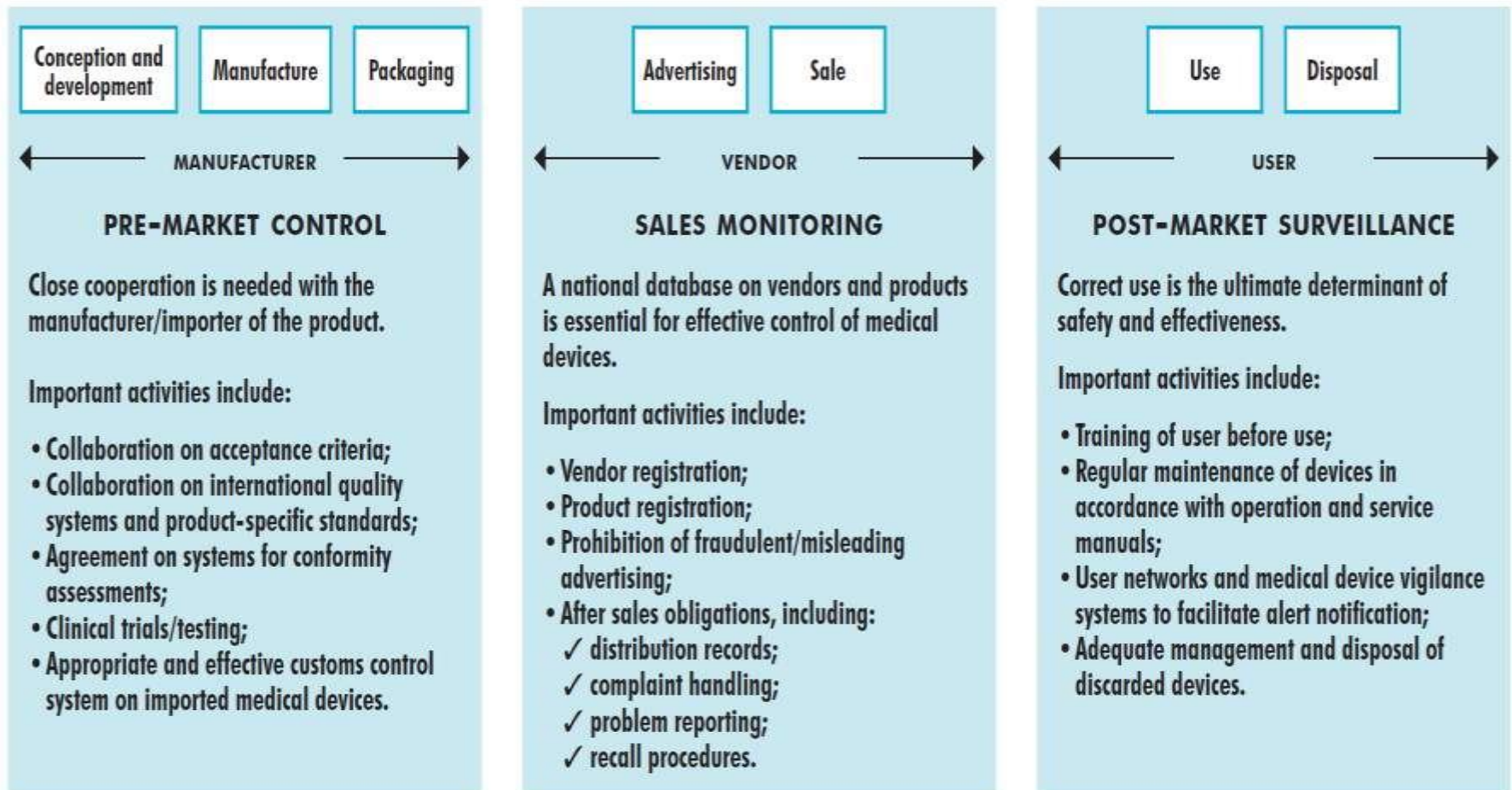
Main aspects of regulation



Medical Devices Industry

- Medical technologies will continue to evolve rapidly
- Top 20 companies invest (average) 8% in R&D
- Rapid product obsolescence (differently from drugs)
- Short product lifecycle
- Importance of having well trained professionals
- Importance of having a competitive environment, enabling the access of population to new technologies

Medical Devices Lifecycle



Activities of the regulated sector

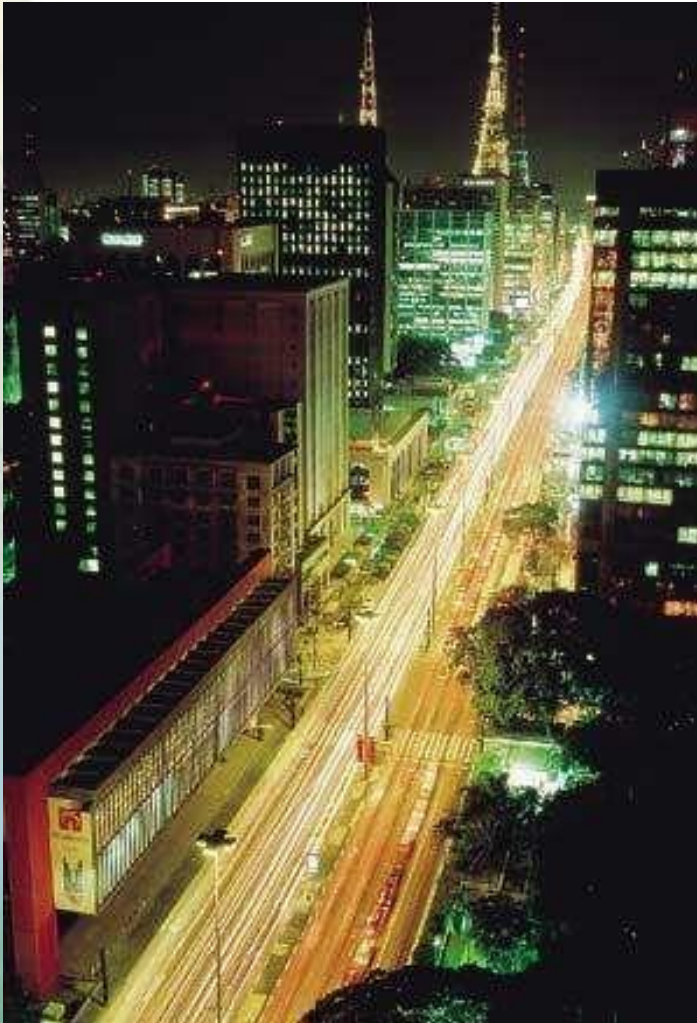
- **Contribute at political level**
 - Show the value our industry brings to the country
 - Enable universal access to new technologies
 - Alignment with government policies
- **Strengthen relationship with Ministries**
 - Participate in industrial policies discussions (Health Industry Complex)
 - Cooperation with Conitec (rational incorporation of technologies)
- **Close collaboration with Anvisa**
 - E.g.: Agenda, IMDRF, Regulatory impact analysis
- **Increase market intelligence**
- **Importance of predictability and legal security**
- **Promote Ethics and foster compliance implementation**
- **Articulate actions along healthcare chain**
- **Promote and expand training**

Abimed





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



- ◆ Founded on June 18th, 1996
- ◆ Non-profit, non-governmental organization
- ◆ 170 active members
- ◆ Member of GMTA, DITTA, ALDIMED
- ◆ Focus on innovation as a tool for access to healthcare and economic development of the Country
- ◆ Support to create an ethical environment to foster competitiveness and industry growth
- ◆ Close cooperation with Regulators and Government to support Brazilian industrial policies
- ◆ Cooperation with medical societies and peer associations as well
- ◆ Training and fostering the education in the sector



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THANK YOU

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