THE BRAZILIAN ENVIRONMENT FOR MEDICAL DEVICES
AGENDA

- Overview Healthcare structure in Brazil
- Healthcare and Medical Devices Market
- Steps to enter the Brazilian Market
- Industrial policies in Brazil
- Highlights of Anvisa’s regulations
- Conclusions
- ABIMED in few words
HEALTHCARE ENVIRONMENT
HEALTHCARE STRUCTURE

Brazilian Constitution

• “Access to healthcare is a right of the citizen and a duty of the State” (Art. 196)

• “Healthcare assistance is open to private enterprise” (Art. 199)
MINISTRY OF HEALTH

Responsible for the execution of health policy

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
TOTAL EXPENDITURE ON HEALTH
(9.5% OF GDP)
R$ 563.1 bi

PUBLIC HEALTH (45.2%)
R$ 254.8 bi
- Federal (36.0%)
  R$ 91.7 bi
- State (28.4%)
  R$ 72.5 bi
- Municipal (35.6%)
  R$ 90.6 bi

PRIVATE HEALTH (54.8%)
R$ 308.3 bi
- Supplementary Healthcare (46.7%)
  R$143.9 bi
- Out-of-pocket expenditures (53.3%)
  R$164.5 bi

Source: ANAHP 2015
BRAZILIAN HEALTHCARE FIGURES

- 6,300 hospitals (70 % private)
- 494,740 hospital beds
- 95,990 supplementary healthcare services
- 432,523 physicians
- 2,58 million other healthcare professionals
- 143,998 dentists
- 70,000 drugstores

Source: CNES, CFM Jan 2015
POPULATION PYRAMID

11.3% of elderly population (60 years old or +)

Brazil 2014 to 2030

2014: 11.3% of elderly population (23 million)

2020: 18.6% of elderly population (41.5 million)

Source: ANAHP / IBGE
A COUNTRY OF CONTRASTS

Economy
• GDP per capita: US$8,651 (2015)
• Inflation rate: 6.3% (2016)
• Basic interest rate: 13.0% (Jan 2017)
• GDP growth: -3.8% (2016)
• Unemployment rate: 12.0% (2016)
• Export: US$185.2bi (2016)
• Import: US$137.7bi (2016)

Population - 2015
• Inhabitants: 204 million
• Growth rate: 1.7% per year
• Life expectancy: 71.9M/79.1 W
• Illiteracy: 8.3% (>15y)

Geography
• Area: 8.514 million km²
• Cities: 5,560 cities
• Coastline: 7,500 km

Sources: IBGE, BC, Copom, PNAD
MEDICAL DEVICES MARKET IN BRAZIL
MEDICAL DEVICES - GLOBAL MARKET (2014)

Global Market
US$ 350 bi

Total Export
US$ 177,7 bi

80% SME
< 50 Employees

90 Categories
10k Types
500k Items

Source: USITC and Saúde 4.0 ABiIS 2015
GLOBAL EXPORT (COUNTRY OF ORIGIN)

- 23% USA
- 13% Germany
- 9% Netherland
- 5% Switzerland
- 5% Belgium
- 40% Others

Source: USITC (2014) and Saúde 4.0 ABIIS 2015
MEDICAL DEVICES – BRAZILIAN MARKET

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<th>Enterprises</th>
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<table>
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Production + (Import – Export)
ORIGINS OF BRAZIL IMPORTATION (2014)

- **USA**: 28%
- **Germany**: 15%
- **Switzerland**: 8%
- **China**: 4%
- **Japan**: 3%
- **UK**: 3%
- **Malaysia**: 3%
- **France**: 3%
- **Others**: 24%

*Fonte: SECEX – Alice WEB e Saúde 4.0 ABIIS 2015*
MARKET SEGMENTATION

- Reagents for In Vitro Diagnostics: 20%
- Laboratory equipment: 14%
- Supply materials: 19%
- Orthosis & prosthesis: 15%
- Other hospital equipment: 19%
- Diagnostic imaging & supplies: 8%
- Dentistry equipment: 3%
- Hospital furniture: 2%
Among the groups of imported products for health, the largest Brazilian dependence occurs in reagents for in vitro diagnostic.
STEPS TO ENTER THE BRAZILIAN MARKET
MAIN LAWS AND RESOLUTIONS

- Law 6360/1975 – Sanitary Surveillance
- RDC 185/2001 – Classes of Risk – Registration/Notification process
- Law 9.782/1999 – Foundation of Anvisa
- Anvisa has a robust and comprehensive regulation for pre and post market
- Anvisa is member of IMDRF – International Medical Devices Regulators Forum

Source: CNES, CFM Jan 2015
MAIN STEPS

- Be officially represented in the country
- Have Anvisa authorization for commercialize
- Have a technical responsible
- Notify or register the product
  - Notification: Products of Risk classes I and II
  - Registration: Products of Risk classes III an IV
  - Classes III and IV require GMP Certificate of the factory
  - Factory inspection may be outsourced through MDSAP
  - Some products may require product certification
  - Registration is valid for 5 years (it will extended up to 10 years)
  - Notification just once
- Focus on post-market activities

Source: CNES, CFM Jan 2015
IMDRF

- Members: Brazil, USA, UE, Australia, Japan, Canada, China and Russia
- Active working groups – e.g. MDSAP, UDI, RSP, NCAR, SaMD
BRAZILIAN INDUSTRIAL POLICIES
HOW BRAZILIAN INDUSTRIAL POLICIES CONTRIBUTE TO R&D

MINISTRY OF HEALTH POLICIES

• PDP – Partnership for Productive Development Technology transfer x governmental procurement
• Offset model – e.g.: Linear accelerators for radiotherapy

MDIC AND MCTI POLICY

• PPB – Basic Productive Process e.g.: Imaging products
HIGHLIGHTS OF ANVISA’S REGULATIONS

• Law 13.043/2014
  • No renewal of AFE
  • Good Manufacturing Practice (GMP) validity up to 4 years (to be regulated by Anvisa)

• Law 13.097/2015
  • Registration: Validity timeframes for some devices may be increased to up to 10 years depending on product characteristics and risks;
  • Inspections for GMP may be outsourced: ANVISA adopted MDSAP
  • ANVISA may expand certifications of laboratories authorized to conduct health surveillance inspections and post-market surveillance.

Note: ANVISA will need to release additional regulations in order to define and implement the allowances made in the law.
ABIMED IN FEW WORDS
ABIMED
BRAZILIAN ASSOCIATION OF HIGH TECHNOLOGY INDUSTRIES OF MEDICAL DEVICES

SPEEDING UP INNOVATION

- Founded in June 1996
- 220 members
- 65% of Market share
- Code of Conduct since 2006
- Partnering with national & international
  - INTERFARMA, ABIMO, CBDL, ABRAIDI, SINDUSFARMA
  - GMTA, DITTA, ALDIMED, ADVAMED
- Member of Institute Health Coalition
- Member of Institute Ethic-Health
THANK YOU

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