REGULATORY CONVERGENCE ON MEDICAL DEVICES – AN INTERNATIONAL TRADE APPROACH
APEX-BRASIL
The Brazilian Trade and Investment Promotion Agency (Apex-Brasil) is a Civil Society Organization linked to the Ministry of Development, Industry and Foreign Trade.

MISSION
To develop the competitiveness of Brazilian companies, promoting the internationalization of their businesses and the attraction of Foreign Direct Investment (FDI).

VISION
Brazil in the World: Innovative, Competitive and Sustainable.
MAIN ACTIVITIES

- Export Promotion
- Investment Attraction
- Internationalization

STRATEGIES

- Market Intelligence
- Entrepreneurial Training
- Internationalization Strategies
- Business and Image Promotion
- Investment Attraction
9 OFFICES WORLDWIDE

SAN FRANCISCO
HAVANA
MIAMI
BOGOTA
LUANDA
DUBAI
MOSCOW
BRUSSELS
BEIJING
APEX-BRASIL EXPORT NUMBERS

- **Total Brazilian exports**
  - 2015: US$191,1bi
  - 2015: 32,2% supported by ApexBrasil
  - 2014 VS 2015: -0,8% (-15,1%*) compared to other exporters

- **Exports of value-added products**
  - 2015: US$126,5bi
  - 2015: 37,7% supported by ApexBrasil
  - 2014 VS 2015: -5,2% (-10,9%*) compared to other exporters

* OTHER EXPORTERS PERFORMANCE
OVER 80
INDUSTRIES SUPPORTED
72
BUSINESS PROJECTS
12,000
SUPPORTED COMPANIES
INITIATIVES TARGETING OVER
200 MARKETS

SUPPORTED SECTORS

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>Product Industries</th>
<th>Services Industries</th>
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<td>67</td>
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TRADE SECTOR PROJECTS

Definition
We develop and support activities to develop companies’ exporting abilities, thus contributing to the promotion of Brazilian industries in the international market. The Trade Sector Projects work with business sectors or productive chains, comprising some of Apex-Brasil’s main initiatives for stimulating the exports of Brazilian products.

Goals
The Trade Sector Projects aim to facilitate Brazilian companies’ access to the main foreign markets, to prospect business and exporting opportunities, and to improve international perception of Brazilian companies, products and services.
Regarding the Trade Sector Projects exports, the performance of companies supported by Apex-Brasil was 74.5% higher than by those not supported, despite the drop in export volume between January and December 2015.

Companies supported by Apex-Brasil participation

Brazilian Exports
Considering the same services and products supported by Apex-Brasil

- US$ 28.7 Bi Companies supported by Trade Sector Projects exports
- US$ 56.5 Bi

*: From January to December 2014, the share was 44.3%
The Sector Project implemented by ABIMO (Brazilian Medical Devices Manufacturers Association) in partnership with Apex-Brasil is named Brazilian Health Devices and its mission is to encourage the exports by the Brazilian health industry companies.
BHD PERFORMANCE IN 2015:

• Companies supported by the project: **157** (125 exporters)

• Supported companies exports: **123.275.021** (US$ FOB)

• Supported companies exports annual growth: + **0,8%** (other exporters had a 10,95% decrease in performance)

• Products (MCNs*): **117**

• Destinations: **134**

* MERCOSUR Common Nomenclature
WHAT THE BRAZILIAN HEALTH DEVICES HAS TO OFFER:

- Business intelligence (information and market analysis);
- Participation in major international trade fairs around the world;
- Organization and promotion of trade missions;
- Business matchmaking rounds in major trade fairs;
- Training for export and international certification;
- Image building;
- Certification Incentive Program;
- Sales Agents in target markets
HOW IMPORTANT IS INTERNATIONAL CERTIFICATION FOR MEDICAL DEVICES INTERNATIONAL TRADE?

• Health Sector is highly regulated and monitored;

• FDA and CE – stand for quality and security in the international market;

• Growing demand of distributors for FDA e CE certified products;

• FDA e CE – competitiveness requirement for new opportunities
IMPACT ON COMPETITIVENESS

Brazilian companies spent at least USD 12,5 thousand individually to obtain the CE Mark; at least USD 20 thousand for FDA;

Not to mention all other countries! For example, for any country in South America, a company might need to spend at least USD 5 thousand only in bureaucracy;

China is the country with the most expensive certification (according to statements from BHD companies), with minimum cost of USD 50 thousand, without most clinical trials needed.
1. Introductory meetings and request for proposal;
2. Choose Consulting Partner with best cost x benefit;
3. Kick off Project with BHD companies;
4. BHD companies application to program;
5. Application assessment by Project team (including Consulting Partner);
6. Selection validation by Steering Committee;
7. Signing Program Terms of Participation;
8. Start individual assessment and service by Consulting Partner;
9. Monitoring Program status by BHD team;
PROGRAM RESULTS SO FAR:
157 BHD companies - 82 have acquired CE certification and 28 FDA certification;
3rd edition CE – 4 companies – IN FINAL STAGE

PLANS FOR THE FUTURE:
Continue to invest in certification for BHD companies
In 2016, the Program will have 8 new posts
Focus on regulatory process for assistive technologies sector
Training on certification process
Data survey on regulatory process in 18 target markets
1. Regulatory Convergence is an issue of vital importance for the international trade in medical devices. It directly impacts companies' competitiveness;

2. From the international trade point of view, initiatives such as the IMDRF can produce a very positive impact;

3. It’s essential that the business world and its Stakeholders be in close contact with the health policy decision-making individuals so as to allow foreign trade in the health sector to take place.
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