Brazilian industry´s activities for international convergence

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Eurofarma
Ampliando horizontes.

ABIFINA

Mission

- Congregate companies, institutes and association in order to stimulate the brazilian industrial development in chemicals, biotechnology and its specialties.
- Founded 30 years ago
- 24 companies associates

Areas

- API
- Medicines and Vaccines
- Raw materials
- Pesticides
- Biodiversity products
- Additives and Catalysts

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PROFILE

OUR PRESENCE

+45 Years

A history of more than **45 years**

Brazil's **1st multinational** pharmaceutical company

Present in **20 counties**

Amongst the **3 biggest** Brazilian pharmaceutical companies

+320 million units of medicines produced in 2017

More than **335 brands** commercialized in Brazil

Operating in **the main** Pharma **segments**

+6,300 employees in Brazil and abroad

87.1%
Latin American market coverage

Controlled Companies & Joint-Ventures

Momenta Farmacêutica

Eurofarma

Produces and commercializes a comprehensive portfolio of prescription and non-prescription medicines. Its production line includes oral and injectable antibiotics mainly penicillins, cephalosporins, and carbapenems.

Supera

Eurofarma, Cristália and MSD

This partnership is responsible for promoting and distributing prescription medicines.

Orygen

Eurofarma and Biolab

Joint-venture with the objective of developing and producing Biosimilars.

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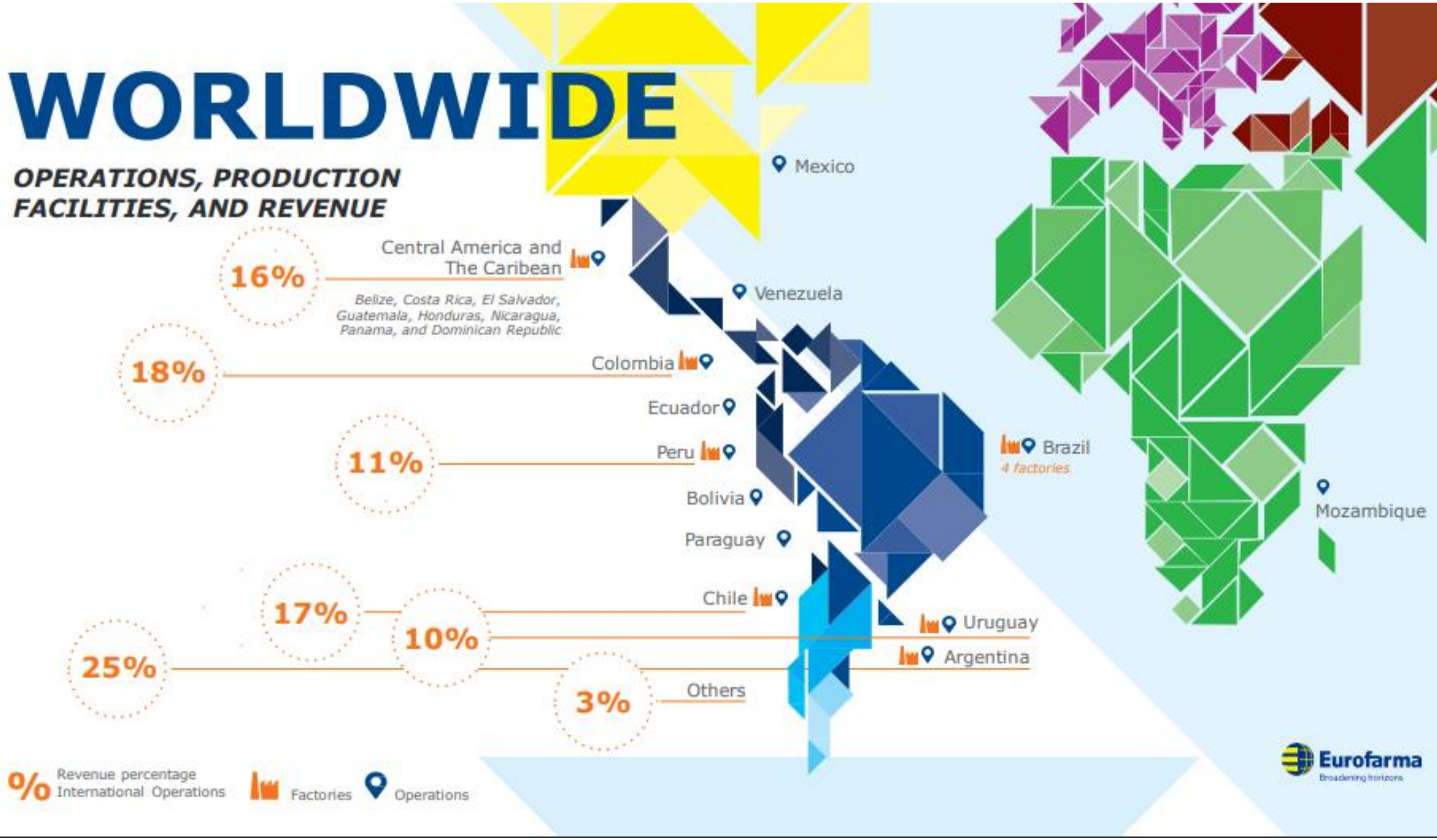
WORLDWIDE

OPERATIONS, PRODUCTION FACILITIES, AND REVENUE



Internacional Operations

Factories:

Argentina
Chile
Colombia
Guatemala
Peru
Uruguay

Joint Venture:

USA

Offices:

Bolivia
Costa Rica
El Salvador
Ecuador
Honduras
Mexico
Mozambique
Nicaragua
Panama
Paraguay
Dominican Republic
Venezuela

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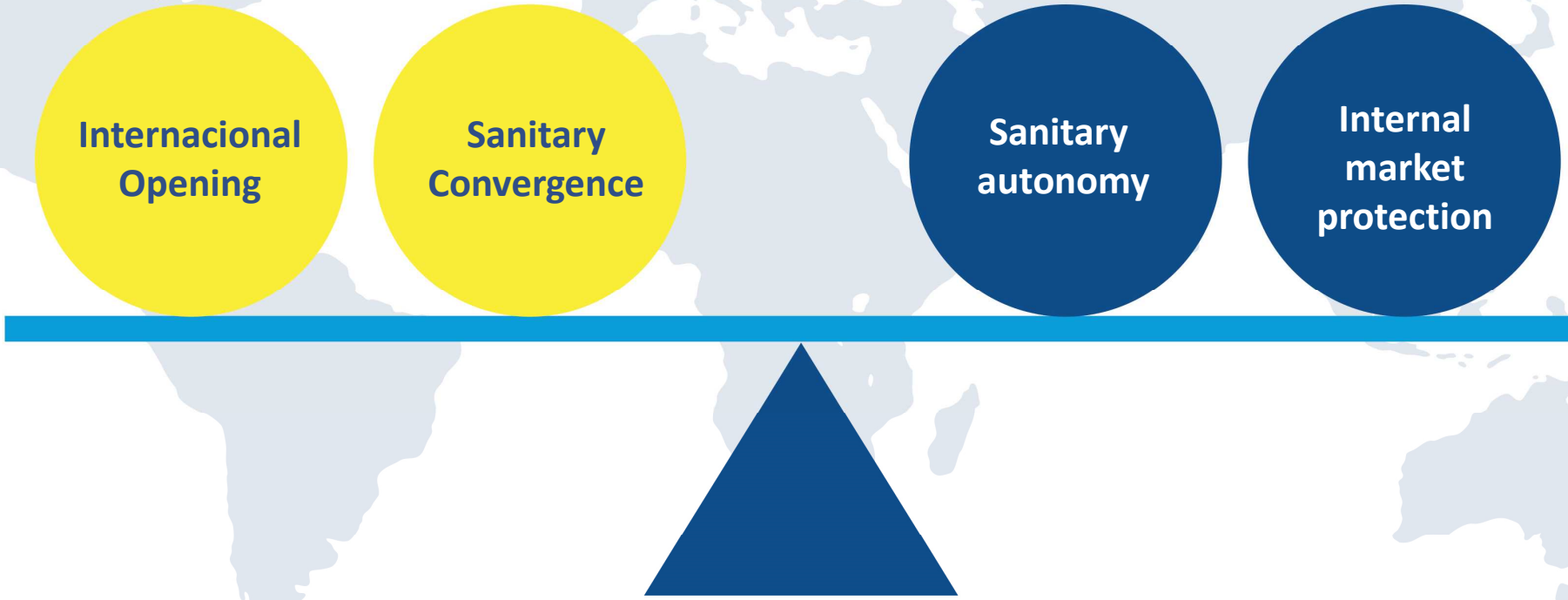
Internationalization Models

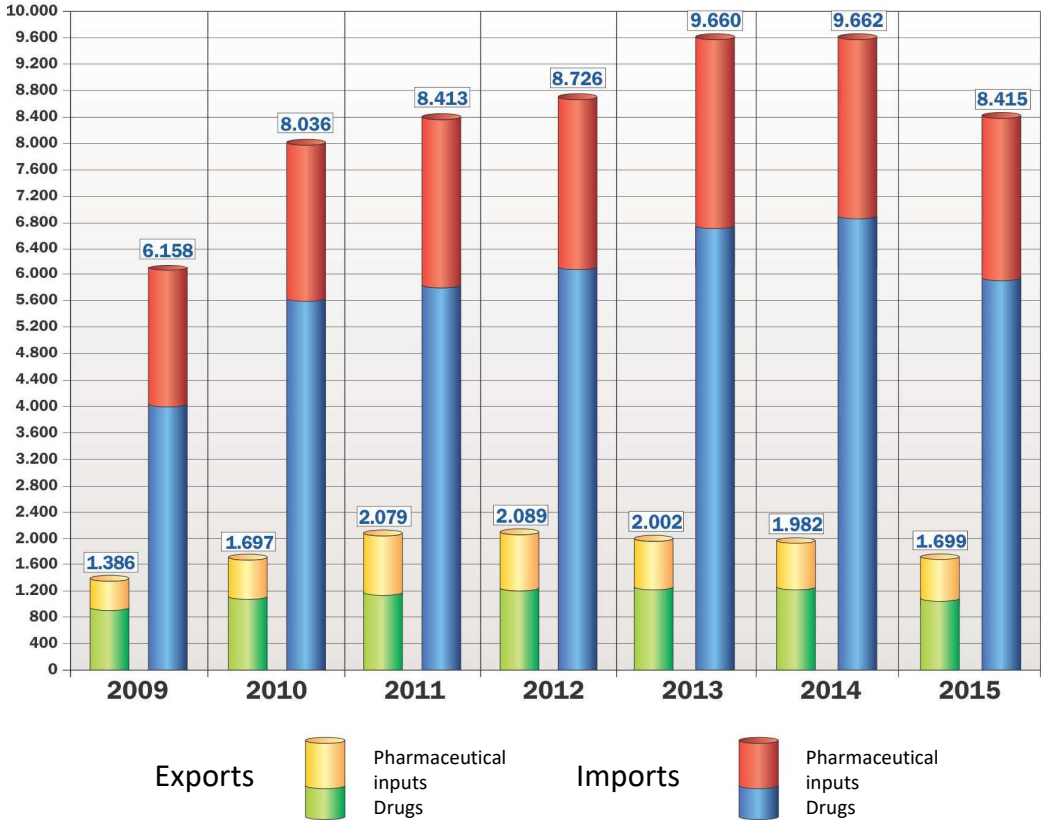
Model	Advantage	Disadvantage
EXPORT **Supply external demand with finished, semi-finished or IFA products.**	• Few investment required • Learning • Cost increase with incremental volumes	• Cost of transportation and logistics • Likely trade barriers • Different regulatory requirements
LICENSING **Assignment of rights to explore brands, products, technologies or processes.**	• Licensee assumes business risk • It shortens the time of entry, reduces the necessary investment and the acquisition of market knowledge	• Dependency of licensees / franchisees • Risk of creating a competitor
DIRECT INVESTMENT (GREENFIELD) Investment from scratch in new commercial, support or industrial operation	• Signs to customers and stakeholders the desire to be in the local market nolong term • Reduction of transport, storage and / or production costs • Reduction of trade barriers and incentives	• Investments • Requires more time, resources and market knowledge • Greater political and economic risks
FUSIONS AND ACQUISITIONS **Purchase or exchange of shares and assets, which may be minority, majority or integral**	• Quick Market Access	• Difficulty finding the target company • Government Restrictions • Integration and post-merger management can be difficult (culture, organization, language, values)
ALLIANCES AND JOINT-VENTURES **Shared-Control Business Association and Go-to-Market Models**	• Knowledge of the local market available • Synergy and complementarity between companies (organization, portfolio, technology, etc.)	• Shared control • Potential conflicts of interest between partners

Benefits of Internationalizing

- Growth - search for attractive markets
- Establishment of regional products and brands (brand globalization)
- Productivity gains - economy of scale in the production of products and processes
- Increased attractiveness to license products regionally
- Product Lifecycle Renewal
- Access to new technologies and innovation (R & D)
- Risk reduction - country and cost of capital
- Access to new sources of funding


Internacional Opening
Sanitary Convergence
Sanitary autonomy
Internal market protection

Pharmaceutical productive chain – Imports and Exports of drugs and pharmaceuticals inputs.
US$ FOB Millons – 2009 to 2015



Large difference betwen imports and exports in pharma chain in Brazil

Difficulties faced by Brazilian companies for exports and internationalization

1. Dossier format
2. Regulatory Registration Requirements
3. Required Documentation
4. GMP Recognition
5. Particularities

Dossiers Format

- CTD (Common Technical Document) -> ICH
- Provision of documentation in different chapters in relation to CTD, making formatting difficult.

Initiatives

- Adapting from the current format to CTD, ACTD

Regulatory Registration Requirements

-> Tests and analyzes not required by Anvisa: Development Report, Analytical Validation, Open DMF.

e.g. Argentina that requires Test of Accuracy that should follow the Argentine Pharmacopoeia, while companies in general use USP or BP.

Initiatives

ICH is an opening opportunity for various markets.
We are redoing the test and analyzes, as required by each country.

Required Documentation

Lack of procedures and automatic recognition of documentation:

For example:

Difficulty of acceptance of Anvisa electronic CPP. Bolivia is reluctant to accept the electronic, only accepts WHO.

Peru accepted after the Sanitary Image Project event held by Abiquifi with the presence of ANVISA.

Possibility of simultaneous submission with Brazil.

GMP Recognition

- Most countries do not recognize GMP ANVISA and require plant inspection in Brazil.
- In Latin America, although several countries recognize the GMP ANVISA, some still require inspection, such as Peru and Colombia.
- PIC/S would be a great opening opportunity for several major markets such as South Africa, Australia and some ASEAN countries. Argentina is already a member.
- EMA went on to recognize the GMP ANVISA of IFAs.

Initiatives

- Adaptation of manufacturing facilities for international inspections.
- Request for international inspection
- Brazil in PIC/s

Countries Particularities

Local Bioequivalence required: Thailand, Japan, Mexico
B.E with WHO references: Southern Africa, Malaysia.

Initiatives:

Redo these studies depending on the Return on Investment

The process of global convergence and the productive sector participation

Opportunities

- Agility in drug availability: increased access;
- Reduction of duplication of efforts;
- To avoid expose patients in new studies;
- Sharing experience and knowledge;
- Adequate allocation of resources, which are often scarce or limited.

Challenges

- Differences between emerging and developed countries, from a structural, regulatory and local development point of view;
- Consistency between convergence initiatives;
- Balance between the adoption of high regulatory standards - according to scientific and technological progress - and the development plans of the industry;
- Adapting smaller companies to international standards;
- Need for impact assessment of the adoption of international standards, by country, from the regulatory point of view, of population access to medicines and market.

THANK YOU

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