

The 1st Brazil-Japan Seminar on
pharmaceuticals and medical devices
regulations



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**Efficiency of product review on
medical devices and pharmaceuticals**

OBJECTIVES

To offer an overview related to Sindusfarma activities, evolution of the Brazilian medicines market, regulation, harmonization and convergences applied to the pharmaceutical industry.

CONTENT

- 1.Sindusfarma – attributions and main activities***
- 2.The evolution and milestones of regulation for pharmaceutical industry.***
- 3.Convergences efforts related to efficacy, safety and quality of medicines***
- 4.Sindusfarma educational and institutional programs***
- 5.Conclusions***



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Legal attributions

The attributions of Sindusfarma, like those of any other Brazilian trade unions, are provided in the Labor Code, and basically include:

- the conduction of studies, legal protection and coordination of the category;***
- collaboration with governmental authorities and other associations towards social solidarity and serving the country's national interests.***



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Main attributions

- ✓ **To assist entities, memberships and professionals in all regulatory and technical subjects;**
- ✓ **To promote events, plenary meetings, and informative bulletins to updating proposes.**
- ✓ **To develop and offer a continuous education annual programs;**
- ✓ **To provide technical information by publishing manuals and books;**
- ✓ **To conduct collective bargaining, agreements, interchange, and cooperation programs with national and international organizations.**



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Services I

The services provided to members in different fields of expertise include:

- newsletters reproducing the legislation and regulations applicable to the pharmaceutical industry;**
- coordination of working groups to study specific themes of interest for the category with a view to organizing the entity's position or structuring educational programs;**
- scheduling informative meetings with members to spread and comments on regulations newly incorporated to the applicable legislation;**



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Services II

- ✓ **customized services for members;**
- ✓ **issuing letters on an exclusive basis to enable members to take part in public bids;**
- ✓ **managing the BES (Sindusfarma Employment Jobs Bank), for both new applicants and pharmaceutical industry demand, connected with the PAP (program to support professionals);**
- ✓ **others**

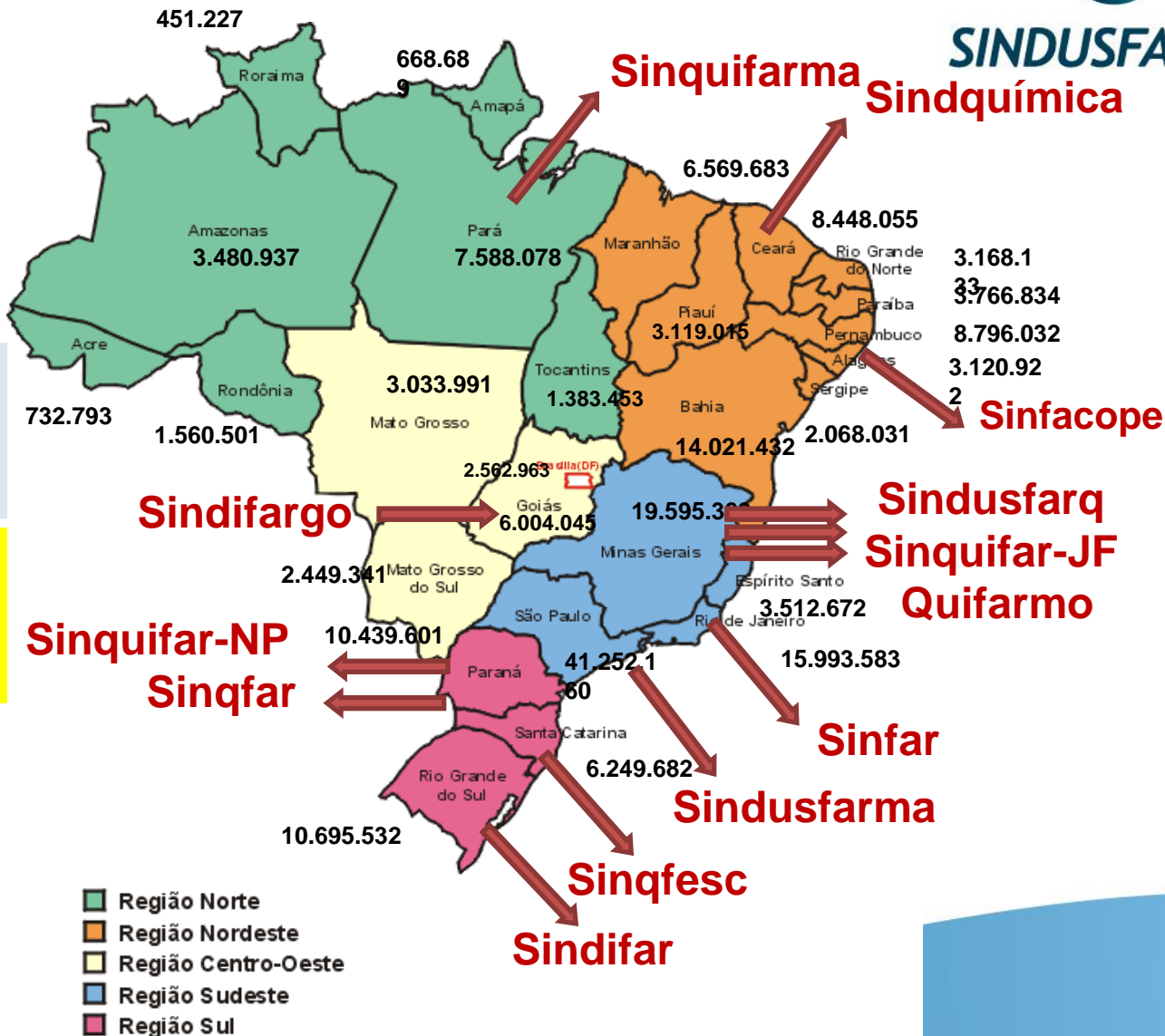
BRAZIL – POPULATION



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**Population
2000
169.799.170**

**Population
2010
190.732.694**

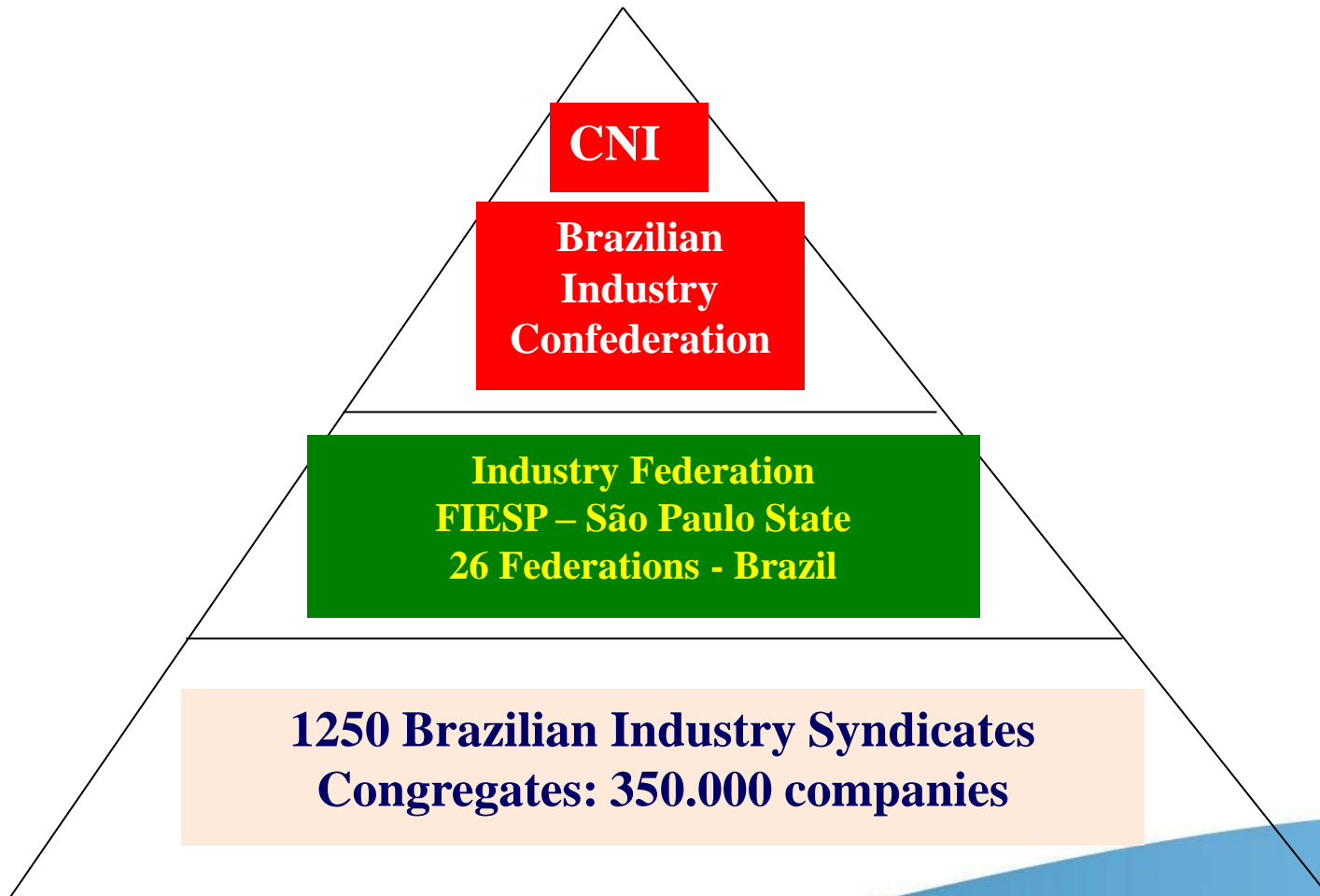


- Região Norte
- Região Nordeste
- Região Centro-Oeste
- Região Sudeste
- Região Sul

Structure Brazilian Industry Representation



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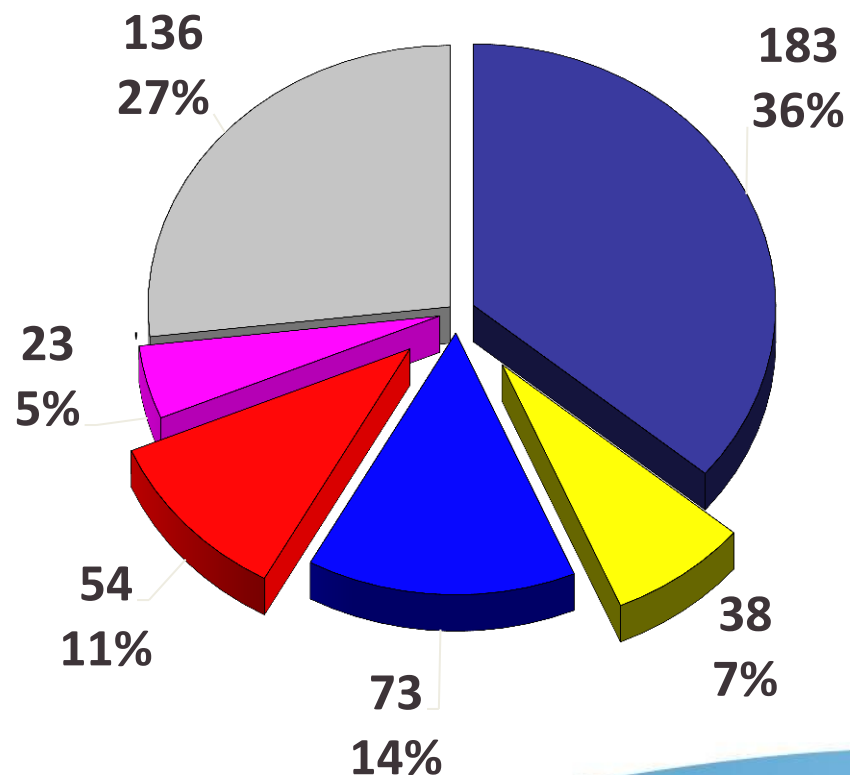
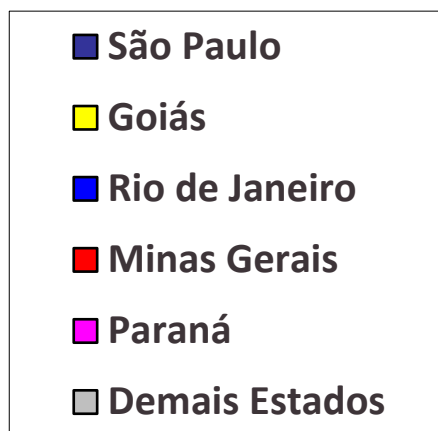


Human Medicines production units Number of establishments/States

Position: 31/12/2012



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Total = 507 companies

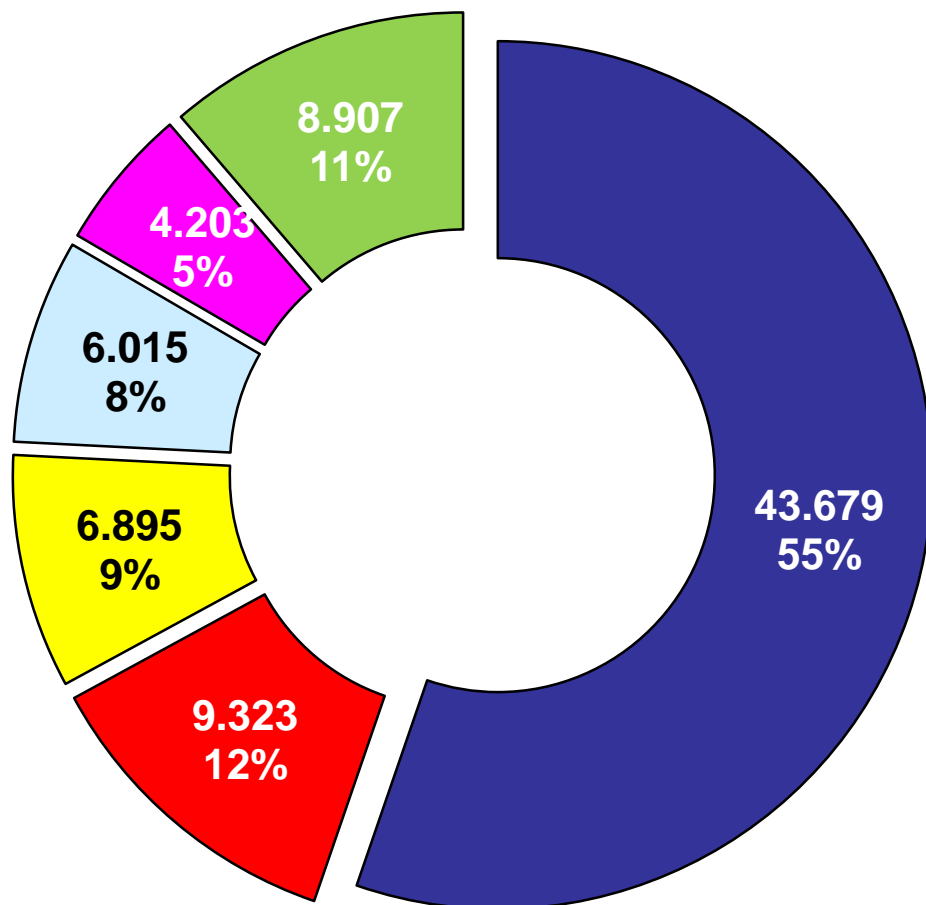
Human Resources – Human Medicines Production

Number employers/States

Position: 31/12/2012



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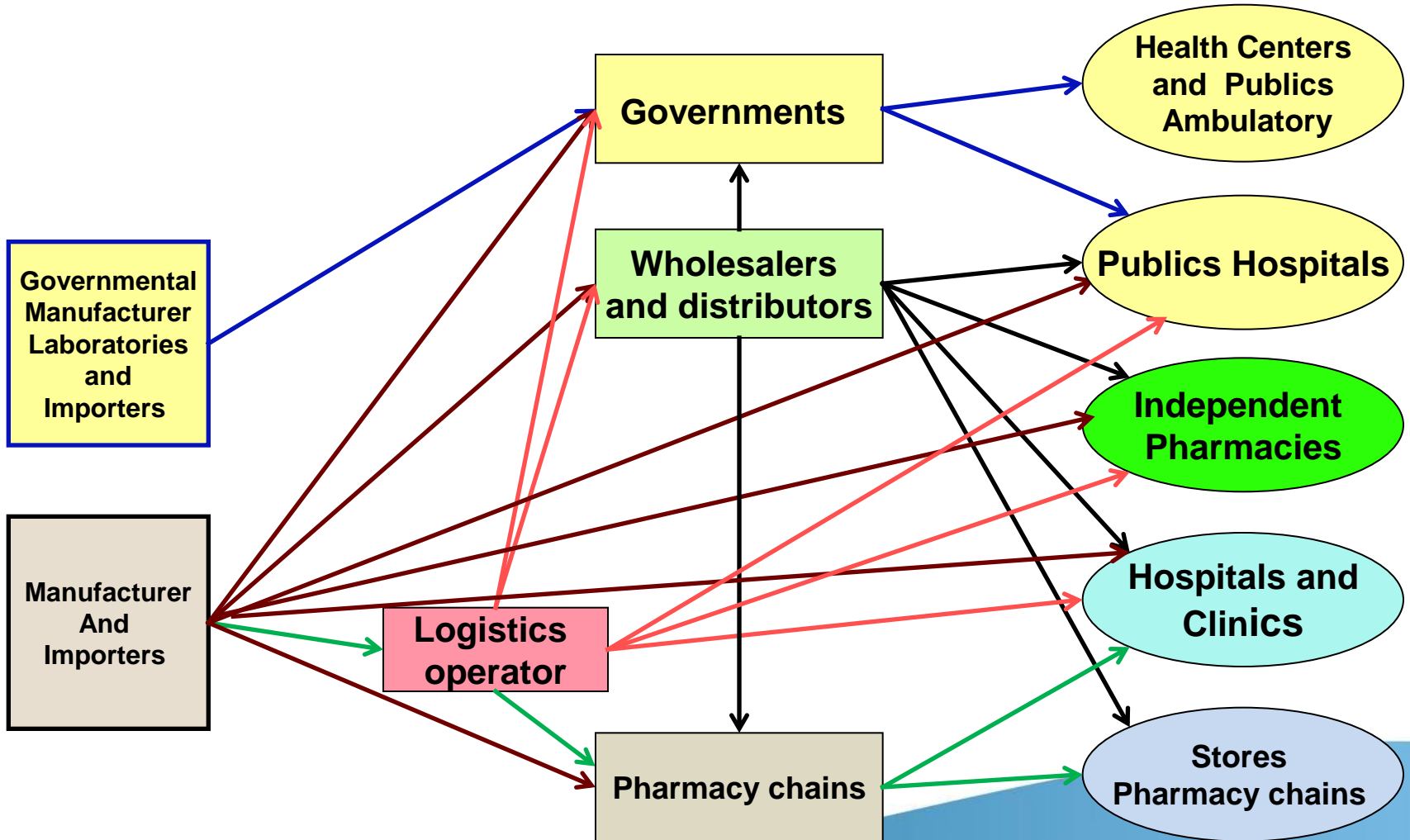
BRAZIL = 79.022 employers

Fonte: Ministério do Trabalho e Emprego - RAIS
Elaboração: Sindusfarma / Gerência de Economia

Brazil - Human Medicines value chain data flow



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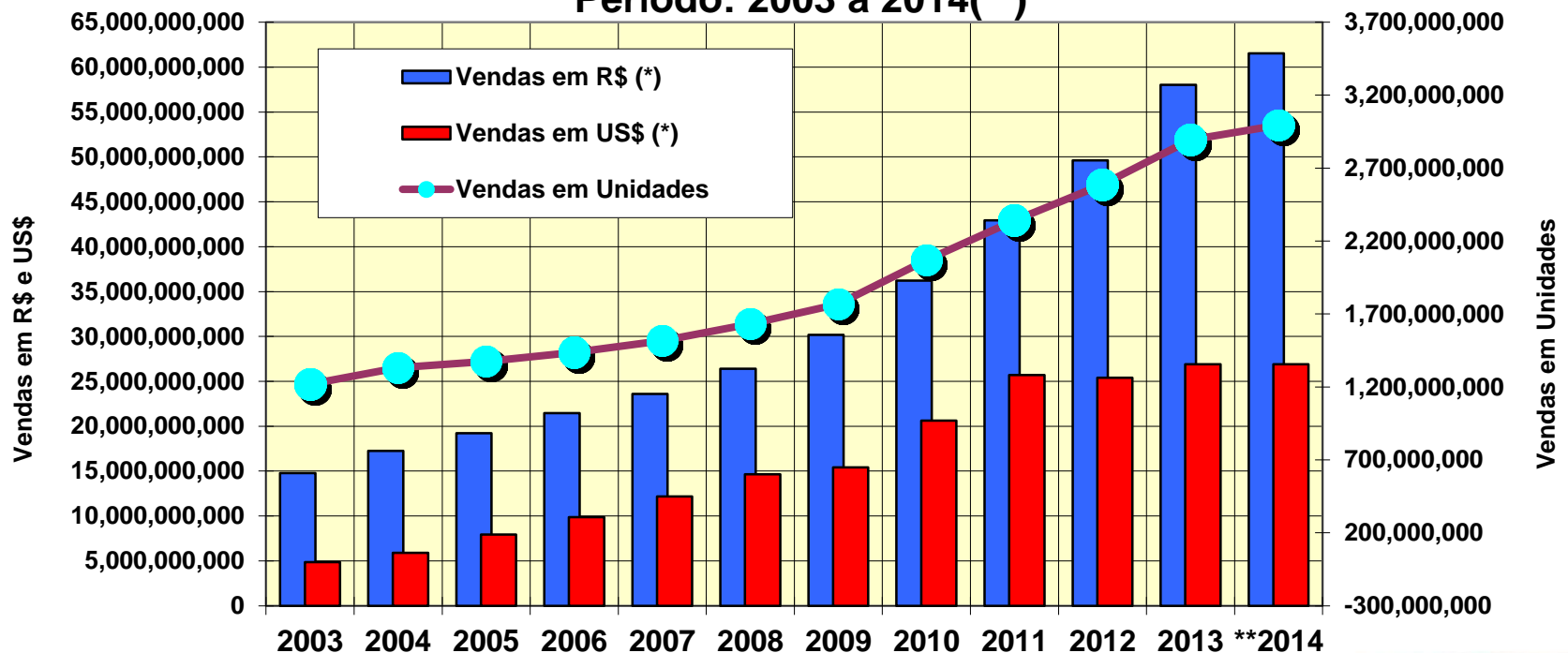


Brazilian Market – Pharmacy channel



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MERCADO FARMACÊUTICO - BRASIL (Canal Farmácia)
Vendas em Reais (R\$), em Dólares (US\$) e em Unidades (caixas)
Período: 2003 a 2014()**



Fonte: IMS Health

Elaboração: Sindusfarma / Gerência de Economia

(**) 12 meses móveis até Junho/2014

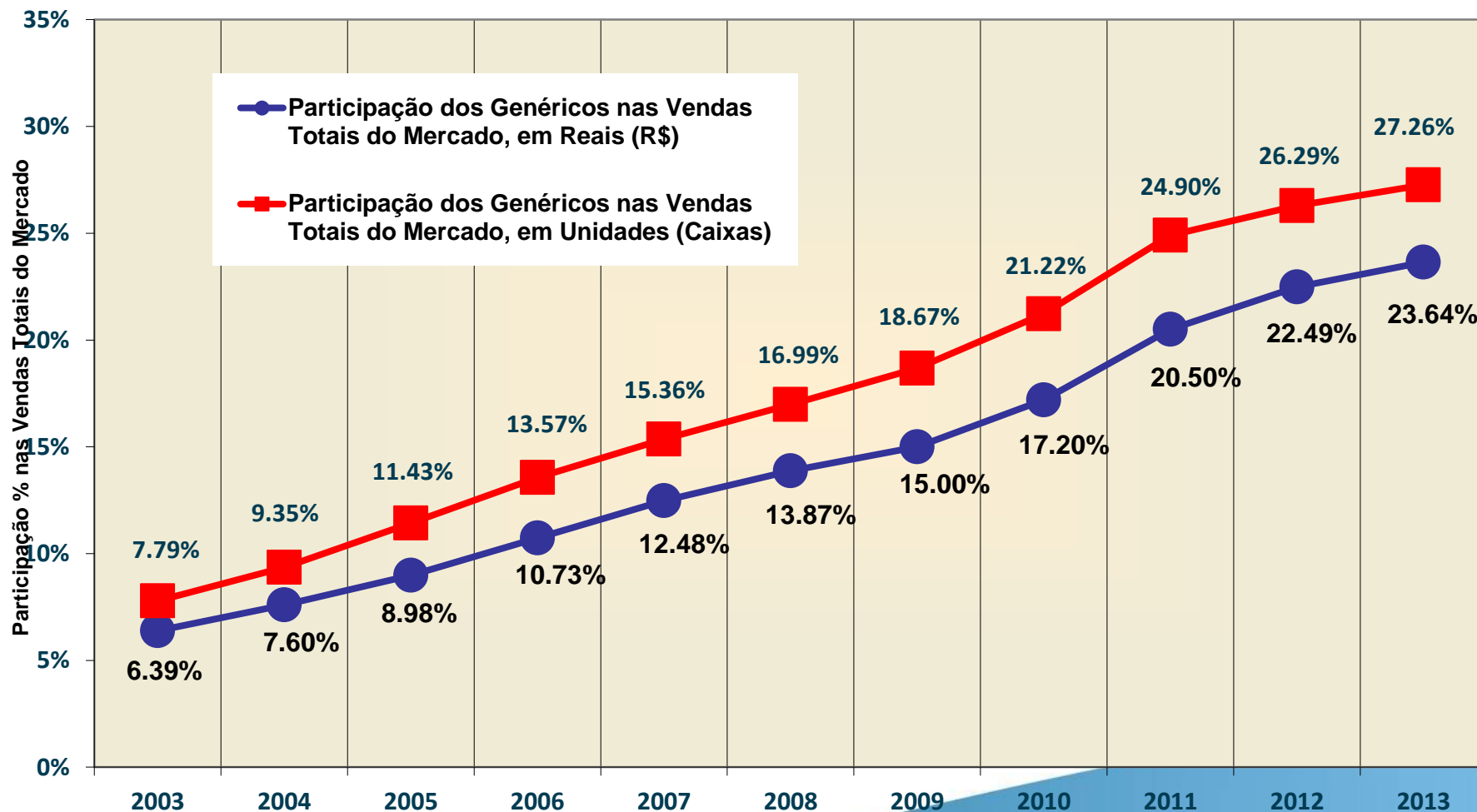
Brazilian Generics Human medicines - (Pharmacy Channel)

Proportion with total market

Período: 2003 a 2013



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Fonte: IMS Health

Elaboração: Sindusfarma / Gerência de Economia

2012 (1)

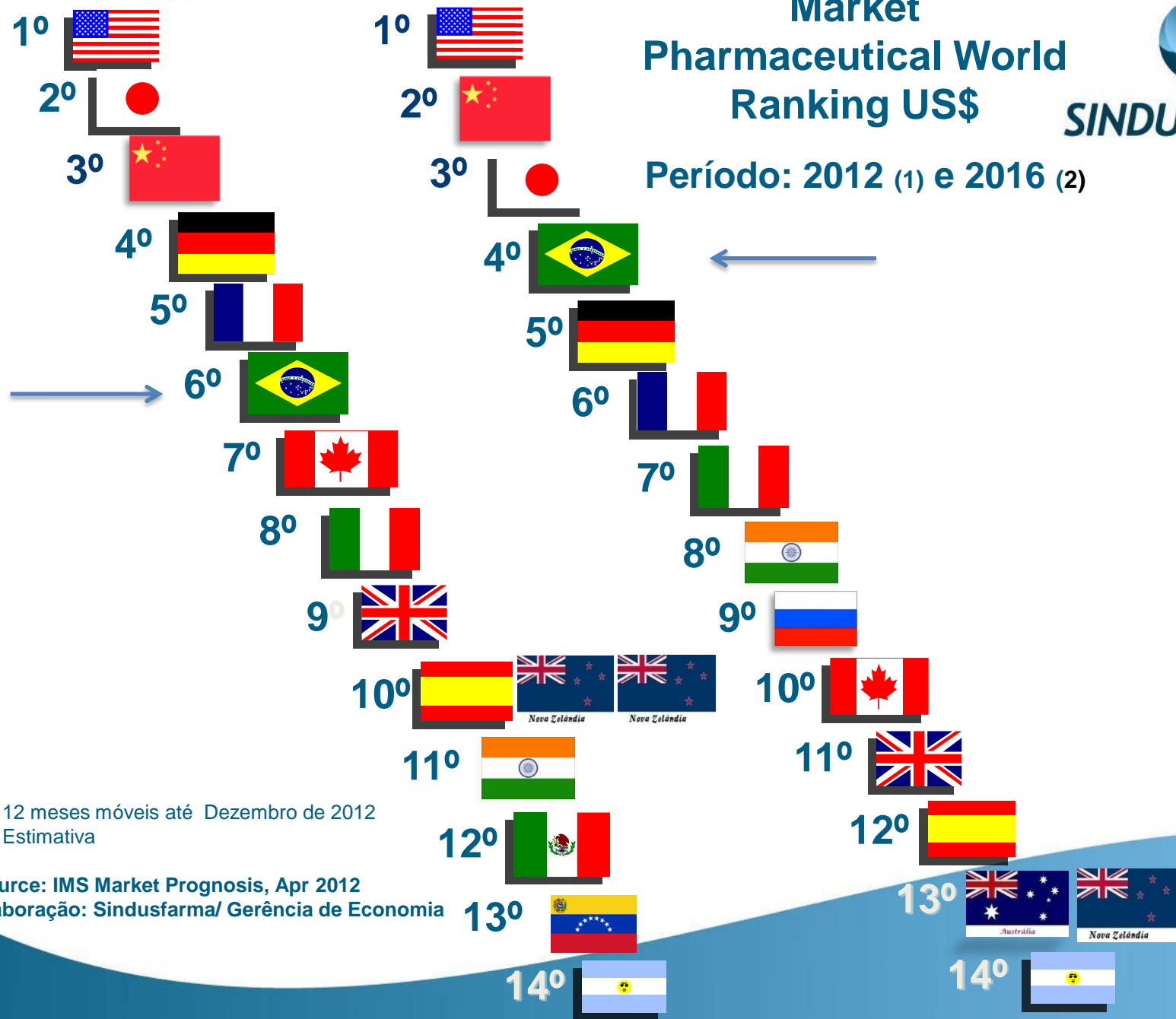
2016 (2)

Market Pharmaceutical World Ranking US\$



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Período: 2012 (1) e 2016 (2)



(1) 12 meses móveis até Dezembro de 2012
(2) Estimativa

Source: IMS Market Prognosis, Apr 2012
Elaboração: Sindusfarma/ Gerência de Economia

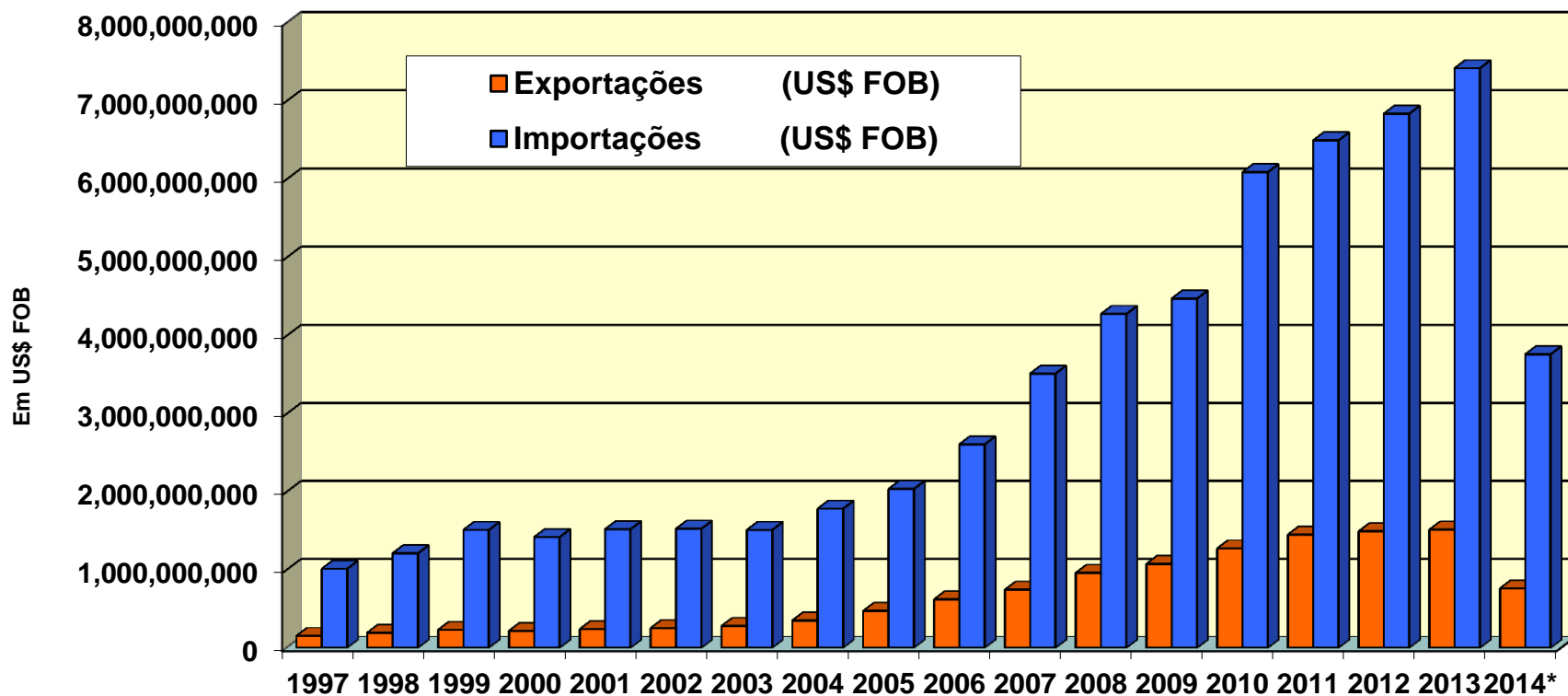
PHARMACEUTICAL PRODUCTS - CHAPTER 30 OF NCM

Evolution of Brazilian Exports/Imports - Period: 1997-2014



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PRODUTOS FARMACÊUTICOS - BALANÇA COMERCIAL EXPORTAÇÕES E IMPORTAÇÕES BRASILEIRAS - CAPÍTULO 30 DA NCM PERÍODO: 1997 a 2014* - EM US\$ FOB



Fonte: MDIC/Secex/Sistema Alice
Elaboração: Sindusfarma / Gerência de Economia

* Acumulado até Junho de 2014

Brazilian Pharmaceutical Industry Legislation



Requirements for drug market authorization

- ✓ *Innovators – RDC 136/2003*
- ✓ *Generics – RDC 16/2007*
- ✓ *Similar – RDC 17/2007*
- ✓ *Specifics – RDC 132/2003 (OTC included)*
- ✓ *Biologics – RDC 315/2005*
- ✓ *Phytotherapics – RDC 14/2010*
- ✓ *Homeopathics – RDC 26/2007*

Brazilian GMP evolution



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- ✓ ***1995: GMP Inspection – Resolution SVS Nº 16/1995, according WHO 1975.***
- ✓ ***2001: GMP Inspection – Resolution Anvisa nº 134/2001, according WHO 1992 and Mercosur.***
- ✓ ***2003: GMP Inspection – Resolution Anvisa nº 210/2003, according WHO 1992 – with local proposals***
- ✓ ***2010: GMP Inspection – Resolution Anvisa nº 17/2010 according WHO 2006 – with local proposals***

Convergences efforts Brazil – Japan related to efficacy, safety and quality of medicines.



- ✓ To learn how could be points of convergences in order to reduce asymmetries in:
 - ✓ Good Manufacturing Practices
 - ✓ Good Distribution Practices
 - ✓ To know the PMDA initiatives related to track and trace of medicines;
 - ✓ To learn how could be implemented the PIC/S to perform inspection extra-zone.

Convergences efforts Brazil – Japan related to efficacy, safety and quality of medicines.



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- ✓ To learn how could be points of convergences in order to reduce asymmetries in:
 - ✓ To know the different categories of medicines and how could be criteria to establish convergences related to have drug market authorization;
 - ✓ To learn how PMDA are conducting knowledge related to safety and efficacy of essentials and non essentials amino acids used in food supplements;
 - ✓ To study the convergences and eventual asymmetries phamacovigilance system;
 - ✓ To learn how could be a process for the cooperation between Brazilian and Japanese Pharmacopeia.

Convergences efforts Brazil – Japan related to efficacy, safety and quality of medicines.



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- ✓ **To learn how could be a cooperation between PMDA – ANVISA in order to contribute for a program to include ANVISA in the ICH concern, considering to attend contingency demand of Japan;**
- ✓ **To establish a continuous cooperation process between PMDA – ANVISA to reduce regulatory asymmetries.**

Tornando acessível o saber

PES - Programa Educacional Sindusfarma

Com uma ampla gama de ações voltadas para a difusão do conhecimento e a educação continuada, o Sindusfarma atende à demanda da indústria farmacêutica pelo aperfeiçoamento contínuo de seus profissionais.

SINDUSFARMA EDUCATIONAL PROGRAM



PES – Sindusfarma Educational Program



SINDUSFARMA

Sindusfarma is a pioneering entity in the publication of manuals and books for the Pharmaceutical Industry oriented to occupational safety issues. Collection with 14 volumes.

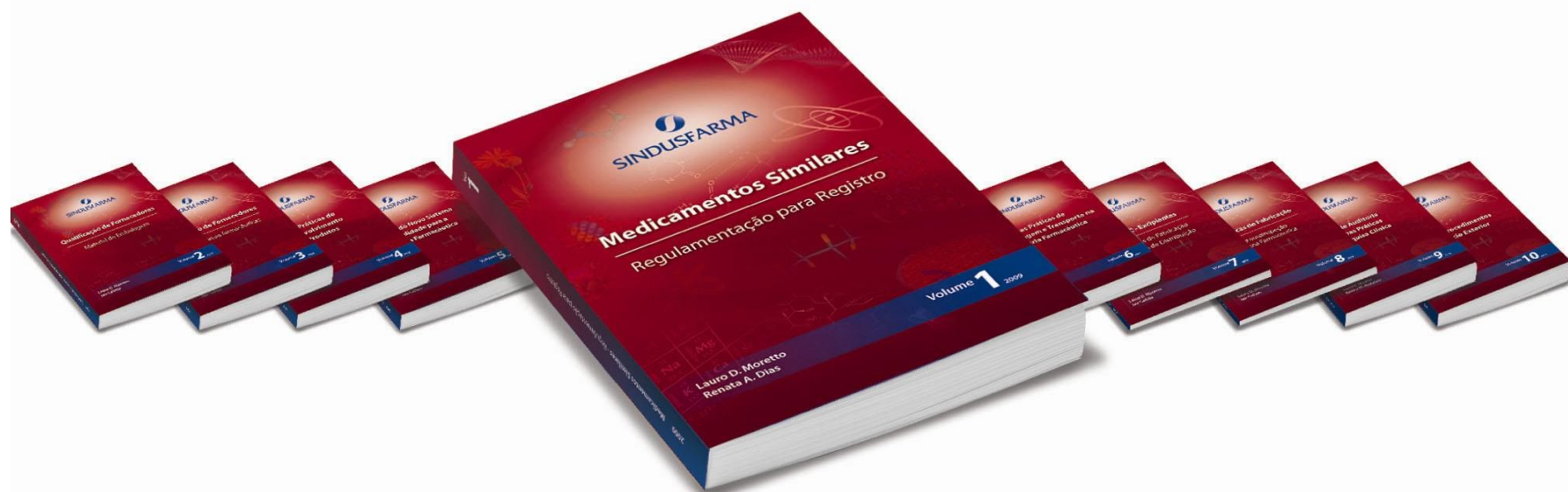


PES – Sindusfarma Educational Program



SINDUSFARMA

Sindusfarma is a pioneering entity in the publication of manuals and books for the Pharmaceutical Industry, particularly on technical-regulatory issues. Collection with 20 volumes.



PES – Sindusfarma Educational Program



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TRIBUTARY COLLECTION

ARRECAÇÃO FISCAL NO BRASIL 2005 A 2011

Análise de evolução dos tributos e sua
relação com os indicadores e eficiência
econômicos de arrecadação do Estado

Marie Cristine Sanchez Amorim
Ronaldo Antônio Gonçalves
Eduardo Bueno de Fozes Parillo

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Arrecadação Fiscal no
Brasil: 2005 à 2011

REDUÇÃO DO ICMS SOBRE MEDICAMENTOS

Marie Estuda os impactos sobre os
medicamentos ao consumidor após a redução
do alíquota do ICMS no Estado do Paraná,
e os reflexos na arrecadação deste tributo.

COORDENAÇÃO GERAL
Gilberto Luiz do Amaral

PARTICIPANTES
Júlio César Oliveira
Leticia Mary Ferraz de Azevedo
Fernanda Sornowich

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Redução do ICMS
sobre Medicamentos

AMPLIANDO A INSERÇÃO INTERNACIONAL DOS SETORES FARMOQUÍMICO E FARMACÊUTICO BRASILEIROS: ALTERNATIVAS ESTRATÉGICAS

Virgínia Eichhoff Paang
Helo Heekin

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abiquifé

ApexBrasil

Ampliando a Inserção Internacional
dos Setores Farmoquímico
e Farmacêutico Brasileiros:
Alternativas Estratégicas

INICIAÇÃO À CLASSIFICAÇÃO FISCAL DE PRODUTOS DA INDÚSTRIA FARMACÊUTICA E CORRELATAS NA NOMENCLATURA COMUM DO MERCOSUL

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Iniciação à Classificação Fiscal
de Produtos da Indústria
Farmacêutica e Correlatas
na Nomenclatura
Comum do Mercosul

Sindusfarma Institutional Books



Edições Comemorativas - *Commemorative Publications*



Livro 25
Janeiros -
1997



Sindusfarma -
7 Décadas -
2003



Sindusfarma -
Trajetória de Ideais
e Conquistas - 2006



A Era Educacional
do Sindusfarma -
2009



Colar Cândido Fontoura
do Mérito Industrial
Farmacêutico - 2011



15 Anos de História -
Prêmio Sindusfarma
de Qualidade - 2011



Sindusfarma
80 anos
2013



The “Cândido Fontoura do Mérito Industrial Farmacêutico Collar” is intended to honor those personalities who stand out for rendering significant services to the industrial pharmaceutical sector and to associative entities of the Pharmaceutical Industry in Brazil.



2009



2009



2010



2011



2012



2013



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The Sindusfarma Quality Award is a recognition for the previous year's outstanding pharmaceutical companies and suppliers, in different categories, to reach the quality standards required by the sector.





Boomerang award
GST award
PES award



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The Boomerang Awards for best practices in training and development, recruiting and selection is a recognition of the efforts of our members in these activities.

GST – Work Health and Safety Management, commitment to compliance with the Regulatory Standards issued by the Labor Ministry, which reflects in the reduction of occupational accidents.

Ceremony – MAM (Modern Art Museum) – August 15th, 2012.





Promotes integration among the professionals of member companies, encourage and stimulate and reward sports teams and individual winners.

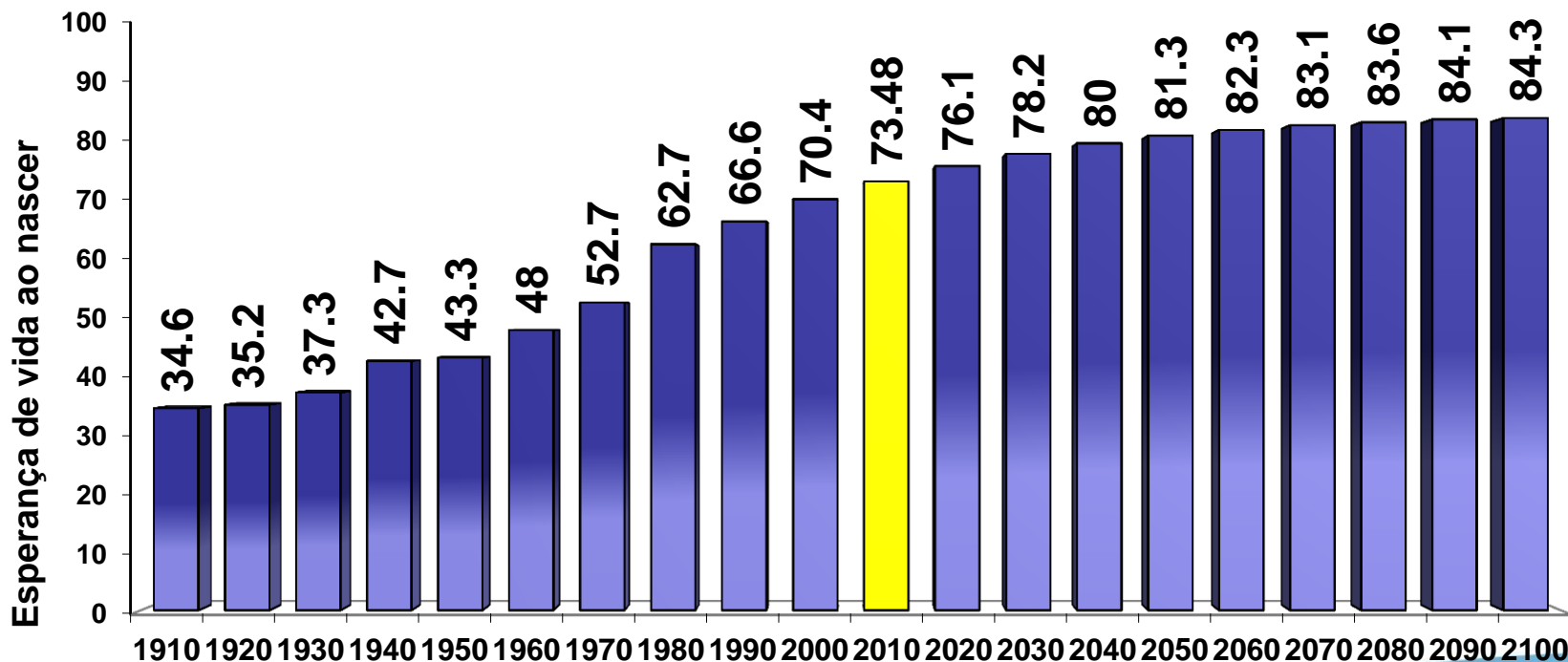
It is an annual event with games and exhibits, under the slogan "**Healthy Living is our movement.**"



Brazil – Life Expectation



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Fonte: IBGE, Censos Demográficos 1910-2000 e Projeção da População do Brasil para o Período 1980-2050.

Elaboração: Sindusfarma/ Gerência de Economia

Conclusions



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- ✓ The “1st Brazil-Japan Seminar on pharmaceuticals and medical devices regulations Time Line” is a real opportunity to joint both ANVISA & PMDA to learn with each other to reach more benefits for Brazilian and Japanese population;
- ✓ To start a process of cooperation with identification of regulatory asymmetries and convergences;
- ✓ To establish a project to increase commercial trade and cooperation for R&D of medicines.



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Obrigado!/Thank you!

www.sindusfarma.org.br

Lauro D. Moretto

Executive Vice President

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