

Pharmaceutical Industry in Brazil

A green outline map of Brazil is centered on the page. The text 'Pharmaceutical Industry in Brazil' is overlaid on the map. The map is filled with a light yellow color, and the text is in a bold, blue, sans-serif font.

Josimar Henrique da Silva
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josimarhenrique@febrafarma.org.br

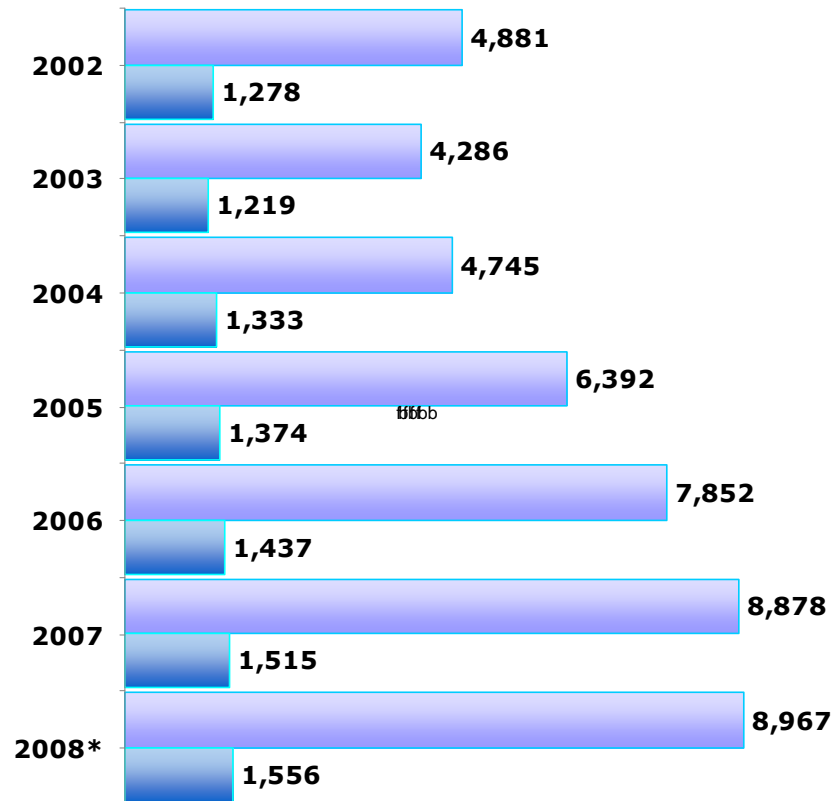
Global Pharmaceutical Market (12 months - December 2007 – Retail Sales)

| Country | Sales 2007 – in Billions of EUR | % of Total Share |
|------------------------------|------------------------------------|------------------|
| North America | 161,384 | 52,86 |
| United States | 150,020 | 49,13 |
| Canada | 11,364 | 3,72 |
| Europe (Top 5) | 78,905 | 25,84 |
| Germany | 23,067 | 7,55 |
| France | 21,388 | 7,00 |
| United Kingdom | 12,745 | 4,17 |
| Italy | 11,680 | 3,83 |
| Spain | 10,025 | 3,28 |
| Japan | 42,6999 | 13,98 |
| Latin America (Top 3) | 17,169 | 5,62 |
| Brazil | 8,878 | 2,91 |
| Mexico | 6,332 | 2,07 |
| Argentina | 1,959 | 0,64 |
| Australia / New Zealand | 5,178 | 1,70 |
| Total | 305,335 | 100,00 |

Source: IMS Health - World Drug Purchases

Pharmaceutical Industry Total Sales (Drugstore; Pharmacy Channel) Amounts X units

**EUR (bi)
Units**



Source: IMS Health

(*)Moving average last 12 months – until May 2008

The Sector's Agenda

Access to Medication

Optimization of Governmental budget earmarked for medication; partnerships with the private sector.

Industrial Development

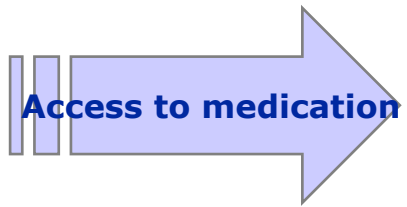
Definition of clear rules and regulations for the economic-sanitary regulatory framework; compliance with intellectual property and its agile enforcement. Industrial policies.

Tax Burden

Cutting taxes down and transferring savings to consumers. Single ICMS tax rate applicable all over the country. Taxation reform.

Regulation of the Economy

Flexibility in price control, mainly in most competitive, non discretionary items (non essential to health). Cooperation mechanism between industry and Government to increase the population access to medication.

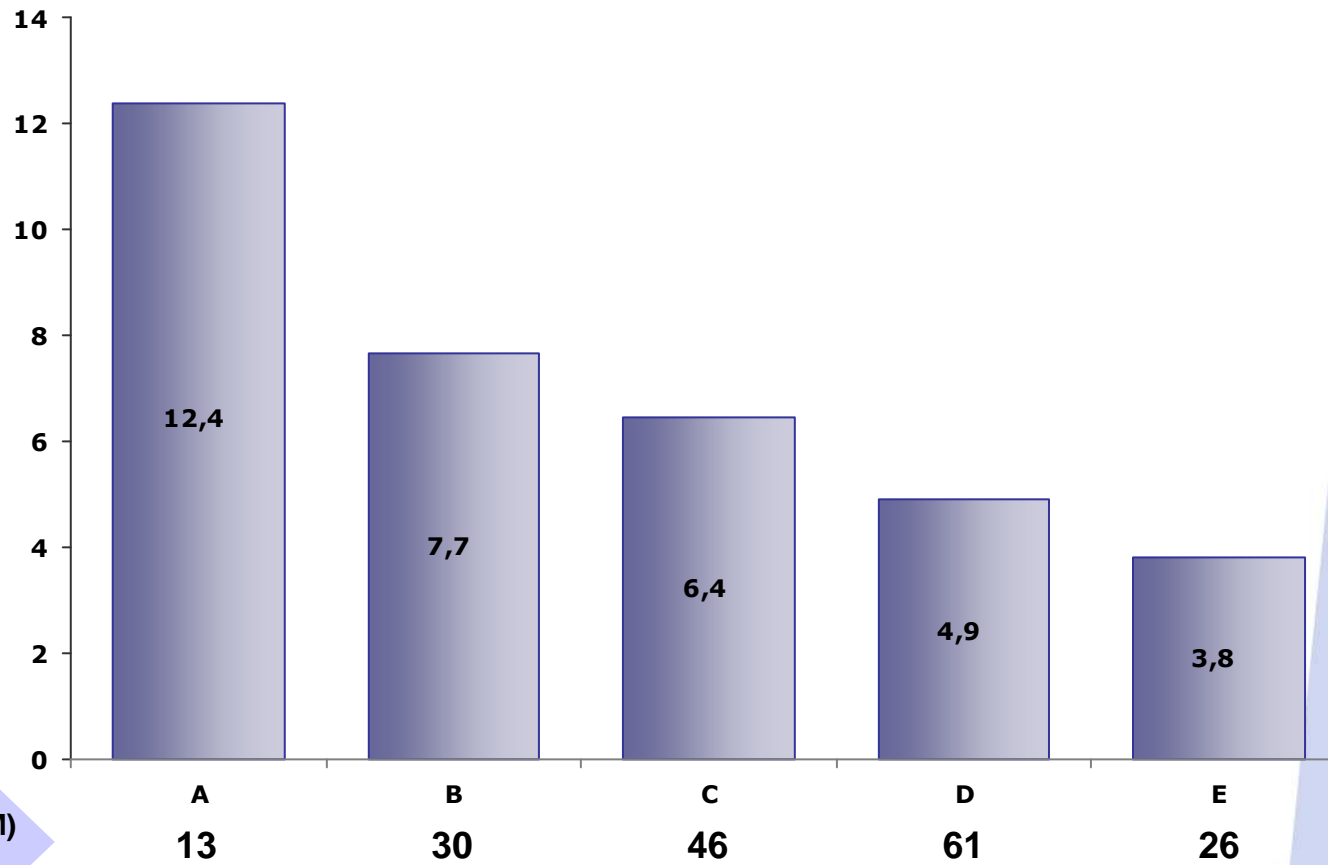


The Sector's Agenda

Lower-income social strata with restricted access to medication

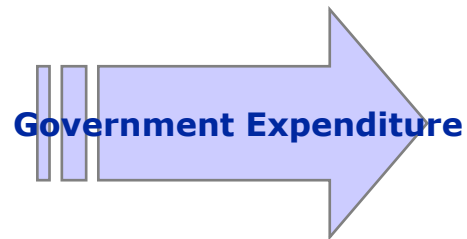
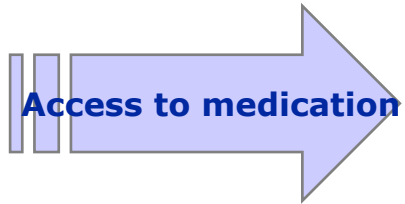
EUR per capita
per month)

Total Market



Total Population I (M)
 $\Sigma = 177M$

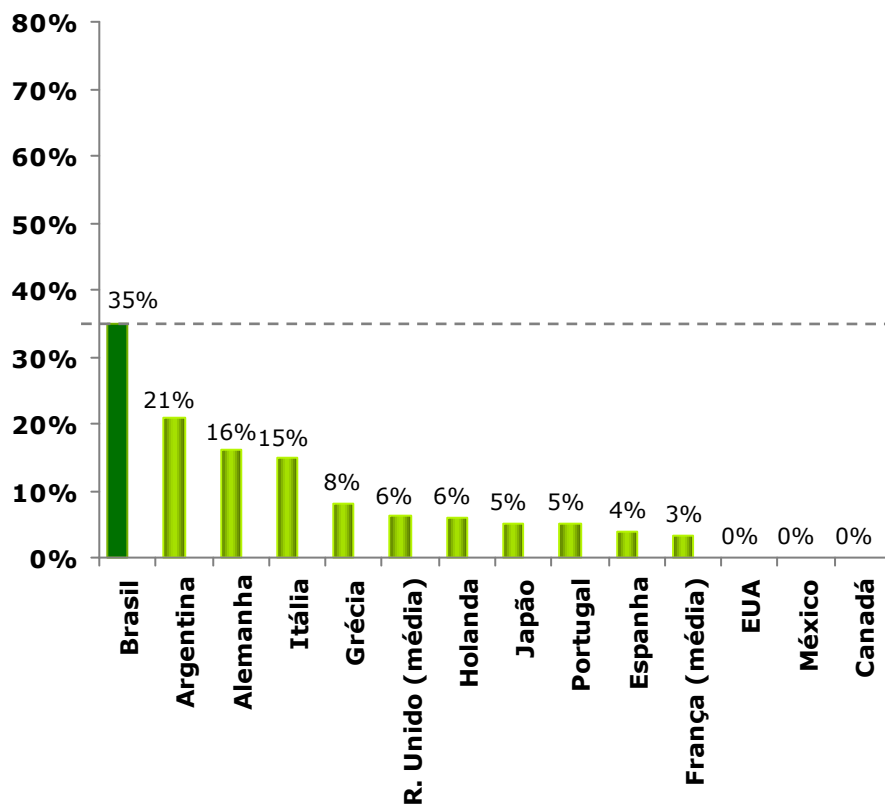
The Sector's Agenda



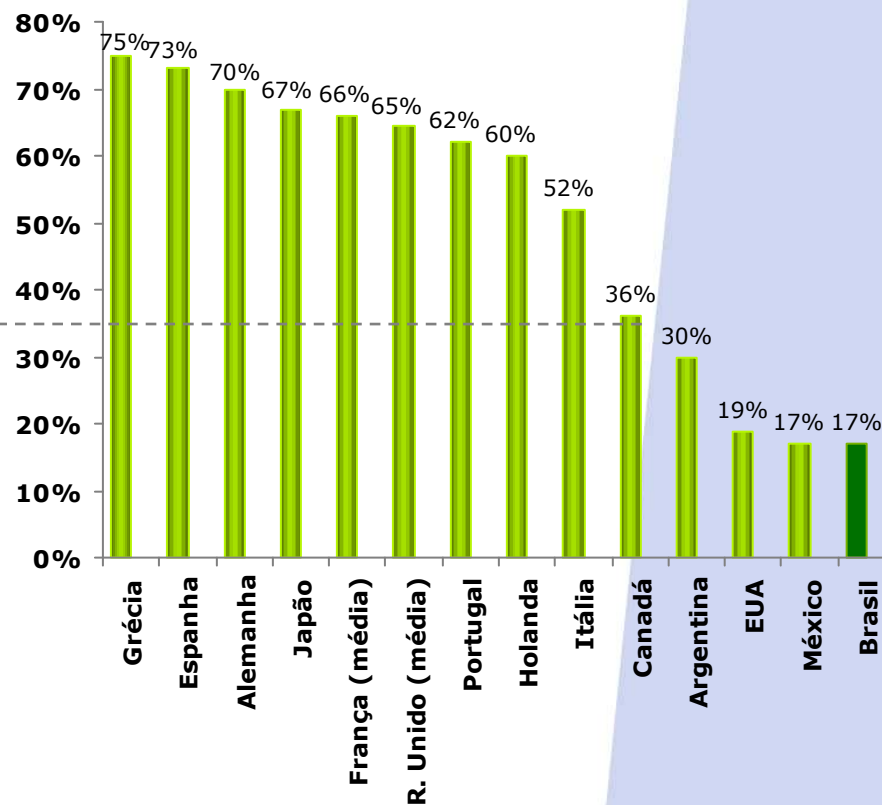
Among the reference countries, Brazil is the only one that spends less with medication than its taxation income.

Brazil is the only country that spends less with medication than its taxation income from medication

Income from taxation on medication



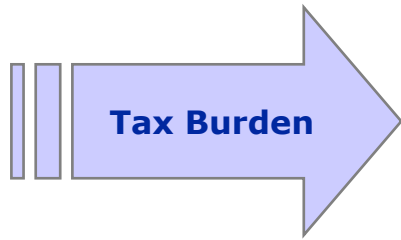
Expenditure with medication (% of total market)



Note: For Germany and Italy it was considered the total taxation income from pharmaceutical sales, including government expenditure. For the remaining countries, it was used the same taxes as in medication. In cases where there are different tariffs (France, for instance: 5.4% for non-reimbursed drugs and 2.1% for reimbursed ones; UK, 7.5% for non-reimbursed drugs, 0% for reimbursed drugs; and Sweden: 25% for non-reimbursed drugs and 0% for reimbursed ones, it was used an average of the tax amounts.

Source: OCDE Health, BCG Knowledge Group, BCG Analysis

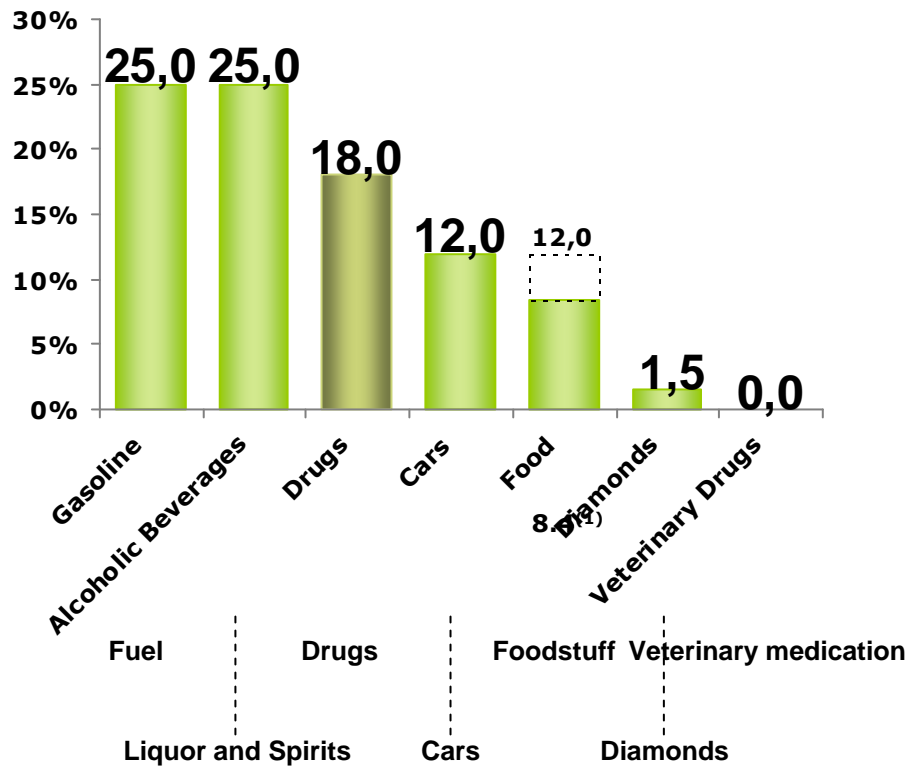
The Sector's Agenda



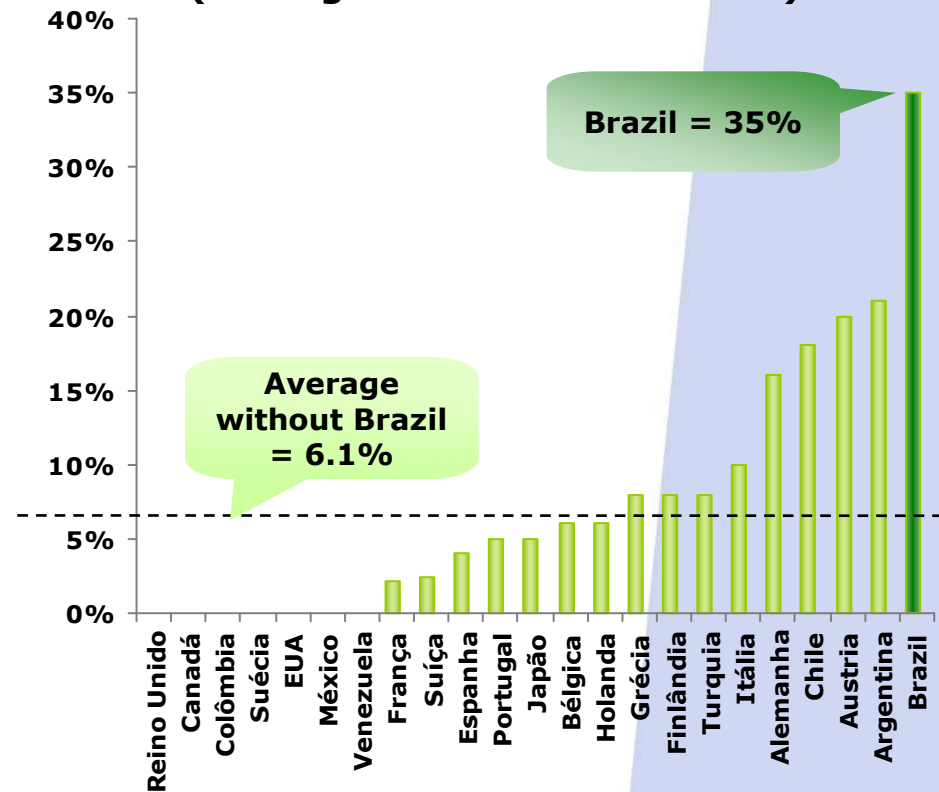
Brazil has the highest tax burden among reference countries.

Taxes levied on medication in Brazil are far beyond other reference countries

ICMS Tax on some products in the state of São Paulo



Taxes on medication in some countries (Average tax burden for Brazil)



Three possible alternatives:

- ICMS exemption with transfer to consumers
- Single ICMS tax rate throughout the country
- Tax collection at the beginning of the chain

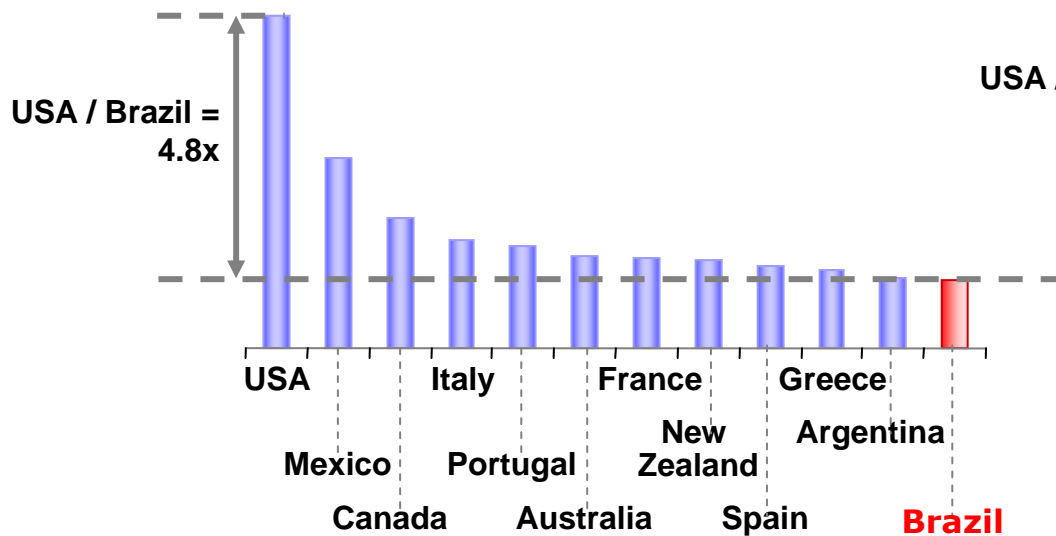
(1) Average



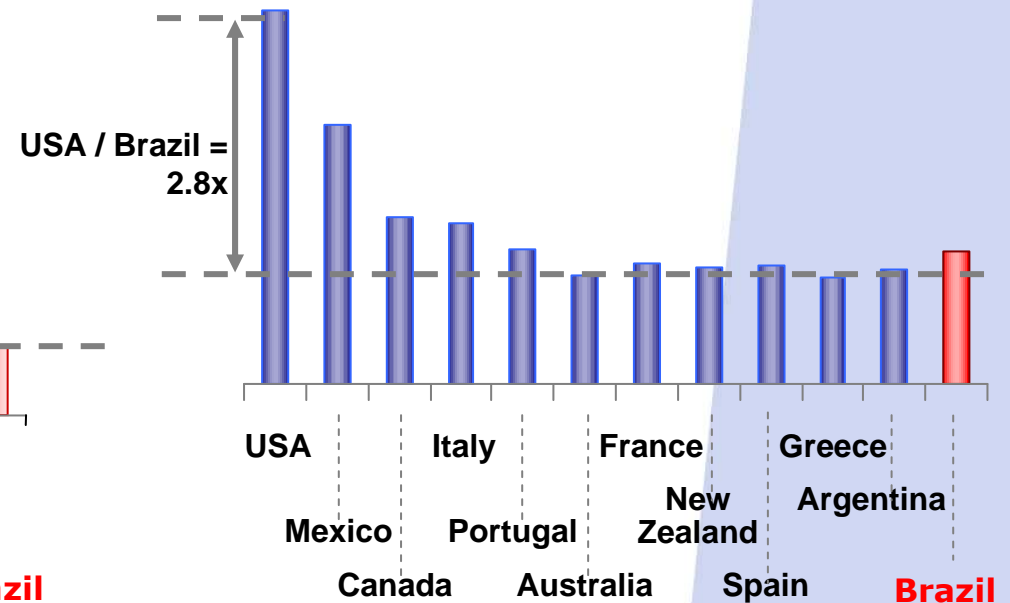
Brazil manufactures medication at low-cost, by this efficiency is not transferred to consumers



Manufacturer's price



Retail prices



Note: Medication: Effexor, Prozac, Zoloft, Generic Fluoxetine, Lexotan, Rivotril, Celebra, Vioxx, Voltaren, Amoxicillin, Viagra, Cialis, Lipitor, AdalateNorvasc; prices as per exchange rate in June 2004

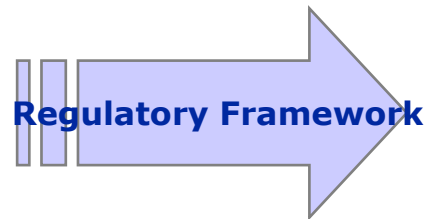
Fonte: IMS PMB; Talogdata; Interfarma; Anvisa; MoH; PMPRB; Rmianz; SFEE; análise BCG



The Sector's Agenda



Definition of clear rules and regulations for the economic-sanitary regulatory framework; compliance with intellectual property and its agile enforcement. Industrial policies.



Research-related regulatory issues: Conep, Inpi, Anvisa.

Definition of price readjustment.

Rules for launching new products.

Medication registration: Uniformity of criteria, terms and tax rates.

Patent analysis and awarding: Anvisa's agreement, terms and data protection.

Transfer prices: Alignment with international rules (OECD).

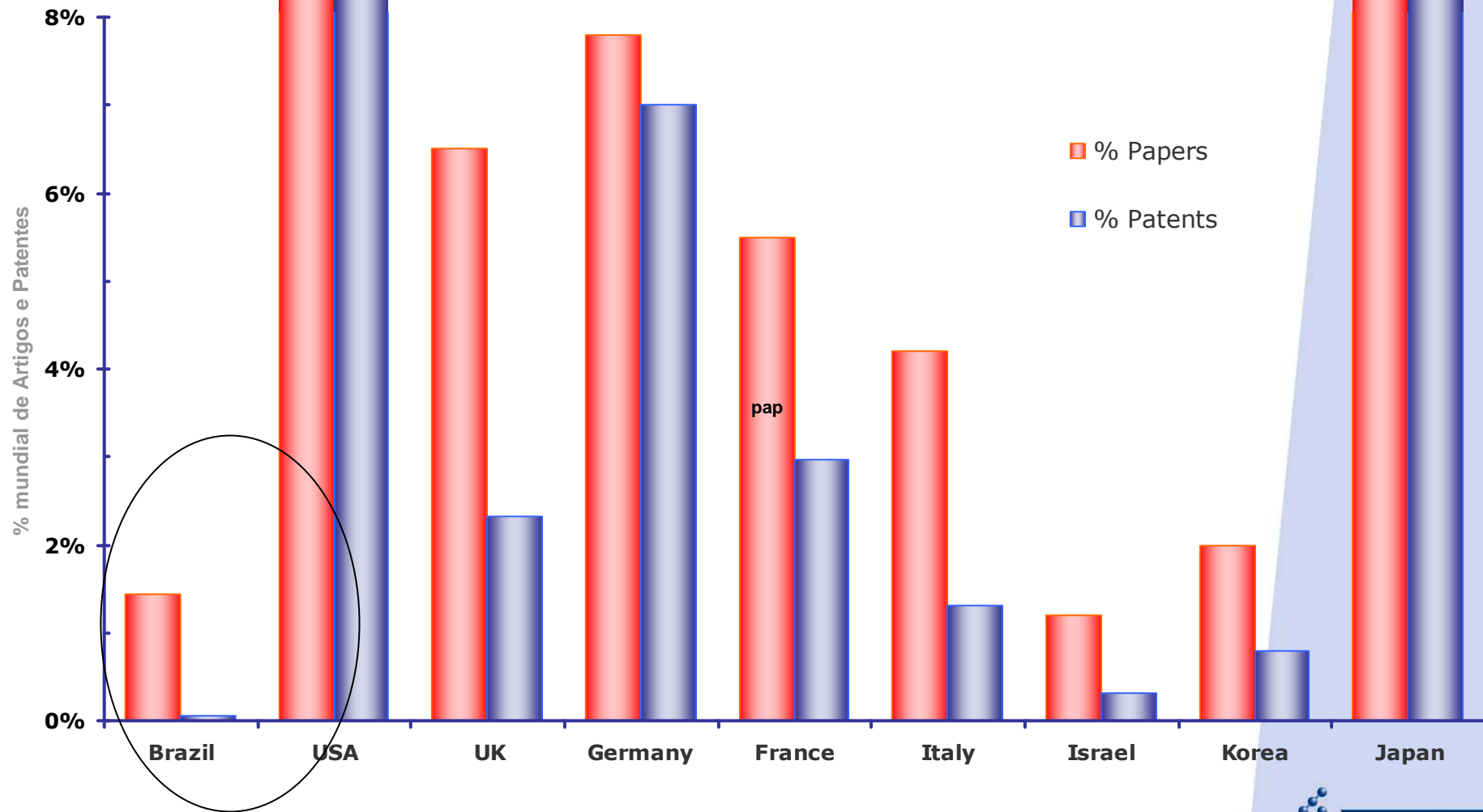
10 Largest Universities (Per number of PhDs)

Doctoral Papers Presented

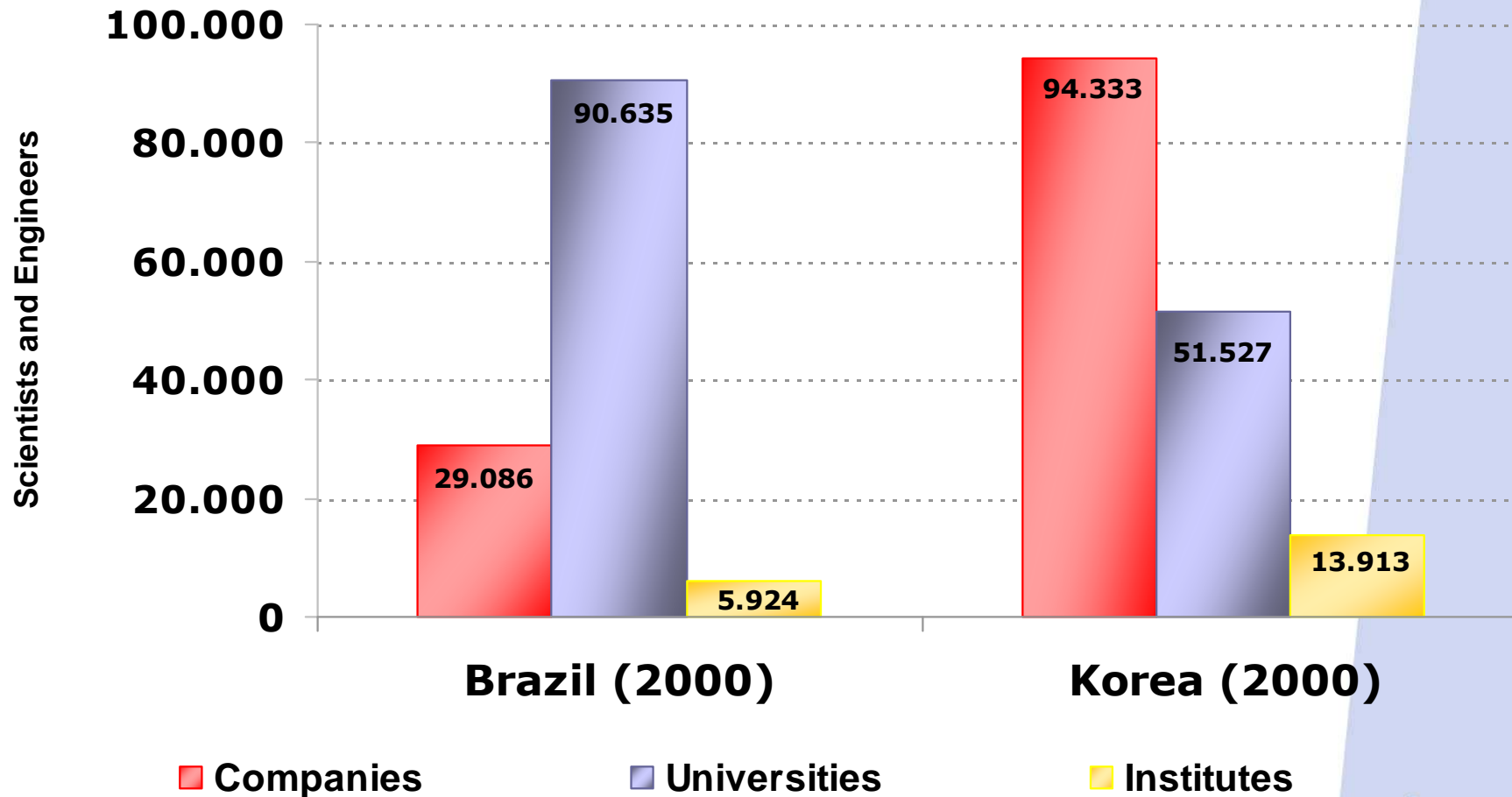
| | | |
|-----|--|--------------|
| 1. | Universidade de São Paulo - USP | 2,180 |
| 2. | Universidade da Califórnia, Berkeley | 767 |
| 3. | Universidade de Campinas – UNICAMP | 747 |
| 4. | Universidade New Southeastern | 675 |
| 5. | Universidade do Texas, Austin | 674 |
| 6. | Universidade do Estado de São Paulo - UNESP | 663 |
| 7. | Universidade do Wisconsin, Madison | 653 |
| 8. | Universidade Federal do Rio de Janeiro - UFRJ | 643 |
| 9. | Universidade do Illinois, Urbana Campus | 618 |
| 10. | Universidade de Michigan | 615 |

Adapted from Brito Cruz, 2005

Scientific Papers and Patents



Brazil and Korea: Scientists and Engineers



Source: Br 1996: Anpei, INEP; Br 2000: MCT, Inep; Korea: <http://www.most.go.kr/>

Research in Phytotherapy

- **20 big and medium sized companies produce phytotherapeutic medicines (Under ANVISA standards edict - RDC 48 and attachments);**
- **Gross sales US\$ 550 mi;**
- **Estimated US\$ 1 bi in 2010.**

Amazon:

20% of all sweet water in the planet

35% of vegetables superior species

There are 220 thousand new living organisms already catalogued in the country.

Why do we have such good scientific production and so few patents/products ?

- Lack of investments
- Gap between University and Industry
- Lack of articulated structure
- Lack of political decision-making
- Lack of legal assurance

The Sector's Agenda



Definition of clear rules and regulations for the economic-sanitary regulatory framework; compliance with intellectual property and its agile enforcement. Industrial policies.

The Sector's Agenda



**Regulation of the
Economy**

Flexibility in price control, mainly in most competitive, non discretionary items (non essential to health).

Cooperation mechanism between industry and Government to increase the population access to medication.



**Price Access and
Control Initiatives**

Price Control is not the ideal mechanism to discipline the market and control disbursements.

It is inefficient to expand access.

Other government initiatives have proven ineffective to expand access.

Topic:

Main Challenges:

Government expenditure

Optimization of Government budget earmarked for medication; partnerships with the private sector.

Regulatory framework

Definition of clear rules and regulations for the economic-sanitary regulatory framework; compliance with intellectual property and its agile enforcement. Industrial policies.

Tax Burden

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Price Access and Control Initiatives

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Febrafarma

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