

IBSA

***HEALTH INNOVATION AND
ACCESS TO ESSENTIAL
MEDICINES***

Brasília, April 13th 2010

Industrial Health Complex and Innovation
Secretary of Science, Technology and Inputs
Ministry of Health



SUS – Unified Health System

SUS Characteristics

1. **Universality:** SUS, as the Brazilian public system, provides healthcare for all, regardless of distinctions and restrictions;
2. **Unity:** one system composed of decentralized unities managed by different governmental levels (Federal, State and Local/Municipal)



SUS – Unified Health System

SUS Indicators

- 70% of the Brazilian population depend on SUS
- 5,900 hospitals
- 64,000 primary care units
- 2,3 billion ambulatory appointments
- 12 million hospital admissions
- 9 million chemo- and radiotherapy procedures
- 300 million laboratory tests
- 1 million CT scans and 160,000 MR
- 6.5 millions echographies
- 8 million hemodialyses procedures



The Health Dimensions

Relation between health and economic development



Dynamic and virtuous process

=

To improve the population living standards +

To allow the economical growth +

To promote structural productive changes

Adapted from Viana, A.L.D. e Elias, P.E.M – *Ciência & Saúde Coletiva* nov. 2007



Industrial Development Context

Brazilian Health Productive Chain

- Health as a promoter of citizenship rights as well as of investments, innovations, income and employment
- Represents 8% of the GDB
- Expenditures surpass US\$ 100 billion/year
- Important source of tax incomes
- Employs 10% of the work force
- Target of most of R&D expenditures



Pharmaceutical market emerging countries

- The Rapid Expansion markets are Brazil, Russia, India, China, South Korea, Mexico and Turkey, at a growing basis of 15% per year;
- These countries are benefiting from government spending on healthcare;
- The main focus of pharmaceutical industry's are the high-growth emerging markets
- The emerging markets demand for innovative medicines.
- The challenge for these countries is to extend health access to all the population.



Industrial Development Context

To overcoming structural bottlenecks

**Growth
Acceleration
Program (PAC)**

Promote R, D&I development

**Science,
Technology and
Innovation Plan
(PACTI)**



**Productive
Development
Policy (PDP)**



**Development of
an Education Plan
(PDE)**

"Mais Saúde"



*To promote education
progresses*

*To attack lacks and to build up
capacities*



Brazilian Health Industrial Complex



Source: Adapted from Gadelha,
2004.



Industrial Health Complex

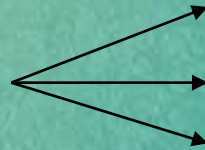
Mais Saúde

- Health as a promoter of citizenship as well as of investments, innovations, income and employment.
- Articulation with economic and sanitary system.
- Decrease the vulnerability of the National Health Policy
- Increase of competitive of public and private companies of the Health Industrial Complex.
- Investments in Official Laboratories of Medicaments in order to build a structure of public production and the transfer of technology of strategic pharminochemicals to Brazil.



SCTIE – Pharmaceutical National Policy

Spreading the access

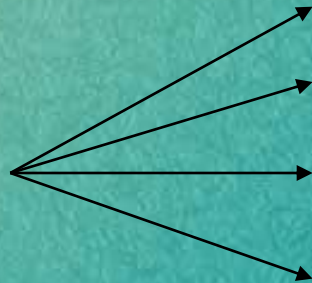


FARMÁCIA POPULAR OF BRAZIL

AQUI TEM FARMÁCIA POPULAR

DRUG FRACTIONING

Regulation



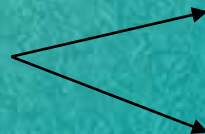
THE INCREASE OF GENERIC ON THE MARKET

REGULATION OF SPECIALIZED COMPONENTS POLITIC

PACTUATION OF CONASS AND CONASEMS IN THE BASIC PHARMACEUTICAL ASSISTANCE – NEW POLITIC

NEGOTIATION OF PUBLIC PRICES FOR STRATEGIC MEDICINES
CMED E AD HOC NEGOTIATION

Public Producers

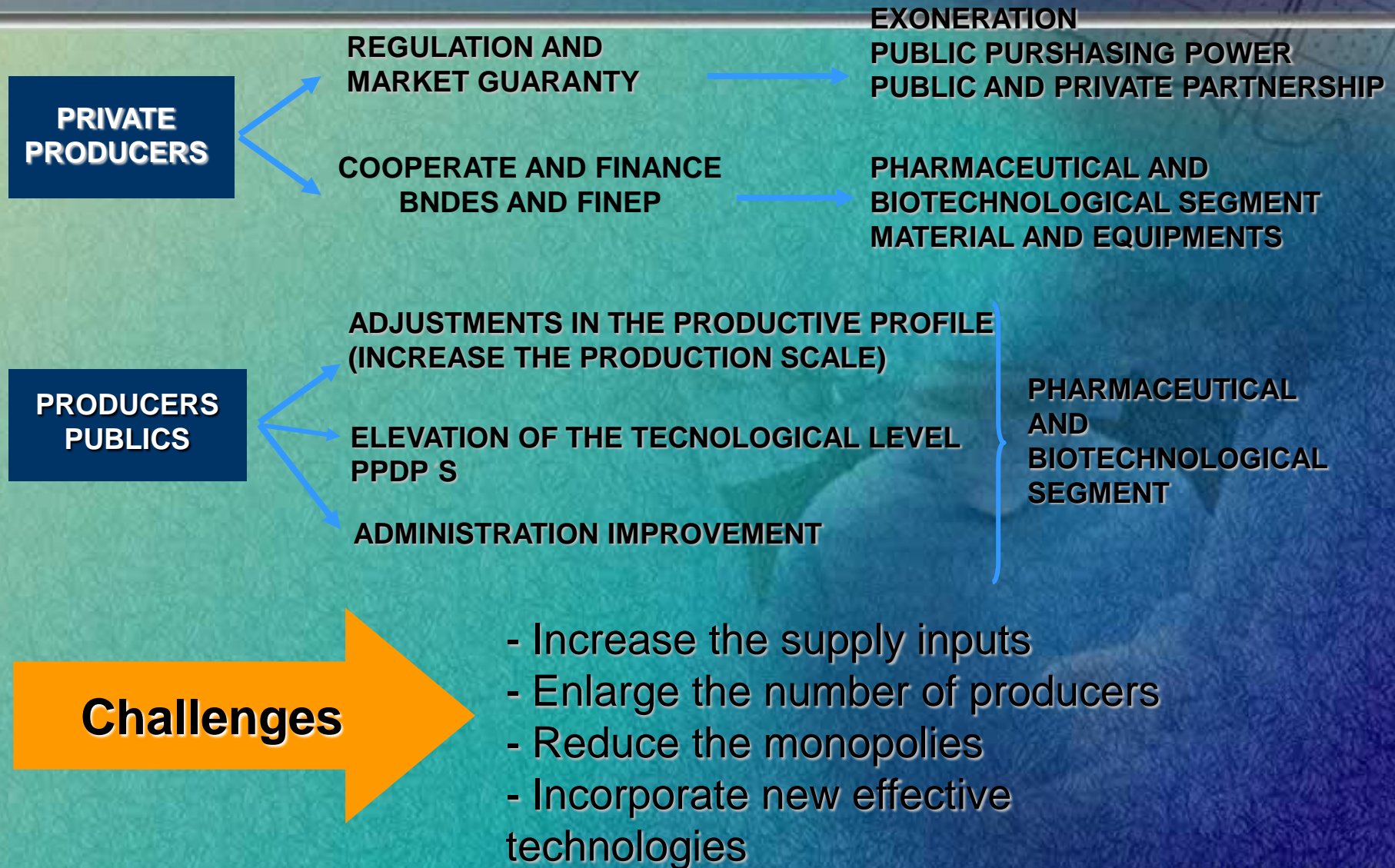


IMPROVEMENT OF THE MONITORING PROCESS OF THE SUS
MEDICINE SUPPLIES
(COOPERATION WITH DECIIS)

ADJUSTMENTS ON THE PRODUCTIVE PROFILE
- BEST PRODUCTIVE PROFILE AND INCREASING OF THE
SCALE PRODUCTION-
(IN COOPERATION WITH DECIIS)



Priorities of the Health Industrial Complex



Executive Group of the Health Industrial Complex - GECIS

- Created by Presidential Decree in 12th of May of 2008
- Goals: to promote measures and concrete actions to implement the Brazilian regulatory mark.
- Installed in 8th of August 2008 – 12 (twelve) meetings
- Members: Ministry of Health (coordinator), MCT, MDIC, MPOG, MF, MRE, Casa Civil, ANVISA, FIOCRUZ, FINEP, BNDES, INMETRO, INPI e ABDI.
- Articulation Forum: 22 civil society representatives, mainly the private industry sector
- Work Groups (11)
 - Concluded: WG Transversal Actions; WG Tributary Exemption of Mercosul and WG Government Purchase, approves partnerships and their results
 - In development: WG Biopharmaceutical Regulation; WG Tributary Issues, 3 WGs for Products and Equipments for Health care



Industrial Health Complex

Regulatory Strategies:

- Selection of Strategic Products for the Public System
- Market assurance for national companies
- Use of the Government Purchase
- Tributary Exemption
- Investment on health services
- Sanitary Regulation
- Companies qualification to supply the public market
- Industrial Property Policy



Industrial Health Complex

Regulatory Instruments:

- Ministerial Ordinance n°. **978/08** (review), disposes on the priority list of strategic products for CIS and SUS, focused on:
 - - Neglected diseases
 - - High cost medicines
 - - New biopharmaceuticals produced by biotechnological route
- Interministerial Ordinance n°. **128/08** (MS, MCT, MDIC and MPOG) Establishes guidelines for public acquisition of pharmaceuticals for the SUS.
- MS Ordinance n° **3031/08** – Establishes criteria to be considered by the Official Laboratories on their raw material acquisition process (guideline to the acquisitions of national pharminochemical inputs).
- MS Ordinance n° **374/08** – Establishes, for the Public Health System field, the National Investment Program to Stimulate the National Production and the Innovation of the Industrial Health Complex.



Industrial Health Complex

Institutional Articulation:

- The Brazilian Development Bank (BNDES/MDIC) - Cooperation Term for developing of programs and research in order to strength the Industrial Health Complex (signed in December 2007).
- The Brazilian Innovation Agency (FINEP/MCT) – Investment on R&D strategic areas for the Industrial Health Complex. It is being invested about R\$ 102 millions in the 2009- 2010 period.



Industrial Health Complex

Tributary Exemption:

- **Mercosul:** Fastening tributary exemption and the return to the taxes adopted by the Common External Tariff (TEC) to strategic medicines and pharmaceuticals, which allows the products not made in Mercosul countries to have a possibility of import taxes reduction till 0%, under special conditions. This benefit must return to their original import rates when made in a Mercosul country – Brazilian Proposal in discussion on Mercosul.
- **Pharmaceutical Industry:** Presenting a proposal based on federal taxes which is focused on the reduction of the PIS/COFINS taxes, in order to avoid extra credit. However, the most significant cost is related to the ICMS, which is the most important Government resource.
- **Products and Equipments for the Health Care Sector:** Preliminarily, still in discuss, involves the articulation of institutions in order to improve the classification of imported products and, consequently, the exemption tributary issues.
- **Exemption of taxes of strategic products**





MARKET DATA
Industrial Health Complex



Health Industrial Complex to overcome

- **Growing commercial deficit of the Health segment**
 - US\$ 700 million/year at the end of the decade of 80,
 - US\$ 7,21 billion in 2008,
 - US\$ 7,14 billion in 2009
 - Products of high knowledge density and technology.
- **Loss of international competitiveness of the industry**
 - Extreme dependency in strategic sectors, in technology as well as basic health needs.
- **Fragility of the Health Industrial Complex**
 - Vulnerability for the Unified Health System (SUS) damaging the well-being of the population



Industrial Health Complex

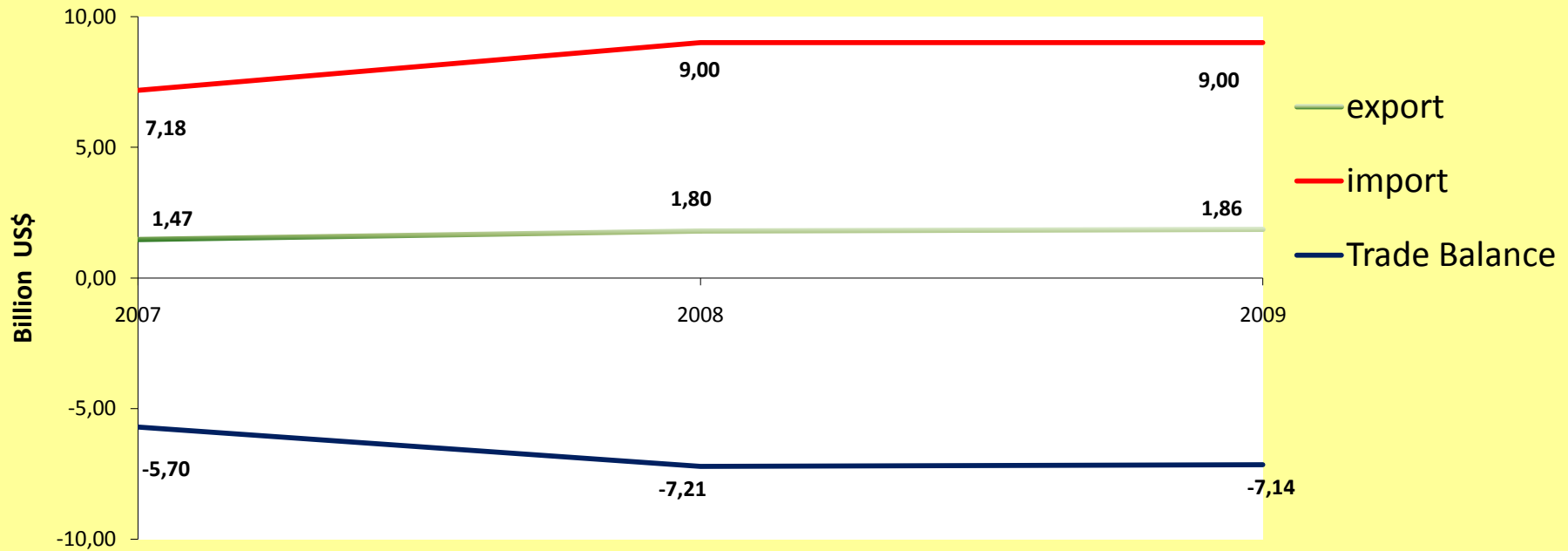
Biological Setor:

- **Vaccines, seruns and hemoderatives:**
 - **Imports:**
 - US\$ 50 million in 1989
 - US\$ 1,4 billion in 2008
 - US\$ 1,5 billion in 2009
 - The most significant products are of high density, knowledge and technology
 - **Exports:**
 - US\$ 1,5 million in 1989,
 - US\$ 37 million in 2008
 - US\$ 42 million in 2009
 - Reduce significance of products of high aggregated-value.



Health Trade Balance

Health Trade Balance (2007/2009)

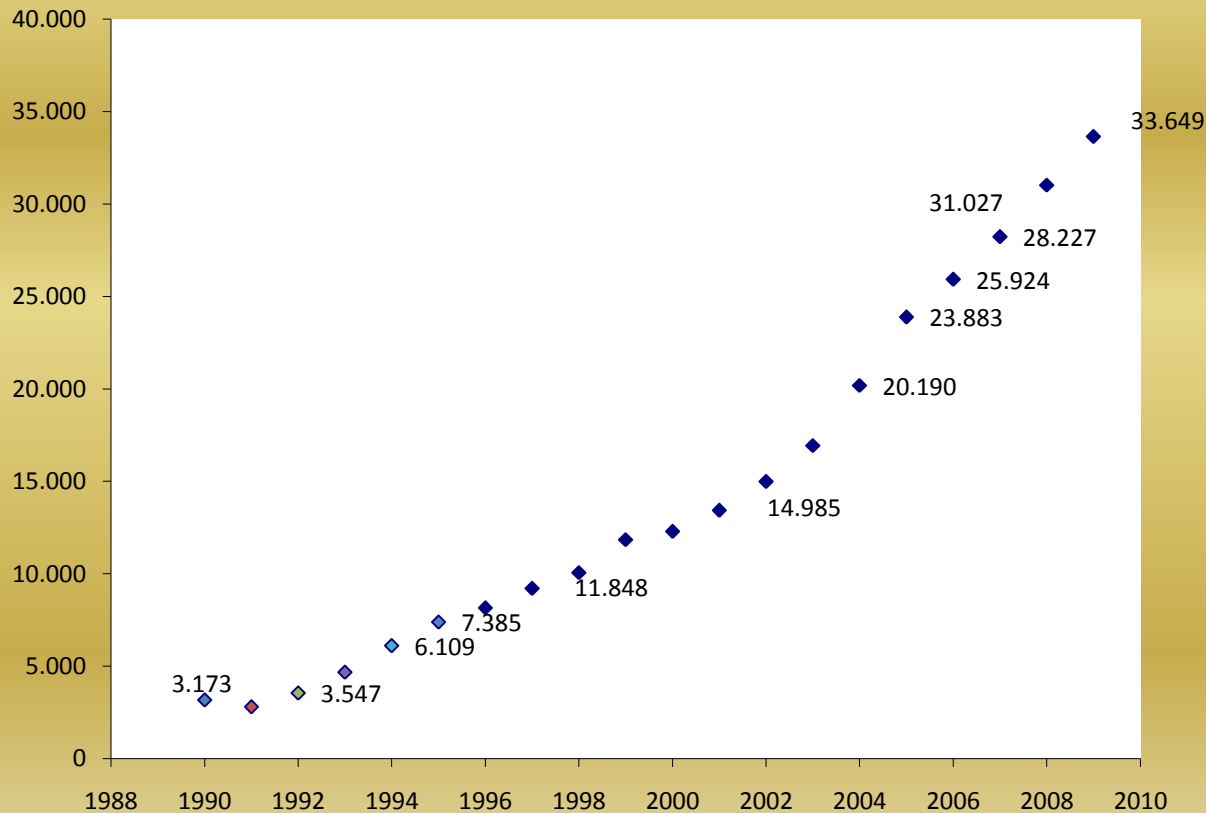


DECIIS based on Secex and Abimo.



Pharmaceutical Market in Brazil

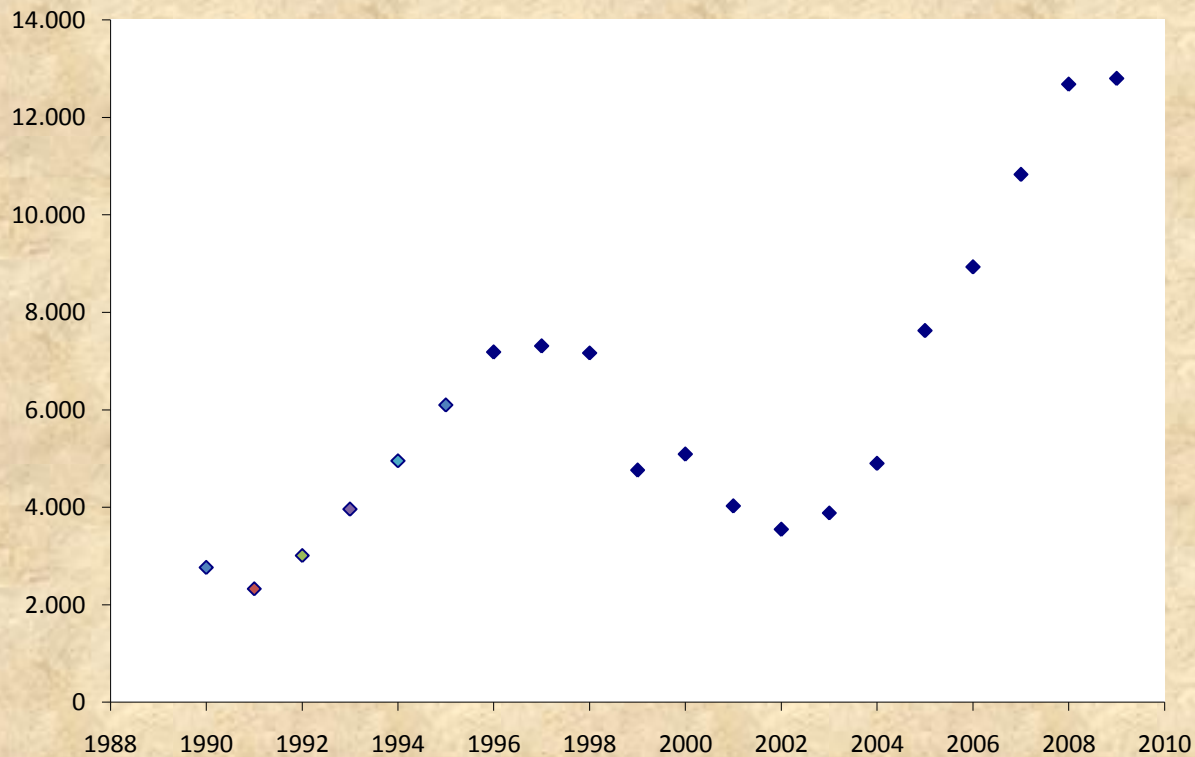
Pharmaceutical Market in Brazil (1990/2009)



Period	Increase
1990/1994	17,8%
1994/2002	11,9%
2002/2009	12,3%

Production of Medicines

Production of medicines
(1990/2009)

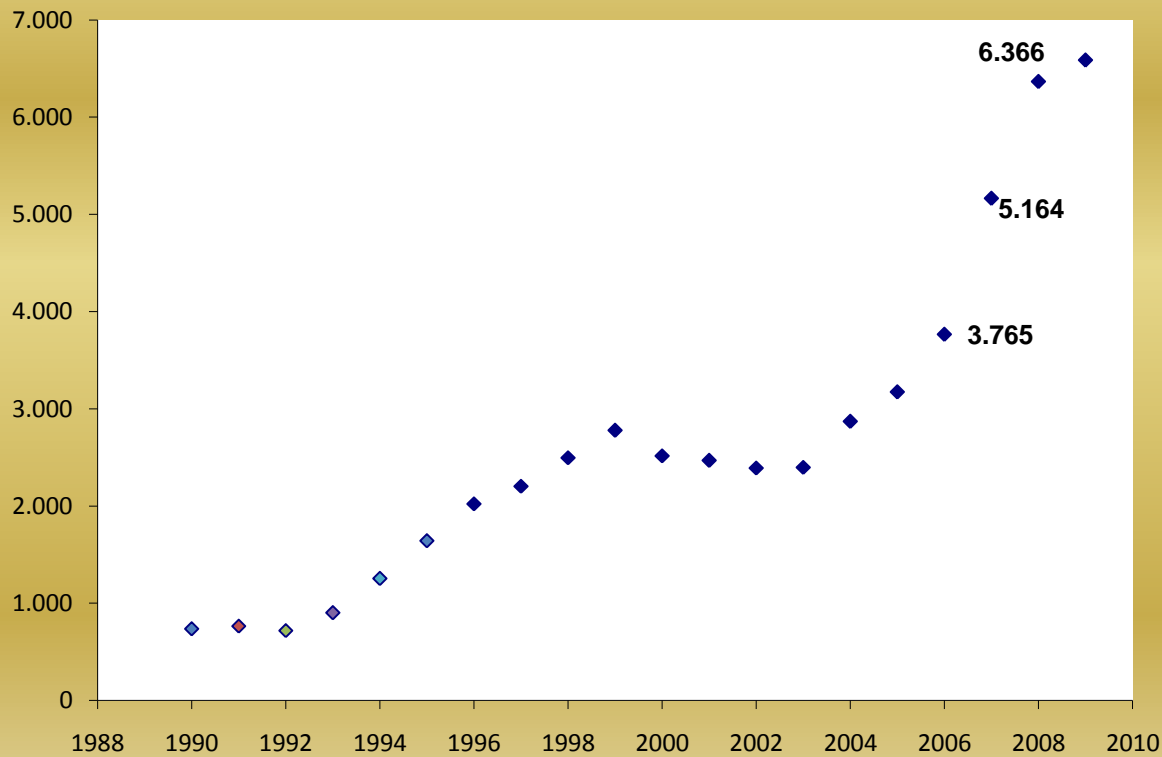


Period	Increase
1990/1994	15,7%
1994/2002	-4,1%
2002/2009	20,1%



Health Industrial Complex Import

Health Industrial Complex Import (1990/2009)

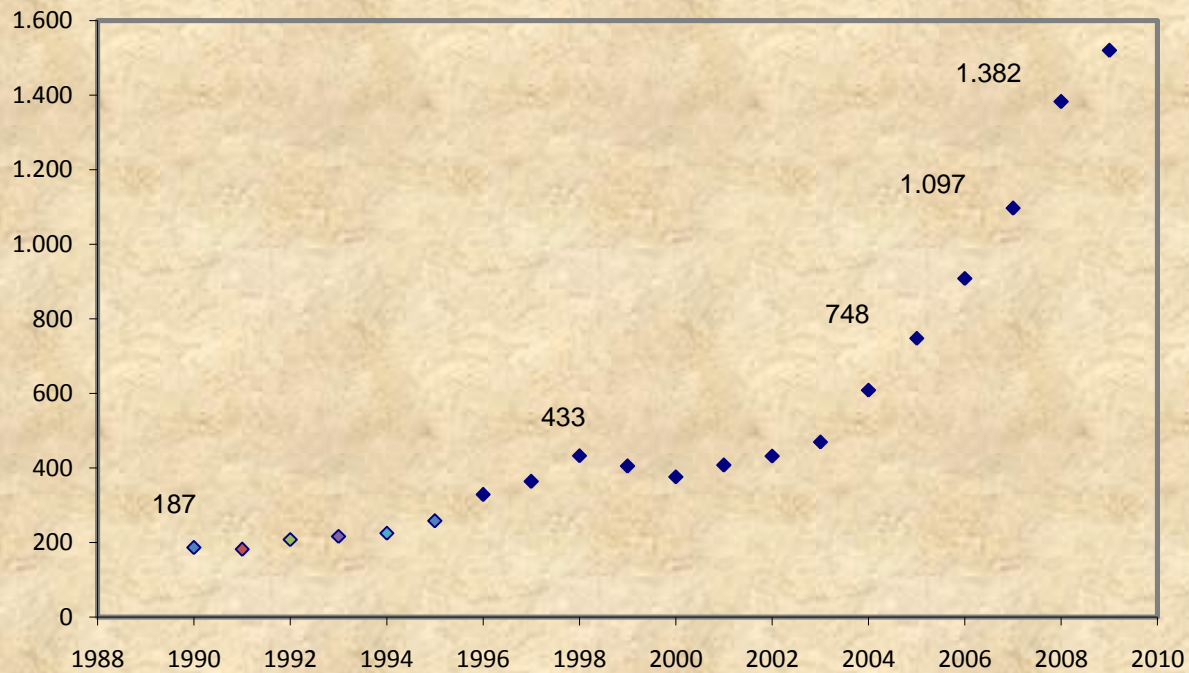


Period	Increase
1990/1994	14,3%
1994/2002	8,4%
2002/2009	15,6%



Health Industrial Complex Export

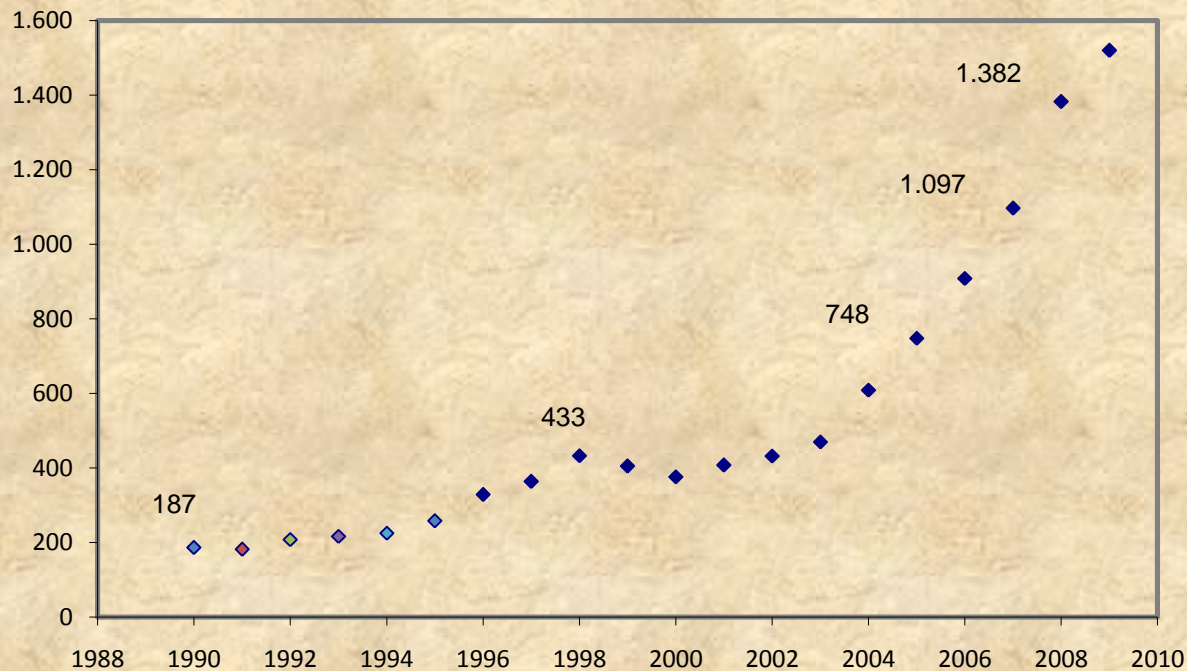
Health Industrial Complex Export(1990/2009)



Period	Increase
1990/1994	4,8%
1994/2002	8,5%
2002/2009	19,7%

HEALTH INDUSTRIAL COMPLEX EXPORT

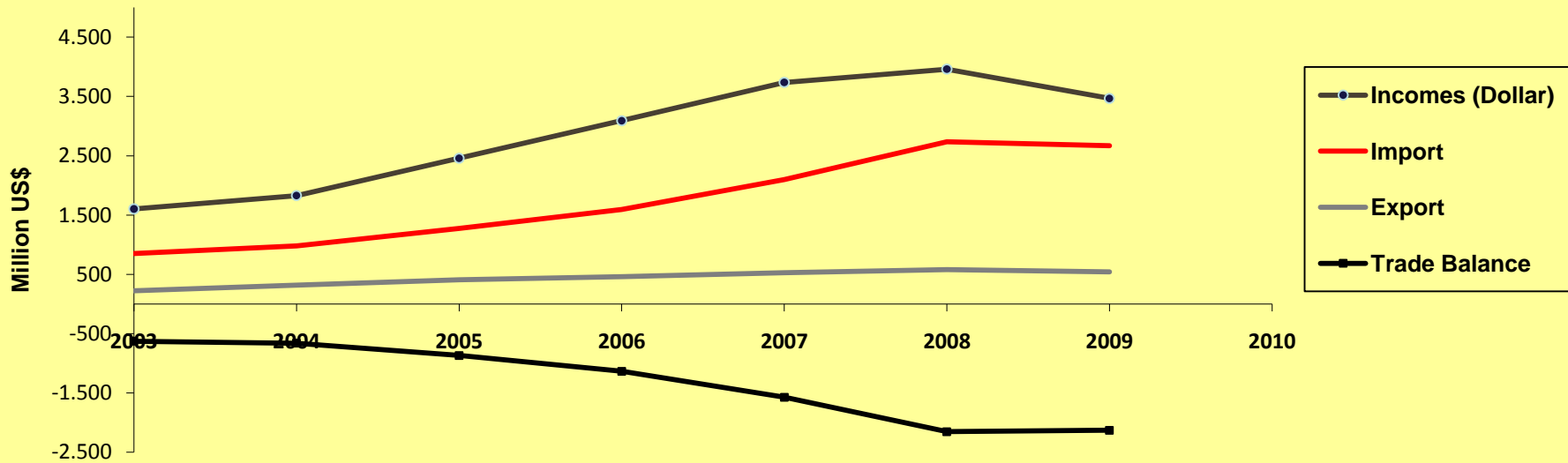
Health Industrial Complex Export(1990/2009)



Period	Increase
1990/1994	4,8%
1994/2002	8,5%
2002/2009	19,7%

Equipments Data

Equipments Data(2003/2009)

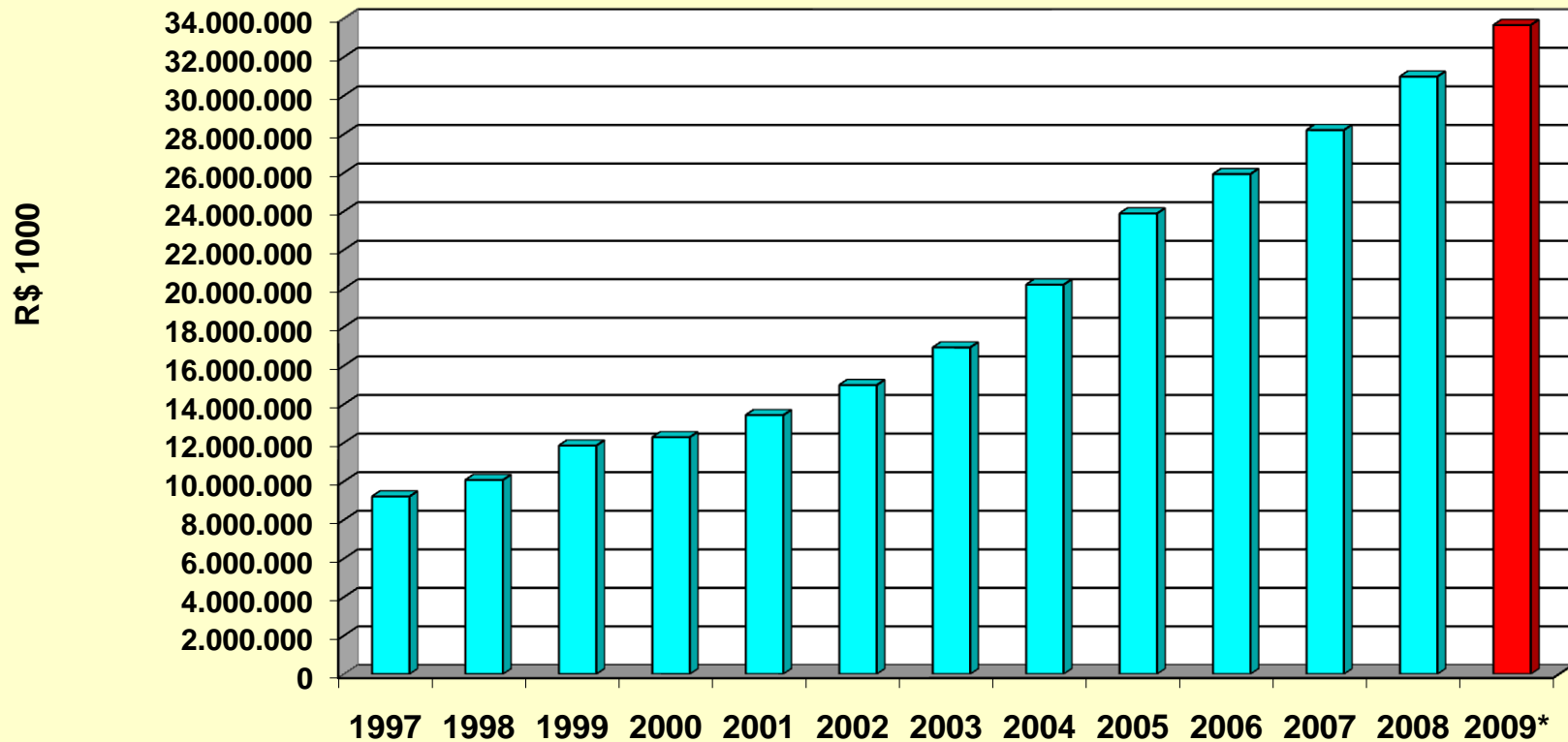


	2003	2004	2005	2006	2007	2008	2009
Incomes (dollar)	1.602	1.828	2.458	3.091	3.737	3.961	3.467
Import	852	980	1.276	1.596	2.098	2.735	2.670
Export	223	318	407	461	525	581	540
Trade Balance	-629	-662	-869	-1.134	-1.573	-2.155	-2.130

Pharmaceutical Market

PHARMACEUTICAL MARKET - BRAZIL INCOMES

Period: 1997 to 2009*



Os dados de 2002 a 2007 foram retificados pelo Grupemef

Fonte: GRUPEMEF

Elaboração: Sindusfarma / Gerência de Economia

(*) Period: Jan to Dec of 2009

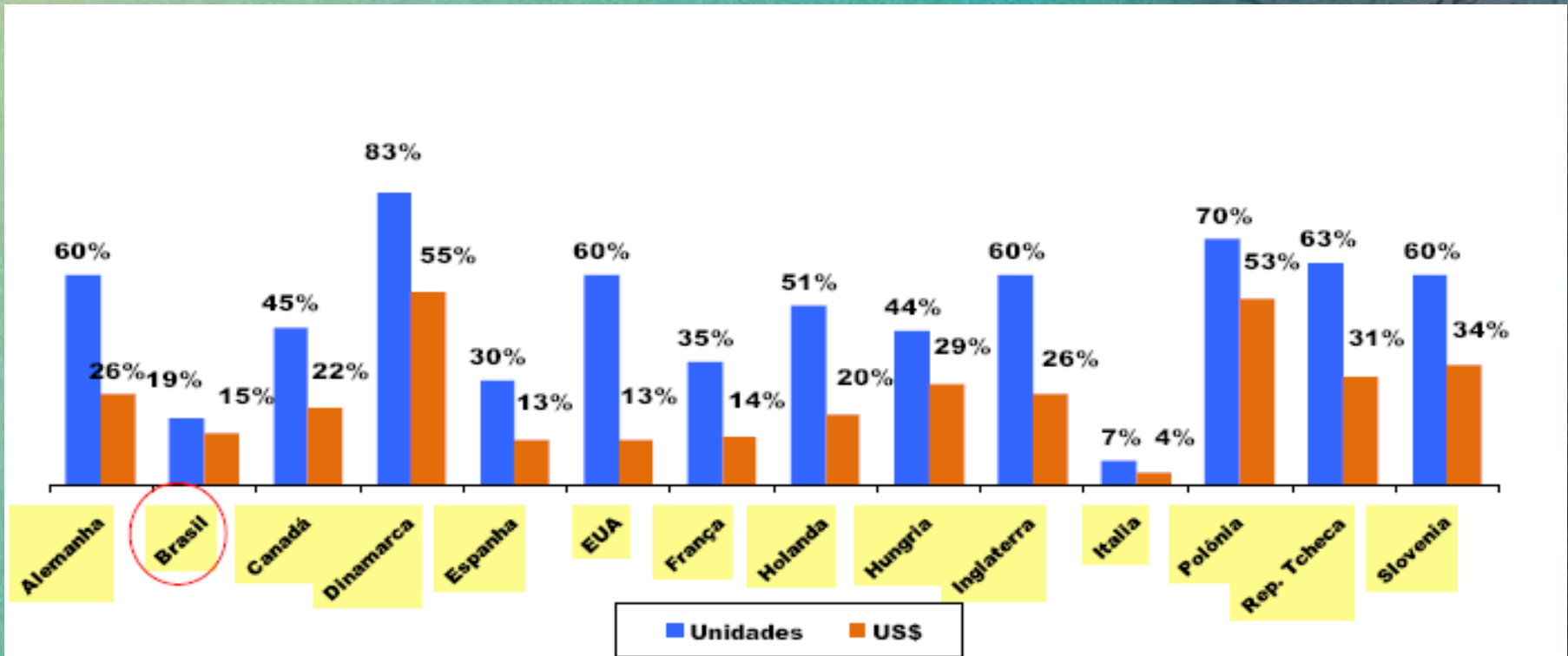
Generic Drugs Market

Year	Number of Companies	Number of Products	Sales in US\$1000	% Increase
2000	8	91	31.022	
2001	18	260	128.923	315,6
2002	24	470	224.214	73,9
2003	26	630	311.684	39,0
2004	34	829	442.747	42,1
2005	45	1.197	706.259	59,5
2006	46	1.457	1.054.461	49,3
2007	52	1.604	1.522.496	44,4
2008	82	2.609	2.024.240	33,0
2009	91	2.836	2.324.260	14,8

Database: IMS Health



Generic Comparative Drugs



Os Genéricos tem maior participação em mercados onde existe efetiva participação do governo através de políticas de reembolso.

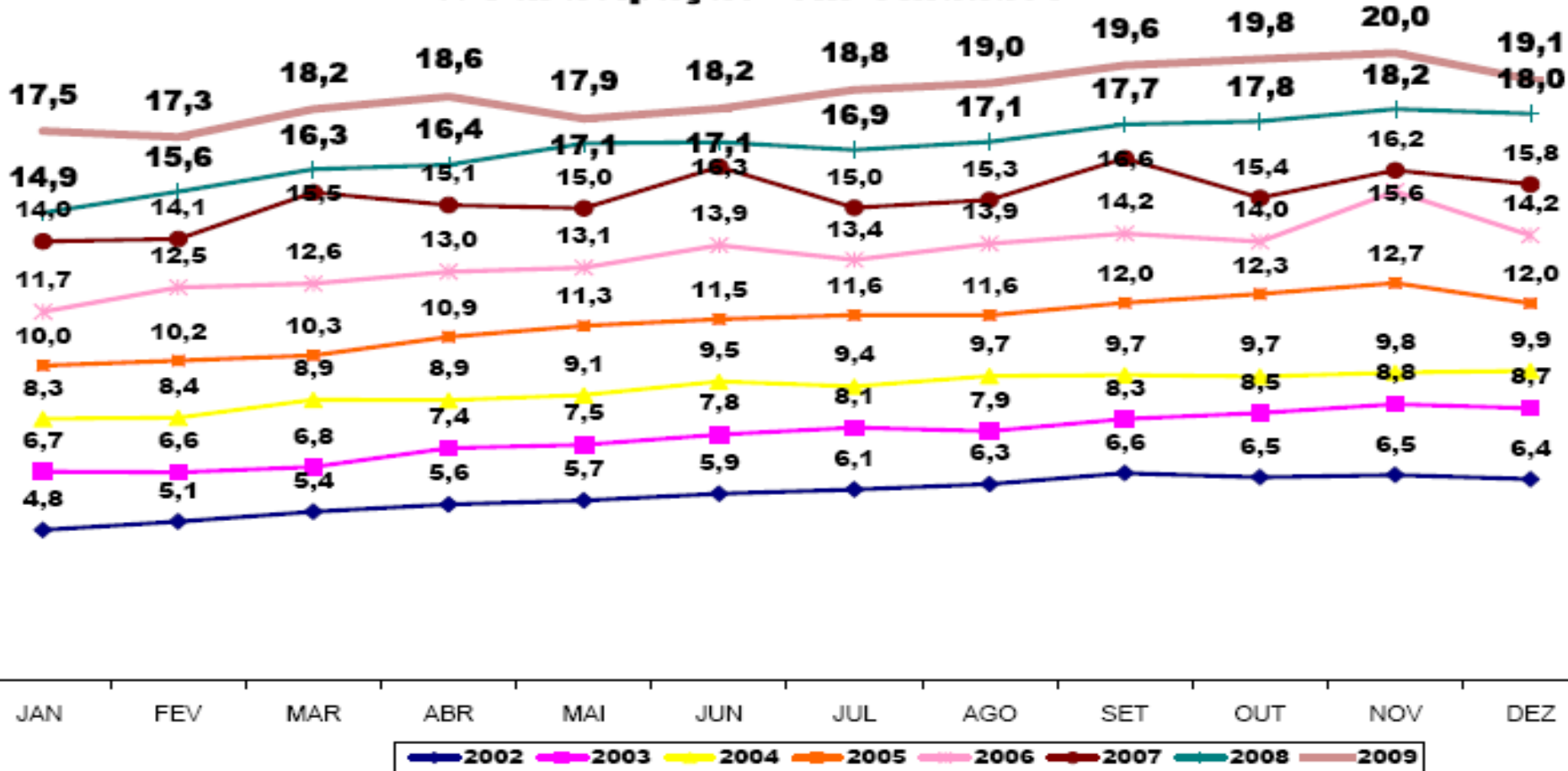
Generic Drugs in Brazil

		2003	2004	2005	2006	2007	2008	2009
Units (bn)	Total Market	1.219,4	1.319,6	1.356,0	1.434,4	1.514,7	1.634,9	1.769,2
	Evol.Index	100,0	108,2	111,2	117,6	124,2	134,1	145,1
	Genéricos	94,8	122,6	154,6	194,1	233,1	277,2	330,9
	Evol.Index	100,0	129,3	163,1	204,7	245,8	292,3	349,0
Value R\$(bn)	Total Market	14.776,7	17.117,8	18.988,4	21.399,5	23.564,0	26.436,1	30.251,1
	Evol.Index	100,0	115,8	128,5	144,8	159,5	178,9	204,7
	Genéricos	943,8	1.294,0	1.700,3	2.291,2	2.941,8	3.658,3	4.535,9
	Evol.Index	100,0	137,1	180,1	242,8	311,7	387,6	480,6



Generic Increasing

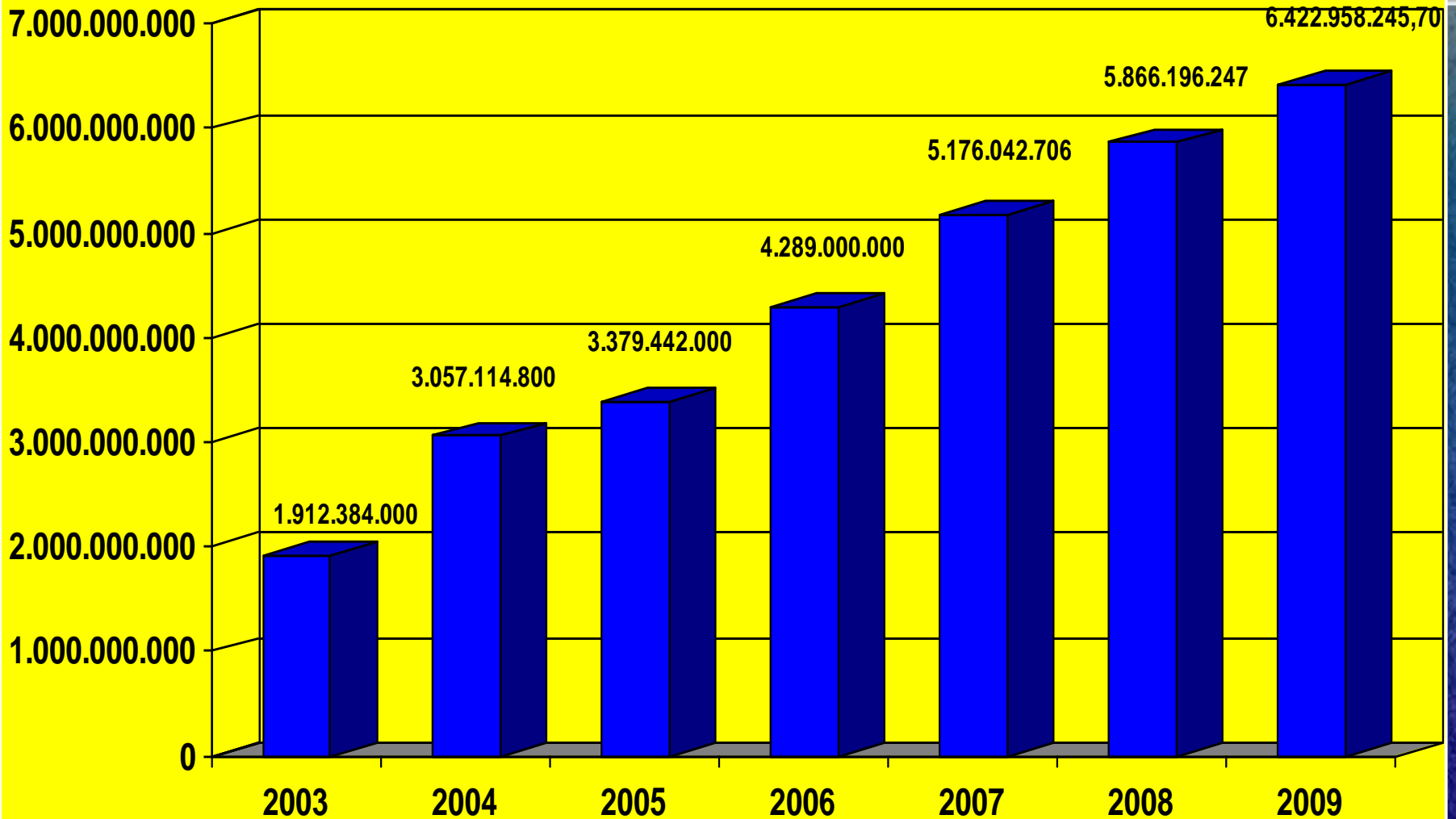
Evolução de Genéricos
% Participação em Unidades



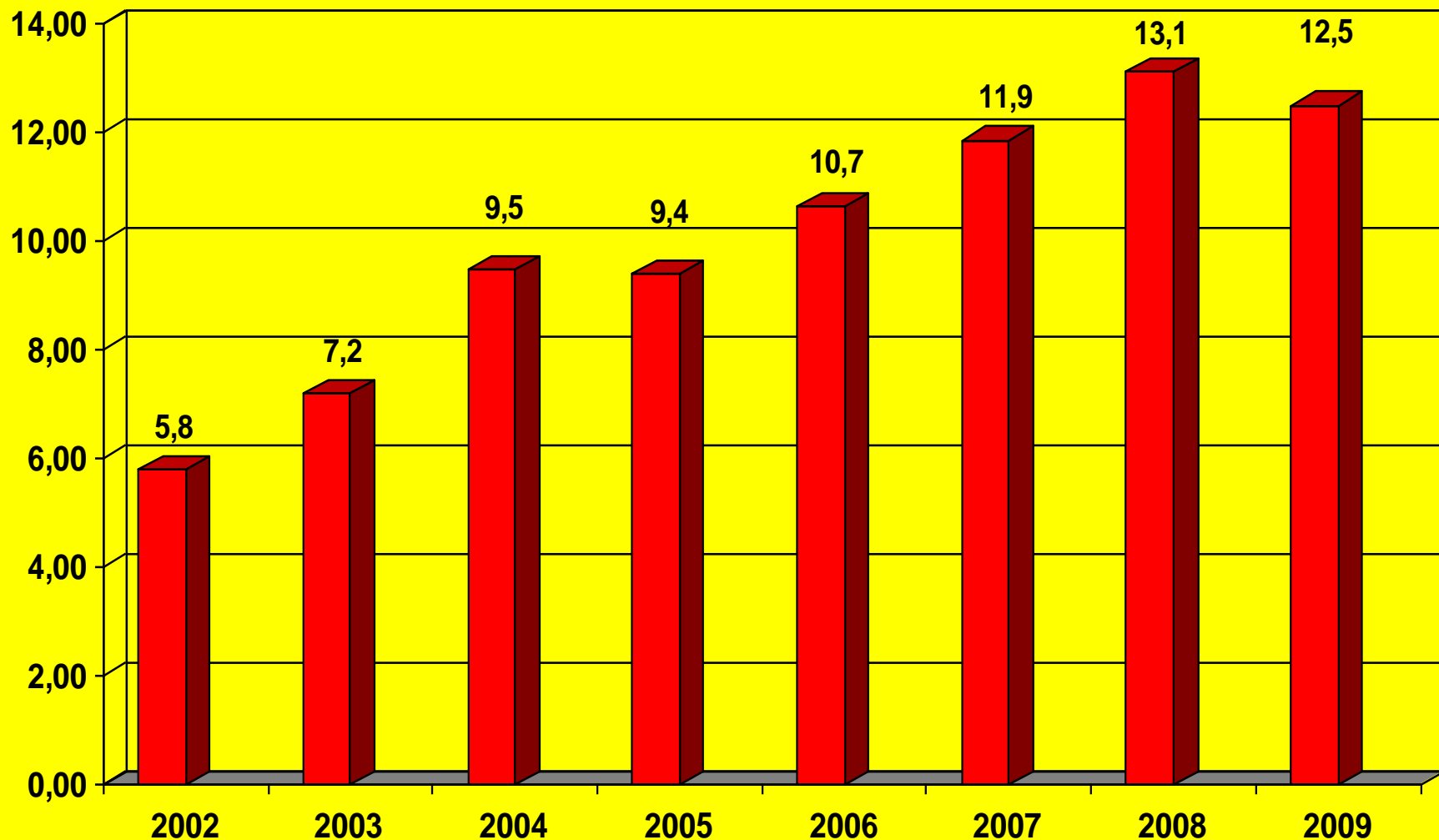
Government Purchase



Acquisitions – MS



Acquisitions – MS



SUS: ACQUISITIONS

Actions	R\$						
	2003	2004	2005	2006	2007	2008	2009
Strategic Drugs	231.584.000	790.309.000	681.000.000	690.000.000	721.050.000	125.576.948	133.981.559
Essential Drugs	176.800.000	248.542.800	228.020.000	290.000.000	316.910.000	893.000.000	865.000.000
Specialized Drugs	516.000.000	813.833.000	1.147.422.000	1.355.000.000	1.956.332.706	2.307.984.000	2.645.200.000
AIDS Drugs	516.000.000	516.000.000	550.000.000	960.000.000	984.000.000	1.013.000.000	758.800.000
Imunobiological	250.000.000	480.590.000	550.000.000	750.000.000	783.750.000	882.500.000	790.846.742
Coagulopathies	222.000.000	207.840.000	223.000.000	244.000.000	280.000.000	300.000.000	308.745.384
Cancer Drugs(1)	300.000.000	320.000.000	340.000.000	370.000.000	400.000.000	450.000.000	500.000.000
F.P	0	0	0	23.150.000	134.000.000	344.135.299	436.784.576
H1N1	0	0	0	0	0	0	483.599.985
State and Municipals	600.600.000	630.383.300	663.742.200	684.500.000	744.633.270	779.798.400	781.000.000
TOTAL	2.812.984.000	4.007.498.100	4.383.184.200	5.366.650.000	6.320.675.976	7.095.994.647	7.703.958.246



**Market Data
Biological Segment**



Industrial Health Complex

Biological Segment (~45% SUS budget - R\$ 3 billions)

- Ministry of Health **expenditure** in biopharmaceuticals
 - 42% of the expenditures represents 2% of consumption
- Serum and vaccines **expenditure**
 - About R\$ 1,0 billion/year (R\$ 2,7 billions/2010). Almost R\$ 2 billion/year after 2010 (plus meningococcus and pneumococcus).
- Hemoderivatives **expenditure**
 - R\$ 300 millions applied for the public system use



Industrial Health Complex

Biological Segment

- **Ministry of Health investments**
 - **About R\$ 275 million in the last few years to finance projects in this field** (Interferon Alfa 2b, CIPBR, DPFI, vaccines and serums, Rotavirus vaccine, yellow fever vaccine, and others)
 - ***Approximately R\$ 200 million more addressed to vaccines against pneumococcus, BCG, Influenza A H1N1 e yellow fever in 2009.***
 - **About R\$ 150 millions invested in the Hemobrás governmental company** to increase the production of blood derivatives.
- **Transversal Funds (FNDCT) and Biotechnology Sector Fund**
 - **R\$ 22 millions in 2009 and 2010** to develop two vaccines:
 - inactivated yellow fever vaccine (Biomanguinhos)
 - Leishmania plus anti-rabic combined vaccine (Butantan Institute)



Industrial Health Complex

Biological Segment

- ***Ministry of Health/Brazilian Development Bank (BNDES) partnership***
 - Research and development
 - Public/Private partnerships – respond to the projects supported by the MS
 - Projects focused on health products production
 - Management Analysis Project about the Public Laboratories
 - Clinical Research Project
 - Government Purchase Project
- ***MCT/FINEP e SCTIE/MS Partnership***
 - The Ministry of Health is advising economic subvention proposals related to the Industrial Health Complex since 2007
 - In the pharmaceuticals and medicines field, products of biotechnological origin are selected as priorities
 - 2008 – R\$ 100 millions
 - 2009 – R\$ 80 millions



Industrial Health Complex

New investments 2010-2011 (other segments)

- ***MCT/FINEP and SCTIE/MS partnership (50% each)***
 - Antiretroviral verticalization
 - 2010 – R\$ 22,5 millions
 - 2011 – R\$ 22,5 millions
 - Equipments
 - 2010 – R\$ 15 millions
 - 2011 – R\$ 15 millions
- ***MCT, BNDES e SCTIE partnership***
 - Fiocruz Health Technology Development Center (CDTS)
 - R\$ 50 millions, 15 millions from SCTIE
 - Equipments
 - 2010 – R\$ 10 millions
 - 2011 – R\$ 15 millions



Industrial Health Complex

New investments 2010-2011 (other segments)

- *Directly invested by the Ministry of Health*
 - Pharmaceutical
 - Qualifying, development and modernization
 - 2010 – R\$ 7 millions
 - 2011 – R\$ 12 millions
 - Equipments
 - 2010 – R\$ 8 millions
 - 2011 – R\$ 12 millions



Industrial Health Complex

Production Development Agreement

Partnerships between public pharmaceutical laboratories and private companies **aim at:**

- Strengthen the public laboratories and **increase/enlarge/broad** their role on the market regulation
- Incentive the local production of high cost products and/or high sanitary and social impact;
- **Incentive / fund /support** the development of the productive capacity of the national pharmonochemical industry



Industrial Health Complex

Agreement for the Production Development

Partnership projects Concluded:

- An amount of eighteen partnership projects fit all the evaluation steps and will sign their Commitment Terms on this meeting.
- Are involved 8 public laboratories, 14 private partners, with 4 of them foreign companies e 10 of them national, for the production of 23 strategic pharmaceuticals for the SUS.
- Direct Government Investments , over R\$ 850 millions per year. Expected annual public safes, R\$ 170 millions, taking into account the next 5 years.



Regulatory Premises

- **Decrease the vulnerability of the National Health Policy**
- **To assure the quality of the products**
- **To guarantee and promote the innovation and technological development in Brazil, focused on improving the competitive and the productive capacity of Brazilian industry, at the Industrial Health Complex.**



Anteprojeto de Lei do Gecis for Government Purchase in Health sector

Definition: "Industrial Health Complex is on the national level, the set of economic activities, public and private need for the state to fulfill its duty to promote the reduction of disease risk and other health problems and ensure universal and equal access to actions and services for its promotion, protection and recovery."

Objective:

Giving the government a special system of bids and contracts, making possible to achieve the needs of the SUS, if properly restricted and tied to specific act of the Minister of Health (nationwide) without hurting the federal agreement and the pact SUS.



APL- Saúde: Conclusions

With the scope presented, it is correct to say that the “APL”

- Reaches it's purpose as an instrument to meet the necessity of specific Health Purchase;
- Justifies it's role as an instrument of the Public Policy;
- Shows it's restrictive role to the adoption of exceptional actions involved in the APL, because it attributes to the Health Ministry the responsibility to specify the object for bidding and contracts, practically case to case;
- Specifies the nacional role for the proposed legislation to the CIS, avoiding eventual federal conflicts;
- Represents a big step, because it breaks a paradigm in the Brazilian Public Purchase.



Intellectual Property Issue

- Brazil ratifies the concept of the supremacy of the public health in relation to the economic and commercial interests
- Recognition of the Doha Ministerial declaration relative to the TRIPS agreement and flexibilities for public health

Intellectual Property Issue

- Impact of the Commercial Agreements on the Access to the Health
- New international agreements, especially free commerce treaties, can limit the application of the TRIPS agreement flexibilities



Intellectual Property Issue

- TRIPS-Plus increase the difficulties to the public health access
- Imposition of non-technical barriers to the development of the generic industry and, consequently, to the access to medicines



The 61.21 Resolution and the National Policy

- *Brazil has a national involvement on improving the innovative capacity in order to increase the public access to healthcare.*
- *Brazilian National Strategy for Science and Technology Development in Health Sector is running harmonically with the major WHA 61.21 objectives.*





THANK YOU!

Zich Moysés Júnior

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Innovation**

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Ministry of Health**

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