



Brazil: ways forward in ensuring access to medicines

Ministry of Health of Brazil
Oswaldo Cruz Foundation
Vice-Presidency of Health Production and Innovation
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Advisor

2012 Russian Pharmaceutical Forum
22 – 24 May 2012, Saint Petersburg



In 1988



- National Constitution –
“Health is a right of all and a State duty”

The Oswaldo Cruz Foundation

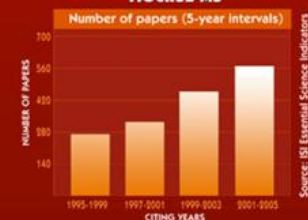
Fiocruz THE OSWALDO CRUZ FOUNDATION

Feet anchored in tradition, eyes turned to the future

Founded on May 25th 1900 under the name Federal Serum Therapy Institute, The Oswaldo Cruz Foundation (Fiocruz) was created with the mission of fighting Brazil's most important public health problems. It was in its laboratories in Rio de Janeiro that in 1909 Carlos Chagas discovered the disease that bears its name – Chagas disease, also known as American trypanosomiasis –, its pathogen (*Trypanosoma cruzi*) and the mechanisms of transmission by reduviid insects ("kissing bugs").

Nowadays, Fiocruz mission encompasses research, technological development and innovation; production of vaccines, drugs, reagents and diagnostic kits; clinical research; delivery of reference health services; education and training of human resources; information and communication; product and service quality control; and the implementation of social programs.

MOST CITED INSTITUTIONS IN CLINICAL MEDICINE FIOCRUZ MS



Research and development: high-quality

According to the Essential Science Indicators of the Institute for Scientific Information (ISI), Fiocruz is one of the most cited institutions in clinical medicine and publishes over 400 research papers per year in high-quality, peer-reviewed international journals.

Future directions

Fiocruz new Center for Technological Development in Health (CDTS in its Portuguese acronym) will start to be built in the Manginhos campus in the end of 2005 and will be operational in 2008. Its facilities include technological platforms, animal experimentation facilities and flexible labs where Fiocruz will work in collaboration with public and private industrial sectors in the joint development of health products.

Collaborations

Fiocruz congratulates the scientists, institutions and funding agencies that made the sequencing of the genomes reported in this issue of Science and is ready to collaborate in the development of new health interventions that are accessible, affordable and appropriate for developing countries.



Actual Scenario

Populational Growth



Demographic transition with
populational ageing



Technological advances in the health
field



Increase in income



Expressive growth of social policies with
reduction of inequalities



health needs



consume in health

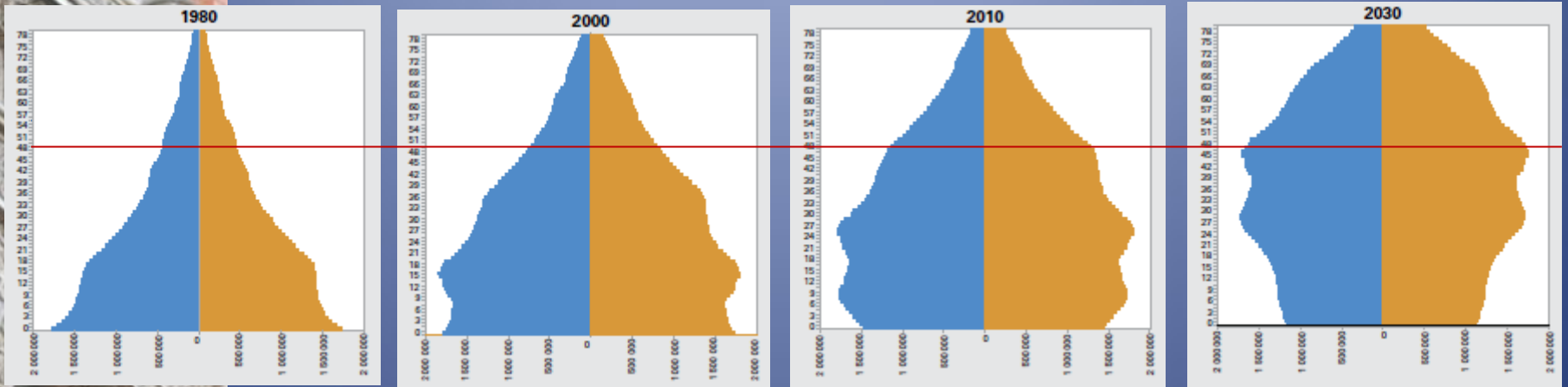


commercial imbalance
in health sector
(U\$ 11 billions)



dependency in areas of
intensive knowledge

Demographic Transition



Source: IBGE, Directory of Research, Coordination of Population and Social Indicators, Projection of Brazilian Population by Sex and Age to the period 1980 – 2030 . Revision 2008.c

A vertical decorative image on the left side of the slide showing a detailed architectural facade of a building, featuring a large arched window and ornate stonework.

Our Perspective

Health as a promotor of citizenship as well as of investments, innovation, employment and wealth

Health represents 8.7% of GDP

Health employs 10% of national workforce

Health expenditures surpass U\$ 100 billions/year

Health is a significant source of income

Health is an important target for R & D

Opportunity



Industrial policy in Brazil with a focus on Innovation

2003 to 2007: PITCE (Industry, Technology and International Trade Policy)

2008 to 2010: PDP (Productive Development Policy)

2007 to 2011: PACTI (Plan of Action for Science, Technology and Innovation for National Development)

2011: Plano Brasil Maior (“Brazil Maior” Plan)

- 19 Competitiveness Councils, 9 Systemic Coordinations

World Ranking of Pharmaceutical Market

(in U\$ billions)

Rank	Country	2010
1	United States	312,2
2	Japan	96,3
3	Germany	45,3
4	France	43,7
5	China	40,1
6	Italy	29,2
7	Spain	25,5
8	Brazil	22,1
9	United Kingdom	21,6
10	Canada	21,6
11	Russia	13,1
12	India	12,3
13	South Korea	11,4
14	Australia	11,3
15	Mexico	10,8
16	Peru	10,6
17	Greece	7,8
18	Poland	7,8
19	Holland	6,9
20	Belgium	6,8

Source: IMS Market Prognosis 2010-2014

Note: Brazil surpassed United Kingdom in 2010 going to the 8th position

Pharmaceutical Industry Sales in Brazil

Last 5 years (in U\$ millions)

2006	2007	2008	2009	2010
9,868	12,18	14,649	15,408	20,541

Source: IMS Health

Sales volume

(in billion units)

2006	2007	2008	2009	2010
1,43	1,51	1,63	1,76	2,06

Source: IMS Health





Growth in Public Purchases

mainly immunobiologics and oncologic medicines

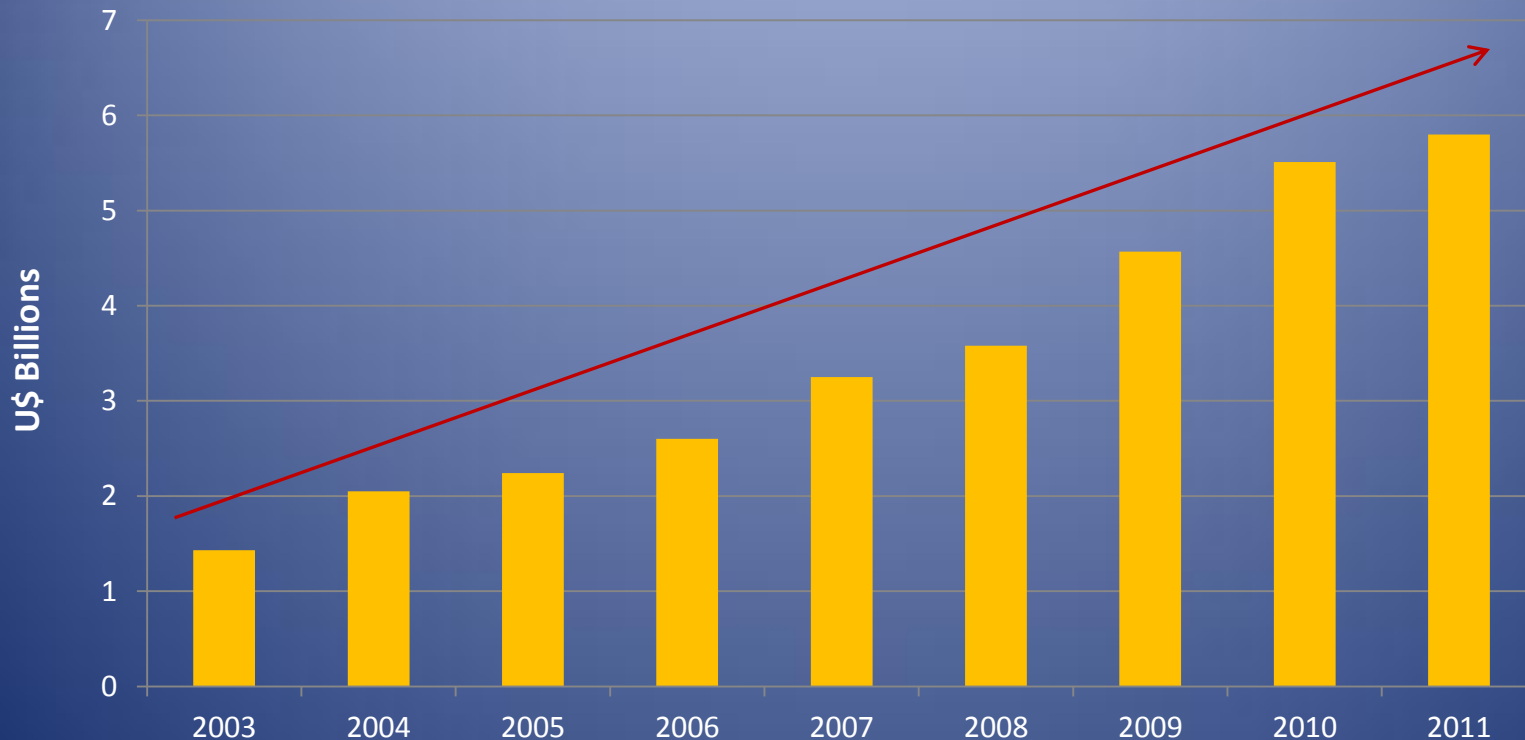
Ministry of Health Programs	2003	2004	2005	2006	2007	2008	2009	2010	2011
MS Strategic Med.	118.155.102	403.218.878	347.448.980	352.040.816	367.882.653	64.069.871	68.357.938	76.530.612	82.653.061
MS Basic Med.	90.204.082	126.807.551	116.336.735	147.959.184	161.688.776	455.612.245	487.244.898	525.510.204	540.816.327
MS Specialized Med.	263.265.306	415.220.918	585.419.388	691.326.531	998.128.932	1.177.542.857	1.349.591.837	1.672.186.735	1.763.008.673
MS AIDS Med.	263.265.306	263.265.306	280.612.245	489.795.918	502.040.816	516.836.735	553.061.224	310.255.102	410.613.265
MS Coagulopathies	113.265.306	106.040.816	113.775.510	124.489.796	142.857.143	153.061.224	130.992.543	166.477.331	210.492.347
MS Popular Pharmacy				11.811.224	68.367.347	175.579.234	182.675.624	177.831.633	395.206.633
MS H1N1							277.346.939		
MS Immunobiologics (sera & vaccines)		251.173.495	287.742.692	244.239.391	424.860.501	407.957.566	412.026.621	1.277.853.897	815.204.082
MS Oncologics (chemotherapy)							626.739.796	751.841.837	
MS Oncologics (radiotherapy)	153.061.224	163.265.306	173.469.388	188.775.510	204.081.633	229.591.837	83.530.612	106.903.061	1.071.428.571
MS Oncologics (iodotherapy)							2.117.347	2.362.245	
States and Municipalities	306.428.571	321.624.133	338.643.878	349.234.694	379.914.934	397.856.327	398.469.388	438.316.327	510.204.082
TOTAL (U\$)	1.435.195.918	2.050.616.403	2.243.448.814	2.599.673.064	3.249.822.733	3.578.107.896	4.572.154.767	5.506.068.984	5.799.627.040

Source: Analisis – DECIIS/SCTIE/MS

Data: SCTIE/MS, SVS/MS, SAS/MS

Increase in Public Purchases

Public Expenditure in Health 2003 - 2011



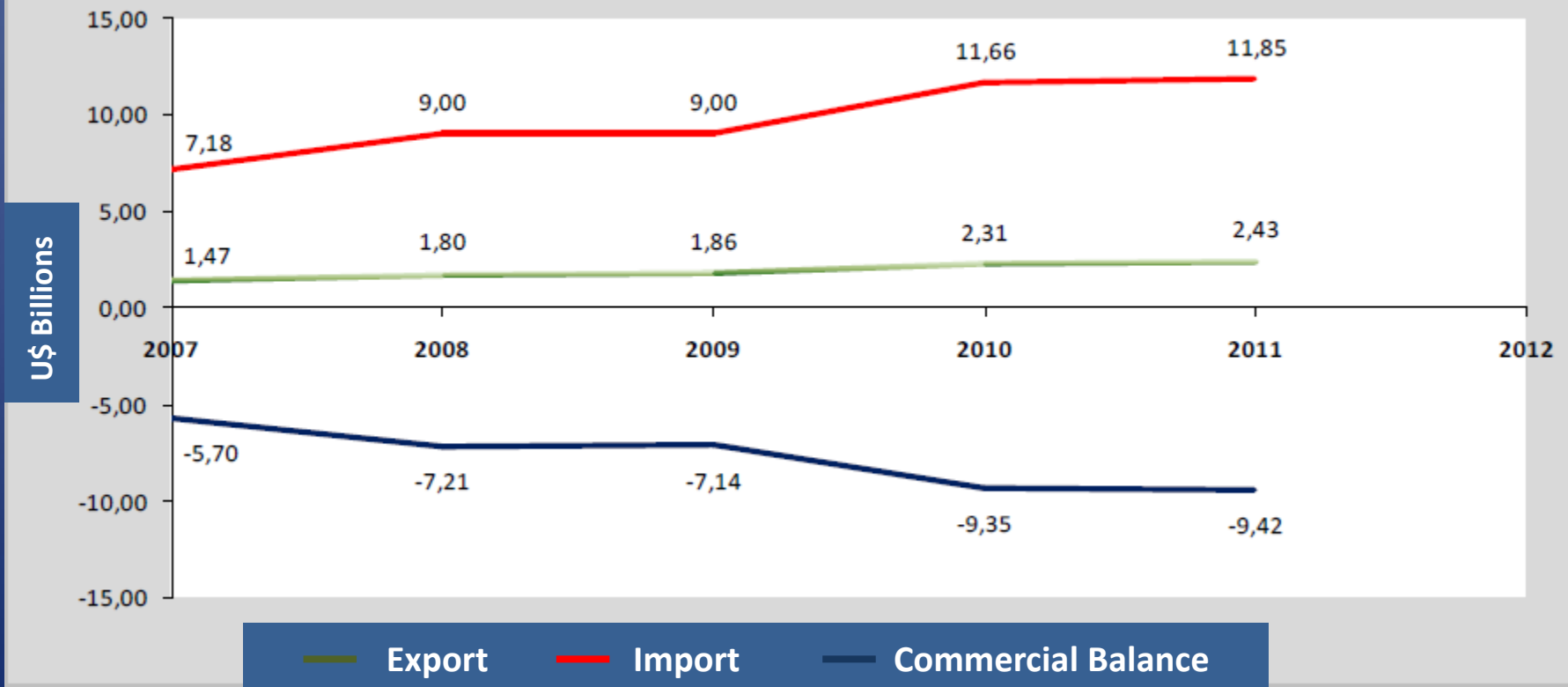
Source: Análisis – DECIIS/SCTIE/MS

Data: SCTIE/MS, SVS/MS, SAS/MS



Commercial Balance Deficit

Commercial Balance of the Health Sector* 2007 - 2011

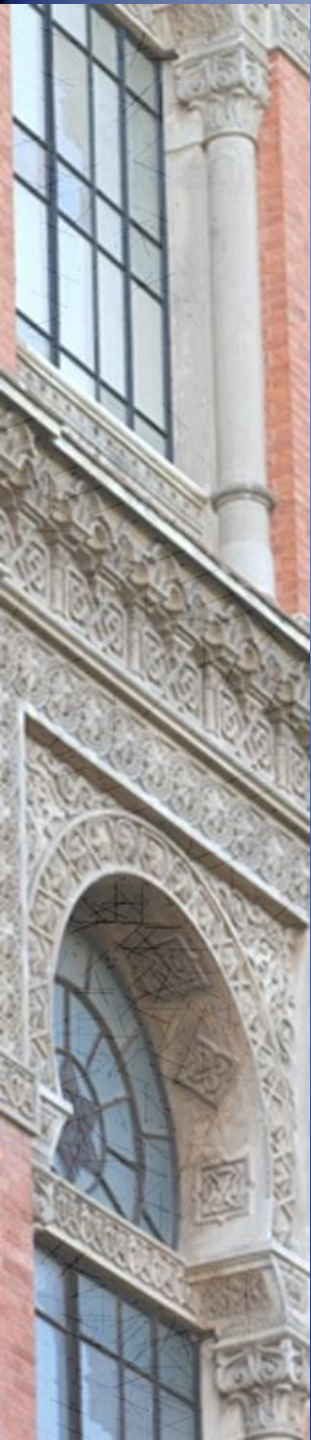


Source: Análisis – DECIIS/SCTIE/MS

Data: SECEX/MDIC

*Commercial Balance of 2011 based in projected data for export and import from January to October 2011, of U\$ 2,03 and U\$ 9,88 billions respectively





"We achieved almost all of the development goals of the millenium before 2015. Almost 40 million Brazilians raised up from poverty to middle class"

"Brazil stands for access to medicines as part of human rights. We know that it is a strategic element for social inclusion, the search for equity and the strengthening of public health systems.
(...)"

Brazil guards the compromises regarding intellectual property but we are convinced that the flexibilities foreseen in the TRIPS of the WTO, in Doha's Declaration about TRIPS and Public Health and in the Global Strategy for Public Health are indispensable for policies that guarantee the right to health."

President Dilma Rousseff 19 Sept-2011

Institutes the Program for Development of Health Industrial Complex and its Managing Committee



Ministério da Saúde
Gabinete do Ministro

PORTARIA Nº 506, DE 21 DE MARÇO DE 2012

Institui o Programa para o Desenvolvimento do Complexo Industrial da Saúde (PROCIS) e seu Comitê Gestor.

Art. 1º Fica criado o Programa para o Desenvolvimento do Complexo Industrial da Saúde (PROCIS), com o objetivo de fortalecer os produtores públicos e a infraestrutura de produção e inovação em saúde do setor público.



Presidência da República
Casa Civil
Subchefia para Assuntos Jurídicos

DECRETO Nº 7.713, DE 3 DE ABRIL DE 2012

Estabelece a aplicação de margem de preferência nas licitações realizadas no âmbito da Administração Pública Federal para aquisição de fármacos e medicamentos descritos no Anexo I, para fins do disposto no art. 3º da Lei nº 8.666, de 21 de junho de 1993.

Establishes preference margins

Defines guidelines and criteria for the establishment of Productive Development Partnerships



Ministério da Saúde
Gabinete do Ministro

PORTARIA Nº 837, DE 18 DE ABRIL DE 2012

Define as diretrizes e os critérios para o estabelecimento das Parcerias para o Desenvolvimento Produtivo (PDP).



Presidência da República
Casa Civil
Subchefia para Assuntos Jurídicos

LEI Nº 10.973, DE 2 DE DEZEMBRO DE 2004.

Dispõe sobre incentivos à inovação e à pesquisa científica e tecnológica no ambiente produtivo e dá outras providências.

Innovation Law





Portaria No. 837 de 18 de abril de 2012

Art. 3º. Objectives of PDP's (Partnerships for Productive Development)

I. rationalization of the State's acquisitional strength through the selective centralization of expenditures in the health field, aiming to reduce costs of acquisition for the NHS (SUS) and to a viable production of innovative products of high essentiality for health, having as focus the ammelioration of the population's access to strategic health facilities

II. stimulus to the joint technologic development and interchange of knowledge to innovation in the field of public and private national producers, turning them competitive and able to face global competition in a permanent basis in a context of everchanging technology;

III. focus in the local fabrication of strategic products to the NHS and of high cost products and/or with great sanitary and social impact, gathering full provision and decreasing the NHS vulnerability with the country's growing wealth;

IV. negotiation of significant and progressive reduction in prices together with the technology transfer process, as long as it is considered strategic to the NHS.



Other Governmental Agencies

ANVISA

National Agency for Sanitary Surveillance

Mission: Protect population's health with efficiency and transparency

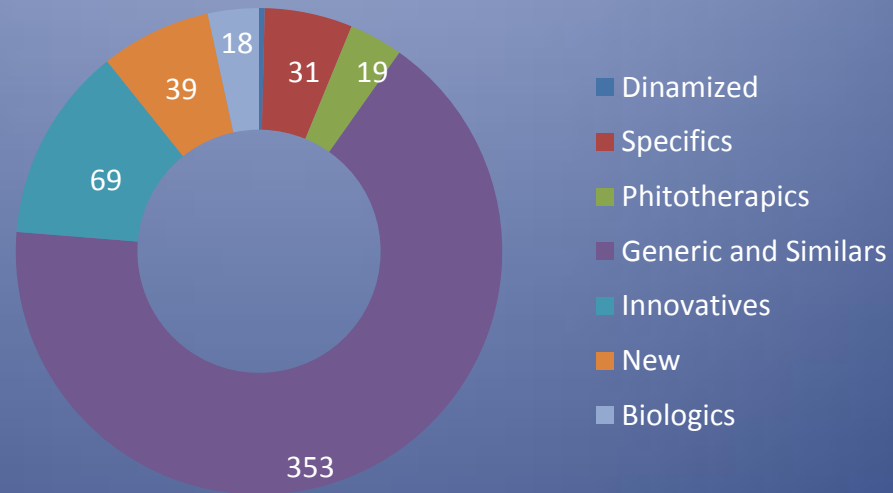
- Created in 1999 has an outstanding role in Brazilian health system deciding the sanitary surveillance policies and regulation
- In the PPPs ANVISA institutes Regulatory Technical Committees to follow up activities related to the development, production, registration and post-registration of medicines originated in partnerships firmied by the Ministry of Health
- “Sanitary Regulation and its challenges in a world without frontiers: improving cooperation between Medicines Regulatory Agencies” - 18th of May – 2012, Geneva, just before the 65th World Health Assembly

ANVISA

National Agency for Sanitary Surveillance

Mission: Protect population's health with efficiency and transparency

Registry of Medicines granted in 2011



Total: 531

Source: ANVISA Annual Activities Report - 2011



National Health Surveillance System

REGION	U\$
North	6.597.760,01
North-East	21.556.294,91
Centre-West	5.858.006,87
Southeast	33.711.056,11
South	12.769.602,11
TOTAL U\$	80.492.720,00

Source: ANVISA Annual Activities Report - 2011



National Socio-Economic Development Bank – BNDES –

In order to boost the potentialities of the Health Industrial Complex instituted the **PROFARMA** – Program for the development of the Health Industrial Complex. The program aims to finance investments of companies based in Brazil, inserted in the Health Industrial Complex, through sub-programs: production, export activities, innovation and restructuring

Strategic Guidelines of the PROFARMA

- Increase competitiveness in the health industrial complex
- Contribute to reduce the vulnerability of National Health Policy
- Articulate ongoing Industrial and Health National Policies

Public Private Partnerships

PRODUCT	THERAPEUTIC INDICATION	PUBLIC LABORATORY	PARTNER
Adalimumabe	Rheumatoid Arthritis and Chron's Disease	IVB	PharmaPraxis
Atazanavir	Antirretroviral	FARMANGUINHOS	Bristol/Nortec
Betainterferon 1a	Multiple Sclerosis	BIOMANGUINHOS	Aché
Cabergolin	Hiperprolactinemia	BAHIAFARMA/FAR	Cristália
Clozapine	Antipsicótico	LAFEPE/NUPLAM	Cristália
IUD	Contraceptive	FURP	Injeflex
Donepezil	Alzheimer's disease	FUNED/FURP	Cristália
Entecavir	Antiviral	FUNED	Microbiológica
Recombinat Factor VII	Hemophyllia	HEMOBRAS	Cristália
Formoterol with Budesonide	Antiasthmatic	FARMANGUINHOS	Chemo
Leflunomide	Rheumatoid Arthritis	LFM	Cristália
Mycophenolate mofetil	Imunossupressor	FARMANGUINHOS	Nortec/Roche
Octreotide	Acromegalia	IVB	Laborvida/Hygéia
Olanzapine	Antipsicótico	LAFEPE/NUPLAM	Cristália
Pramipexol	Parkinson's disease	FARMANGUINHOS/FURP	Boehringer/Nortec
Quetiapine	Antipsicótico	LAFEPE/NUPLAM	Cristália
Raloxifene	Osteoporosis	LFM	Nortec
Raltegravir	Antiretroviral	LAFEPE	MSD/Nortec
Rifampicin, Ethambutol, Isoniazid and Pyrazinamide	Tuberculosis	FARMANGUINHOS/FURP	Lupin
Riluzol	ALS	LFM	Cristália
Ritonavir	Antirretroviral	LAFEPE	Cristália
Rivastigmine	Alzheimer's disease	IVB	Laborvida/Mappel
Sevelamer	Chronic Renal Disease	BAHIAFARMA/FAR	Cristália/ITF
Sirolimus	Imunessupressor	FARMANGUINHOS	Libbs
Tacrolimus	Imunessupressor	FARMANGUINHOS	Libbs
Taliglucerase alfa	Gaucher's Disease	BIOMANGUINHOS	Pfizer/Protalix
Tenofovir	Antiretroviral	FUNED	Nortec/Blanver
Tenofovir	Antiretroviral	LAFEPE	Cristália
Botulinum Toxin	Muscle relaxant	LAFEPE	Cristália
Ziprasidone	Antipsicótico	LFM	NPA/Heterodrugs

Source: III National Pharmaceutics Forum, Rezende K.S, Ministry of Health, November 2011



Preference Margins

Selected products, categorized in 3 major groups of strategic products to SUS and classified in 6 types, according to the degree of productive integration and technologic intensity

Group I – Medicines and API's

Group II – Strategic Pharmaceutical Materials (adjuvants)

Group III – Integrated Biologic Products

Considerations about selected products:

- Purchases correspond to at least U\$ 1,8 billion of the U\$ 5,8 total expenditure in 2011, with an increasing trend in face of demographic, economic and social changes and in changes of the SUS
- Responsible for about 20% of external deficit of the sector in the Health Industrial Complex, having doubled in the last 5 years
- Potential impact of U\$ 65 millions on GDP, generating 3.095 new jobs and with an impact in tax revenues of about U\$ 16,2 millions

Creation of the Interministerial Public Purchases Committee, on a temporary basis, to propose and follow up the application of preference margins, integrated by 5 Ministers of State (Ministry of Finances, Ministry of Planning, Budget and Management, Ministry of Development, Industry and Commerce, Ministry of Science and Technology, Ministry of Foreign Affairs)



Recent Initiatives in the Private Sector

Creation of BioNovis

– joint venture of 4 national laboratories (Aché, EMS, União Química & Hypermarchas) – aiming biomedicines, having as main target R&D, production, distribution and commerce of biotechnological products, with investments of U\$ 250 million. “Maybe the most important investment in the history of Brazilian pharmaceutical industry”, according to Dr. Odnir Finotti, president of BioNovis.

Creation of Orygen Biotecnologia

- joint venture of another 4 national laboratories (Cristalia, Eurofarma, Libbs & Biolab). The new company also targets biomedical products with an equivalent investment of about U\$ 200 – 250 millions.

Oswaldo Cruz Foundation

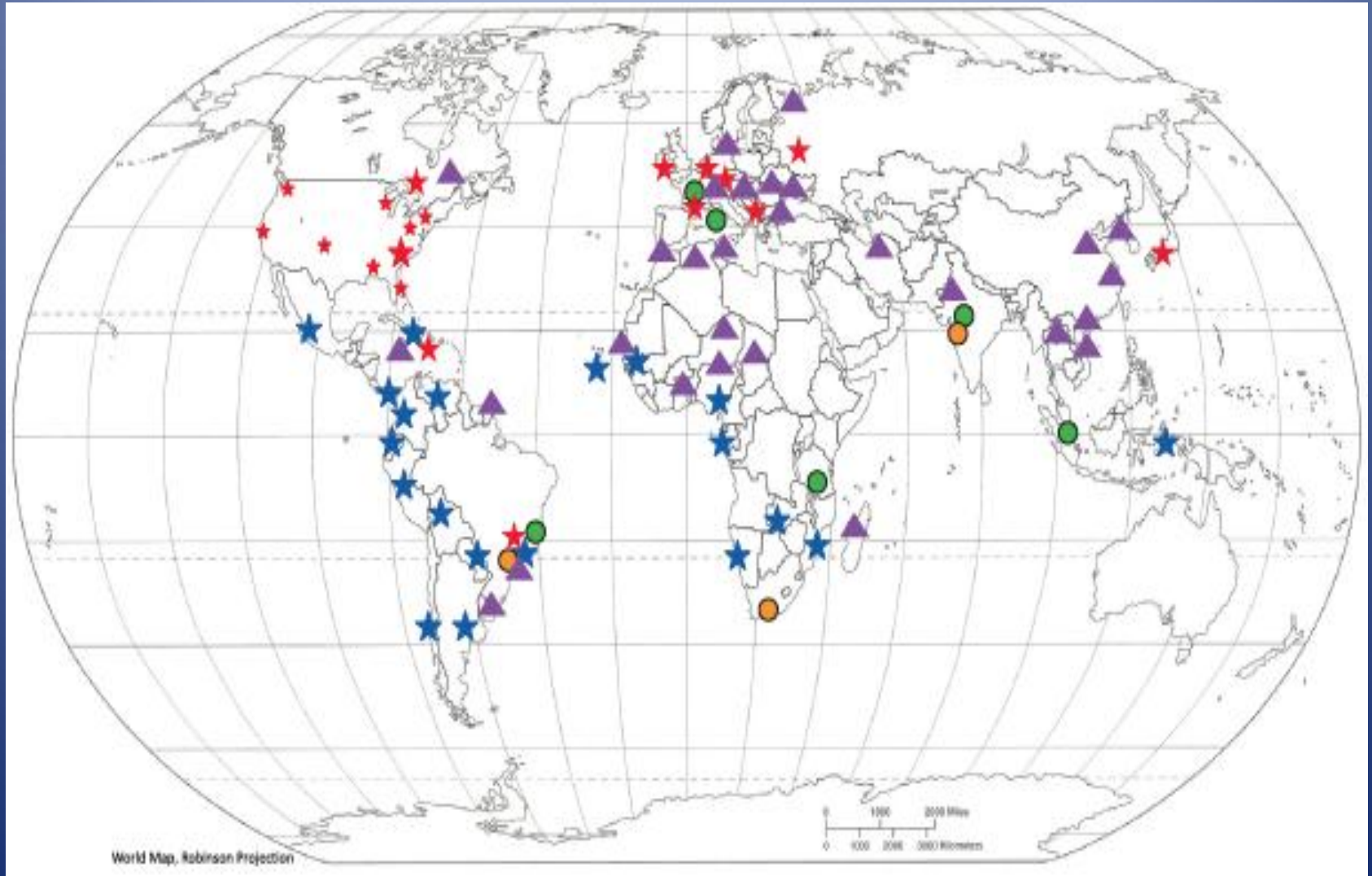
The National Dimension

22 Units



IOC
ENSP
IPEC
IFF
ICICT
INCQS
COC
EPSJV
FAR
BIO

Fiocruz: The international dimension



coop. received ★

coop. offered ★

DNDI ●

IBSA ●

Pasteur Network ▲





Oswaldo Cruz Foundation FIOCRUZ

PHARMACEUTICAL PRODUCTION*

- Drugs against malaria, leishmaniasis, leprosy, TB, Chagas disease, hepatitis
- Anti-retrovirals: zidovudine, nevirapine, lamivudine, indinavir, estavudine, didanosine, efavirenz
- Phytotherapeutic drugs
- Drugs for allergy, hypertension, diabetes and anemia treatment
- Interferon – α } partnership with Cuba
- Eritropoietin }

*50 different products

Hoping to welcome you in
Rio de Janeiro - Brazil

Thank you!