

DNDI Partner's Forum

BRAZIL PERSPECTIVE FOR NEGLECTED DISEASES RESEARCH AND INNOVATION

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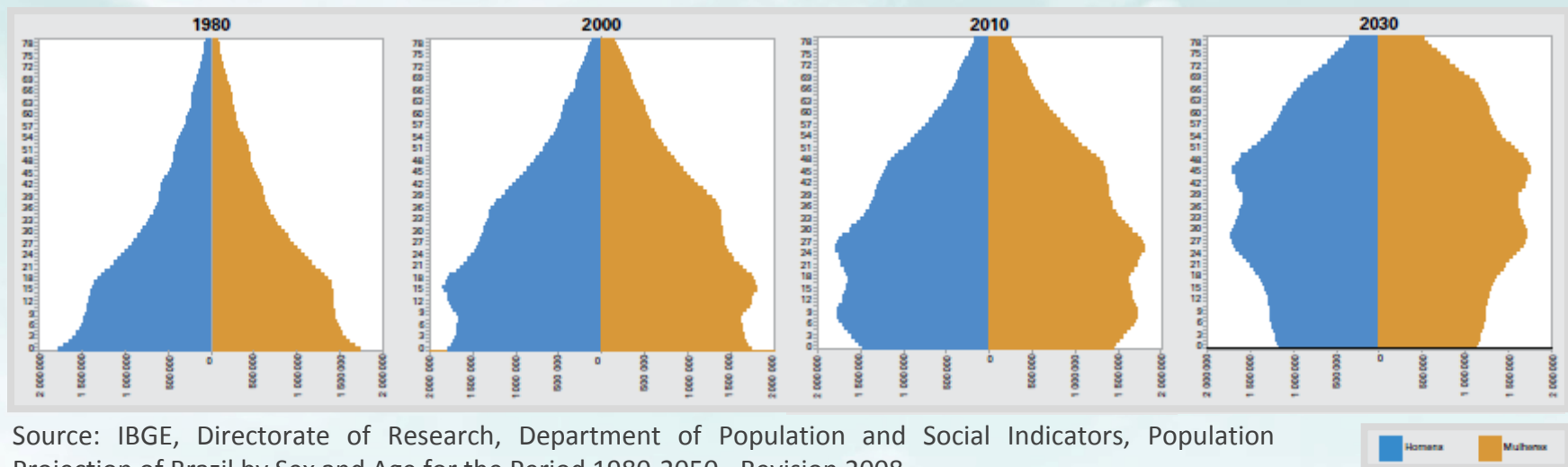
Secretary of Science, Technology and Strategic Products
Ministry of Health

Rio de Janeiro, December 2nd, 2011

CURRENT SCENARIO

DEMOGRAPHIC TRANSITION

- Population aging and change on epidemiologic pattern: increasing chronic diseases burden



Source: IBGE, Directorate of Research, Department of Population and Social Indicators, Population Projection of Brazil by Sex and Age for the Period 1980-2050 - Revision 2008

Risk: Neglected diseases become even more neglected.

CURRENT SCENARIO

Ranking mundial do mercado farmacêutico (em US\$ bilhões)

Rk	País	2010
1	Estados Unidos	312,2
2	Japão	96,3
3	Alemanha	45,3
4	França	43,7
5	China	40,1
6	Itália	29,2
7	Espanha	25,5
8	Brasil	22,1
9	Reino Unido	21,6
10	Canadá	21,6
11	Rússia	13,1
12	Índia	12,3
13	Coreia do Sul	11,4
14	Austrália	11,3
15	México	10,8
16	Peru	10,6
17	Grécia	7,8
18	Polônia	7,8
19	Holanda	6,9
20	Bélgica	6,8

Fonte: IMS Market Prognosis 2010-2014

Nota: Brasil ultrapassou o Reino Unido em 2010 e subiu para o oitavo lugar.

LARGEST CONSUME IN HEALTH

Faturamento da indústria farmacêutica no Brasil

Últimos 5 anos (em R\$ milhões)

2006	2007	2008	2009	2010
21.452	23.583	26.398	30.175	36.249

Fonte: IMS Health

Faturamento da indústria farmacêutica no Brasil

Últimos 5 anos (em US\$ milhões)

2006	2007	2008	2009	2010
9.868	12.180	14.649	15.408	20.641

Fonte: IMS Health

Volume de vendas no Brasil

(em bilhões de unidades)

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

Fonte: IMS Health

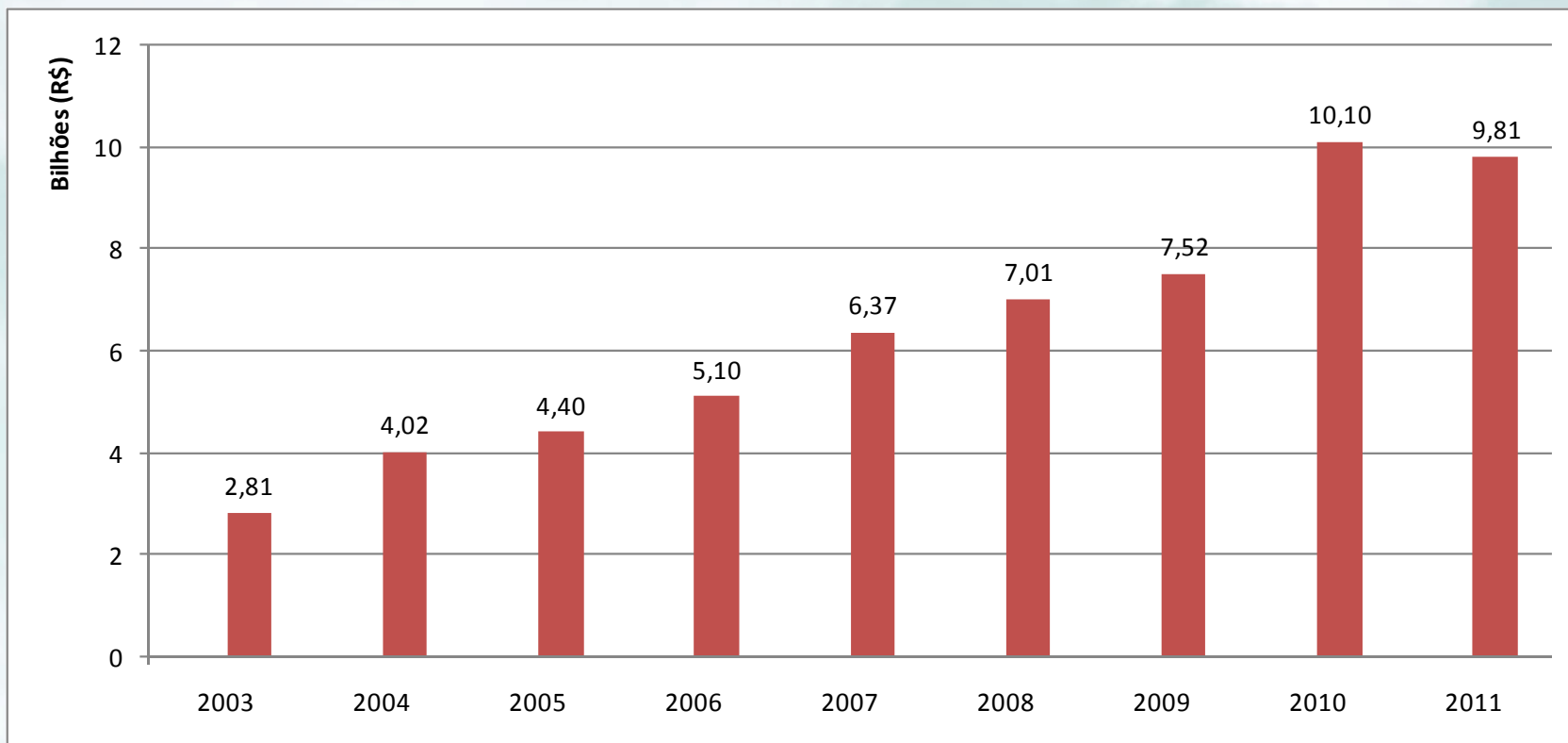
Source: Interfarma Guide 2011.



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INCREASE IN THE PUBLIC PURCHASING



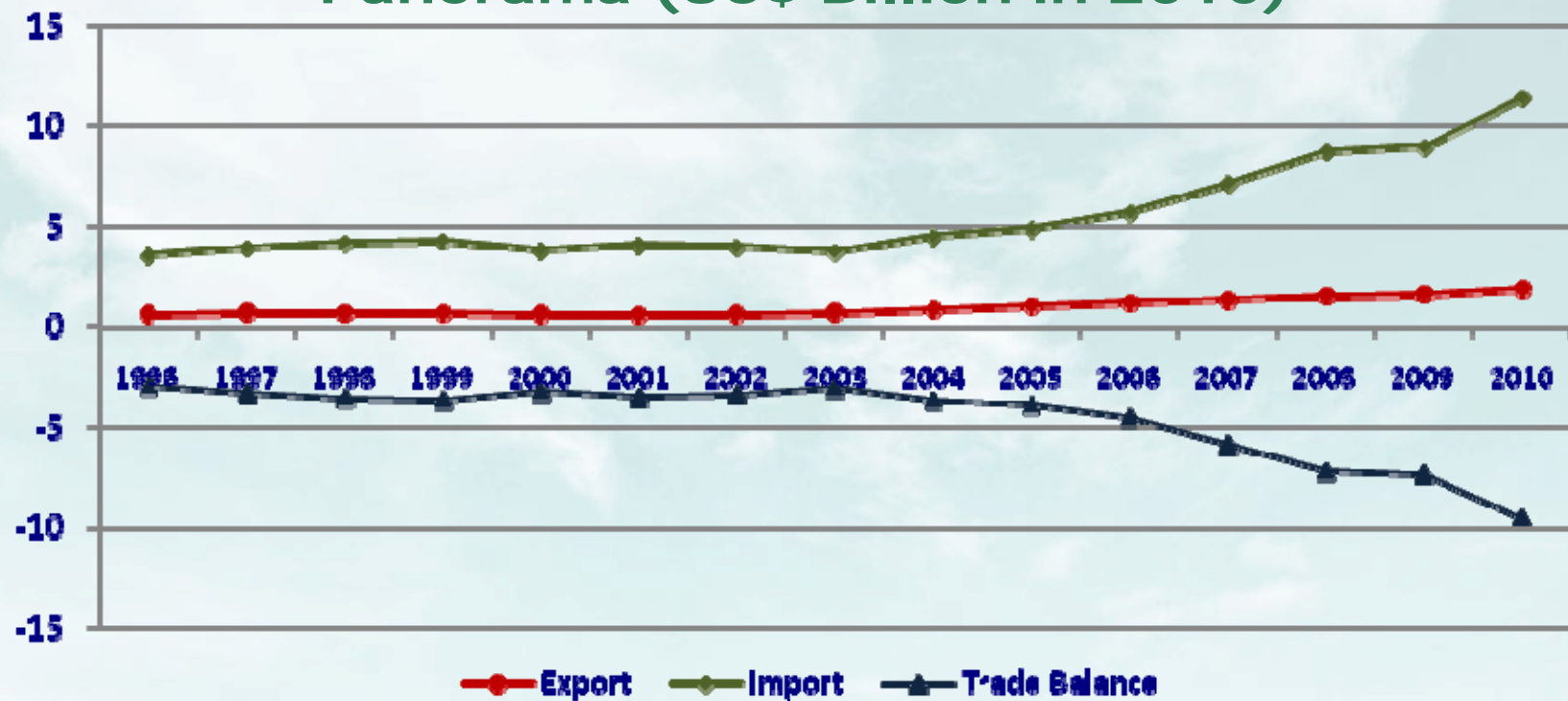
Fonte: Elaboração SCTIE com base nos dados do DAF, DECIIS e NIES/SVS



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Evolution of the Health Trade Balance: General Panorama (US\$ Billion in 2010)



Source: Elaborated by GIS/FIOCRUZ, from Alice Web data (SECEX/MDIC). Accessed January 2011.

The deficit is at the US\$ 10 billion level - one of the areas in the country that is most dependent besides being central to social policy



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CONCRETE ACTIONS OF THE MINISTRY OF HEALTH

STRATEGIES FOR THE PRODUCTION AND TECHNOLOGY DEVELOPMENT

- 1 ▶ Strengthening of Industrial Policy
- 2 ▶ Strengthening the National Productive Park
- 3 ▶ Use of the Public Purchasing Power

Executive Group of the Industrial Health Complex - GECIS

- ▶ Created by Presidential Decree on May 12th, 2008
- ▶ It is intended to promote measures and concrete actions to implement the regulatory framework on health
- ▶ Composed by **14 public institutions**
MS (coordinator), MDIC (co-coordinator), MCTI, MPOG, MF, MRE, Casa Civil, ANVISA, FIOCRUZ, BNDES, INPI, ABDI, INMETRO and FINEP
↳ “Executive Committee” of the Plano Brasil Maior health area
- ▶ Forum of Articulation: **22 representatives** of business associations, unions and other representatives of civil society
↳ “Council of Sectoral Competitiveness” in the Plano Brasil Maior

MoH CONCRETE ACTIONS



MoH CONCRETE ACTIONS

2 THE STRENGTHENING OF NATIONAL INDUSTRIAL PLATFORM

This action runs through

- ▶ Increasing investment in Public Labs
- ▶ Fostering network

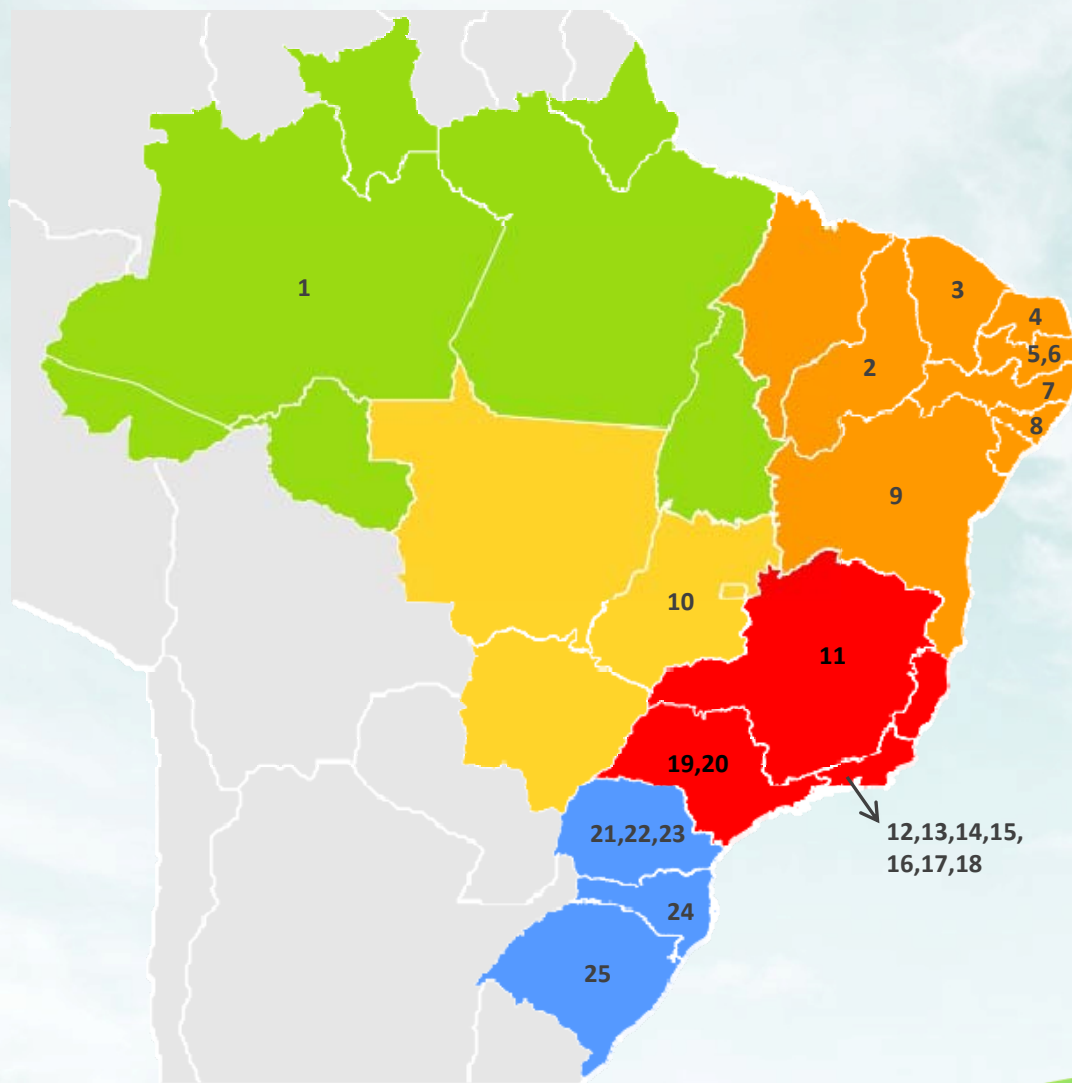
MoH CONCRETE ACTIONS

Investment in Public Labs

YEAR	INVESTMENTS IN PUBLIC PRODUCERS
	R\$
2000	8.812.586
2001	26.978.423
2002	9.406.964
2003	36.000.000
2004	77.966.751
2005	60.707.485
2006	67.869.412
2007	54.802.006
2008	42.936.947
2009	29.775.122
2010	42.654.963
2011	54.262.011
TOTAL	512.172.670

Source : DECIIS/SCTIE/MS, data from GESCOM/SISPORT/MS.

MoH CONCRETE ACTIONS



- 1- CEPRAM/AM*
- 2- NTF/PI*
- 3- FFOE/CE*
- 4- NUPLAM/RN
- 5- LTF/PB*
- 6- LIFESA/PB*
- 7- LAFEPE/PE
- 8- LIFAL/AL
- 9- BAHIAFARMA/BA
- 10- IQUEGO/GO
- 11- FUNED/MG
- 12- IVB/RJ
- 13- LQFEX/RJ
- 14- LQFA/RJ
- 15- LFM/RJ
- 16- FAR-MANGUINHOS/RJ
- 17- BIO-MANGUINHOS/RJ
- 18- FAP/RJ
- 19- BUTANTAN/SP
- 20- FURP/SP
- 21- LPM-UEL/PR*
- 22- LPEMC/PR*
- 23- TECPAR/PR
- 24- LAFESC/SC**
- 25- LAFERGS/RS*

*Inativo **Desativado

MoH CONCRETE ACTIONS

Fostering Network

- ▶ Articulation of Pre-Clinical Pharmacology Centers (Ordinance n. 8/2011)
- ▶ Creation of the National Network for the Development and Innovation of Anticancer Drugs (REDEFAC)
- ▶ Strengthening of the Brazilian Network of Bioequivalence (REQBIO)
- ▶ Consolidation of the Laboratory for **IFAs** Analysis (LAIF/PUC/RS)
- ▶ **Consolidation of a strategic network of clinical research: neglected diseases, oncology, neurosciences**
- ▶ Network on Health Technology Assessment

MoH CONCRETE ACTIONS

3

USING PUBLIC PURCHASING POWER

The optimization of public procurement comes through:

- ▶ **Partnerships for Productive Development**, with tech transfers
- ▶ **Technological Orderings**, which are linked to specific demands

MoH CONCRETE ACTIONS

- ▶ **30** final products, being 28 medicines, DIU and quick test
- ▶ **29** formal partnerships*
- ▶ **9** groups of disease covered
- ▶ **32** partners, 10 public laboratories and 22 private ones

HEALTH PUBLIC PURCHASING POWER

- ▶ **R\$ 4 billion/year** in public procurement
- ▶ **R\$ 1,7 billion/year** is the average savings estimated
- ▶ **US\$ 700 million/year** is the expected foreign currency savings

*Without considering three partnerships for vaccines production (Seasonal Influenza, Pneumococcal e Meningococcal), which had estimated savings of about R\$ 800 millions..

MoH CONCRETE ACTIONS

The Ministry of Health gives priority to policies and investments aimed at:

- ▶ **Research and Innovation in Health**
- ▶ **Productive and Technological Development**
- ▶ **Assessment and Incorporation of Technologies**
- ▶ **Pharmaceutical Assistance**

FOCUS ON INCREASING ACCESS

MEDICINES FOR NEGLECTED DISEASES

PRODUCT: “Tuberculostático 4 em 1”

MEDICINES FOR NEGLECTED DISEASES

“Tuberculostático 4 em 1”

- ▶ **PDP:** announced in 2009, fixed-dose combination 4 x 1 (Rifampicina + Isonizida + Etambutol + Pirazinamida)
 - ▶ **Partners:** Minister o Health, Farmanguinhos, Lupin
- Innovative Design – There is no domestic producer of the drug, now available to SUS through the PAHO Revolving Fund
- ▶ **Forecast for comercialization:** 2013 or 2014
 - ▶ **Technology Transfer:** includes domestic production of the drug
 - ▶ **Economy in government procurement,** forecasting savings of approximately R\$ 380,000.00 in five years
 - ▶ **Number of patients in treatment:** an estimation of 74,000 patients

MEDICINES FOR NEGLECTED DISEASES

“Tuberculostático 2 em 1”

- ▶ **Current Producers:** Nuplan, Lqfex, Furp (Isoniazida + Rifampicina 100+150 mg and 200+300mg)
- ▶ Development of new presentations 75+150 mg (capsule) by Nuplan and Lqfex

MEDICINES FOR NEGLECTED DISEASES

PRODUCT: Benznidazole for Chagas Disease treatment

MEDICINES FOR NEGLECTED DISEASES

Benznidazole

- ▶ **Used to treat patients with Chagas disease, neglected disease due to low profitability of the drug and technical difficulties**
- ▶ **In 2007, Roche, hitherto the only manufacturer worldwide, announced the shutdown of the production of benznidazole, and in 2009 donated the rest of the IFA to Brazil**
- ▶ **The Ministry of Health is committed to joint actions aimed at ensuring the world's supply**
- ▶ **Brazil is now the only world producer of benznidazole**

MEDICINES FOR NEGLECTED DISEASES

National Production of Benzonidazole Ministry of Health – ANVISA – Lafepe – Nortec

- ▶ **Lafepe:** is the drug producer. In November 2011, it started production with the new IFA, provided by Nortec
- ▶ **Nortec:** it completed the transference of technology, providing Lafepe 320 Kg of the IFA benznidazole, as accorded in contract.
- ▶ **ANVISA:** this institution together with the Ministry of Health, tracks and monitors the entire production process of the IFA and the drug
- ▶ **It is being developed to submit pediatric presentation**

MEDICINES FOR NEGLECTED DISEASES

Benzonidazole

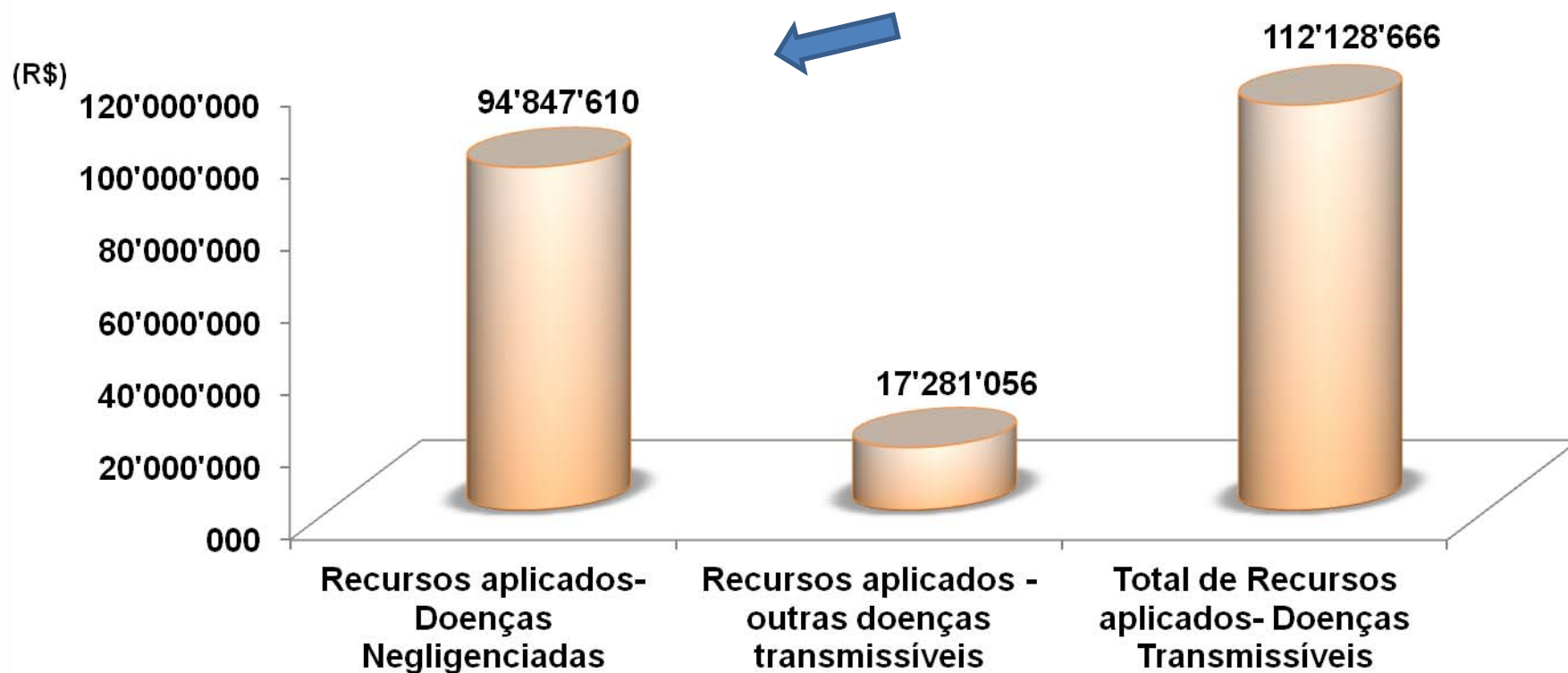
- ▶ **Confirmed the availability of 3.200,000 tablets until the end of 2011**
- ▶ **Brazil has donated, MSF/PAHO, 55,000 tablets for immediate assistance to Paraguay**
- ▶ **IT has been already provided by Lafepe 173,000 tablets, which are awaiting for PAHO's authorization for shipment.**

FOSTERING RESEARCH IN NEGLECTED DISEASES

- **INCTs supported by SCTIE involving the following themes:**
 - **National Institute of Science and Technology in Dengue (INCT-D);**
 - National Institute of Science and Technology of Drugs and Medicines (INCT-INO FAR);
 - **National Institute of Science and Technology Innovation in Neglected Diseases (INCT-IDN);**
 - National Institute of Science and Technology for Pharmaceutical Innovation (INCT-if);
 - **National Institute of Science and Technology in Tuberculosis (TB-INCT);**
 - **National Institute of Science and Technology of Vaccines (INCTV).**

FOSTERING RESEARCH IN NEGLECTED DISEASES

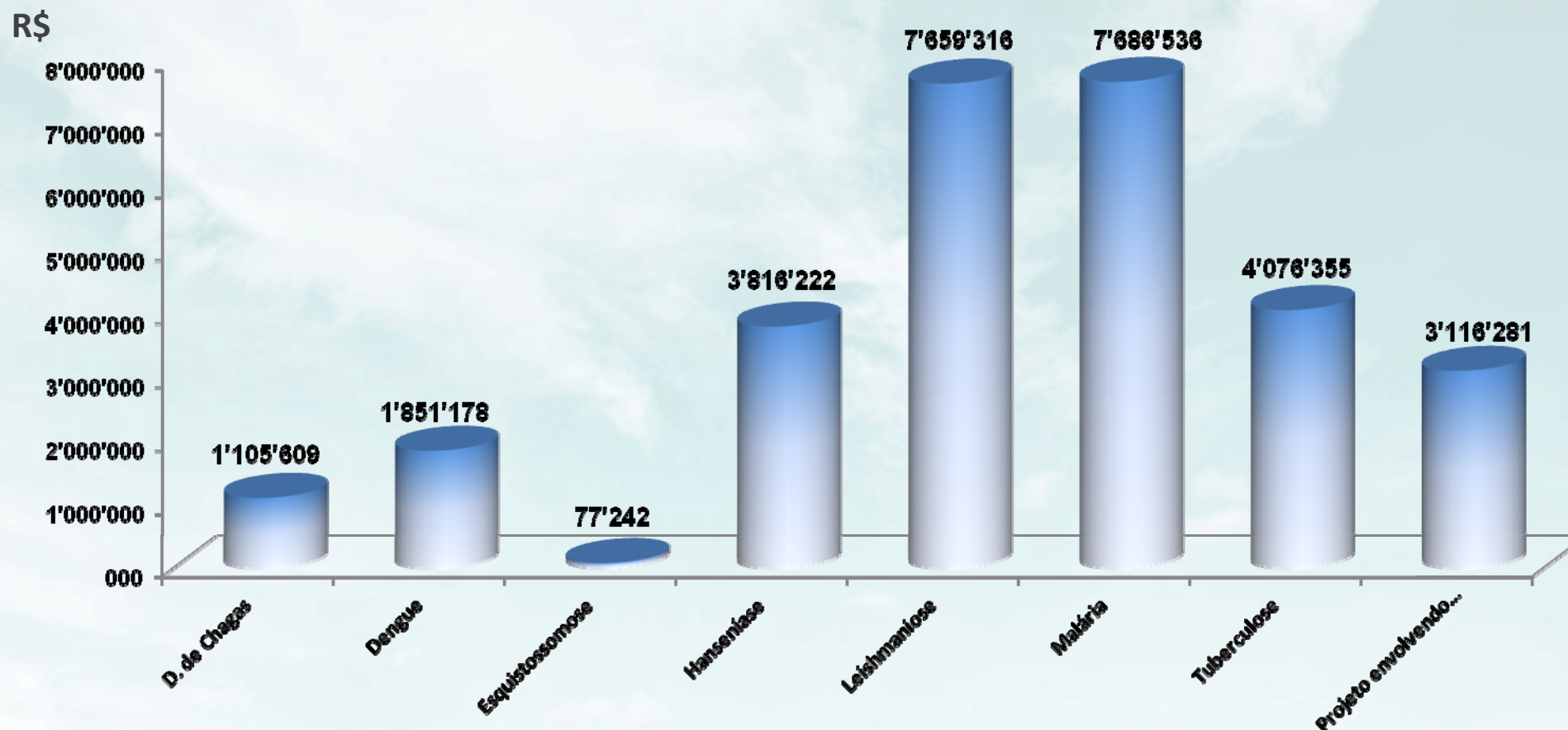
Graphic 3 - Resource Amount (R\$) applied to the funding of research projects on neglected diseases, DECIT / SCTIE, 2002 to 2010.



Source: Managerial Database of Decit. Available on <www.saude.gov.br/pesquisasaude>. Accessed on Nov 15th, 2011

FOSTERING RESEARCH IN NEGLECTED DISEASES

Graphic 5 - Funds Invested (R\$) In research projects on drugs for neglected diseases - DECIT / SCTIE, 2002 to 2010.

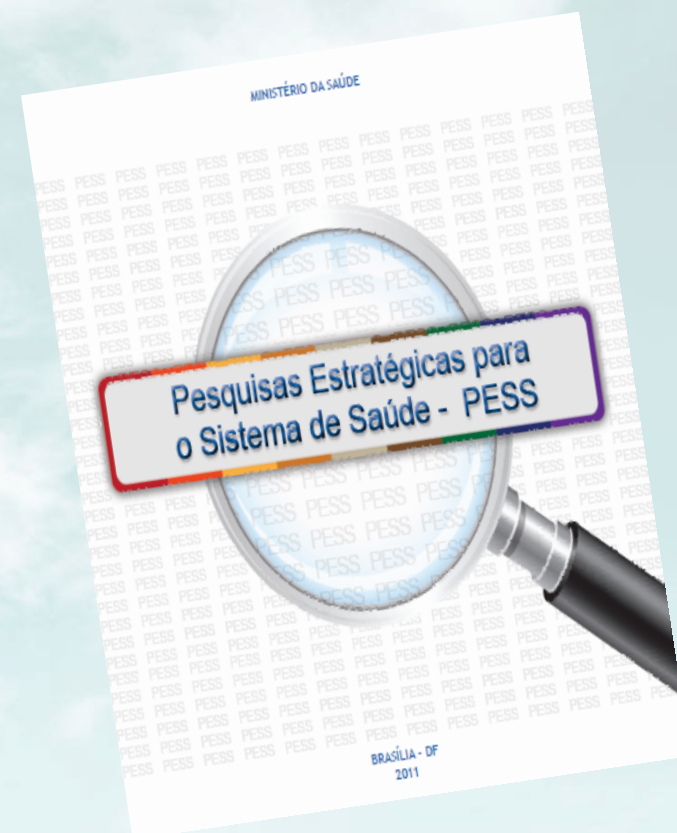


Source: Managerial Database of Decit. Available on <www.saude.gov.br/pesquisasaude>. Accessed on Nov 15th, 2011.

Strategic Research for the Health System

Research Perspectives:

✓ The challenge consists in using the available resources to invest in researchs related to the **strategic goals of the current Policy**.

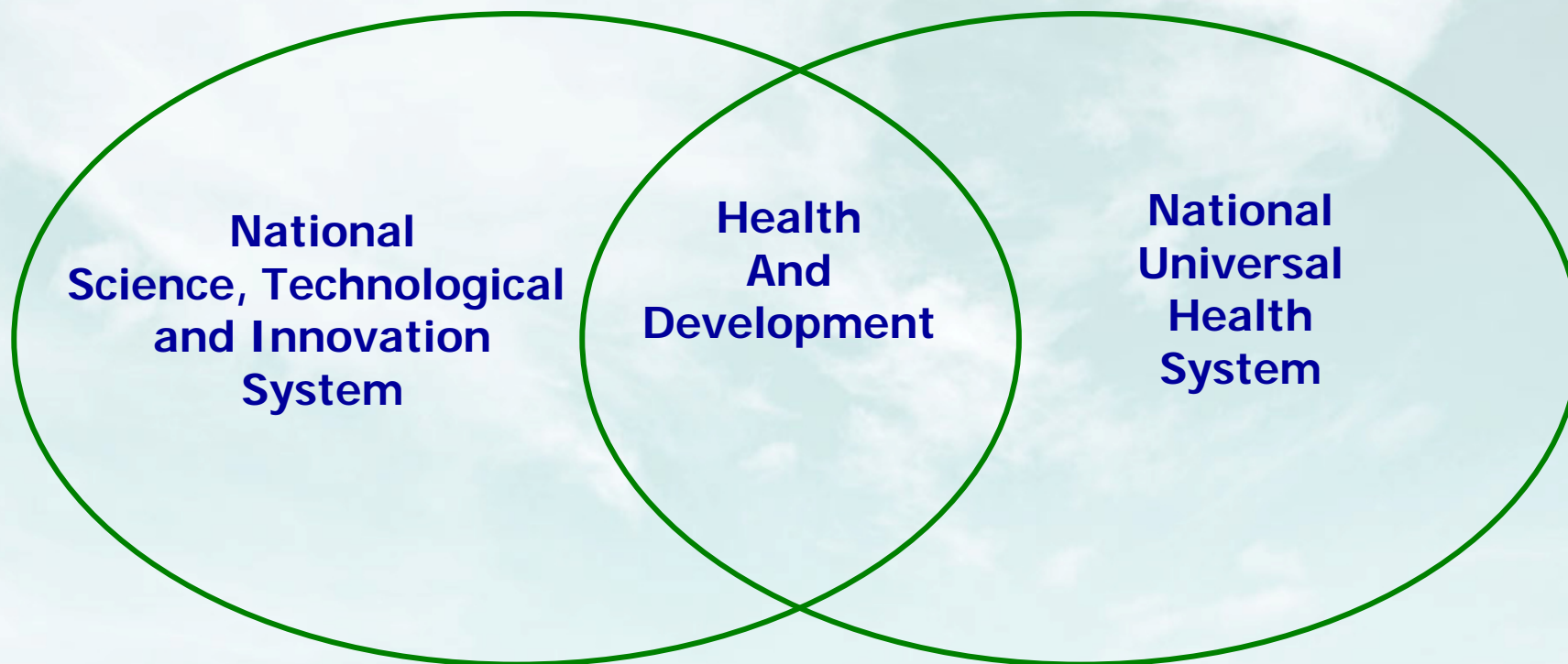


Future perspectives of research in neglected diseases in The Health Policy Agenda

Objetivos Estratégicos do Sistema de Saúde Brasileiro (Plano Plurianual 2012-2015)



Health and Development: The base for a global health action



Thank you!

Carlos Augusto Grabois Gadelha