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
DEMOGRAPHIC TRANSITION

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

Risk: Neglected diseases become even more neglected.
CURRENT SCENARIO

LARGEST CONSUME IN HEALTH

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

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


**Faturamento da indústria farmacêutica no Brasil**
Últimos 5 anos (em R$ milhões)

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
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<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
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Fonte: IMS Health

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<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
</table>

Fonte: IMS Health

**Volume de vendas no Brasil**
(em bilhões de unidades)

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>1,43</td>
<td>1,51</td>
<td>1,63</td>
<td>1,76</td>
<td>2,06</td>
</tr>
</tbody>
</table>

Fonte: IMS Health
INCREASE IN THE PUBLIC PURCHASING

<table>
<thead>
<tr>
<th>Year</th>
<th>Bilhões (R$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>2,81</td>
</tr>
<tr>
<td>2004</td>
<td>4,02</td>
</tr>
<tr>
<td>2005</td>
<td>4,40</td>
</tr>
<tr>
<td>2006</td>
<td>5,10</td>
</tr>
<tr>
<td>2007</td>
<td>6,37</td>
</tr>
<tr>
<td>2008</td>
<td>7,01</td>
</tr>
<tr>
<td>2009</td>
<td>7,52</td>
</tr>
<tr>
<td>2010</td>
<td>10,10</td>
</tr>
<tr>
<td>2011</td>
<td>9,81</td>
</tr>
</tbody>
</table>

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

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 Comitte” 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
This action runs through

- Increasing investment in Public Labs
- Fostering network
## MoH CONCRETE ACTIONS

### Investment in Public Labs

<table>
<thead>
<tr>
<th>YEAR</th>
<th>INVESTMENTS IN PUBLIC PRODUCERS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>R$</td>
</tr>
<tr>
<td>2000</td>
<td>8,812,586</td>
</tr>
<tr>
<td>2001</td>
<td>26,978,423</td>
</tr>
<tr>
<td>2002</td>
<td>9,406,964</td>
</tr>
<tr>
<td>2003</td>
<td>36,000,000</td>
</tr>
<tr>
<td>2004</td>
<td>77,966,751</td>
</tr>
<tr>
<td>2005</td>
<td>60,707,485</td>
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<tr>
<td>2006</td>
<td>67,869,412</td>
</tr>
<tr>
<td>2007</td>
<td>54,802,006</td>
</tr>
<tr>
<td>2008</td>
<td>42,936,947</td>
</tr>
<tr>
<td>2009</td>
<td>29,775,122</td>
</tr>
<tr>
<td>2010</td>
<td>42,654,963</td>
</tr>
<tr>
<td>2011</td>
<td>54,262,011</td>
</tr>
<tr>
<td>TOTAL</td>
<td>512,172,670</td>
</tr>
</tbody>
</table>

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- LEPEMC/PR*
23- TECPAR/PR
24- LAFESC/SC**
25- LAFERGS/RS*

*Inativo  **Desativado
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
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**.
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**
PRODUCT: “Tuberculostático 4 em 1”
“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 commercialization**: 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
“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
PRODUCT: Benznidazole for Chagas Disease treatment
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
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**
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 Lafa Pe 173,000 tablets, which are awaiting for PAHO’s authorization for shipment.
○ 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-INOFAR);
- 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.

FOSTERING RESEARCH IN NEGLECTED DISEASES

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

The challenge consists in using the available resources to invest in researches related to the strategic goals of the current Policy.
Future perspectives of research in neglected diseases in The Health Policy Agenda
Health and Development: The base for a global health action

- National Science, Technological and Innovation System
- Health And Development
- National Universal Health System
Thank you!

Carlos Augusto Grabois Gadelha