Innovation Policies to Meet the Challenges of Neglected Diseases

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Outline of Presentation

- Background – The Neglected Diseases Challenge and the Crisis of Access to Medicines in Developing Countries
- Innovation, Intellectual Property and Technology Transfer
- Innovation Policies- Brazilian Initiatives: Closing the Access Gap
The Neglected Diseases Challenge

WHO estimates that over 1 billion people – one sixth of the world's population – suffer from one or more neglected tropical diseases. With limited political voice.

For many neglected diseases, the medicines are old, toxic, expensive and often in short supply.

Less than 1% of the nearly 1,400 drugs registered between 1975 and 1999 were for tropical diseases.

Human Rights Dimension

Universal Declaration of Human Rights
Everyone has the right to a standard of living adequate for the health and medical care

"Noncommunicable diseases are imposing a growing burden upon low- and middle-income countries, which have limited resources and are still struggling to meet the challenges of existing problems with infectious diseases," said Dr Catherine Le Galès-Camus, WHO.

Chronic diseases cause more than half of all deaths worldwide, 80% of which occur in low-income and middle-income countries.

Neglected disease problem + Rising of chronic disease

threaten developing nations’ capacity to improve the health of their populations.

“existence of large gaps in the availability of medicines and a wide variation in prices which render essential medicines unaffordable to poor people”

United Nations
Availability of Medicines

critical factors in this access gap

- irrational use of medicines
- unfair financing
- unreliable delivery systems
- inadequate regulatory systems
- high medicines prices

Innovation, Intellectual Property and Technology Transfer

How can IP help developing countries to acquire access to modern technologies?

local innovation  local production
Intellectual Property
Capacity Building and Development

Capacity building in developing countries – not trivial task

Complex interactions with technology policy, industrial policy, trade policy competition policy

Use of Trips flexibilities

Poor competition infrastructure

IP litigations and disputes
Trips-plus Agenda and Other Problems

- Bilateral agreements
- Data exclusivity
- Patent linkage
- New anti-counterfeiting initiatives
- Extension of patent protection
- Follow-on patents (evergreening)
- Decreasing patent quality
- Patents of excessive breadth
- Overlapping patent rights
Development and establishment of a set of policies and initiatives to face a double burden of communicable and chronic diseases.
Building an universal health system

Right to Health: citizen’s right established in 1988 Federal Constitution healthcare for all citizens that has to be provided by the State

Unified Health System [Sistema Único de Saúde – SUS]

- Basic foundations
  - Universality of access to health services
  - Equality of healthcare (non discriminatory basis)
  - Community participation
  - Decentralized management

Defined in Law 8.080 (general guidelines) and Law 8.142 (social control), of 1990
“Despite Brazil’s strength in basic scientific and medical research, a large proportion of the population still suffers from ill health. Diseases such as tuberculosis and leprosy are highly prevalent in poor populations, and about 46,000 people die each year from infectious diseases.”

Morel; Carvalheiro; Romero; Costa; and Buss
The Road to Recovery
Nature Outlook 2007
Brazil

Neglected disease problem

Rising of chronic disease

Trade balance in the health sector shows a relevant deficit due pharmaceutical products imports
U$700million (80s)
U$7billion (2008)

vulnerability of the Brazilian social policy

Source: Gadelha, 2009.
Strengthening Brazilian innovation capacity

- Unified Health System (1990)
- National Health Surveillance Agency (1999)
- Popular Pharmacy Programme (2004)
- National STD/AIDS Programme (1983)
- Mais Saúde Programme (2008)
- Health Industrial Complex

Broadening the basis of financial supporters and creating new methods of funding and financial incentives (e.g., Support Programme for the Development of the Pharmaceutical Productive Chain - Profarma-BNDES)

Source: Guimarães, 2008.
Fiocruz has established cooperation agreement with India’s Medical Research Council and South Africa’s Medical Research Center.

Fiocruz has been expanding bilateral cooperation in Latin America, Africa, Europe and North America.

The partnership with Cuba is facilitating the transfer of technology concerning the production of interferon alpha and erythropoietin to Fiocruz (Biomanguinhos), which could generate a yearly saving of around US$ 16 million for the Brazilian National Treasury.

In 2008, Fiocruz (Farmanguinhos) launched a project to construct a factory in Mozambique for the production of HIV/AIDS drugs.

Brazil will invest U$23 million in the factory, which will be built using Brazilian technology. Raw materials will come from India.
FIOCRUZ today

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 his name – Chagas disease, also known as American trypanosomiasis -- its pathogen (Trypanosoma cruzi) and the mechanisms of transmission by reduvid 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

Number of papers (5-year intervals)

Future directions
Fiocruz new Center for Technological Development in Health (CTDH) in its Portuguese acronym) will start to be built in the Mangalinhos campus in the end of 2005 and will be operational in 2008. Its facilities include technological platforms, clinical 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 comprises the scientists, institutions and funding agencies that made the sequencing of the genomes reported in this issue of Science possible and are ready to collaborate in the development of new health interventions that are accessible, affordable and appropriate for developing countries.

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.

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Center for Technological Development in Health
CDTS/FIOCRUZ
CDTS main facilities

- Technological management
- Animal facility BSL III
- Flexible Laboratories
- Technological Platforms (information)
- Technological Platforms (products)
- Support Laboratories
CDTS main facilities
Full Commitment

Implementation of WIPO Development Agenda

Resolution WHA 61.21 on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property