Research and Development in the Perspective of Sustainability and Human Rights

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HTAi – Health Techonology Assessment international

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Diseases Classification

Geographic Distribution and Investment in R&D

- Global
- Neglected
- Most Neglected
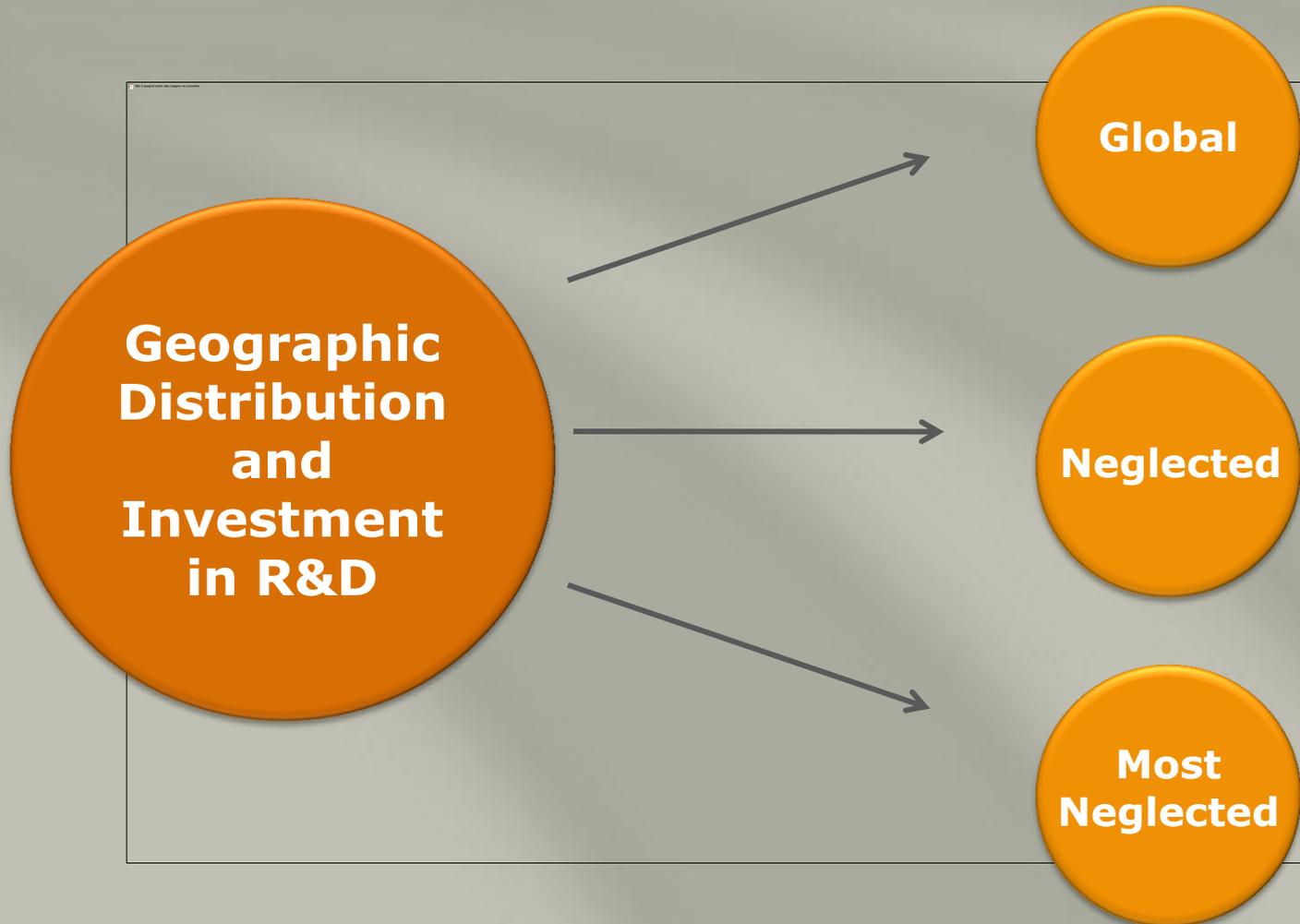
Source: World Health Organization, 2000; Morel, 2005.

Diseases Classification: Global Diseases

Global Diseases

- occur on developed countries and developing countries
- in both cases there is a large number of vulnerable populations

- Cancer
- Cardiovascular diseses
- Mental ilness and neurological disorders

- there are market incentives for R&D in developed countries
- most people cannot afford the medicines
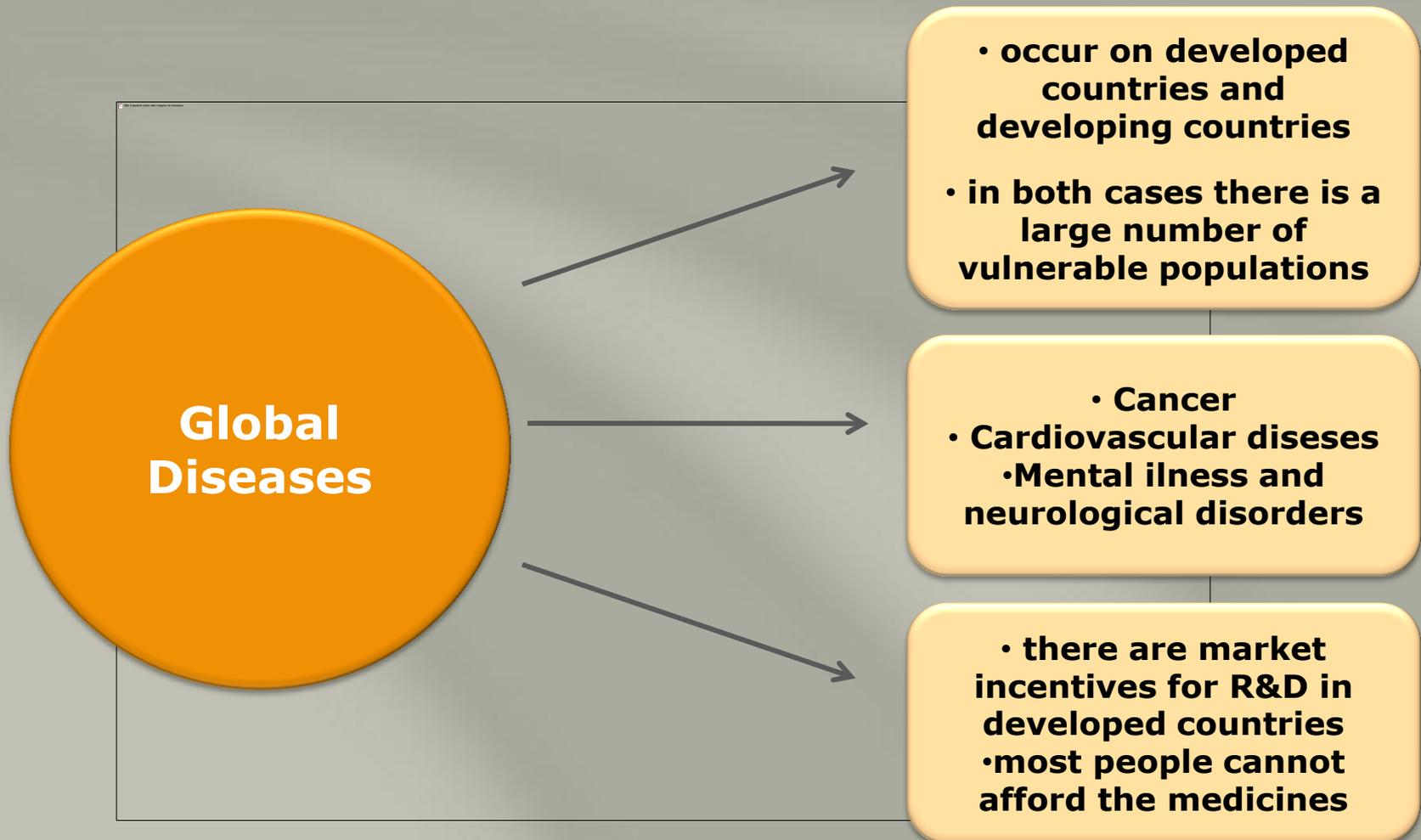
Source: World Health Organization, 2000; Morel, 2005.

Diseases Classification: Neglected Diseases
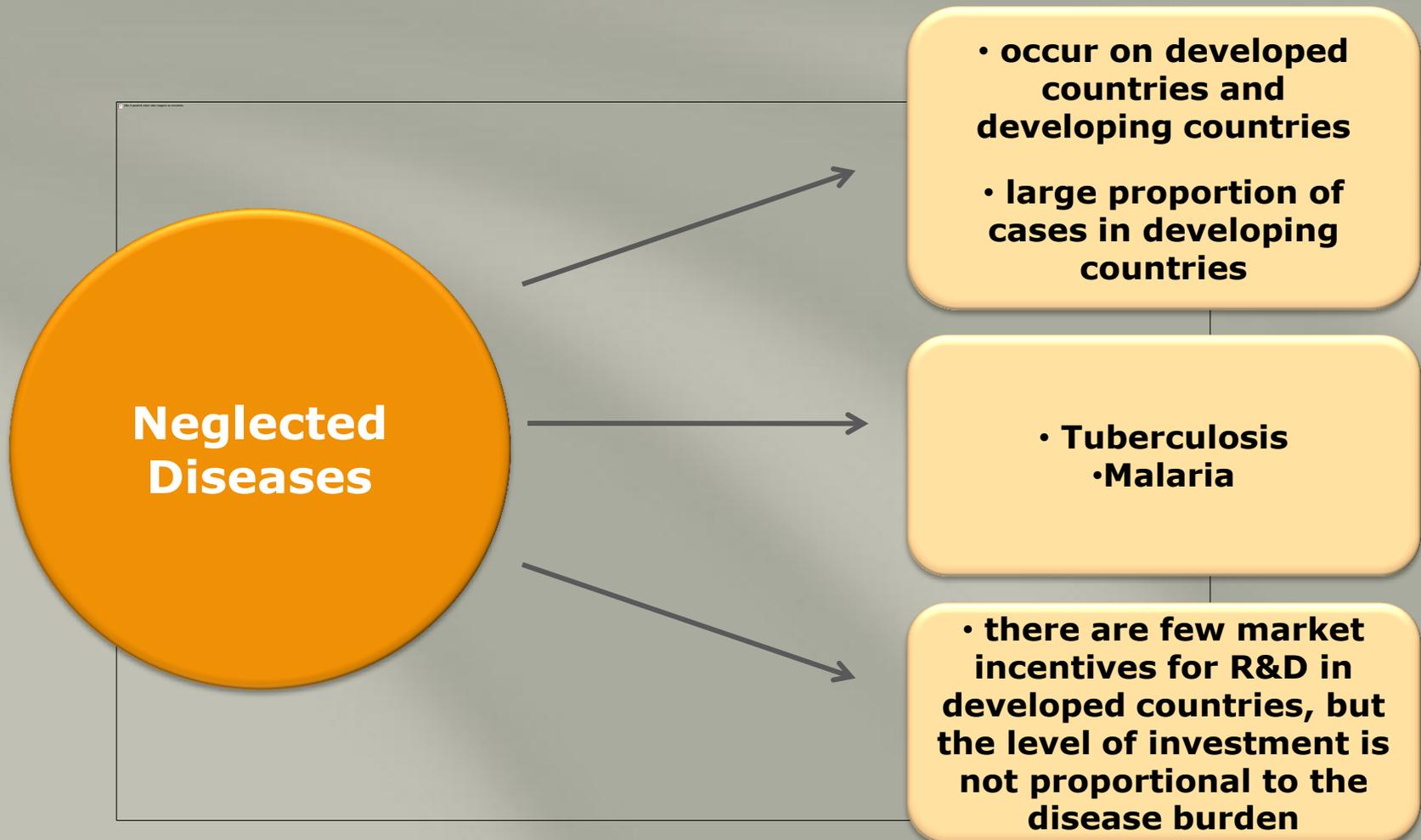
Neglected Diseases

- occur on developed countries and developing countries
- large proportion of cases in developing countries

- Tuberculosis
- Malaria

- there are few market incentives for R&D in developed countries, but the level of investment is not proportional to the disease burden

Source: World Health Organization, 2000; Morel, 2005.

Most Neglected Diseases

- **related almost exclusively with developing countries**

- **Chagas disease**
- **Leishmaniasis**

- **scarce R&D in developed countries**

Source: World Health Organization, 2000; Morel, 2005.
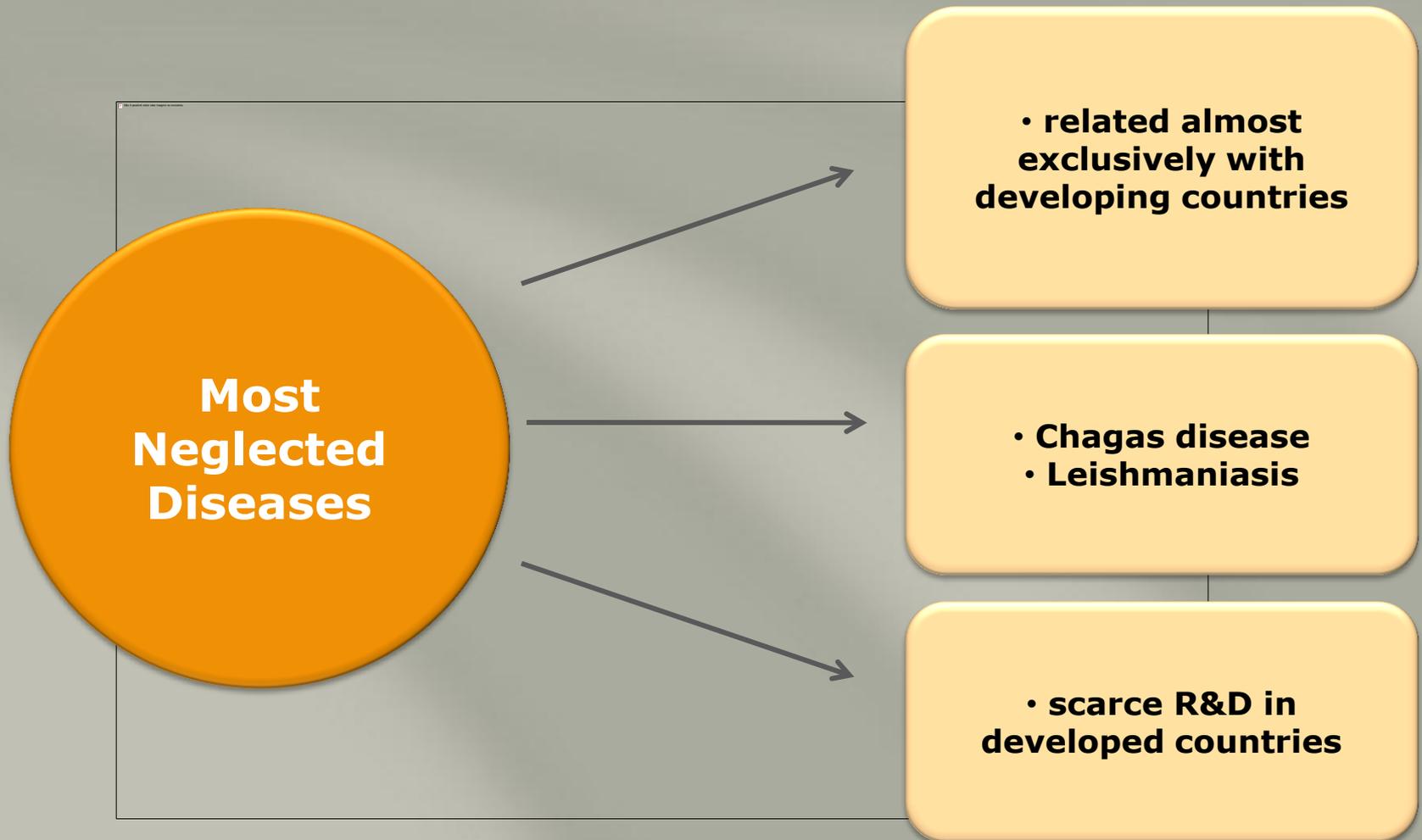
Pharmaceutical needs

What kinds of needs does the pharmaceutical market cover?

A represents Global Diseases,

such as cancer, cardiovascular diseases, mental illness and neurological disorders, which constitute the major focus of the R&D-based pharmaceutical industry. Although affecting developed and developing countries, most people in developing countries who have needs for drugs to treat these diseases cannot afford them, and are thus not covered by the pharmaceutical market.

B represents Neglected Diseases,

such as malaria and tuberculosis (TB), for which the R&D-based pharmaceutical industry has only marginal interest. Although also affecting people in wealthy countries, for example TB patients or people who get malaria while travelling, these illnesses primarily affect people in developing countries.

C represents the Most Neglected Diseases,

such as sleeping sickness, Chagas disease and leishmaniasis, which exclusively affect people in developing countries. Because most of these patients are too poor to pay for any kind of treatment, they represent virtually no market and for the most part fall outside the scope of the drug industry's R&D efforts, and thus outside the pharmaceutical market.

Z represents the part of the pharmaceutical market for products addressing conditions other than those which are purely medical (such as cellulite, baldness, wrinkles, dieting, stress and jet-lag), which nonetheless represent a highly profitable market segment in wealthy countries.
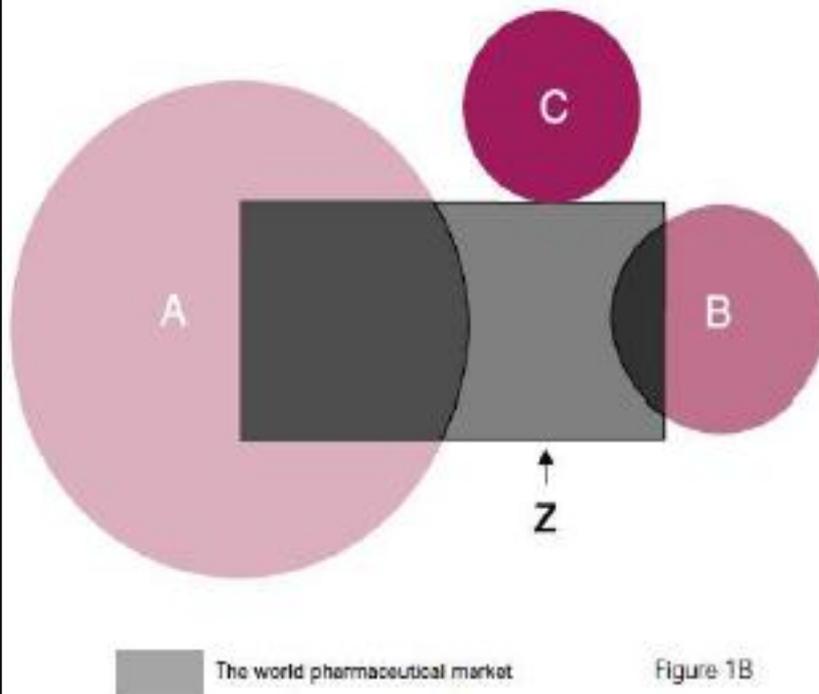
The world pharmaceutical market   Figure 1B

Source: Morel, 2010 in RJ Regional Symposium - Brazilian Academy of Sciences - Innovation for Neglected Diseases, 2010.
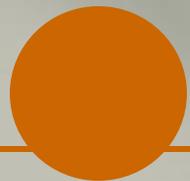
First Problem

Only 10 per cent of global health research (R&D) is devoted to conditions that account for 90 per cent of the global disease burden

1990

1998

promotes the reduction of inequalities in health research

Source: International Policy Network, 2004.

Global Health R&D Financing Agenda

- **President´s Emergency Plan for AIDS Relief (PEPFAR)**

- **Global Fund**

- **Gates Foundation**

- **International Finance Facility Immunisation (IFFIm)**

- **UNITAID**

- **Advance Market Commitments (AMC)**

**Experts, and industry have proposed a number of new ideas, including both "push" mechanisms to finance R&D and "pull" incentives to spur private sector investment**

Recent Innovations In Health R&D Financing:
- Grants for PDPs (push);
- Government grants to small and medium-size companies (push);
- Advance market commitments (AMCs—pull);
- FDA priority review vouchers (PRVs—pull).

Source: DNDi (Drugs for Neglected Diseases initiative) - Financing neglected disease R&D: principles and options - March 22, 2010
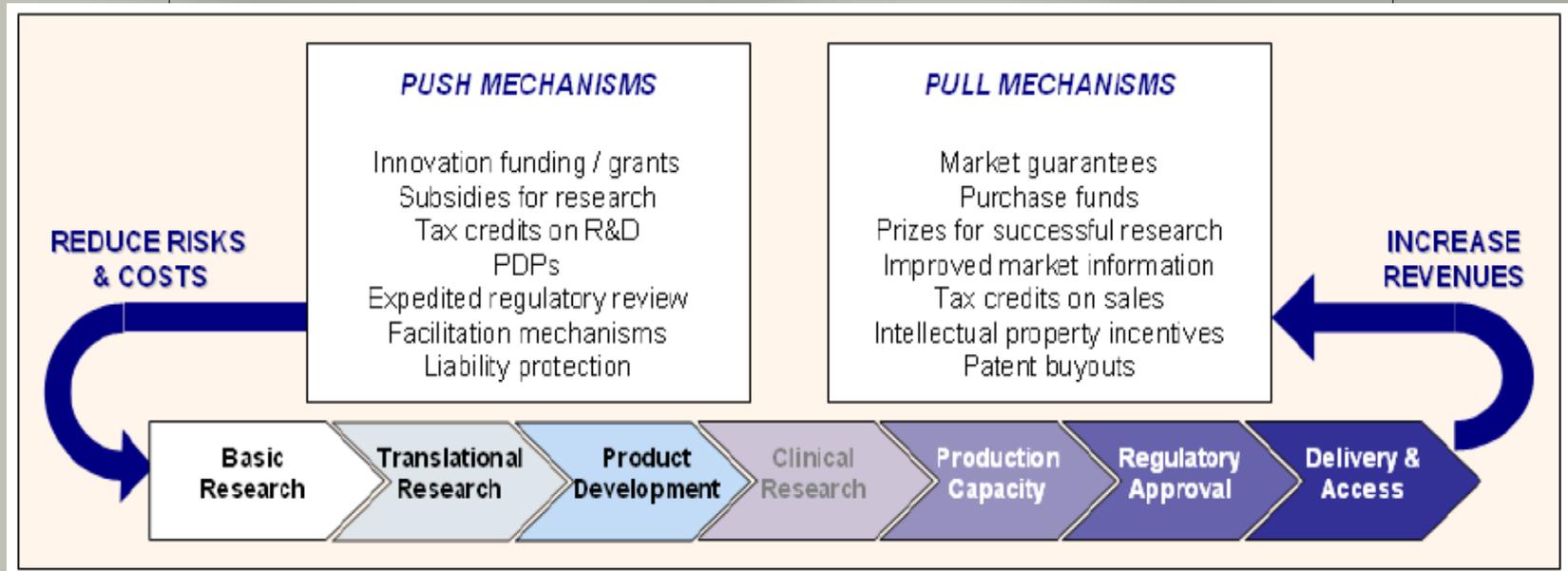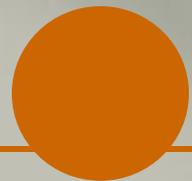
Second Problem

Human Rights dimension and the neglected diseases

• **Association between their prevalence and conflict and violation of human rights;**

• **The neglected diseases affect mainly the poor, who have no economic and political power and are very often neglected by their governments;**

• **Most affected populations live in remote areas with limited or no access to treatment or prevention;**

• **"*Civilization is judged by the treatment of its minorities.''* Mahatma Gandhi**

Deaths, poverty-related diseases and developed-country diseases

Table 1 Deaths caused by poverty-related diseases[20]

% of deaths caused by/in	High mortality low-income countries	Low mortality low-income countries	High-income countries
Infectious and parasitic diseases	34.1	24.8	2.1
Respiratory infections	9.9	8.0	3.7
Perinatal and maternal conditions	8.4	6.8	0.4
Nutritional deficiencies	1.3	1.1	0.0
Tropical diseases	0.5	0.3	0.0
Total 'poverty-related' diseases	54.1	40.7	6.2

Table 2 Deaths caused by 'developed-country' diseases[21]

% of DEATHS caused by/in	High mortality developing countries	Low mortality developing countries	Developed countries
Malignant neoplasms (cancers)	6.3	9.9	21.2
Diabetes	0.6	1.5	1.7
Neuropsychiatric disorders	1.3	1.4	2.9
Cardiovascular diseases	18.9	23.4	47.8
Respiratory diseases (asthma)	4.0	6.7	5.0
Digestive diseases	2.7	3.4	3.7
Total 'developed-countries' diseases	33.8	46.4	82.3

Source: International Policy Network, 2004.

| Sixth MDG – Main goals

To combat HIV / AIDS, malaria and other diseases | **Goal 7 –**
Until 2015, have halted the spread of HIV / AIDS and begun to reverse the actual trend |
	Goal 8 – **Until 2015, have halted the incidence of malaria and other major diseases and begun to reverse the actual trend**
	Goal 8.A – **Until 2015, have reduced incidence of malaria and tuberculosis**
	Goal 8.B – **Until 2010, have eliminated leprosy**

Source: IPEA, 2010.
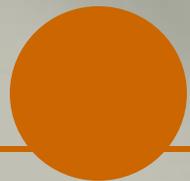
Strategies

Ministry of Health (MS) spending on drugs and neglected diseases in Brazil – 2007: Organizar a sociedade civil

Gastos do MS com medicamentos para a assistência farmacêutica e ocorrência de AIDS, hepatites virais e hanseníase, mais tuberculose, leishmanioses e malária –2007
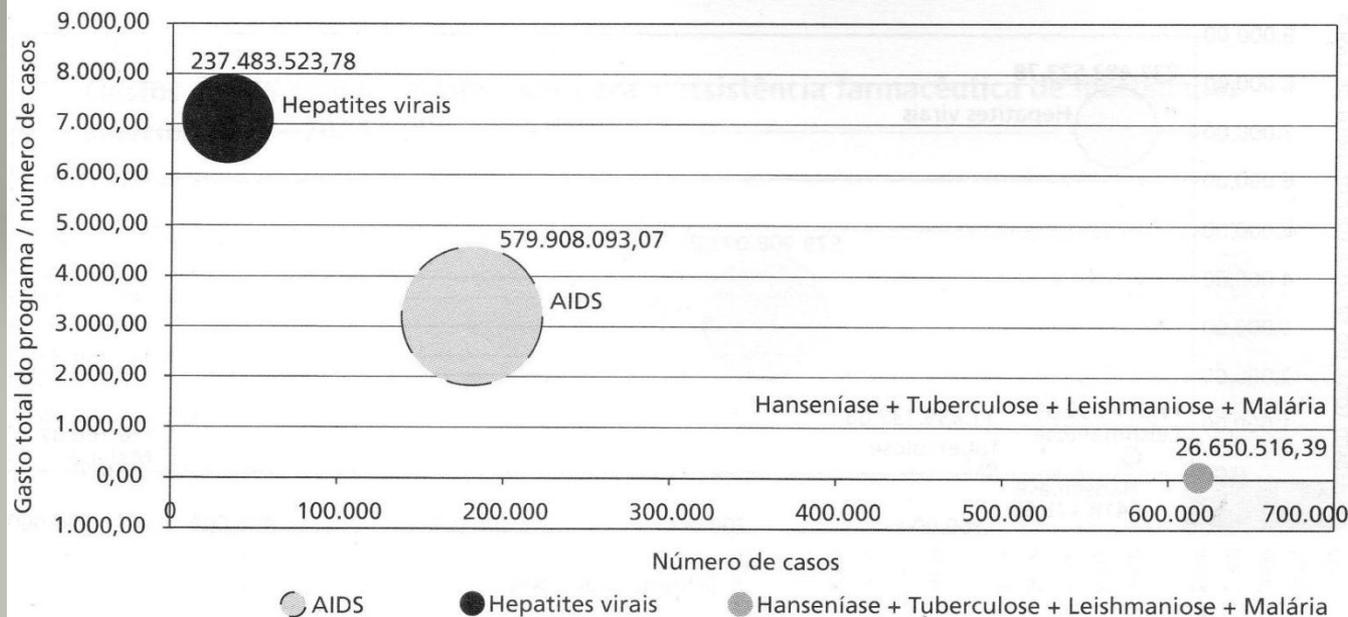
Fontes: SIASG; DESD/MS; Sinan/DEVEP/SVS/MS e SIVEP-Malária.
Obs.: Valores deflacionados pelo IPA de medicamentos; ano-base 2005.
O gasto federal com medicamentos para cada programa foi extraído da tabela completa que consta de Ipea ([s.d.]).
Os dados de ocorrência de AIDS correspondem ao número estimado de pessoas que receberam TARV em 2007, segundo a OMS e o UNAIDS.
Os dados de ocorrência de hepatites virais correspondem ao número de casos notificados, em 2007, de hepatite B mais hepatite C, no Sinan.
Os dados de ocorrência de hanseníase e tuberculose correspondem ao número de casos notificados desses agravos, em 2007, no Sinan.
Os dados de ocorrência de leishmanioses correspondem ao número de casos notificados de LTA mais LV, em 2007, no Sinan.
Os dados de ocorrência de malária correspondem ao número de casos notificados desse agravo, em 2007, no Sinan e no SIVEP-Malária.
Os dados sobre os gastos com medicamentos para o tratamento das hepatites virais estão sujeitos à revisão.
As hepatites virais não fazem parte dos medicamentos do grupo estratégico, mas pertencem à categoria de fármacos de alto custo. Foram inseridas no gráfico para permitir uma comparação com as doenças do grupo estratégico.

Source: IPEA, 2011.

Outline of Health Technology Assessment, Decision - making and Implementation : Contribuir para a acumulação tecnológica
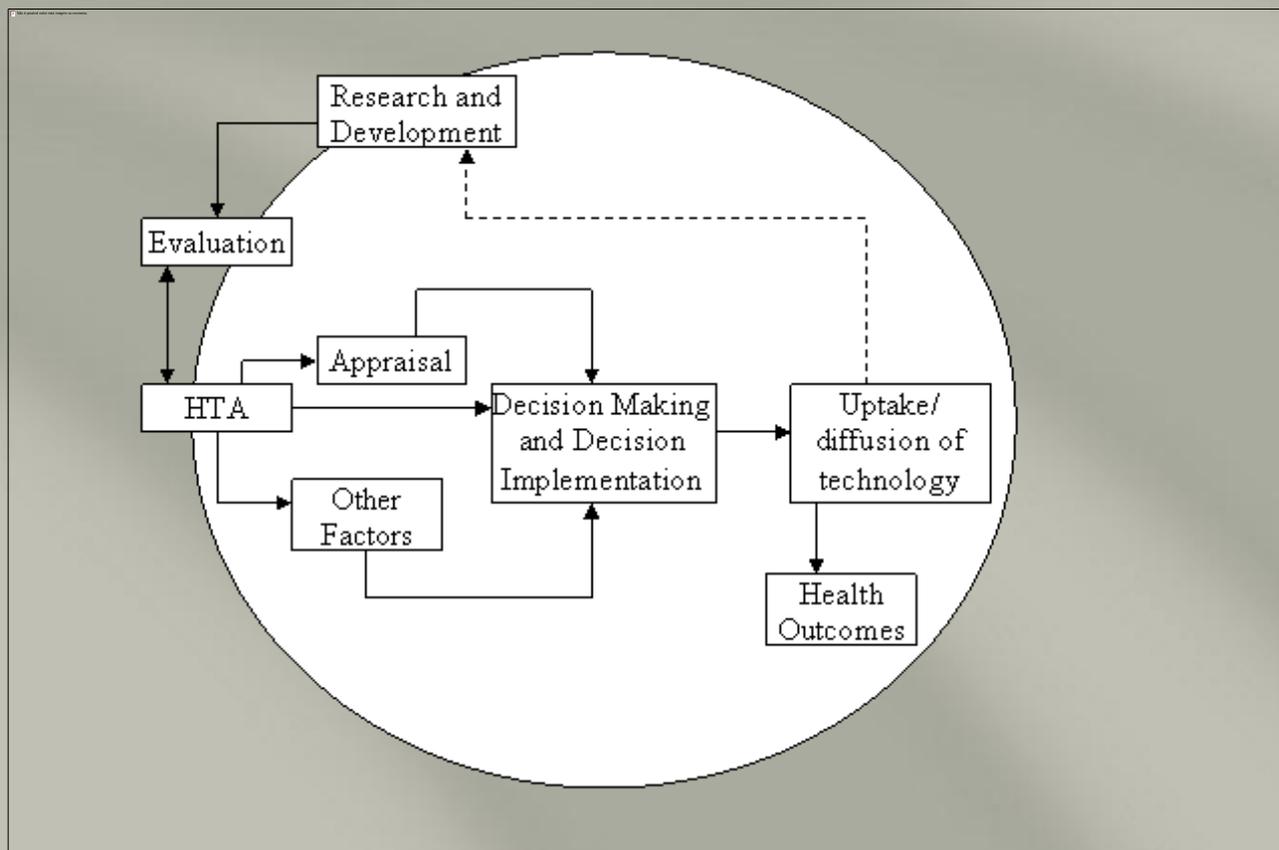
Source: OECD, 2005, p. 22

Group Economics of Innovation

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