Incentives and Financing Mechanisms to promote R&D for HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases

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Disease categories

Type I: rich and poor countries
- HIV/AIDS

Type II: more in poor countries
- TB, Malaria

Type III: only in poor countries
- Neglected tropical diseases
Adult HIV prevalence (15-49 years), 2012
By WHO region

Prevalence (%) by WHO region

- Western Pacific: 0.1 [<0.1-0.2]
- Eastern Mediterranean: 0.2 [0.1-0.2]
- South-East Asia: 0.3 [0.3-0.4]
- Europe: 0.4 [0.3-0.5]
- Americas: 0.5 [0.4-0.6]
- Africa: 4.5 [4.2-4.8]

Global prevalence: 0.8% [0.7-0.9]
Tuberculosis

Estimated TB incidence rates, 2012
Malaria

% Population at risk
- Insufficient data
- 0 - 20 %
- 20 - 40 %
- 40 - 60 %
- 60 - 80 %
- 80 - 100 %
Status of endemicity of visceral leishmaniasis, worldwide, 2012

Number of new VL cases reported, 2012

- >1 000
- 500 - 999
- 100 - 499
- <100
- 0

No autochthonous cases reported
Not available
Not applicable
Distribution of countries or areas at risk of dengue transmission, worldwide, 2008

Countries or areas at risk of dengue transmission
Distribution of human African trypanosomiasis (T.b.gambiense), worldwide, 2012
Trend in Product development

II
- HIV/AIDS
- TB
- Malaria

III
- Neglected tropical diseases

Vaccines
Diagnostics
Drugs
Why are few new medical products available for neglected diseases?

Not enough investment in research and development
Why low investment in R&D?

- Private sector:
  - R&D Costs and risks
  - Investment not likely to be recouped through sales
  - Demand is high but low individual purchasing power
Why low investment in R&D?

- Public sector:
  - Policy choice: intellectual property incentive will not drive private R&D
  - Budget restriction
  - Priority setting
  - Mismatched – focus on basic research, time lags
Who should pay for R&D in neglected diseases?

- Public sector
- Donors
- Private sector
General government expenditure on health as a percentage of total government expenditure (in US$), 2011 *

* Based on data updated in October 2013.
How should resources be allocated?

Discovery  Clinical Trials  Manufacturing

Academia  Biotech  Small firms, CROs  Pharma

Regulatory approval
Health R&D Ecosystem

Source: Morel 2005, WHO 2006
More financing and other incentives

what are the options?
CEWG criteria for assessment

- Public health impact
- Efficiency/cost-effectiveness
- Technical feasibility
- Financial feasibility
- Intellectual property
- Delinking R&D cost from price
- Access
- Governance, accountability, transparency
- Capacity-building and technology transfer for developing countries
More financing and other incentives: what are the options?

- “Push” by reducing cost of R&D

- Pay upfront
  - Pooled funds, to whom to allocate?
  - Direct grants to selected stakeholder
  - Fund clinical trials in developing countries
More financing and other incentives: what are the options?

- “Push” by reducing cost of R&D
  - Indirect
    - Open approaches to innovation: Open drug discovery, open-access publishing
    - Mandate equitable licensing for public funded projects
    - Pre-competitive R&D platforms
    - Patent pools
    - Priority review voucher
    - Transferable intellectual property rights
    - Fast track regulatory review
    - Regulatory harmonization
    - R&D tax breaks
More financing and other incentives: what are the options?

- “Pull” by paying for R&D outputs
  - Create attractive market = how big to set the incentive?
  - More ideas than experience
    - Purchase and procurement agreements, i.e. Advanced purchasing commitments
    - Milestone prizes and end prizes
    - Funds to make end-payments (Health Impact Fund)
How to mobilize more funding?

- Increase country contributions
  - Taxation

- Increase donor funds
Can developing countries implement or support these mechanisms?

- Global, regional or national application
- Variance of costs among mechanisms
- Financial (resources that may be allocated) and R&D capacity (to participate in R&D activities)
Why do we need a more coordinated approach to implementation of mechanisms?

- Pooled financing for cost efficiency
- Long term sustainability /viability of R&D
- Avoid duplication and competition for funds

Requires:
- Concerted priority setting and mechanism selection
- Agree on common principles
How to coordinate?

- Global R&D observatory
- Global agreement under WHO