

**Policy Department  
Economic and Scientific Policy**

**STRATEGIES FOR THE IMPROVEMENT OF  
GLOBAL HUMAN HEALTH**

(IP/A/STOA/SC/2005-177)

This study is the outcome of the workshop organised by the European Parliament in Brussels on 29 June 2006 : "Strategies for the Improvement of Global Human Health". This project was commissioned by STOA under Framework Contract IP/A/STOA/FWC/2005-28.

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## **Executive summary**

This report is the final Deliverable of the project Global Human Health commissioned by the Scientific and Technology Options Assessment (STOA) of the European Parliament and carried out by the European Technology Assessment Group (ETAG). It contains the summary of the workshop Strategies For The Improvement Of Global Human Health held on 29 June 2006 at the European Parliament in Brussels. The issues and recommendations raised at the workshop suggest topics for future technology assessment projects for STOA.

Main issues raised were:

- lack of successful coordination and cooperation in drug R&D;
- lack of investment in research of neglected and rare diseases;
- inequitable pricing of medicine;
- lack of considering health systems issues in research and funding;

Main recommendation are summarised as follows:

- More effort is needed in research and development of medicine against antimicrobial resistance (AMR), influenza antivirals, medicine to alleviate or prevent the symptoms of cardiovascular disease and research of neglected and rare diseases.
- More funds need to be allocated and available funds shifted more efficiently to public-private interactions overseeing the whole range of research and development activities from fundamental research to marketing.
- More health systems research needs to be funded, taking into account cultural issues of prescription, use, access, affordability, and distribution of medicine.
- Viable forms of cooperation between academia, industry and government should be promoted for all European countries and beyond, such as IAVI, EDCTP, and the planned EU Institute of Health, in order to build a common research agenda.
- A comprehensive review of all funding tools available to the European Commission initiatives should be conducted.
- European regulations should ensure that the quality of drugs exported is not inferior from drugs used within the EU.
- Prices of medicine are too often unaffordable and inequitable and the price composition should be analysed and made transparent.
- More opportunities should be created for stakeholders to deliberate directly with members of the European parliament.

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## **Introduction**

This report is the final Deliverable of the project “Global Human Health” commissioned by the Scientific and Technology Options Assessment (STOA) of the European Parliament and carried out by the European Technology Assessment Group (ETAG). It contains the summary of the workshop ‘Strategies For The Improvement Of Global Human Health’ held on 29 June 2006 at the European Parliament in Brussels. The issues raised at the workshop inform the following STOA project on Global Human Health.

Firstly, the background to the project will be stated. Secondly, the main issues raised throughout the workshop and the recommendations made will briefly be reviewed. The proceedings and presentations of the workshop as well as the list of participants are given in the annex.

### **1 Background**

The following section contains the information provided to the workshop participants as input for discussion. Together with the presentations (see annex) this background note constitutes the basis for the ensuing discussion and the recommendations.

#### *Health and medicine*

The value of medicine as part of the package of tools to promote health in general is uncontested. The place of medicine in the intervention against disease is subject of rather greater controversy. As knowledge increases about the biology and mechanisms of disease, so too, does the awareness that alleviation of diseases or plagues depends on the appropriate use of, and the balance between social, environmental, and medical tools. But practices in health suggest that the balance is not always being maintained. What are the innovations needed to improve global health?

Science and technology certainly influence our health and health care systems. Medical technology is more or less successfully used for prevention, screening, diagnosis and treatment or alleviation of a variety of diseases. Our individual and cultural perceptions of health are swayed by the ease of use of such technology, that is, medicine and medical devices (f.i. delivery mechanisms, imaging technology).

European citizens rely on the accessibility of health services, including health and treatment information, state of the art medical examinations, medicine and health insurance, while many people outside the EU lack access to essential health care.

Overall, medicine are a most valuable and valued health technology. They are central to the effectiveness of public health systems yet their development is primarily driven by market forces. Notably, only 10% of the world’s medical research is targeted at conditions that account for 90% of the global disease burden.

#### *Problems and responsibilities*

Medicine consumption worldwide is considerable. Diseases travel and cross geographical borders while the availability of medicine is not necessarily as elastic. Particularly poorer countries have difficulties to provide an adequate, affordable supply of medicine to their public.

The trouble of unequal health and healthcare systems in the North and South is intimately connected to the availability and affordability of medicine: mismatches between the need for and the development and supply of medicine.

These ‘pharmaceutical gaps’, as identified in the Priority Medicine for Europe and the World Report (WHO 2004), are defined to be “diseases of public health importance for which pharmaceutical treatments either do not exist [...] or are inadequate” (WHO 2004).

They occur because of many intertwined reasons, some of which have to do with the interplay between the pharmaceutical industry, the markets for medicine and government policy. This interplay is suffocating the development of medicine for all kinds of diseases: poverty-related or neglected diseases (like tuberculosis, sleeping sickness, malaria), infectious diseases (like HIV/AIDS, influenza), rare diseases (still 10% of all diseases) and chronic diseases (like diabetes).

In rich countries, where infrastructure is good, health has been to a great extent *medicalised*, and there is a tendency of excessive medical consumption and over-reliance on pharmaceutical treatment to cure all illnesses. In poor countries, a lack of adequate infrastructure is blamed for the absence of medicine to tackle pressing needs, especially where other interventions are insufficient or unsuitable. Neither rich nor poor countries are getting the medicine they need within comprehensive, balanced health systems (HAI 2004).

#### *Market failure*

In developed and developing countries alike, the trouble emerging from pharmaceutical gaps points largely to mismatches between prevalence of disease, research, development and availability of advanced medication. Market mechanisms determine the availability of medicine and compromise public health policy efforts. Generally put, the profit-oriented pharmaceutical industry has little interest in developing drugs when there is limited demand, huge demand but lack of purchasing power, or sufficient demand but lack of research - amongst other reasons.

Several remedies have been devised to offset the effects of market failure, e.g. the national funding schemes of Member States and the Framework Programmes of the European Commission. A number of concerted actions of governments, as the European and Developing Countries Clinical Trials Partnership (EDCTP), and public-private joint ventures, such as the Innovative Medicine Initiative (IMI) have taken off. Yet, to what extent did these initiatives manage to counter the effects of market failure? What else is needed?

#### *Government failure*

The drug development process is lengthy and costly. Due to shortage of public funding, academics and research centres became more and more dependent on the financial aid and the research priorities of the industry. Intellectual property rights seem to inhibit the equal distribution of medicine worldwide. Patent law is difficult to change. Approaches to respond to government failure focus mainly on collaboration efforts and distribution of responsibilities and commitment. Successful government incentives also include patent extensions as in the case of orphan drugs.

Governance involves us all, that is: industry, markets, users and governments alike. Public authorities in Member States have a social responsibility to ensure that such concerns are reflected in their policies.

## 2 Main issues resulting from workshop discussion

This chapter states the aim of the meeting, the guiding questions for discussion and the main outcomes of the workshop. The issues raised reflect the main discussion topics of the workshop. The recommendations reflect the participants' suggestions for strategies for the improvement of health and can for the most part be translated into topics for technology assessment projects.

### 2.1 Aim of the workshop

The aim of the STOA Global Human Health workshop was:

- to discuss and draw up a list of priority interventions to help increase access to and promote the production and optimal use of quality medicine;
- to inform the contents of the following STOA Global Human Health project(s);

To this end the participants of the workshop:

- briefly reviewed major health distribution problems and assessed the redressing measures in place by means of short presentations and questioning; (see proceedings in annex);
- discussed policy recommendations on how to bend disastrous health statistics and how to effectively develop and put to use (old and new) medical technologies, in particular, medicine; (see 2.3 for main issues raised)
- came forward with initiatives for further practice-oriented modes of collaboration on the problem of global health distribution for the agenda of the European Parliament. (see 2.4 recommendations)

### 2.2 Guiding questions

Guiding questions for discussion were:

- How can we ensure that our medical needs are protected and considered in medicine development?
- How can worldwide availability and affordability of medicine be improved?
- How can government health policies correct for market failures?
- How can we ensure that medicine are used in an optimal way?
- What are further European strategies needed to improve global health?

## 2.3 Main issues raised in the workshop

Four speakers were invited to contribute to and fuel the discussion revolving around medicine development and use. After a series of short presentations on global health hazards and pharmaceutical gaps (Richard Laing, WHO), European health research funding (Octavi Quintana Trias, EC), private-public interactions in neglected disease drug development (Mary Moran, George Institute) and pricing and affordability of medicine (Marg Ewen, HAI) participants engaged in a discussion on main issues to be tackled. See annex for proceedings of meeting and presentation slides.

The main issues raised during the presentation and the ensuing discussion are summarised and explicated as follows:

- *lack of successful coordination and cooperation in drug R&D;*
- *lack of investment in research of neglected and rare diseases;*
- *inequitable pricing of medicine;*
- *lack of considering health systems issues in research and funding;*

### *Lack of successful coordination and cooperation in drug R&D*

Successful drug R&D requires effective cooperation and communication among all partners in the production process. While the expertise and resources are available, cooperation and coordination is lacking. The presentation of the Netherlands Top Institute Pharma was considered a best practice and similar initiatives in other countries were strongly encouraged. However, it was also mentioned that the Dutch initiative was financed by extraordinary means, the gasbaten (special revenue of the gas exploitation in the Netherlands) and replication in other countries would therefore be unlikely.

### *EC funding*

European public fundraising efforts are lagging behind private initiatives e.g. the Gates Foundation. It becomes clear that common objectives, such as the fight against terrorists or a major health threat, such as the flu pandemic, are useful to allocate needed funds for research and development. EC countries are stretching their health budgets to meet ends. Medical doctors are migrating in between countries and from east to west. Soon e.g. Germany may need more doctors which may result in importing larger numbers of doctors from the accession states rather than reviewing the national system of education and health care employment. Capacity building in drug research and development and the role of public-private partnerships were discussed. Variations in ownership, leadership, partnership influence capacity building and ultimately transfer of technology. EC needs to review its efforts in capacity building in drug R&D. The funding programmes of FP6 invite the applications of PPPs. Yet, only few PPPs use this opportunity. It turns out that DG research mostly finances collaborative research with an emphasis on pre-competitive research. In order to allow for more innovative ways of drug development the areas of funding need to be reconsidered.

It was suggested that if the value of ongoing research activities is not clear, they should be stopped (example of EDCTP). This suggestion was given to (radically) review the funding priorities of the European Commission.

#### *Lack of investment in research of neglected and rare diseases*

The major *pharmaceutical gaps* were discussed and the priority list as presented in the WHO report Priority Medicine for Europe and the World (Kaplan 2004) should be used for follow-up activities and further checked with ongoing European initiatives as part of FP6 and FP7. More effort is needed in research and development of medicine against antimicrobial resistance (AMR), influenza antivirals and medicine to alleviate or prevent the symptoms of cardiovascular disease, such as the combination (“poly”) pill for the secondary prevention of ischemic heart disease.

The epidemiology and strategies against the spreading of antibacterial resistance is being researched by another STOA project. First results should be presented in fall 2006. Poverty-related diseases, such as tuberculosis, are no longer just a problem of third countries but are closing in to the European borders. Environmental changes as well as mobility of people need to be taken into consideration when setting priorities for health research expenditures.

There is a conspicuous disproportion in medical research funding: only 10% of available funds is targeted at conditions that account for 90% of the global disease burden.

#### *Product development*

Product development was found to be shortcoming in terms of type of research. Most investments focus on fundamental research. However, only few initiatives fund the whole chain of development and see to it that at the end of the line a product will reach the market.

#### *Inequitable pricing of medicine*

Prices of medicine are non-transparent and often inequitable. Especially patients in accession states and countries beyond EU borders cannot afford needed medicine. In third countries, it is not always clear how drug prices are composed and how governments influence drug prices. The lack of transparency and standardisation in drug pricing suggest a monopolistic European drug market. The situation was compared to the communication sector and it was suggested to use the reaction to roaming of telecom providers as an example. Here, self-regulation did not work and a strategy of harmonisation had to be enforced by the public sector. Question was whether the telecom case could be used as a model for legal government intervention in drug price regulation.

Affordability issues in third countries are highly focused on outcome which make it difficult to talk about input. A sector-policy dialogue is needed on how governments in third countries influence drug prices and how Europe can have an effect on such policies in third countries.

### *Ensuring equal quality of drugs*

The quality of drugs exported to developing countries varies substantially from the quality of drugs for the European market. It was suggested that the European Parliament should look into this issue and the possible amendments of regulations available.

### *Lack of considering health systems issues in research and funding*

It was repeatedly stated that aspects of health systems research, such as drug use, access, affordability, and distribution of medicine need to be taken into account at the funding level. Strategies for the improvement of health should be viewed from the right perspective and be placed closer to the human being rather than being a purely political or administrative tool.

### *Related documents*

The European Academy of Arts and Sciences has published a report that may be considered as an additional document to formulate policy strategies for the improvement of health: *Health is Wealth, Strategic Visions for European Healthcare at the Beginning of the 21st Century*; Citation: Felix Unger. Springer-Verlag, Berlin, Heidelberg, 2004.

## 2.4 Recommendations for STOA

Recommendations derive from the issues discussed and include topics that are viable for STOA to tackle.

### *Lack of successful coordination and cooperation in drug R&D*

Investigate viable forms of cooperation between academia, industry and government for all European countries, such as, IAVI, EDCTP, and the planned EU Institute of Health, in order to build a common research agenda.

### *EC funding*

The presentation of the available funding schemes of the 6<sup>th</sup> Framework Programme led to the suggestion to conduct a comprehensive review of all funding tools available to the European Commission initiatives. Questions could be: How appropriate are they? How are they connected? What part of the drug research chain is funded? What are the most efficient funding mechanisms in terms of product development? It was also recommended that the European Commission needs to (radically) review the funding priorities and its efforts in capacity building in drug research and development.

### *Lack of investment in research of neglected and rare diseases*

More effort is needed in research and development of medicine against antimicrobial resistance (AMR), influenza antivirals, medicine to alleviate or prevent the symptoms of cardiovascular disease and research of neglected and rare diseases.

### *Product development*

More funds should be allocated and available funds shifted more efficiently to public-private interactions overseeing the whole range of research and development activities from fundamental research to marketing.

### *Inequitable pricing of medicine*

In third countries, it is not always clear how drug prices are composed and how governments influence drug prices. It should be investigated whether and how Europe could have an effect on drug policies in third countries. The price composition should be analysed and made transparent. European regulations should ensure that the quality of drugs exported is not inferior from drugs used within the EU.

### *Lack of considering health systems issues in research and funding*

A general lack in health systems research was felt and participants stated that studies on rational use of drugs, pricing and affordability are interrelated and cannot be tackled separately. More health systems research needs to be funded, taking into account cultural issues of prescription, use, access, affordability, and distribution of medicine. Aspects of health systems analysis need to be added consistently to new medical research proposals to make the research more culturally applicable and useful.

### *EP communication*

Participants particularly appreciated the workshop as an opportunity to directly consult with a member(s) of the European parliament. It was desirable to create more such opportunities.

## **Annexes**

- 1 List of abbreviations**
- 2 Agenda and proceedings of workshop**
- 3 Presentation slides**
- 4 Speakers' bios**
- 5 List of participants**
- 6 Related documents**

## **1 List of abbreviations**

AMR	Antimicrobial Resistance
DG	Directorate General
EDCTP	European and Developing Countries Clinical Trials Partnership
ETAG	European Technology Assessment Group
EU	European Union
FP	Framework Programme
HAI	Health Action International
HIRO	Heads of International Research Organization
IAVI	International AIDS Vaccine Initiative
IMI	Innovative Medicine Initiative
MEP	Member of European Parliament
R&D	Research & Development
PPP	Public Private Partnerships
STOA	Scientific and Technological Options Assessment
WHO	World Health Organisation

## 2 Agenda and proceedings of workshop

### Strategies for the Improvement of Global Human Health

European Parliament, Rue Wiertz 60, 1047 Brussels

**Thursday 29 June 2006, 9:00 - 13:00**, Altiero Spinelli A3 E-3

Workshop organised as part of the Project “Global Human Health” commissioned by the Scientific and Technology Options Assessment (STOA) of the European Parliament and carried out by the European Technology Assessment Group (ETAG)

### Agenda

- |             |   |
|-------------|---|
| 9:00        | Welcome by Dorette Corbey, MEP, chair                                       |
| 9:10        | Introduction by Elisabetta El-Karimy, Rathenau Institute/ ETAG Group        |
| 9:15        | Presentations and discussion moderated by Wilbert Bannenberg, PH consultant |
| 9:25-9:40   | Richard Laing, WHO  |
| 9:50-10:05  | Octavi Quintana-Trias, DG Research, EC                                      |
| 10:15-10:30 | Mary Moran, George Institute of International Health                        |
| 10:40-10:55 | Margaret Ewen, Health Action International (HAI)                            |
| 11:05-11:15 | Odile Leroi, EDCTP  |
| 11:20       | Discussion and agenda setting   |
| 12:50       | Conclusions by Dorette Corbey, MEP  |

### Proceedings

The meeting started at 9:00 with the opening remarks of Dorette Corbey, MEP.

Thereafter followed a brief introduction of the ETAG group by Elisabetta El-Karimy, Rathenau Institute, of the scope of the ETAG group and the purpose of this meeting. See for details the online information on ETAG [www.itas.fzk.de/etag](http://www.itas.fzk.de/etag) and STOA [www.europarl.europa.eu/stoa/default\\_en.htm](http://www.europarl.europa.eu/stoa/default_en.htm)

The purpose of the workshop was to discuss and draw up a list of possible priority interventions to help increase access to and promote the production and optimal use of quality medicines informing the STOA project on Global Human Health.

A total of 32 stakeholders attended the event. See for contact details the list of participants hereafter.

Dr. Wilbert Bannenberg (MD, MPH), a public health consultant with extensive experience in the field of health and medicines, led the participants through the various presentations and facilitated the consequent discussion.

## **Presentations and strategies suggested**

### ***Richard Laing, WHO, Geneva***

The presentation of Mr. Richard Laing, WHO, focused on the Priority Medicines for Europe and the World report produced by WHO to identify the European and Global Pharmaceutical gaps for the present and the future. The methodology of the report combined Burden of Disease assessments, evaluation of efficacy of existing pharmaceutical interventions, assessment of global trends and threats and an assessment of neglected diseases from a perspective of social solidarity. The report concluded that a commonality of interest exists between developed and other countries for chronic diseases (“what is good for Europe in chronic diseases is also good for the world”) but that for infectious and other neglected diseases special efforts will be needed to deal with market failures. The leading priority areas were antibacterial resistance, pandemic influenza and the need for a Fixed Dose Combination product for the secondary prevention of heart disease. Barriers to innovation whether regulatory or pricing related are reviewed and alternative approaches suggested. <http://mednet3.who.int/prioritymeds/report/index.htm>

Recent developments since the presentation of the report in November 2004, such as, the Top Institute Pharma, were discussed. Laing stressed the need for new medicines, particularly antimicrobials and HIV medicines. He said that having good medicines does not guarantee the use of such medicines. The effect of the recently reached WHO agreement on access remains unclear.

Strategies suggested are:

- the innovative use of databases for drug evaluation purposes (referring to the Australian study on linking databases of prescribing, dispensing and outcome data)
- the stimulation of translational research (defined here as spanning from basic to pre-clinical)
- increasing capacity to produce vaccines (and increase global vaccine coverage)

### ***Octavi Quintana Trias, Director of Health Research, DG RTD, EC***

Mr. Quintana’s presentation gave an overview of the European Commission’s activities linked to global health, spanning from actions devoted specifically to health issues that affect developing countries (e.g. poverty-related diseases within FP6, EDCTP), over contributing to global (Global HIV vaccine enterprise, HIRO initiative) and European activities (IMI), to specific actions which are dedicated both to Europe and Developing countries (SARS, influenza).

The initiatives described cover a great field of health research: from discovery to human testing. Mr. Quintana stressed the multi-sectoral approach of FP6 funding policy especially regarding poverty-related diseases. The scheme also welcomes applications from developing countries. FP7 will intensify the cooperation with third countries. EC funding does not suffice to conduct large-scale clinical trials and concerns were raised about leaving this responsibility in the hands of the private sector.

EDCTP is based on article 169 which allows member states to merge funds and funding schemes. The EC contribution of 200 mio Euro is supposed to be matched by an equal contribution of member states and a third share.

For the moment, it remains to be seen how member states will be sharing their resources and integrating their research programmes.

The global HIV vaccine enterprise (GVE) follows another strategy (best practice?): partners share a common research plan with each partner funding and carrying out their own bit.

The Heads of International Research Organisations (HIRO) meet regularly to coordinate efforts and discuss proceedings of needed health research.

The Innovative Medicines Initiative (IMI) is meant to tackle scientific bottlenecks for industry in Europe. This scheme (440mio/year for 7 years) entails companies sharing resources among each other. Concerns were refuted of EC giving funds to industry. IMI does not necessarily follow a public health approach; the goal being to create incentives for industry to conduct research in Europe and boost the number of European patents. The draft strategic agenda is available online:

[http://ec.europa.eu/research/fp6/pdf/innovative\\_medicines\\_sra\\_final\\_draft\\_en.pdf](http://ec.europa.eu/research/fp6/pdf/innovative_medicines_sra_final_draft_en.pdf)

The total amount and recipients of EC funding schemes received due attention in the discussion. EC is the biggest funder in Europe of (basic) research on malaria, hiv/aids and tbc. Yet extra funding for neglected diseases, beyond existing schemes, could be considered – in particular funding for successful product development approaches, in addition to existing collaborative or basic research. Questions were also raised about whether EC funding should include incentives for competitive research. Last but not least, the ‘PR problem’ of the EC was brought up.

### ***Mary Moran, George Institute of Health, Sydney***

The presentation highlighted the resurgence of neglected disease drug development since 2000, examining where these new products are coming from and which R&D methods are most effective, as measured against a range of metrics including health value, innovation, cost and timelines. Dr. Moran argued that there is a great lack of public funding of product development.

The Public Private Partnership (PPP) approach outperformed both the public or industry-alone approaches to R&D. Dr Moran noted that this referred to PPPs as formal drug development organisations, not simply to the act of public-private partnering which, in contrast, did not account for many successful projects. While performance within the PPP R&D model varied, this variation can be tracked to funding shortfalls and the levels of industry involvement during the development process.

Based on empirical findings, strategies are suggested to optimise EC investment in neglected disease R&D and reduce donor risk:

- EC needs to fund product R&D as well as systems R&D: Systems funding is important (trial sites/ regulatory & platforms) but there’s no point having good systems without products to put through them;
- Product funding needs to be given in more efficient ways: Support the most efficient R&D model (PPP organisations), Fund R&D not secondary goals (a proven recipe for waste / failure), Target the gaps (e.g. industry input to PPPs);
- Donor risk associated with product funding can/ should be minimised: Spread risk

across the global ND drug portfolio (6-7 products globally means you can't fail); Share risk with other donors; Remove the need to "pick winners";

Discussion revolved whether or not EC funding goes to actual product development. DG RTD states that there is funding for product development – not only basic research! - (125 mio Euro during FP6). Dr Moran noted that most of this was not for neglected diseases (Dr Trias had previously noted a figure of \$21 million for neglected diseases in FP6); and that this small neglected disease component did not go to the successful PPP model but rather to less successful traditional EC approaches such as large-scale collaborations and one-off partnerings between academics and usually small companies. As a result, she noted that  $\frac{3}{4}$  of new neglected disease products are now coming from PPP organisations that are NOT funded by the EC. Moreover, if funding is broken down to individual diseases it reveals insufficient for product development, since this figure is spread over the 4-year FP timeline as well as across AIDS, TB and malaria and across drugs, vaccines and diagnostics.

Performance indicators need to be taken into account in evaluating neglected disease drug R&D, i.e., are developed products used in developing countries? 12 out of 13 industry-alone projects are unsuccessful because of issues of cost and suitability (delivery mechanisms, not fitting lifestyle, some toxic)!

As a best practice, the case of IRFF/ Industry R&D Facilitation Fund was introduced. Problem seemed to be that EC funds are meant to target research initiatives and are not used to fund facilitating groups such as PPPs or for out-contracting (as would be IRFF), with EDCTP being an exception.

### ***Margret Ewen, HAI, Amsterdam***

The presentation addressed the price, availability and affordability of medicines are major determinants of access to treatment. Surveys undertaken using the WHO/Health Action International price measurement methodology have exposed unaffordable treatments (as much as 50 days wages need to buy 30 days supply), medicines priced at over 80 times an international reference prices, governments purchasing expensive originator brands rather than cheaper generic equivalents and applying numerous taxes on medicines, extremely poor availability of medicines in the public sector, and excessive mark-ups charged by pharmacists and dispensing doctors. These findings, and others, were presented plus policy options to lower prices and make treatments more affordable.

Her research uses the median price ratio showing the factor of government procurement price and patient price. It shows that the same originator products are sold at different prices in different countries. The composition of prices differ, and the consequent ratio of profit. The availability of drugs varies among countries and private/ public sectors.

In the discussion the question was raised whether abolishing taxes actually leads to price reduction. Similarly, whether only purchasing generics would lead to more affordable drugs. It was argued that also the fee for doctors and pharmacists in developing countries has to be considered when talking affordability; issue is larger than just price of medicines! Moreover, some studies show customers refusing to be treated with free generics and preferring expensive originator drugs.

Strategies suggested are:

- Price transparency and regular monitoring of prices – from the manufacturer’s selling price to the patient price; look at component costs to increase affordability;
- Abolish taxes and duties on essential medicines;
- Increase the use and acceptance of generics;
- governments: waive fees, fast-track generic applications, purchase generics at low prices;
- dispensing: compulsory generic substitution, control mark-ups in private and public sector;
- consumers and health professionals: education on generics

On June 28 a related stakeholder meeting on gaps in drug development took place in Brussels organised among others by the European and Developing countries Clinical Trials Partnership, EDCTP. *Odile Leroy, executive director of EDCTP*, attended the STOA workshop and shared the major outcomes of the meeting with the participants. See for more details on “Connecting the Chain. Towards a comprehensive approach to delivering affordable medicines against poverty-related diseases.”

[www.edctp.org/Announcements.42.0.html](http://www.edctp.org/Announcements.42.0.html)

Dr. Leroy gave a short introduction of the composition and work of EDCTP. The platform consists of 14 member states plus Switzerland and Norway. Total budget: 400 mio Euro. She maintains that Europe has lost its leading place in product development. EDCTP is to counter this development but is not enough by itself.

Main gaps are: product development, translational research and access to medicines. To this end, more coordination of donors and actors is needed; technical level is present yet political commitment lacking to connect the chain.

The question whether EDCTP intends to broaden the scope beyond the three present diseases was countered with: we need to show first that we can handle the three.

### **Next steps**

The meeting ended at 13:00 with the conclusion of Dorette Corbey and her appreciation of the available expertise and discussion.

The outcomes of the workshop are used to inform the STOA project on Global Human Health. The final report of the workshop will summarise the major themes. A first ‘opinion’ on the content of the new project will be formulated by the Rathenau Institute by the end of August reporting to the ETAG group and the STOA panel.

# PRIORITY MEDICINES FOR EUROPE AND THE WORLD

**Richard Laing**  
**World Health Organization**  
**Geneva**

**Brussels**  
**June 2006**



1

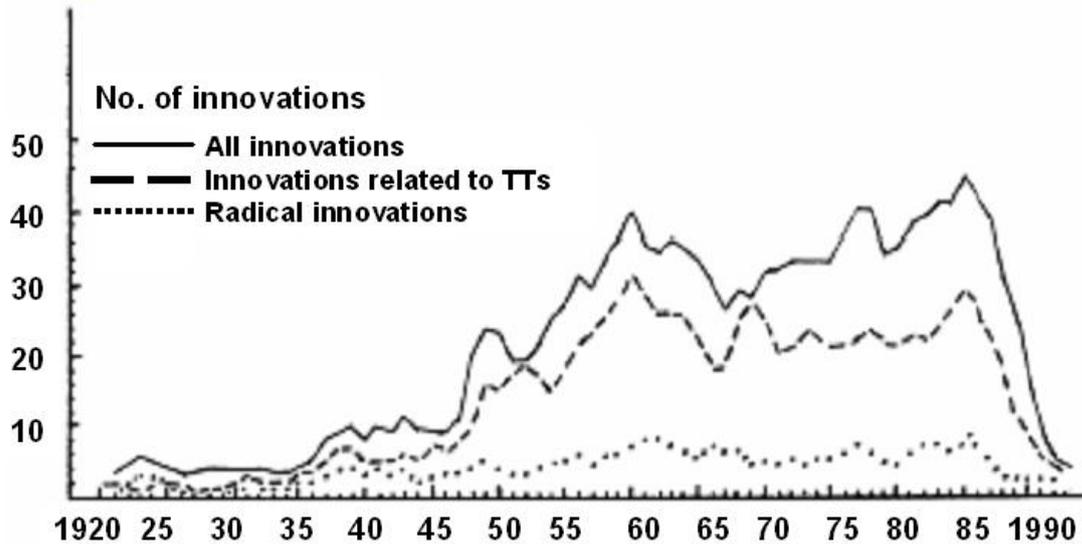
## Context/Background

- Pammoli, G-10 and EU Commission Reports
  - Europe was *"lagging behind in its ability to generate, organize, and sustain innovation processes that are increasingly expensive and organizationally complex."*
- The Lisbon and Barcelona European Councils: the "3% solution"
- Framework Programmes FP6 → FP7 & Technology Platform for Pharmaceuticals
- European and Developing Countries Clinical Trials Partnership (EDCTP)



2

## The decline of pharmaceutical innovation in the 90s



Source: *Research Policy*, 30, Achilladelis B, Antonakis N. The dynamics of technological innovation: the case of the pharmaceutical industry. Pages 535-538.



## Objectives of Priority Medicines Project

- Provide a **methodology** for identifying pharmaceutical "gaps" from a public health perspective, for Europe and the World .
- Provide a public-health based pharmaceutical **R&D agenda** for use by the EU in the 7th Framework Programme,

**“Good public policy should spend public funds on areas of greatest public needs”**

4



# "Priority Medicines"

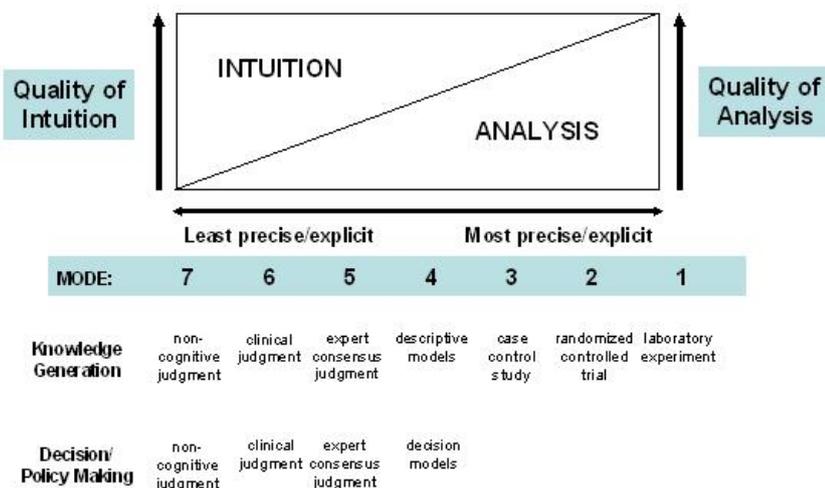
- **Medicines which are needed to meet the priority health care needs of the population but which have not yet been developed.**
- **“pharmaceutical gap”**: when treatment for a **disease/condition**:
  - does not yet exist OR
  - will become ineffective soon OR
  - is available but the delivery mechanism or formulation is not appropriate for the target patient group.

5



## Prioritization must be multifactorial

A Cognitive Continuum Framework

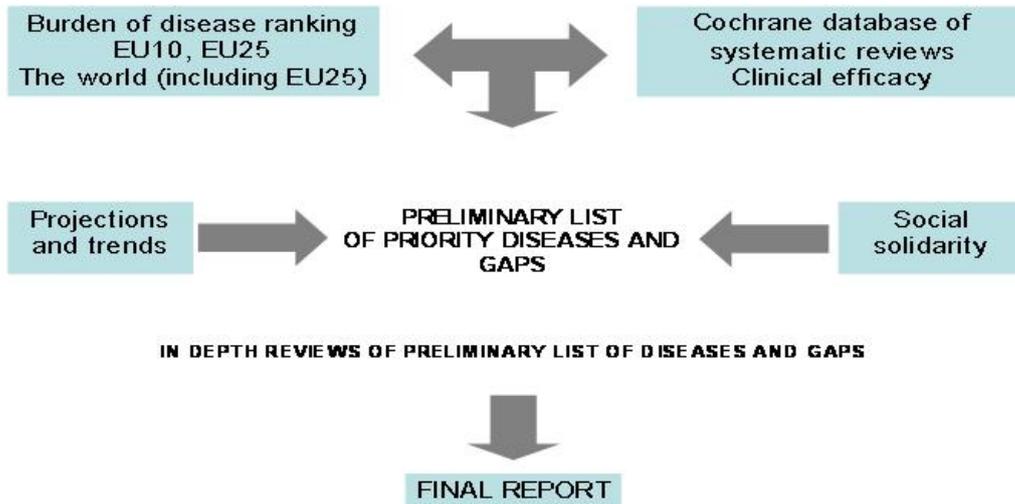


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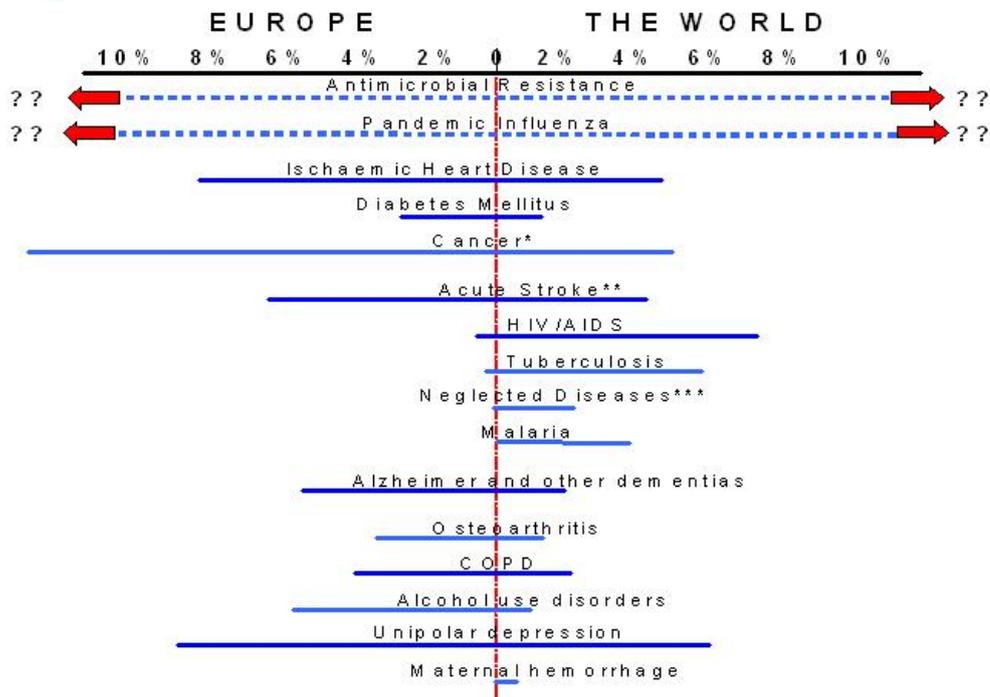
Source: Adapted from Dr. Kenneth Hammond, Univ. Colorado, USA & NICE (UK)



# Generating a Preliminary List of Diseases and Gaps

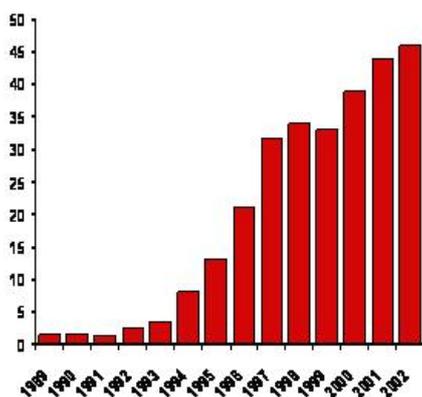


## "Commonality of interest"

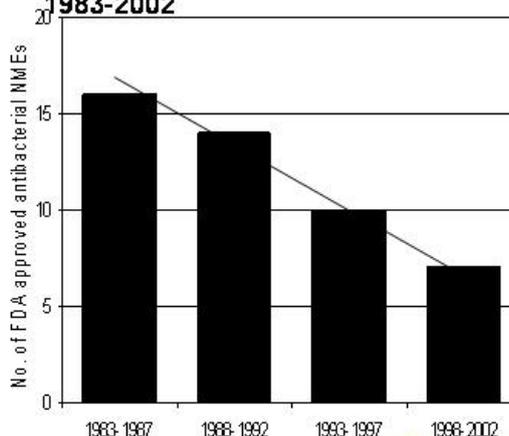


# The Rise of Antibacterial Resistance and the Decline in Innovation

The proportion of MRSA among positive blood cultures of Staphylococcus Aureus in England & Wales 1989-2002



Antibacterial new molecular entities approved for use in the United States 1983-2002



9



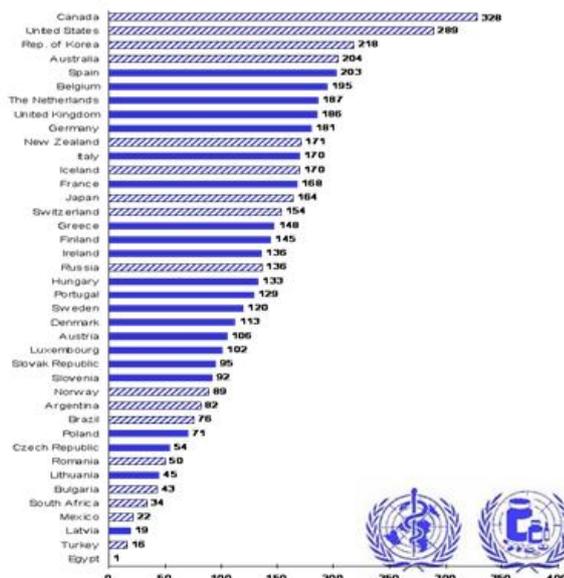
## Global Public Health Threats (2)

### Pandemic Influenza:

- Overdue for a new pandemic
- Uptake of existing vaccines is poor
- Current capacity to produce either vaccines or antiviral medicines is not sufficient

10

Rates of vaccine distribution per 1000 total population by country



## Secondary Prevention of Cardiovascular Disease & Stroke

- Patients with a heart attack or stroke could reduce their risk of a repeat attack by 66% by taking 4 medicines (good evidence)
- Yet uptake is low <20%
- The "polypill" using fixed dose combination (aspirin, statin, ACE inhibitor and beta-blocker or thiazide diuretic) deserves further urgent study.
- NZ trial about to start
- Indian company will register FDC product in India in 2007

11



## Removing Barriers to Innovation

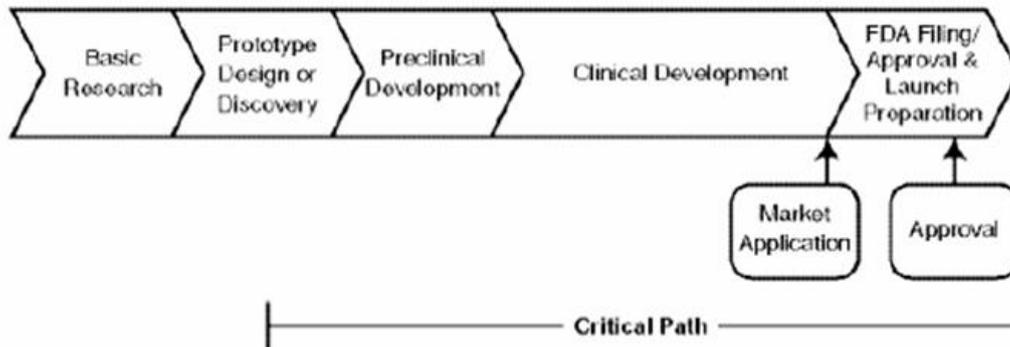
- In March 2004, EMEA, FDA, Rawlins and Industry (Middleton) have all proposed similar measures to remove regulatory barriers
- **All papers except EMEA neglect Phase IV as a key part of the innovation process!**

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## FDA Critical Path report What about Phase IV?

Figure 4: The Critical Path for Medical Product Development



\* Note: Clinical drug development is conventionally divided into 3 phases. This is not the case for medical device development. This is why preceding figures look slightly different.

13



## EMA Road map to 2010

- Objectives
  - Top quality scientific assessment
  - Timely access to safe and effective innovative medicines
  - **Continuous monitoring of medicinal products**  
*“A proactive approach to pharmacovigilance”*
  - Access to Information
  - Special needs for veterinary medicines

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## **Need for Comparative Trials or outcome monitoring after conditional release**

- **Comparative studies** provide critical information on head to head comparisons.
- Use of national prescribing, dispensing and outcomes databases may facilitate such studies
- Allow for early conditional registration with comprehensive outcome monitoring for both safety and effectiveness

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## **Top Institute Pharma & Mondrian Project** (<http://www.tipharma.nl/home.php>)

- Top Institute Pharma has been created in Netherlands to address Priority Medicines issues combining Government, Pharma industry and academia
- Initial funding for 4 years total 250 m Euros
- Two rounds of proposals already done with 6 themes and 7 disciplines
- Includes a theme on 'Efficiency Analysis of the Process of Drug Discovery and Development'.
- Within this theme, the Mondrian project aims to establish a total population laboratory that will be able to assess effectiveness as well as safety

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## Conclusions

### Priority Medicines for Europe and the World

- Commonality of interest exists for chronic diseases between Europe and the World
- Priorities can be set based on evidence, trends and projections and social solidarity
- **Highest priorities are antibacterial resistance\*, influenza, cardiovascular disease\* and neglected diseases**
- Pricing issues and barriers to innovation strongly affect the European industry
- Innovative use of data bases from EU country health systems may be an alternative approach for innovation\*
- The EU needs to find a way to support translational research for market failure pharmaceutical gaps

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## Priority Medicines Project

For further questions, please contact:

**laingr@who.int**

**wak@bu.edu**

**+41-22-791-4533**

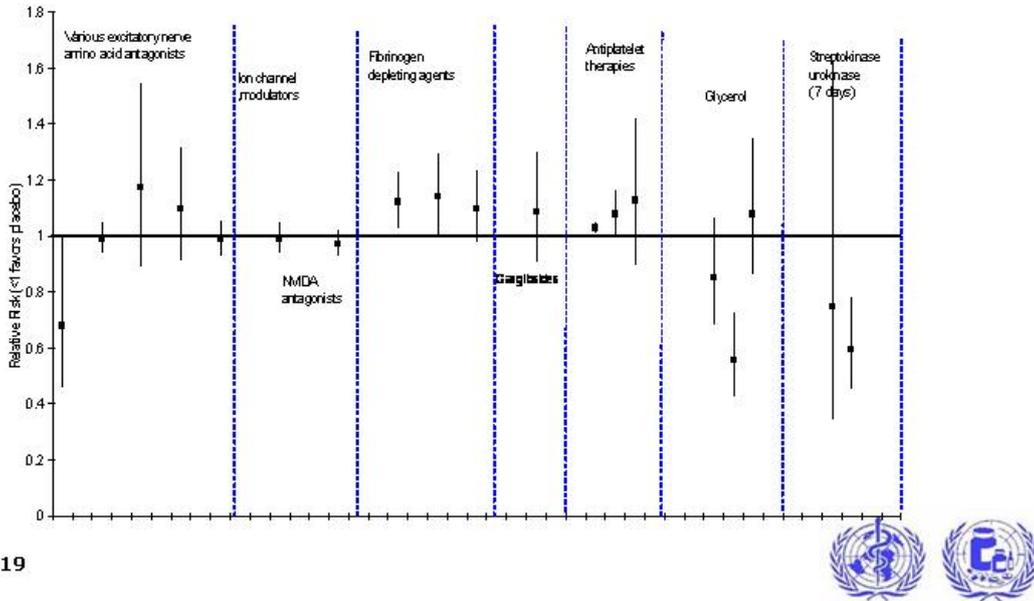
<http://mednet3.who.int/prioritymeds/report/index.htm>

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# Pharmaceutical "Gap"

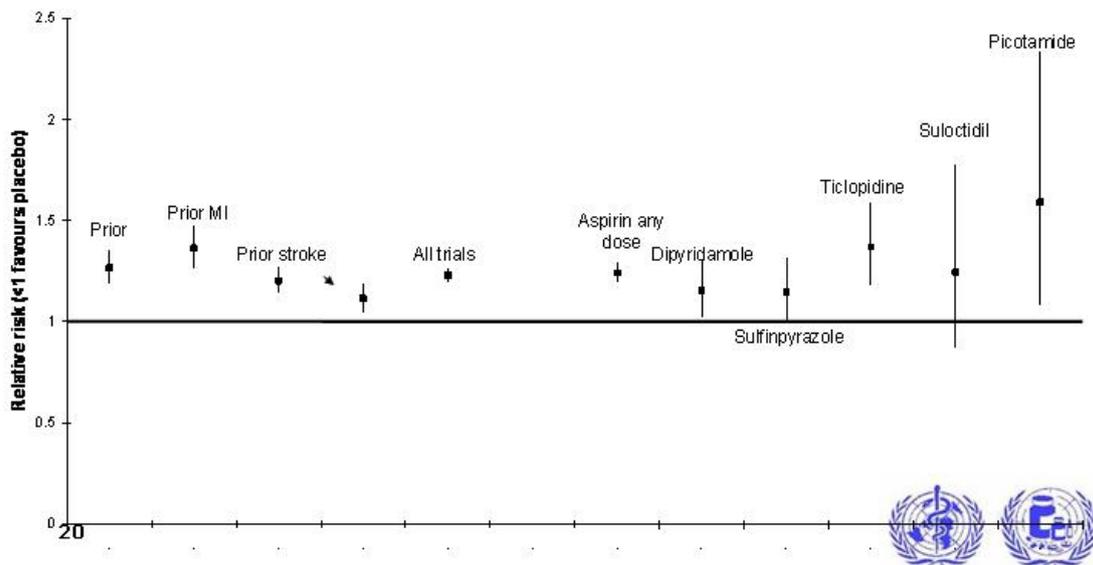
Treatment of ACUTE Stroke (Outcome: Survival at end of treatment or follow-up, unless noted otherwise)



19

# Example of an absent pharmaceutical gap

Secondary prevention of occlusive event (Stroke/MI) with antiplatelet therapy



20

 EUROPEAN COMMISSION  
Community Research



## Global Human Health Research addressed by the European Commission present/future



**Octavi Quintana Trias**  
Director – Health Research  
DG Research - European Commission



1 29 June 2006 

 EUROPEAN COMMISSION  
Community Research

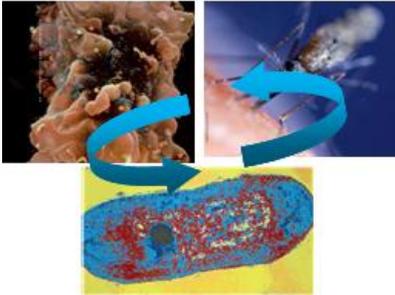
## Global Human Health Research Overview of EC activities

- **Poverty-related diseases**
- **EDCTP**
- **International collaboration**
- **Global HIV Vaccine Enterprise**
- **Antibiotic Resistance**
- **HIRO initiative**
- **IMI**
- **Emerging diseases**

2 

## The example of Poverty Related Diseases (PRD):

### Programme for Action: An overall EC Political Framework For Global Human Health



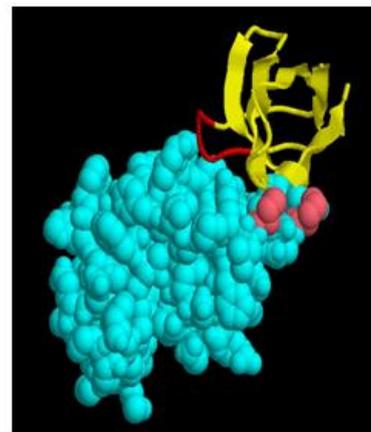
- **Trade:**  
Make pharmaceuticals more affordable for Developing Countries (TRIPS, Doha, etc.)
- **Development:**  
Existing health-related interventions (Global Health Funds)
- **Research:**  
New interventions against the three diseases

3



## Principles of EC Research Policy on PRDs

- Establish an overall framework for the whole development of new interventions (from discovery to human testing)
- Involve scientists and stakeholders from disease endemic areas
- Involve industry – large and SME
- Partner and coordinate with International Organisations and stakeholders (e.g. WHO, GVE, PPPs)



4





## Poverty Related Diseases in FP6

- **Collaborative Research funding (€ 218 million)**

- ❖ **Large consortia for Translational Research: public-private partnerships between academia, SMEs and large pharma industry – focus on basic and preclinical research up to early testing (5-20 m€, 10-50 partners, 4-7 years)**
- ❖ **Small scale, high risk projects (max. 1 m€, 2 years, young researchers)**

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## EDCTP



- ❖ **Programme funding: European Developing Countries Clinical Trials Partnership (200 m€ EC contribution)**
  - ❖ **Product development focusing on phase II-III clinical trials in Sub-Saharan Africa**
  - ❖ **Long-term partnership between EU and Developing Countries to fight HIV/AIDS, Tuberculosis and Malaria**

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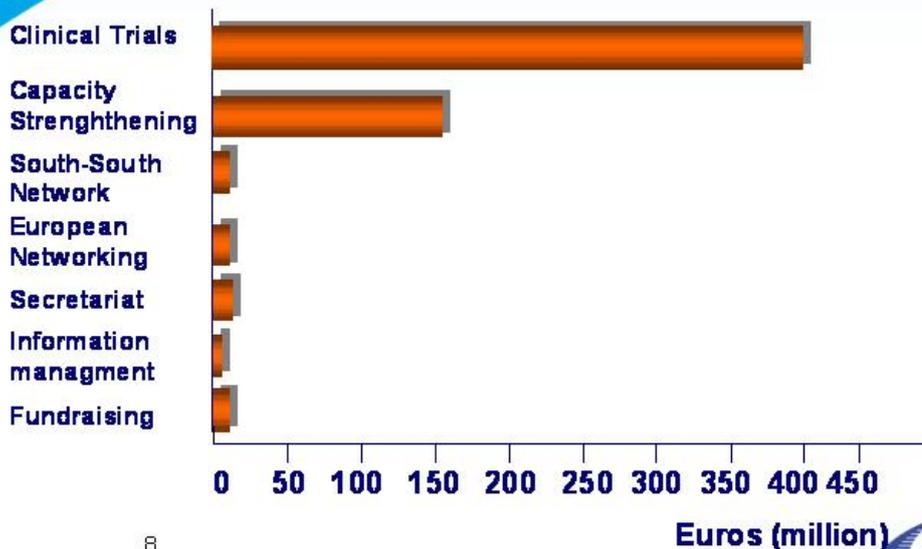
## Global features EDCTP

- **Long-term sustainable initiative (10-20 years)**
- **Shared ownership** of European and Developing Countries
- **Integration of European National Programmes**
- **North-South Partnership to conduct clinical trials (drugs, vaccines, and new interventions) focussed on Africa for the 4 first years**
- **Capacity building and networking** in developing countries
- **Contribute to bridge "10/90" gap (investment to tackle diseases prevailing in developing / developed countries)**

7



## Proposed EDCTP expenditures during the first 5 years



8



## International Collaborative Health Research (INCO) FP6 project focus and location

*Number of projects and budgets (Mill. €):*

• Neglected infectious diseases:	21 (41)
• Health Systems/Policy research:	12 (25)
• Other areas:	6 (10)
• "Developing countries":	32 (67)
• Mediterranean countries:	5 (4)
• Western Balkan:	2 (4)

9



## FP7 - COOPERATION INCO: Dual approach

### 1. OPENING OF ALL THEMES TO THIRD COUNTRIES

### 2. SPECIFIC INTERNATIONAL COOPERATION ACTIONS (SICA)

- **Identification of problems affecting third countries**
- **Cooperation with and in third countries in finding solutions to such problems**
- **Dedicated activities within and across themes in order to address issues of global importance**

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## Global HIV Vaccine Enterprise

Alliance of independent organizations  
dedicated to accelerating the development  
of a preventive HIV vaccine by:

- **Shared scientific plan**
- **Increased resources**
- **Greater collaboration**

Executive Director: Dr. Adel Mahmoud

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## Better use of Medicines: **Addressing antimicrobial resistance**

- **Improved knowledge**

- Understanding the molecular mechanisms of drug resistance
- Ecology of resistance (interplay fitness/virulence/resistance)

- **New treatments**

- Novel molecular targets for new drugs
- Alternatives to antibiotics (peptides, immunotherapy)

- **Improved disease management**

- Lower Respiratory Tract Infections
- Nosocomial Infections

- **Better use of available drugs**

- Optimize prescribing behaviour / better patient compliance
- Access to diagnostic tests
- Assess global burden on health systems from drug resistance



## HIRO Initiative

Meetings of the **Heads of International Research Organisations dedicated to health research** (e.g.: NIH, UK-MRC, DFG, INSERM, Australia-MRC, Canada-MRC, Japan Council on Science Policy, Chinese Academy of Sciences, Wellcome Trust, Gates Foundation, etc.)

- One major issue addressed: global health
- Taking place on regular basis
- Informal discussion

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## Innovative Medicines Initiative: EU Challenges Pharmaceutical R&D

### The Challenges – European, Industrial and Scientific

- Escalating, unsustainable, drug development costs
- High failure rates
- Pharmaceutical R&D moving out of Europe
- Public spending on health R&D lower and stagnating as compared to the US
- Private investments in sector (VCs, etc.) much lower than in the US, and increasing risk adversity among investors
- Scientific breakthroughs has not given the expected results
- Fragmentation of research efforts – basic, clinical and in industry



# Innovative Medicines Initiative (IMI)

## Long term objective

To increase competitiveness of European biopharmaceutical sector and foster Europe as the most attractive place for pharmaceutical R&D, thereby enhancing access to innovative medicines for patients.

## How?

By removing the major bottlenecks in drug development, to which research is the key

15



## The Strategic Research Agenda

- A unique achievement involving all stakeholder sectors
- Will encourage inward investment (Lisbon goal)
- Will produce benefits for healthcare and patients
- Provides a means of gaining competitive advantage for Europe if we act fast
- Will provide "toolbox" for drug development, not new drugs!

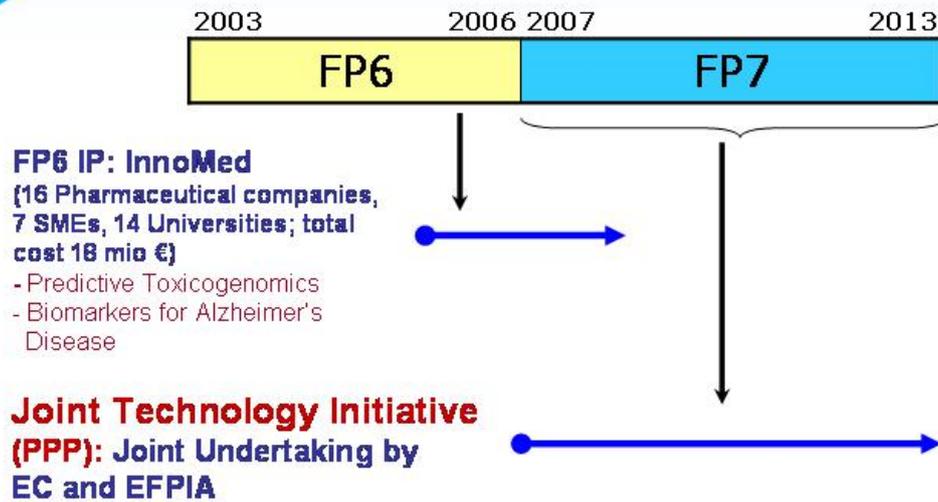
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FEEDBACK TO: European Commission Website <http://ec.europa.eu/imi>  
Copyright (c) 2006 Innovative Medicines Initiative

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## Innovative Medicines Initiative Implementation of SRA across EU RTD Framework Programmes



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## Health threats to both EU and the world: Emerging Infectious Diseases

### • SARS

- Clinical manifestations of SARS, including infectiousness
- Support to Diagnostics, Therapeutics & Vaccines
- Risk modelling

### • Influenza

- Vaccines
  - Improved: immunostimulatory (adjuvants)
  - New: broad-covering, long lasting
- Antiviral drugs
  - Drug discovery
  - Monitoring drug resistance
- Build partnership with affected regions

18



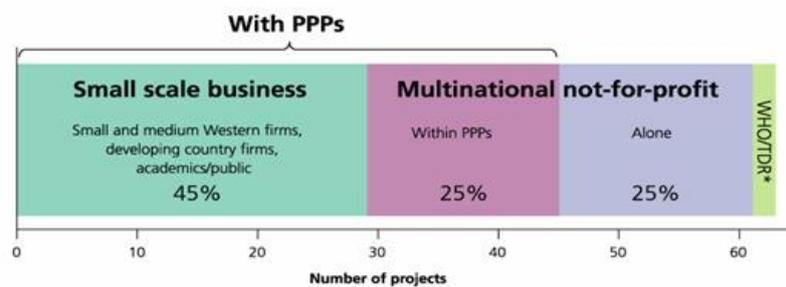
# Neglected disease drug development

## Funding for success

Dr M Moran  
mmoran@thegeorgeinstitute.org  
Pharmaceutical R&D Policy Project  
The George Institute for International Health  
June 2006



## Neglected disease R&D: A newly-active field

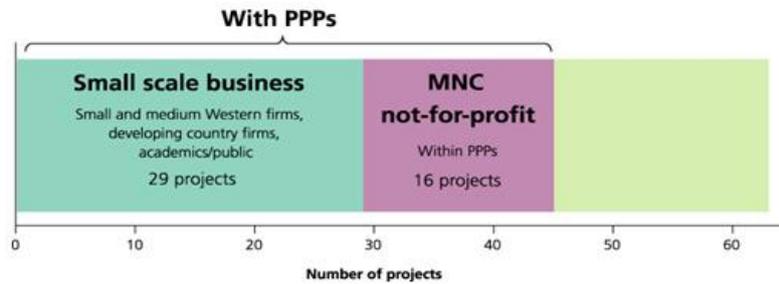


\*Unable to verify details for three WHO/TDR projects.

- Major R&D increase since 2000
  - 63 projects (by start 2005)
  - Translates into 8-9 new neglected disease drugs by 2010
- Large and small companies; predominantly in public-private partnerships
- Happening *outside* government policies and incentives and largely without government funding



## Public-Private Partnerships (PPPs)



- PPPs now conduct 75% of all projects, including with small and large companies
- Increasing trend to partnering by large companies: their preferred approach



## Performance: Health value

Public-private partnering delivered the highest health value products

### Industry-alone

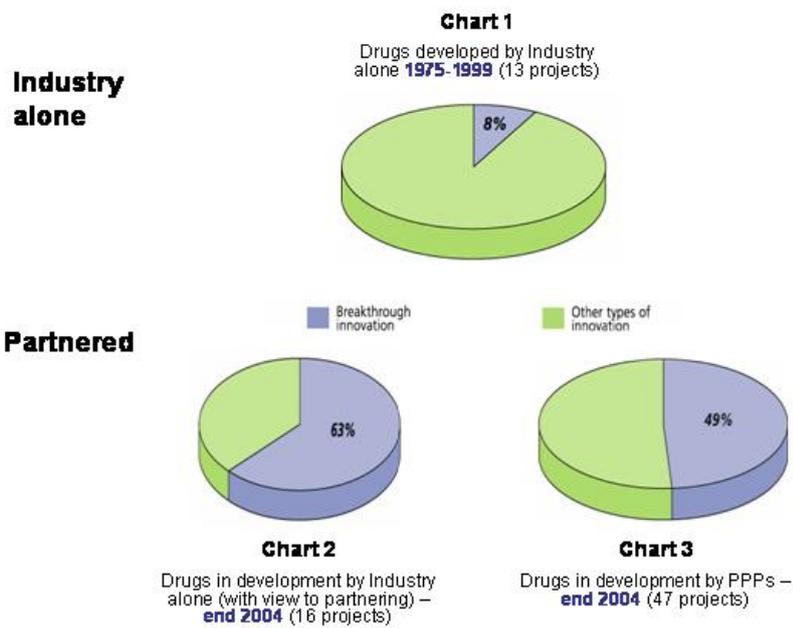
- 12 of the 13 neglected disease products under the industry-alone model had a **low overall health value** to developing country patients

### Partnered

- 3 of these 8 "partnered" products **contributed significantly to reducing global health burdens**
  - halved the global burden of onchocerciasis between 1990 and 2000 (ivermectin)
  - eradicated schistosomiasis in major parts of the world (praziquantel)
  - introduced the first suitable new paediatric anti-malarial for decades (Coartem)



## Performance: Level of innovation



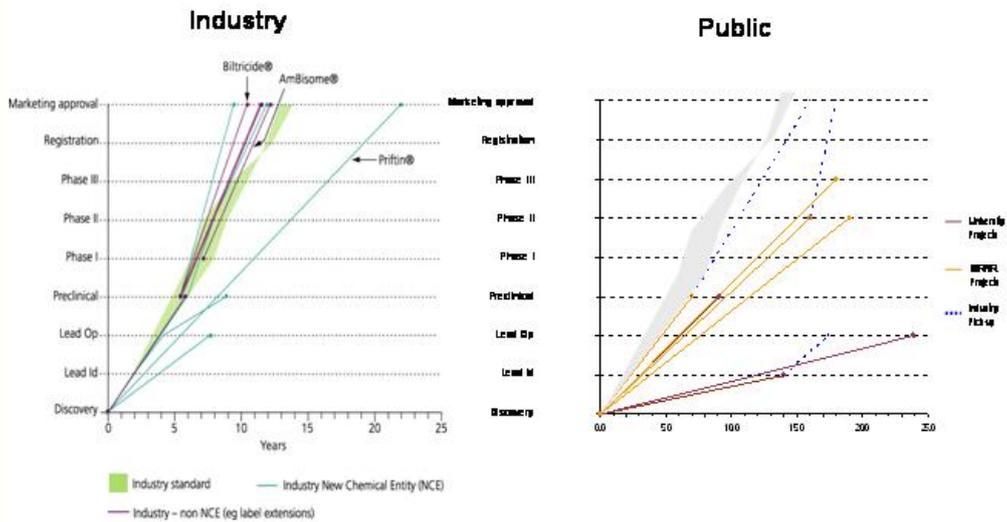
## Performance: R&D cost (PPPs)

Project Name	Type of project	R&D costed	Indication	Cost * US \$million	Unquantified pro bono input
<b>ACTUAL COSTS</b>					
FAS II	New chemical entity	Lead Identification	Malaria	2.7	Nil
PFT inhibitors	New chemical entity	Lead Identification	Malaria	2.2	Some expert advice and data from BMS
Pyronardine-artesunate	Fixed dose combination	Predinical (+3 months Phase I)	Malaria	5.3	Shin Poong's input (formulation chemistry)
PA-824	New chemical entity	Predinical	Tuberculosis	4.5	Expert advice from ex-company employee
Synthetic Peroxide	New chemical entity	Discovery Lead Identification Lead optimisation Predinical (+6 months Phase I)	Malaria	11.5	Expert advice from Roche
<b>PROJECTED COSTS</b>					
Pyronardine-artesunate	Fixed dose combination	From predinical up to registration	Malaria	15-20	
PA-824	New chemical entity	From predinical up to end of phase III	Tuberculosis	86	

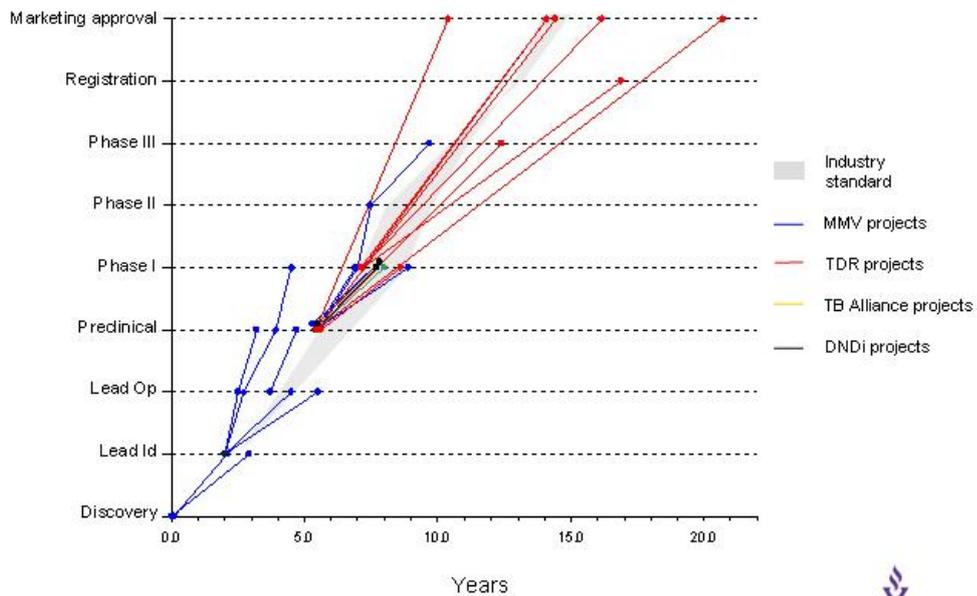
\* We have used internal budgets, and added pro-rata'd indirect scientific costs.



## Performance: Development timelines (1)



## Performance: Development timelines (2)



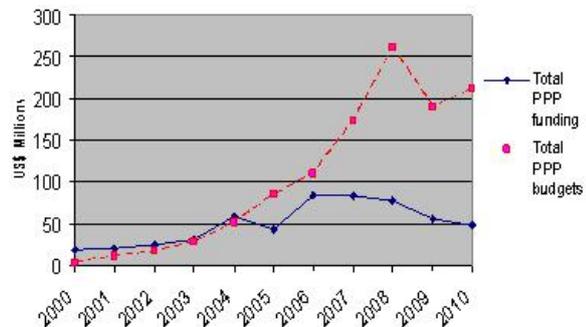
## Performance-funding gap for drug PPPs

First round PPP funding (2000-2005)

- Philanthropic **80%**
- Only 4 Govts: UK, Dutch, Swiss, US
- EC < 1%

2006: High performance means second round funding now needed

- 1 new Govt donor: Ireland
- Boost from existing donors
- **Still 80/20**



More gov't's need to contribute



## Findings

1. **Neglected disease drug development is now being driven by PPPs**
2. **The PPP approach performs better than either public alone or industry alone R&D**
  - Common sense but ...
3. **Performance varies between and within PPPs due to**
  - Lack of funding
  - Lower level of industry input/ expertise (in-house/ project)
4. **Donor funding for neglected disease drug R&D needs to be take these findings into account**



## Strategies for improved neglected disease treatments

---

### 1. The EC needs to fund product R&D as well as systems R&D

- Systems funding is imp't (trial sites/ regulatory & platforms) but there's no point having good systems without products to put through them

### 2. Product funding needs to be given in more efficient ways

- Support the most efficient R&D model (PPPs)
- Fund R&D not secondary goals (a proven recipe for waste / failure)
- Target the gaps (e.g. industry input to PPPs)

*Donor risk associated with product funding can/ should be minimised*

- Spread risk across the global ND drug portfolio (6-7 products globally means you can't fail)
- Share risk with other donors
- Remove the need to "pick winners"



## A policy proposal that fulfils all these strategies: Industry R&D Facilitation Fund (IRFF)

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The IRFF is a single, simple mechanism to fund industry input to all drug PPPs for all neglected disease R&D (malaria, TB, sleeping sickness etc);

The IRFF has been designed to:

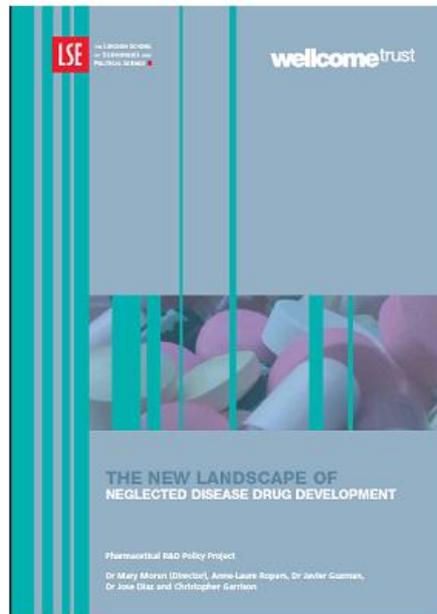
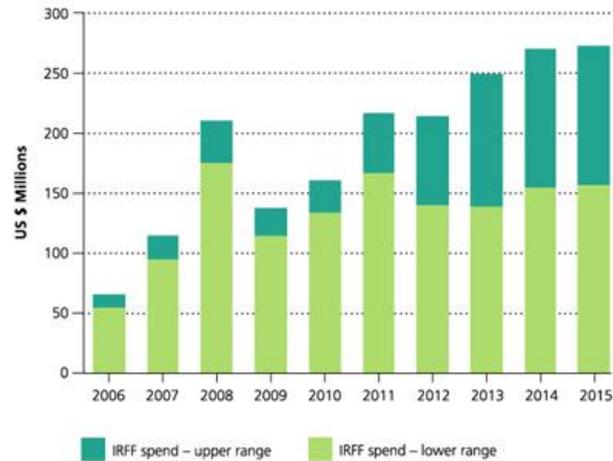
- Support the most efficient R&D approach (PPPs)
- Further improve performance within this approach by targeting weak spots:
  - ✓ Increasing funding flows
  - ✓ Increasing input of industry activity and expertise to PPP projects
- Minimise donor risk

Industry and the drug PPPs are supportive, or have already endorsed it



## IRFF: High return for a low investment

- Average US **\$7 million/year per OECD country** to subsidise all industry input into all PPP neglected disease drug R&D to 2015
- Average <\$140 million/year until 2010 – plateaus at average \$200 million/year



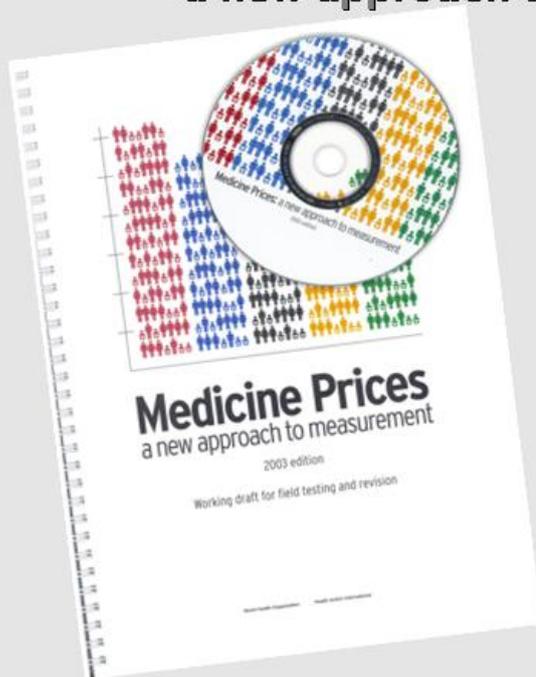
# Medicines too costly and too scarce

Margaret Ewen  
Health Action International Europe



1

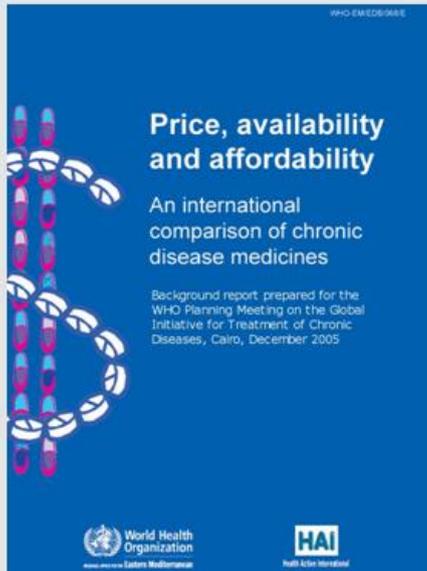
## Medicine Prices a new approach to measurement



- WHO/HAI methodology
- Launched World Health Assembly, 2003
- Measures medicine
  - > prices
  - > availability
  - > affordability
  - > component costs
- 40+ surveys to date in all regions of the world

2

## Price, availability and affordability analysis



- 14 chronic disease medicines
- 5 conditions: asthma, diabetes, epilepsy, hypertension, psychiatric disorders
- 30 surveys
- Public sector procurement prices and patient prices in the public and private sector
- Affordability: Number of days the lowest paid unskilled government employee must work to purchase 30 days treatment

[www.haiweb.org/medicineprices](http://www.haiweb.org/medicineprices)

3

## Median price ratios

### Median price ratio

ratio of median price across the facilities surveyed by an international reference price

### International reference price

Management Sciences for Health (MSH) International Drug Price Indicator Guide (adjusted to 2003)

Recent procurement prices offered predominantly by not-for-profit suppliers to developing countries for multi-source generic products.

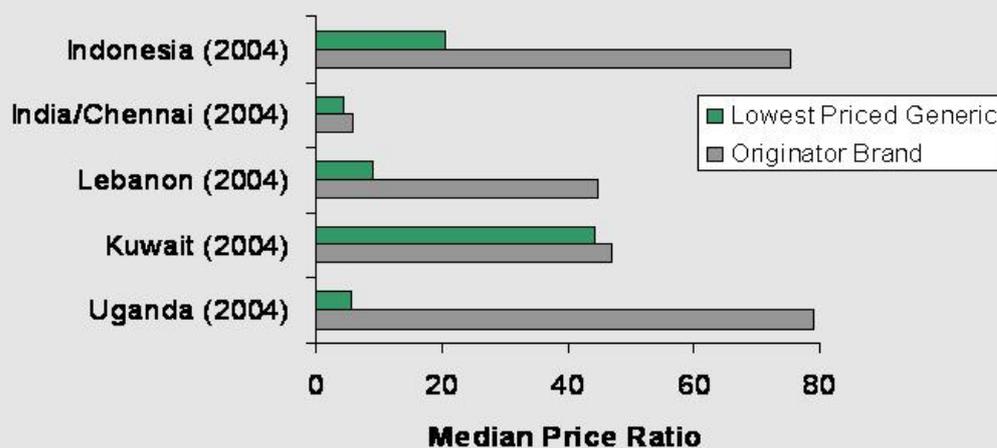
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## Median price ratios, public sector

	Public sector Procurement price		Public sector Patient price	
	Originator	Generic	Originator	Generic
<b>captopril 25mg tab</b>				
Kenya (2001)	12	4.17		
Morocco (2004)	37.65	12.80	free	free
Indonesia (2004)	-	1.35	21.80	1.69
Mongolia (2004)	-	1.58	-	2.89
<b>phenytoin 100mg cap</b>				
Indonesia (2004)	-	2.19	-	21.46
<b>glibenclamide 5mg tab</b>				
Chad (2004)	-	1.29	-	4.49

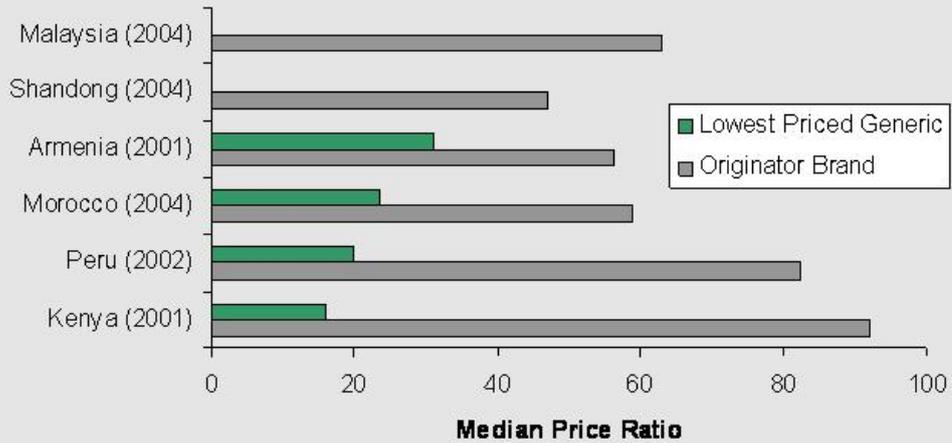
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## Median price ratios, atenolol 50mg tab, private retail pharmacies



6

## Median Price Ratio, fluoxetine 20mg cap, private retail pharmacies



7

## Availability: glibenclamide 5mg tab

	<i>Public sector</i>		<i>Private sector</i>	
	<b>Originator</b>	<b>Generic</b>	<b>Originator</b>	<b>Generic</b>
<b>Shandong (2004)</b>	<b>0%</b>	<b>5%</b>	<b>0%</b>	<b>5%</b>
<b>Mali (2004)</b>	<b>0%</b>	<b>5%</b>	<b>55%</b>	<b>45%</b>
<b>Lebanon (2004)</b>	<b>0%</b>	<b>10%</b>	<b>100%</b>	<b>98%</b>
<b>Morocco (2004)</b>	<b>0%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

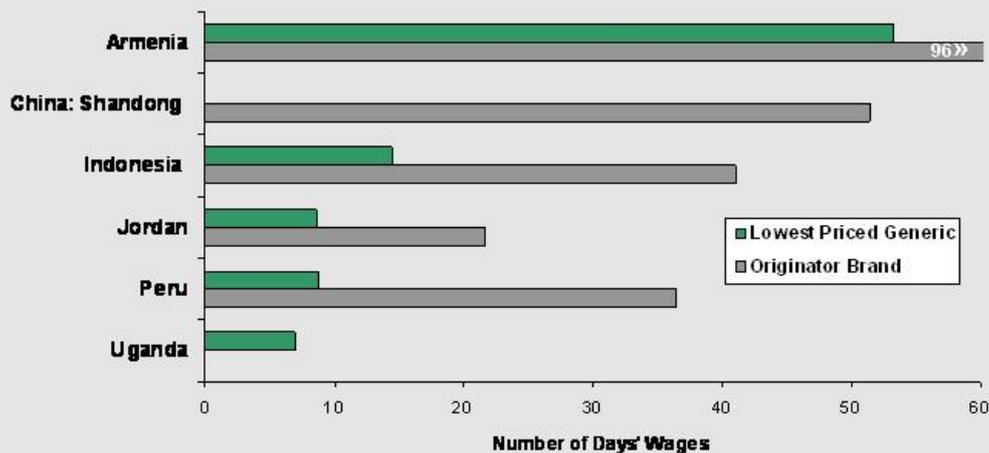
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## Availability: beclometasone inhaler 50mcg/dose

	Public sector		Private sector	
	Originator	Generic	Originator	Generic
Chad (2004)	4%	0%	18%	0%
Maharashtra (2005)	0%	0%	0%	10%
Mongolia (2004)	0%	0%	0%	4%
Philippines (2002)	15%	0%	9%	1%
Indonesia (2004)	0%	0%	2%	0%
Morocco (2004)	25%	65%	5%	50%

9

## Affordability: fluoxetine 40mg tab/day 30 days treatment, private retail pharmacies



10

## salbutamol inhaler 0.1mg/dose: availability vs affordability

	EML	Availability Public sector facilities		Affordability Private retail pharmacies	
		Originator	Generic	Originator	Generic
<b>Uganda (2004)</b>	yes	0%	0%	5.6 days	2.0 days
<b>Mali (2004)</b>	yes	0%	0%	4.2 days	2.7 days
<b>Indonesia (2004)</b>	no	13%	0%	4.1 days	-

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## Taxes on Medicines

### Tajikistan (private sector, imported medicines)

**VAT 20% Customs duty 5% Tax 1-5%**

+ transport charges, wholesale & retail mark-ups

Eliminate taxes: cumulative mark-up 123% → 74%

### Mongolia (private sector, imported generic)

**Customs duty 5% stamp duty 1% VAT 15%**

+ wholesale & retail mark-ups

Eliminate taxes: cumulative mark-up 98% → 63%

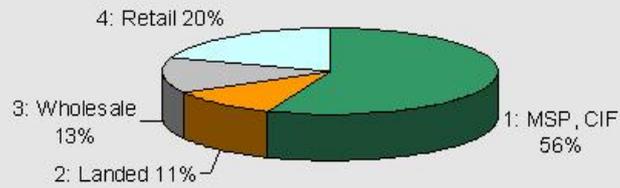
### Indonesia

**VAT 10%** - charged twice

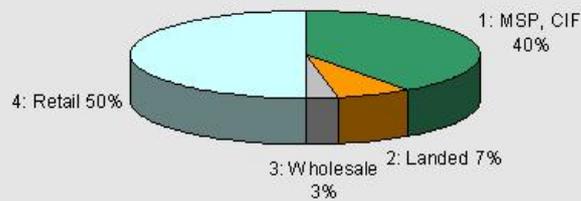
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## Malaysia: atenolol 50mg tab private retail pharmacies

### Originator (patient price: 72 RM)



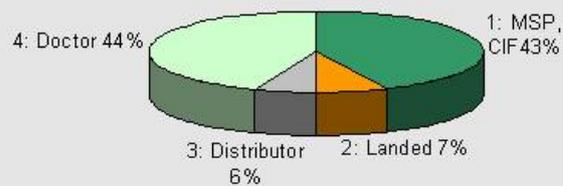
### Generic (patient price: 24 RM)



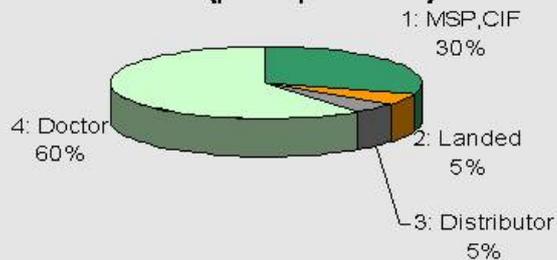
13

## Malaysia: atenolol 50mg tab dispensing doctors

### Originator (patient price 94.29 RM)



### Generic (patient price 32 RM)



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## **Public sector component costs: Chad**

Official rates for generics:

- Statistics tax 2%
- Central Medical Store mark-up 16%
- Regional Medical Store mark-up 25%
- Health facility mark-up 30%

Cumulative mark-up: 92%

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## **Many policy options**

- Off-patent medicines - purchase low priced quality generics, public and private sector
- Patented medicines – equitable prices, use the flexibilities of trade agreements to introduce generics while a patent is in force
- Aid generic competition eg fast-tracking, waive registration fees
- Compulsory generic substitution where brand premiums exist

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## Many policy options

- Stop taxing essential medicines and control pharmacists remuneration – linked to service not value of medicine
- Where there is little competition, consider regulating prices - from manufacturers' selling price to margins in wholesale and retail.
- Educate doctors and consumers on availability and acceptability of generics, and publicise the price of generics
- Separate prescribing and dispensing

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## Strategies for health improvement



- **Price transparency and regular monitoring of prices** – from the manufacturer's selling price to the patient price
- **Abolish taxes and duties on essential medicines**
- **Increase the use and acceptance of generics**
  - governments: waive fees, fast-track generic applications, purchase generics
  - dispensing: compulsory generic substitution, control mark-ups
  - consumers and health professionals: education on generics

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## 4 Speakers' bios

### STOA WORKSHOP

#### STRATEGIES FOR THE IMPROVEMENT OF GLOBAL HUMAN HEALTH

European Parliament, Brussels, 29 June 2006

**Wilbert Bannenberg** qualified as a medical doctor at the Free University, Amsterdam, the Netherlands, in 1982. He obtained Masters degrees in Public Health (London School of Hygiene and Tropical Medicine, 1985) and Epidemiology (Netherlands Epidemiological Society, 1994). He has 20 years experience as a freelance public health consultant, in which he completed more than 70 missions to developing countries in the field of essential medicine and national drug policies, for DGIS, DFID, DANIDA, WHO, World Bank and the European Union. From 1996 to 2000 he was the co-ordinator of the South African Drug Action Programme (SADAP), which assisted the Department of Health in implementing the National Drug Policy. In 2001 he was WHO pharmaceutical technical advisor in the South Africa office. Since January 2002 he is working again as a freelance consultant in the areas of essential medicine, HIV/AIDS and public health. He is a partner in the HERA group, based in Belgium.

#### **Richard Laing**

Richard Laing is a physician who worked at all levels for 18 years in the Ministry of Health Zimbabwe. After receiving post graduate degrees in public health and health policy he spent 13 years in Boston USA. He initially worked for an international consulting company establishing the International Network for the Rational Use of Drugs. He was then a professor of international public health at Boston University School of Public Health before joining WHO in mid 2003 as a medical officer. He has served on a number of WHO Expert Committees. He has an extensive list of academic publications and is one of the editors and authors of the standard text *Managing Drug Supply*. At WHO, he is responsible for editing the *Essential Drugs Monitor* and for coordinating training and research related to promoting rational use of drugs in the community. He was one of the authors of the *Priority Medicine for Europe and the World* report.

#### **Octavi Quintana Trias**

Octavi Quintana is an MD MPH specialist in Critical Care. He has worked as attending physician in an Intensive Care unit for 8 years. He served as Director of the Regional Hospital of Málaga( Spain). Former Director of International Affairs of the Ministry of Health and Consumer Affairs of Spain. Former President of the Spanish Society on Quality Assurance. Former President of the Steering Committee on bioethics of the Council of Europe. Former Vice-President of the European Group of Ethics of the European Commission. Director of a series on medicine at the State Spanish TV. He has participated as health coordinator of humanitarian crisis in Rwanda, Bosnia and Kosovo. Mr Octavi Quintana is the Director for Health Research at the European Commission, in DG Research and Technology Development since May 2002.

### **Mary Moran**

MBBS (Bachelor of Medicine, Bachelor of Surgery, Hons); Grad Dip FAT (Foreign Affairs & Trade); FRSM

Dr Mary Moran trained as a medical doctor, working for 13 years in Emergency Medicine at teaching and affiliated hospitals in Australia. A post-graduate degree in intl. relations and politics at University of NSW and Monash University (1995) led her into a career with the Australian Department of Foreign Affairs & Trade, including a diplomatic posting to London where she focused on climate change negotiations and international trade. Mary subsequently worked for three years with Medecins Sans Frontieres, initially as Director of the Access to Essential Medicine Campaign in Australia and later as a Europe-based advocate on a range of issues relating to access to medicine for neglected patients. In 2004, she founded the Pharmaceutical R&D Policy Project (PRPP) at the London School of Economics & Political Science, and continues as PRPP Director following the unit's transfer to The George Institute, Sydney, in 2006.

### **Margaret Ewen**

Margaret is a pharmacist working in the European office of Health Action International in Amsterdam. She co-ordinates two projects with the WHO - on medicine prices and drug promotion. She also led a campaign in Europe against relaxing the ban on direct-to-consumer advertising of prescription medicine. Before joining HAI Europe, Margaret was a senior advisor with the New Zealand Ministry of Health.

## 5 List of participants

### STOA WORKSHOP

#### STRATEGIES FOR THE IMPROVEMENT OF GLOBAL HUMAN HEALTH

European Parliament, Brussels, Room A3 E-3, 29 June 2006, 9:00-13:00

#### List of participants

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## 6 Related documents

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Corbey, D. and G. Bakker. *Medicine in a global context: A plea for public leadership*.

Ewen, M. and D. Dey. *Medicine: too costly and too scarce*. HAI, 2005.

Gelders, S., M. Ewen, N. Noguchi, R. Laing. *Price, Availability and Affordability. An international comparison of chronic disease medicine*. Background report prepared for the WHO Planning Meeting on the Global Initiative for Treatment of Chronic Diseases held in Cairo in December 2005. Health Action International/WHO.

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