



Access to medicines – a requirement for peace, health and medical work

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Peace, Health and Medical Work
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Access to essential medicines is fundamental to human rights

- The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition
- Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services
- Governments and the international community have an obligation to see the right to health progressively realised, which includes the responsibility for prevention, treatment and control of disease, and the creation of conditions to ensure access to health, facilities, goods and services
- Access to goods and services include – of course – the provision of essential medicines necessary for the prevention and treatment of prevalent diseases

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Key facts and figures

- One third of the world's people lack access to the medicines they need - rising to 50% in parts of Asia and Africa
- Up to 50% of medicines are inappropriately prescribed, dispensed or sold, leading to wasted resources and potentially resulting in patient harm
- Patients improperly use up to 50% of medicines, resulting in reduced treatment efficacy and potentially leading to resistance
- In developing countries, medicines account for 60% - 90% of household expenditures on health. Inappropriate prescription, high prices, low quality and improper use mean that the poor often receive little health benefit for their spending on drugs

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Essential medicines

- Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.
- Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.
- The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations, exactly which medicines are regarded as essential remains a national responsibility.

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In 32 countries 50% of the population lacks regular access - Why is access limited?

- Have to pay out of pocket
 - **lack of insurance**
- Where medicines are **free in public sector, availability is poor**
 - inefficient distribution system
 - Public spending insufficient and decreasing
- **High prices** in private sector because of
 - **patent issues** and belief in brands and 'the newer the better'
 - unregulated private sector
 - push for newer more expensive drugs
- Drugs for important diseases do not exist
 - lack of **research and development**

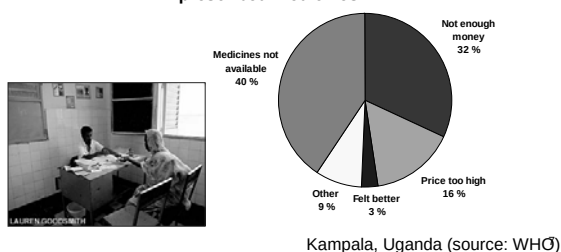


Prices, affordability, availability and financing



28% of people could not obtain all prescribed medicines - barriers were money, prices, availability

Reasons for not obtaining all prescribed medicines



Wider problems of medicine prices

- Medicines have variable and often high prices, are unaffordable for large sectors of the global population and a major burden on government budgets
- Burden falls directly on most patients in developing countries – but little is known about the prices people pay and how these prices are set, from the manufacturers' selling price to the patient price
- Trade agreements can severely affect the price and availability of medicines
- Many developing countries do not have pricing policies

But, the prices of medicines are well above their production costs so there is great scope for reductions

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Antimalarials Mefloquine (Lariam®) prices 2000

- Average retail price in **Tanzania** for 100 is 549 USD
- Max retail price in Norway for 100 is 308 USD

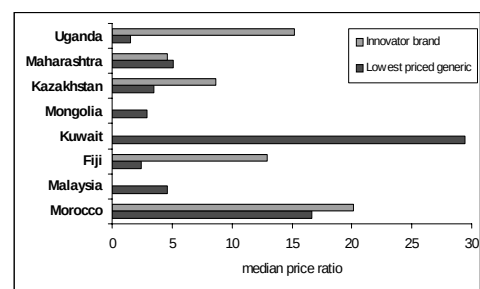
Norway:

- very small market
- not reimbursed
- Nordic text on label and box
- Nordic package insert but: max retail price (= price control)

Purchasing power in Norway 100 times higher, i.e. price in Tanzania 200 times higher

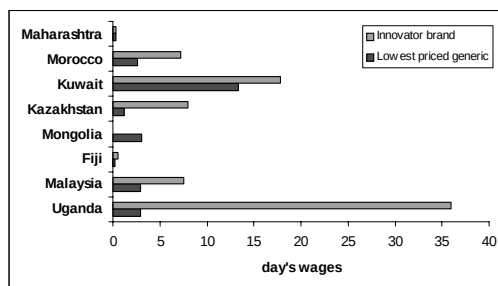
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Brand vs generic prices in relation to an international reference price for amoxicillin 250mg caps, private pharmacies



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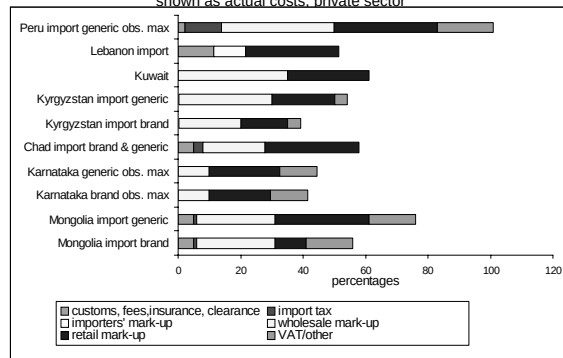
Affordability – day's wages, lowest paid unskilled govt. worker, needed to buy 30 days ulcer treatment with ranitidine 150mgx2/d



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Add-on component costs - governments are also taxing the poor

shown as actual costs, private sector



salbutamol inhaler 0.1mg/dose: availability vs affordability

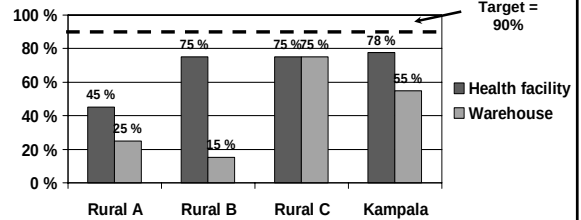
	EML	Availability Public sector facilities		Affordability Private retail pharmacies	
		Originator	Generic	Originator	Generic
Uganda (2004)	yes	0%	0%	5.6 days	2.0 days
Mali (2004)	yes	0%	0%	4.2 days	2.7 days
Indonesia (2004)	no	13%	0%	4.1 days	-

Marg Ewen, HAI 2006

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% availability varied 2-fold among health facilities, 5-fold among warehouses

% availability of key drugs in public sector



Uganda (source: WHO) 14

Impact of lack of affordable medicines on reproductive health

A lack of affordable medicines and other health commodities has a direct impact on the health of mothers and children. E.g., the UN Population Fund (UNFPA) estimate that each US\$ 1 million shortfall in support for contraceptives means an estimated 360 000 more unwanted pregnancies; 150 000 additional induced abortions; 800 maternal deaths; 11 000 infant deaths; and 14 000 additional deaths of children under 5.

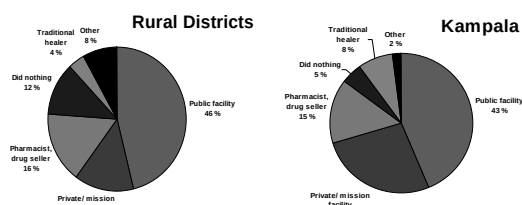
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Health insurance coverage varies considerably

Regions/Countries	Population coverage for countries with health insurance
	Median
Established Market Economies	> 95
Middle Eastern Crescent	50
Latin America and Caribbean	35
Asia and Islands	10
Sub-Saharan Africa	8
India	5
China	30

Source: WHO/DAP, ARA

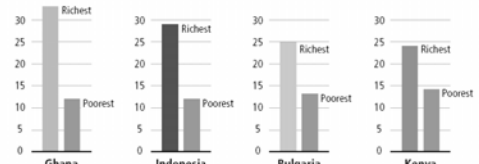
Sources of care in rural districts and Kampala, Uganda - households rely heavily on public services



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Public health spending neglects poor people and favours the wealthy...

Share of public spending on health services (percent)



Sustainable financing - how

- Increase public funding for health, including for essential medicines
- Reduce out-of-pocket spending, especially by the poor
- Expand health insurance through national, local, and employer schemes
- Target external funding at specific diseases with high public health impact
- Explore other financing mechanisms, such as debt-relief and solidarity funds

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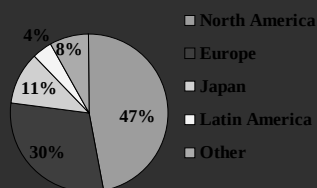
Possible options to lower prices

- Regional pooled procurement with open tenders
- Governments to use the flexibilities of TRIPS Agreement to introduce generics while patent is in force
- Governments to facilitate quick penetration of generics when patent is about to expire
- Stop taxing essential medicines
- Where there is little competition, governments should consider regulating prices - from manufacturers' selling price to margins in wholesale and retail
- Educate doctors and consumers on availability and acceptability of generics
- Prescribe by INN and have a generic substitution policy

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I. Global Pharmaceutical Market before and after TRIPS

Worldwide Pharmaceutical -- Sales 2005



Total Sales: \$565.9bn

Source: IMS

MFJ International, LLC
A Global Consulting Firm



The skewed pharmaceutical market

- 15% of the world's population consumes 91% of the world's production of pharmaceuticals, by value
- Developing country markets constitute 88% of vaccine sector volumes, but only 18% of global revenues from vaccine sales
- Africa constitutes just 1.1% of the global pharmaceutical market, by value
- Every year more than US\$ 70 billion is spent on health research and development by the public and private sectors. An estimated 10% of this is used for research into 90% of the world's health problems. This is known as "the 10/90 gap"

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TRIPS-agreement

Trade Related Aspects of Intellectual Property Rights

- a World Trade Organisation (WTO) agreement aimed at strengthening and harmonising aspects of the protection of intellectual property at the global level. It includes trademarks and patents as well as other forms of intellectual property
- Minimum standards for protection of patent rights and copyright
- minimum 20 years patent protection (EU, USA, Japan and Australia have 24-25 years)
- covers both process and product patents
- deadlines for national implementation:
 - 1996 industrialised countries
 - 2000 developing countries
 - 2006 the poorest 49 countries (2016 after DOHA)

Medicines only a small part of the agreement

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Patents

- Patents protect *inventions*, for both products and processes, i.e. gives the owner a monopoly over the invention, usually for 20 years
- In all fields of technology
- Patent criteria: novelty, inventive step, industrial application (TRIPS Art.27)
- For pharmaceuticals, the invention is often a new molecule or family of molecules for the treatment (or prevention) of a particular disease (protected by what is known as a 'product' or 'substance' patent, or
- - a method of producing a drug (protected by what is known as a 'process' or 'methods' patent)

→ there can be more than one patent for a single medicine!!

Why patents? Seems all pain .. where is the gain?

- Stimulate innovation – a debate over this concept
- Publication of patents: dissemination of information, technical knowledge
- Grant a monopoly – preventing others from using, making, selling, and marketing the product for a time-limited period

The situation pre- TRIPS

- India Patents Act, 1970 no patents on Pharmaceutical products (Based on German model)
- Brazil, No Pharmaceutical Patents
- Pharmaceutical products became patentable in West Germany, 1967; France 1967; Italy 1979; Spain 1992
- Until early 1990s, approx. 50 developing countries either excluded medicines from patentability or provided shorter periods of protection or operated conditions which restricted patent holders' rights

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Compulsory licence

Article 31 TRIPS

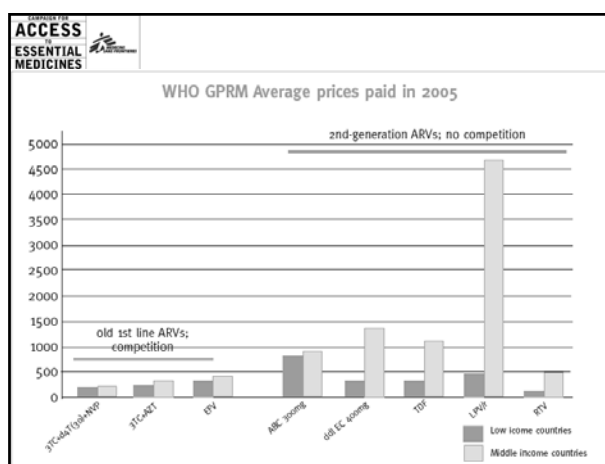
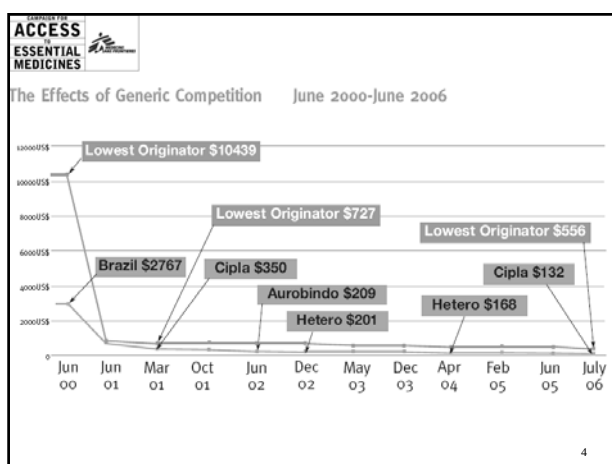
- Government grant of licence to 3rd party to use patent without consent of patent holder
- Right to determine grounds for compulsory licence
- NOT just for emergencies
- Conditions for grant: prior negotiations, compensation to patent holder, appeals process
- After DOHA: permission to import if the country has no production capacity

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Hand to hand combat - role of civil society

- Thailand:
 - PLWA (people living with aids) groups revoked the Ddi patent (didanosine)
 - Opposition to patenting of AZT/3TC combination (Combivir®)
- South Africa:
 - TAC (activist group) used competition law to force licenses on key AIDS drugs produced by GSK and BI
- India:
 - pre grant opposition by patient groups, e.g. Glivec®, antiretrovirals
- (Brazil, China)

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Bargain...

- *'Patents constitute a temporary monopoly, but in the end society benefits'*

Fred Hassan,
CEO of Schering-Plough president of IFPMA on 10 Oct '06

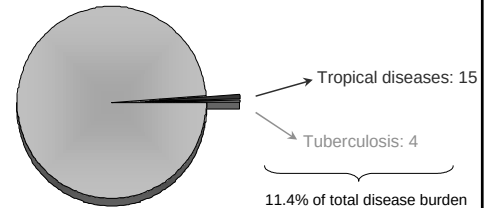
But Does It?

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Fatal Imbalance

- 1975-1999: 1,393 new chemical entities marketed
- Only 1% of new drugs developed are for neglected diseases
- 1999-2004: + 163 NCEs, + 3 new drugs for neglected diseases



Trouiller et al., Lancet 2002, 359:2188-94; updated figures: Torreele, Chirac 2005

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Innovation in decline?

- 68 % of the 3,096 new products approved in France between 1981 and 2004, brought 'nothing new' over previously available preparations. (2005 by *La Revue Prescrire*.)
- Barely 5 % of all newly-patented drugs in Canada considered as 'breakthrough.' (2005 *British Medical Journal*)
- 1000 new drugs approved by the US FDA between 1989 and 2000, over $\frac{3}{4}$ have no therapeutic benefit over existing products. (2002 *NICHM*)

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TRIPS: A Bad Bargain (1)

"All the evidence we have examined suggests IP hardly plays any role at all in stimulating R&D on diseases prevalent in developing countries, except for those diseases where there is a large market in the developed world (for example diabetes or heart disease) ...

Higher levels of intellectual property protection have not resulted in increased drug R&D for global health needs."

UK Commission on Intellectual Property Rights³⁴
(CIPR) 2002

TRIPS: A Bad Bargain (2)

- *" There is no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals on TYPE II and particularly Type III diseases. Insufficient market incentives are the decisive factor."*

WHO Commission on Intellectual Property Innovation and Public Health (CIPIH). April '06

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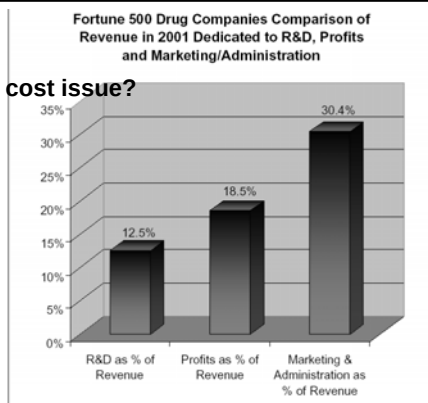
TRIPS: A Bad Bargain (3)

"We have no model which would meet the need for new drugs in a sustainable way" ... "You can't expect for-profit organisations to do this in a large scale. If you want to establish a system where companies systematically invest in this kind of area you need a different system"

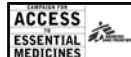
Daniel Vasella, CEO Novartis in Financial Times 30/09/'06

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Is it a cost issue?



Source: Public Citizen analysis of company annual reports; *Fortune* magazine, April 2002, Fortune 500 (www.fortune.com)



AIDS Treatment

- 42 million people HIV positive
- 6 million in immediate need of treatment
- 1.3 million receive ARVs
- **50 % depend on generic ARVs mostly from India**
- **87 % of all new patients treated by MSF receive generic FDCs**

Ellen 't Hoen, HAI conference 2006

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Impact of lack of affordable medicines on HIV/AIDS in Africa

A lack of affordable medicines and other health commodities has a direct impact on the number of people that receive treatment for HIV/AIDS. In 2004 around 75 000 Africans had access to antiretrovirals (the drugs that keep the virus load low). First line treatment may cost around USD 292 per year if generics are purchased from India; when the patients need second line treatment, the cost may increase to around USD 1594.

In addition, HIV-positives may need treatment for other infections such as tuberculosis and fungal infections.

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The 10 challenges are:

1. Inequities in ART coverage, both between and within countries.
2. Procurement problems, due to a lack of coordination between both donors and actors at a national level.
3. Treatment interruptions due to stock-outs of both first and second-line drugs, and paediatric formulas.
4. Inaccessible diagnostic tests, which means that not enough people are aware of their HIV status, and monitoring of treatment needs and efficacy is suboptimal.
5. Recurrent transport costs, and user-fees, which challenge continued access and adherence to ART.
6. Overburdened health workers, due to a lack of investment in health services and the rapid scale-up of ART.
7. Continuing stigma and discrimination of people in need of treatment, especially affecting intravenous drug users and other vulnerable groups.
8. Lack of adherence and nutritional support for ART users.
9. Uncoordinated action at all levels of planning and implementation, resulting in missed opportunities for a better continuum of HIV/AIDS care.
10. Planning for sustainability of ART programmes, including future needs for second line treatments.



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Research and Development (R&D)

- Governments and pharmaceutical manufacturers are the main funders of the R&D of new medicines
- Investment in health R&D is concentrated in the industrialised countries
- Only 10% of R&D spending is directed to the health problems that account for 90% of the global disease burden (the 10/90 gap)

Current barriers to drug development for neglected diseases

- Cost of Research and Development (R&D)
- Regulatory barriers
- Protection of intellectual property



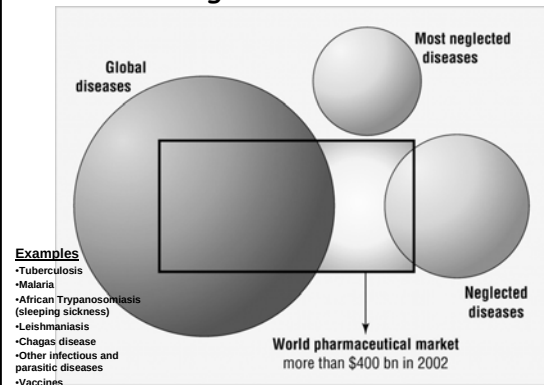
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The pharmaceutical industry

- Multinationals (also called research-based), e.g. Pfizer, Lilly, Merck, GSK. Develop and patent medicines, but often has a generic division or a contract with a generics company to produce copies after patent expiry. Power increased through mergers. Charges the highest price a market is willing to bear.
- Generic manufacturers which manufacture copies after patent expiry. They comprise large international companies, national companies, branches of multinationals. Some of them are not-for-profit suppliers to public sector in developing countries

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Neglected diseases



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R&D: A Tufts University study says the cost is \$802 million

- The full capitalized resource cost of new drug development was estimated to be \$802 million (2000 dollars). This estimate accounts for the cost of failures, including research on compounds abandoned during development, as well as opportunity costs of incurring R&D expenditures before earning any returns.

– Press release, Tufts Center for the Study of Drug Development (CSDD), November 30, 2001.

James Love, Cptech, www.cptech.org

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R&D: The Global Alliance for TB Drug Development October 2001 report, *The Economics of TB Drug Development*, estimates a new TB drug can be discovered and developed for \$115 to \$240 million

- Includes cost of failures
- Total R&D costs estimated at \$115 to \$240 million including:
 - Discovery costs at \$40 to \$125 million
 - Development costs at \$76 to \$115 million

James Love, Cptech, www.cptech.org

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Public/Private Partnerships - the solution?

- Attempt to fill gaps in the health needs of developing countries through
 - - establishment of public-private collaboration
 - - networks
 - - partnerships
- Private sector: for-profit and not-for-profit
- Public sector: international organisations, development and aid agencies, governments, academia

Public-private collaborations

- Product development partnerships (PDPs)
- Partnerships for improving access to pharmaceuticals
- Global coordination and financing mechanisms
- Partnerships for strengthening health systems

Roffe P et al. Negotiating Health 2006

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Portfolio-based product development partnerships

- **HIV/AIDS**
 - Int AIDS Vaccine Initiative (IAVI)
 - SA AIDS Vaccine Initiative (SAVI)
 - Int Partnership for Microbicides (IPM)
 - Global Microbicide Project
 - Microbicide Development Project
- **Malaria**
 - Medicines for Malaria Venture (MMV)
 - Malaria Vaccine Initiative (MVI)
 - European Malaria Vaccine Initiative (EMVI)
- **Tuberculosis**
 - Global Alliance for Tuberculosis Drug Development (TB alliance)
 - Aeras Global TB vaccine foundation
 - Foundation for Innovative New Diagnostics (FIND)
- **Other diseases**
 - Drugs for Neglected Diseases Initiative (DNDi)
 - Institute for One World Health (IOWH)
 - Pediatric Dengue Vaccine Initiative
 - Human Hookworm Vaccine Initiative
 - Rotavirus Vaccine Accelerated Development and Introduction Plan
 - Pneumococcal Vaccine Accelerated Development and Introduction Plan

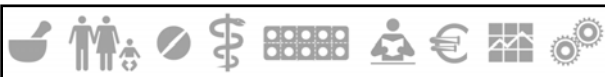
Roffe P et al. Negotiating Health 2006

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Partnerships for improving access to pharmaceuticals

	Donation	Discounted pricing	Manufacture	Other licensing
HIV/AIDS	Diflucan® (Pfizer) Viramune® (BI) Merck drugs Botswana within ACHIP	AAI (Multicompany)		Various
Tuberculosis			MDRTB drug production technology transfer	
Malaria		Coartem® (Novartis)		
Leprosy	Multidrug therapy (MDT) (Novartis)			
Lymphatic filariasis	Albendazole through GAEF (GSK)			
Trypanosomiasis	Eflornithine, etc. (Aventis)			
Onchocerciasis	Mectizan® (Merck)			
Contraceptives				Concept Foundation ₁

Roffe P et al. Negotiating Health 2006



Vietnam

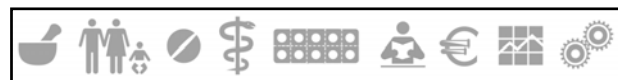
Currently 7 different PPI programs all being implemented at the same time in Vietnam

- PEPFAR
- CDC Life Gap
- WHO project Preventing HIV in Vietnam
- World Bank HIV/AIDS Prevention Project
- Clinton Foundation
- DND
- WHO 3 by 5 Initiative

Some Emerging Challenges

- health systems – cannot cope with the implementation of so many different programs, different reporting criteria, lack of skilled staff, quality of care
- adherence – costs for tests, ARVs, transport, stigma, drug resistance, confidentiality
- equity and accessibility – access to health care and ARVs for IDUs (intravenous drug users) and CSWs (commercial sex workers)
- ethical issues – quality of work and quality of care, doctors and patients selling drugs
- community involvement – lack of involvement of PLWHA in care and treatment
- drug policy and patent issues – compulsory licensing, registration of relevant ARV drugs in the first and second line, review and amend existing patent law and existing drug registration regulations

Pills, Politics and Practice 25 YEARS OF PROMOTING PEOPLE-CENTRED MEDICINES POLICY

Kenya

Achievement Gap

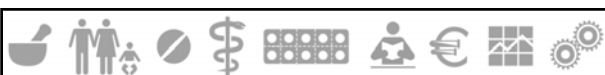
- 280,000 Kenyans need ARVs
- 18,000 are on ARV therapy
- Programs vary in their use of national guidelines, prescribed regimens, management of donor funding conditions, levels of community involvement, and medicines procurement strategy
- For example, the national clinical manual for ARV providers recommends the use of Fixed Dose Combinations. However there is no monitoring in the non-governmental sectors to ensure that the national protocols are being followed.

Largest ARVs programs: PEPFAR, MSF, Mission Hospitals

PEPFAR – launched February 2004

- Great pressure from US State Department to get 15,000 Kenyans onto ARVs in first 12 months of launch.
- A PEPFAR employee voiced concern that because there is intense pressure to meet this year's targets, PEPFAR may focus on a more accessible population of PLWHAs, neglecting those who are most vulnerable, and hardest to reach populations.

Pills, Politics and Practice 25 YEARS OF PROMOTING PEOPLE-CENTRED MEDICINES POLICY

Recurrent transport costs, and user-fees, which challenge continued access and adherence to ART.

"I came from very far over 50 kilometres from here. Before I come to the hospital I have to plan the money for a journey fare to the clinic. In fact my extra drugs got finished yesterday." (Male ARV user).

"I once missed my appointment for refill because there were no vehicles coming here. I was in the stop from early morning and by noon I went back home. Fortunately I still had some medications." (Male ARV user).

"Sometimes I do not have bus fare to come here for my drugs so I miss out while others get them (Kenyan ART user)"

Pills, Politics and Practice 25 YEARS OF PROMOTING PEOPLE-CENTRED MEDICINES POLICY




Donations - the rich peoples 'gifts' to the poor




Key messages

- Properly used, essential medicines save lives, reduce suffering and improve health
- By improving access to essential medicines and vaccines, up to 10.5 million lives could be saved each year worldwide: 4 million in Africa and South-East Asia alone
- Concerted action is needed to ensure fair and sustainable financing, affordable prices, reliable health and supply systems, and the rational use of medicines. Efforts are also needed to develop new vaccines, drugs and other health technologies that meet developing country needs
- This requires partnerships between developing country governments and healthcare providers, donors, international agencies, non-governmental organisations, pharmaceutical and biotechnology companies and the broader private sector, as well as consumers and health researchers

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"Does anyone deserve to be sentenced to certain death because she or he cannot access care that costs less than US\$2 a day? Is anyone's life worth so little? Should any family become destitute as a result? Should children be orphaned? The answers must be no, no, no and no! Yet this is what is happening. Every day."

Dr Brundtland, July 2002, quoted in Lancet 2006; 368: 541-5 (Schwartlander B et al.)

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