

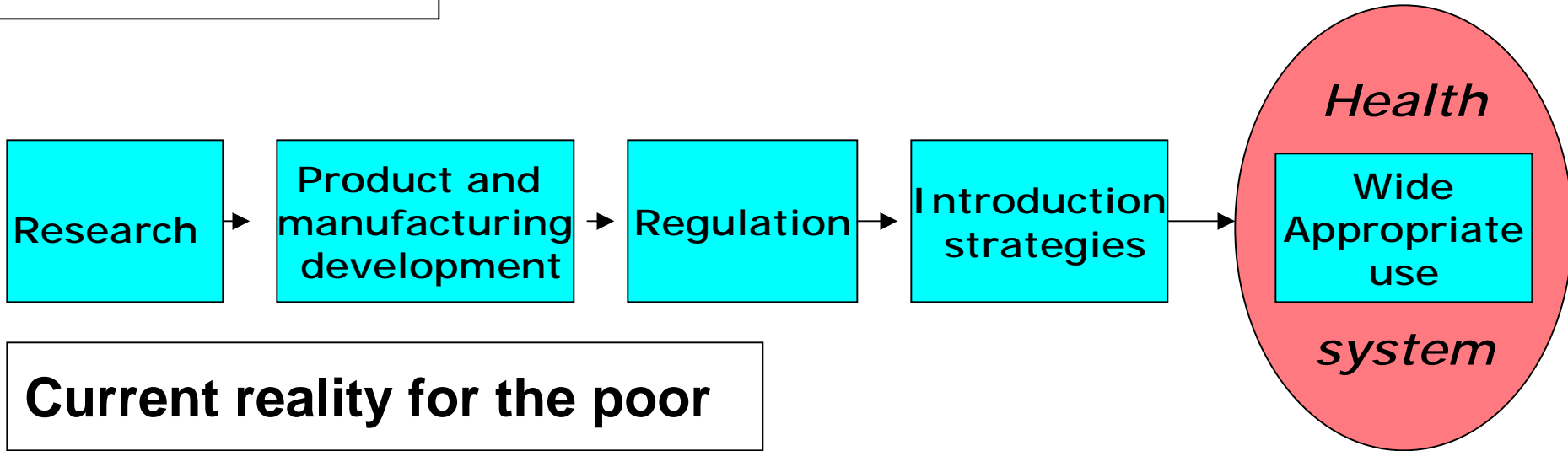
- **Donation or discount-based drug
'access' programs for tropical diseases
and HIV/AIDS**

Initiative on Public-Private Partnerships for Health
Global Forum for Health Research, Geneva
with
Institute for Health Sector Development and London
School of Hygiene and Tropical Medicine

13 January 2005

Impediments to better health in developing countries

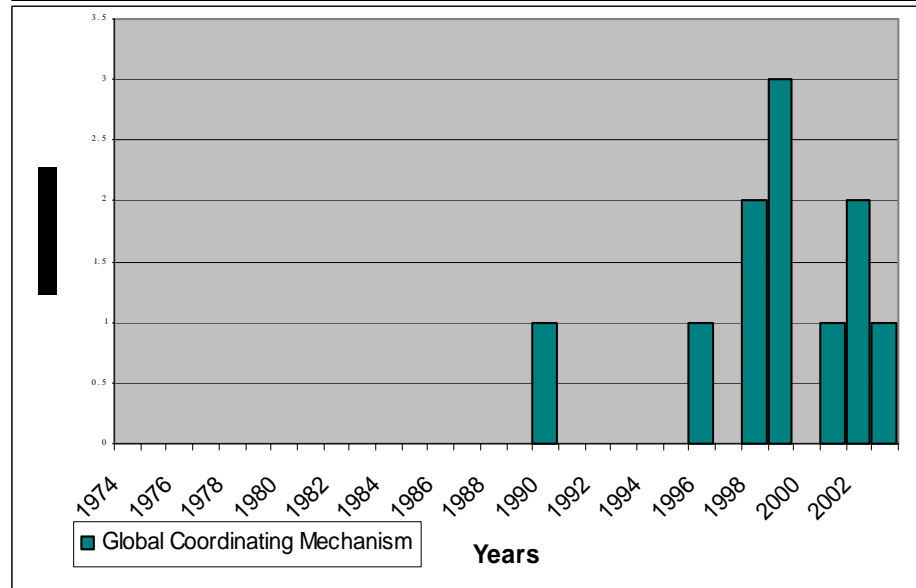
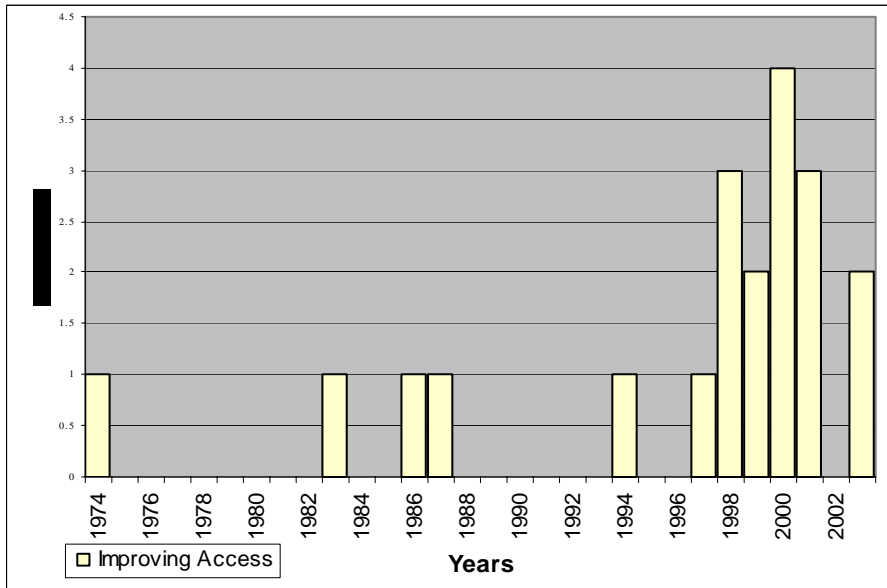
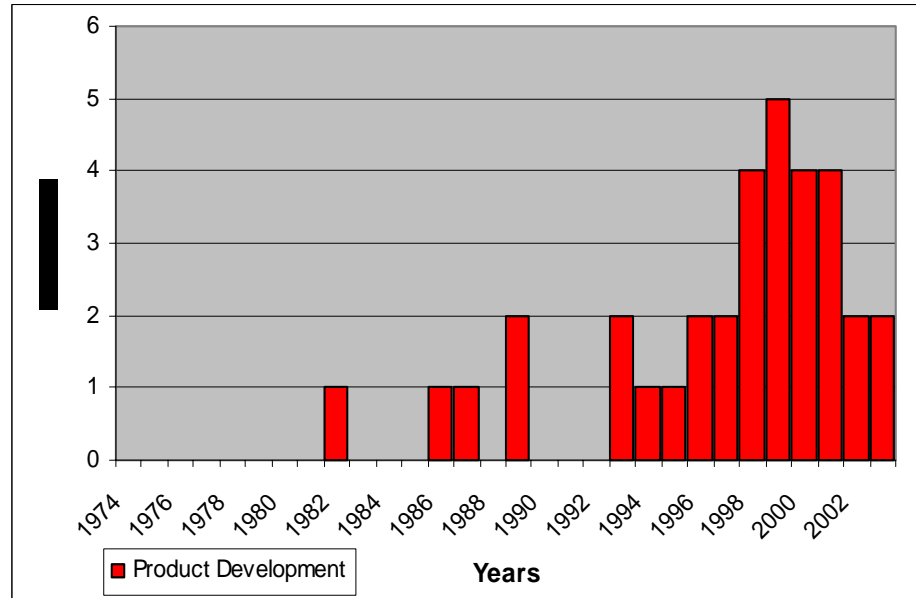
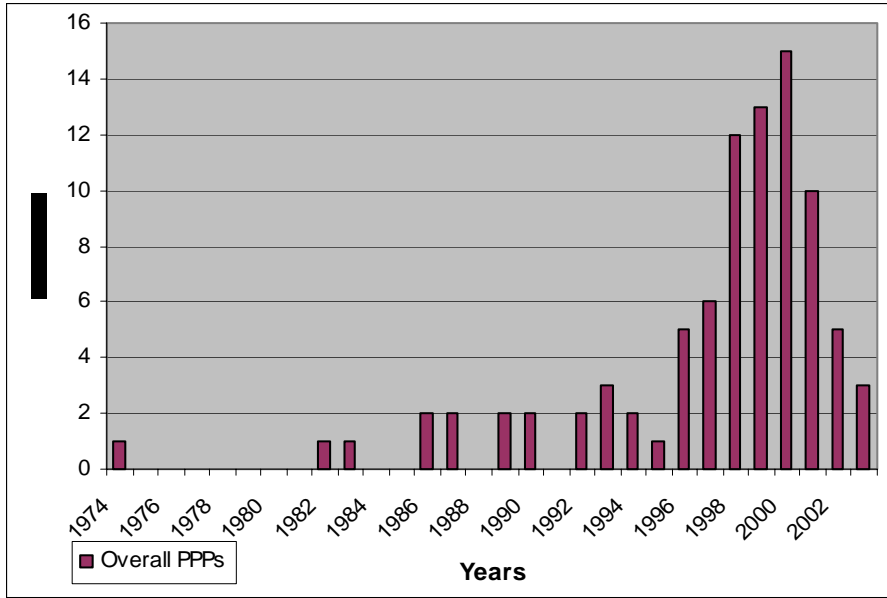
Ideal situation



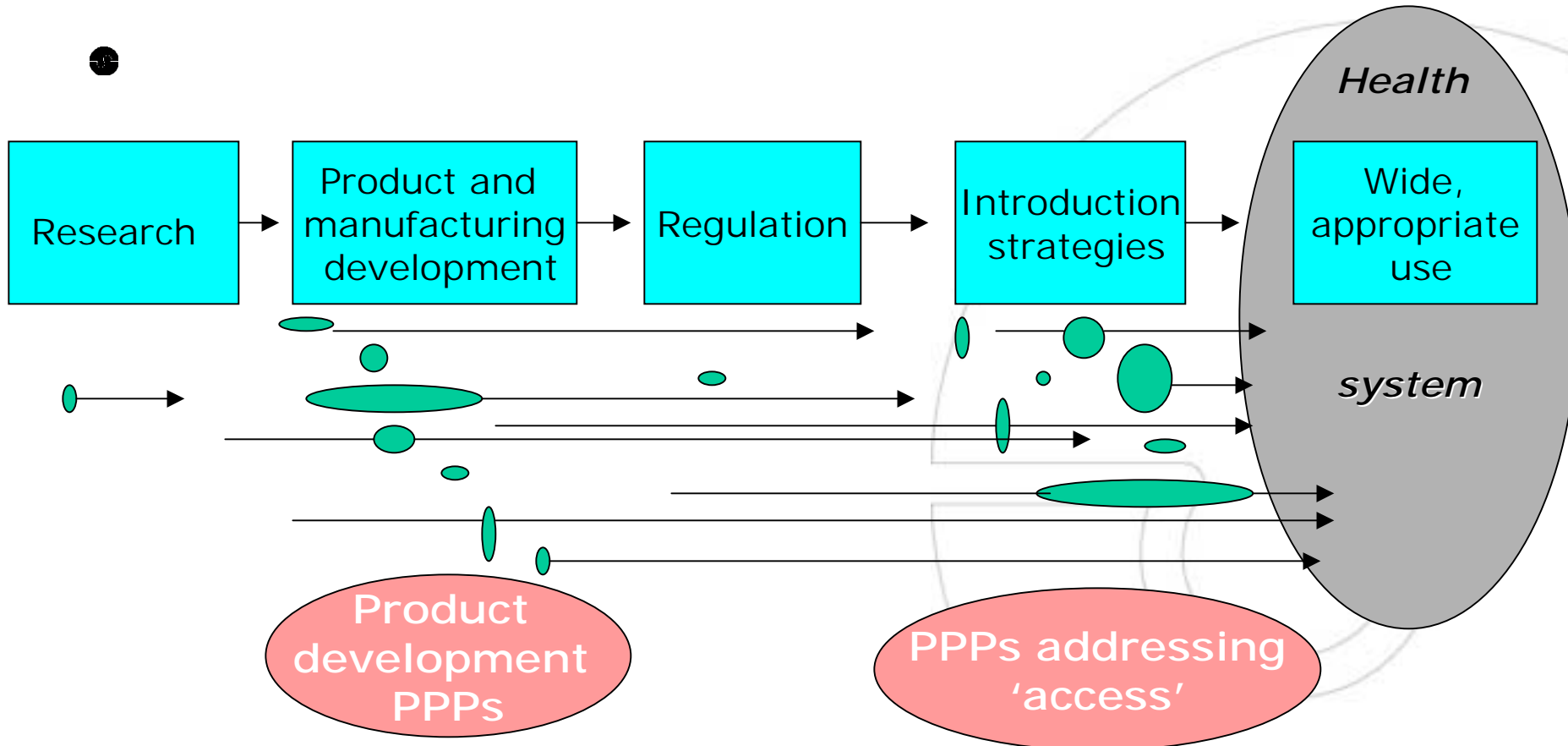
Current reality for the poor



Trends in 'partnering'



PPPs addressing health product development and delivery: Current activities



Drug Access PPP Study

Tropical Disease PPPs: Sri Lanka, Uganda & Zambia

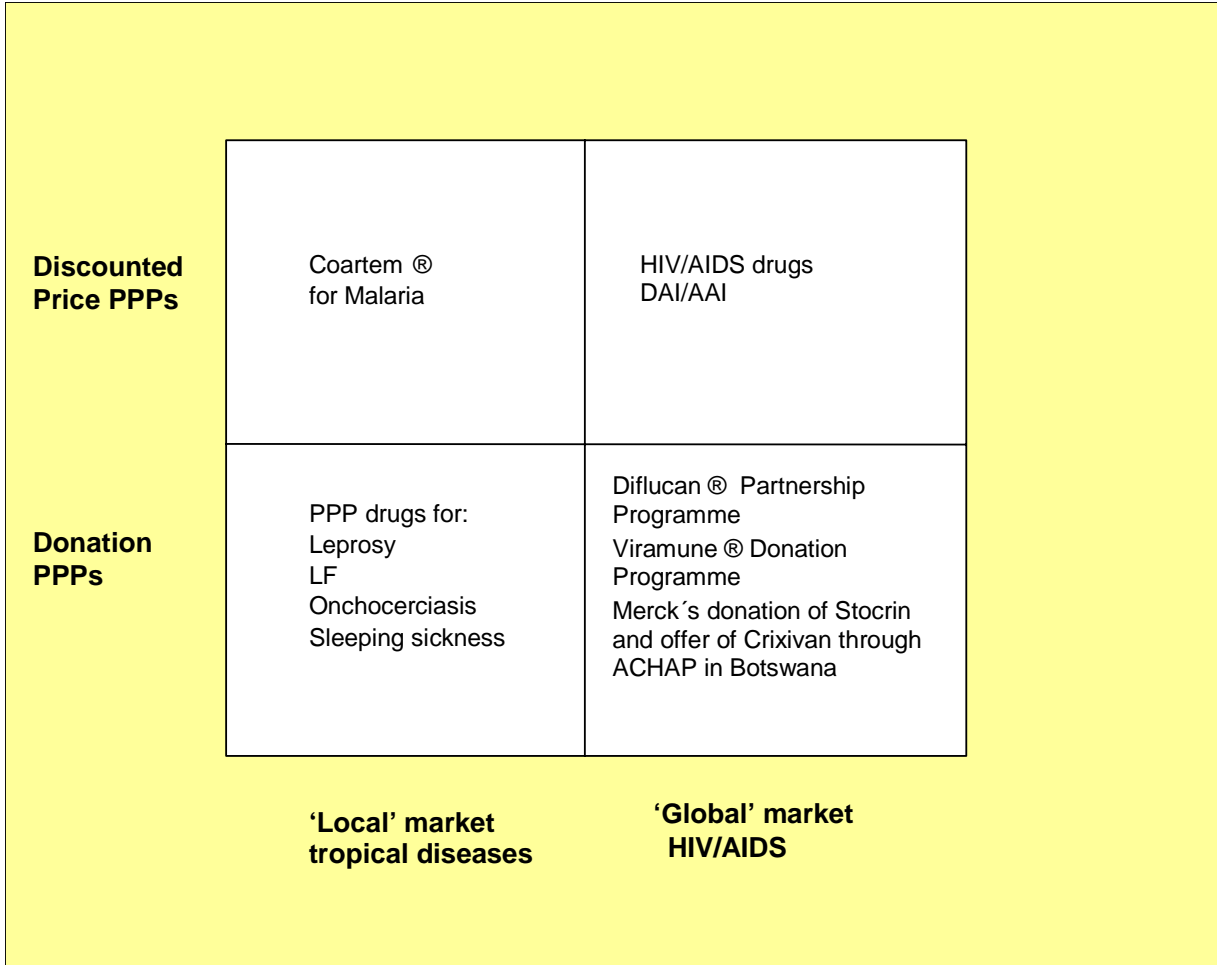
- **Karen Caines, IHSD**

Terms of Reference

Country level studies (not global)

To assess the health and health systems impact of public-private partnerships for improving access to pharmaceuticals in relation to leprosy, LF, malaria, onchocerciasis, sleeping sickness and HIV/AIDS, where pharmaceutical companies are involved as partners in supplying free or discounted drugs.

Specifically, to examine issues of ownership, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of [big pharma] commodity-focused access PPPs as distinct from other comparable programmes.



Study Approach

- examined all PPPs of this kind operating in 4 countries selected by DFID: pilot 2003 in Uganda, and in 2004 Botswana, Sri Lanka and Zambia
- information-gathering before fieldwork about PPPs under study, country context, relevant national disease control programmes - supplemented during fieldwork, quantitative where possible
- semi-structured interviews
- visits to districts; each PPP/programme examined in at least one district in each country
- all current PPPs of this kind were examined at least once at country level, with the exception of the International Trachoma Initiative.

A dynamic situation

One caveat: the reports present findings from fieldwork undertaken in Uganda in May 2003; Sri Lanka and Zambia in March 2004, and Botswana in May 2004.

They provide a snapshot in time of what continues to be a rapidly evolving situation, especially in relation to HIV/AIDS drugs and to the wider system impact of multiplying GHPs, most notably the GFATM.

Q: Why structure analysis by PPP diseases, rather than form of PPP - eg donation, discounted price etc?

A: Many more similarities across PPPs (in terms of structure, governance and mode of operation) if grouped by disease type than by end price of the product.

Tropical disease PPP/drug characteristics (except Coartem)

- TD PPP drugs cheap; generally sole source; for some diseases, supply challenges (eg tryps)
- no markets in rich countries; little risk of drug diversion
- TD PPPs operate within the context of wider global or regional health partnerships
- WHO (or APOC) as the major public partner in the PPP, dealing direct with countries
- PPPs linked to time-limited disease global/national elimination or control programmes. Little prospect of major new markets.
- all donations (except Coartem).

Tropical Disease PPPs by country

| PPP | Uganda | Sri Lanka | Zambia |
|-------------------|--------|-----------|--------|
| Leprosy | yes | yes | yes |
| LF | yes | yes | x |
| Oncho-cerciasis | yes | x | x |
| Sleeping sickness | yes | x | x |
| Coartem (malaria) | x | x | yes |

Study Tropical Disease PPPs and GHPs

| PPP | GHP/Prog. |
|---|--|
| <p>LEPROSY PPP DONATION: 1999 WHO/Novartis Agreement to donate Multi Drug Therapy (MDT) until 2005 to help eliminate leprosy; Agreement being extended to 2010.</p> | <p>GAEL; WHO Leprosy Elimination Project</p> |
| <p>LF PPP DONATIONS: 1998 WHO/GSK Agreement to donate all the albendazole required for elimination of LF; and 1998 Merck commitment to donate all the Mectizan® (ivermectin) required for as long as required to eliminate LF in African countries where onchocerciasis and LF co-exist.</p> | <p>GAELF; WHO Programme to Eliminate LF (PELF)</p> |
| <p>ONCHOCERCIASIS PPP DONATION: 1987 Merck/ Mectizan® Donation Program (MDP) commitment to donate all the Mectizan® required for as long as required to eliminate onchocerciasis as a public health problem.</p> | <p>APOC; OEPA; (OCP)</p> |
| <p>SLEEPING SICKNESS PPP DONATIONS WHO/Aventis MOU: 2001–2006 donations of pentamidine, melarsoprol, eflornithine. Bristol Myers Squibb: raw materials for one year’s supply of eflornithine. WHO/Bayer MOU: 2002–2007 donations of suramin, nifurtimox.</p> | <p>WPRESS</p> |
| <p>COARTEM (MALARIA) : PPP DISCOUNTED PRICE 2001–2011 WHO/Novartis Coartem® Public Purchase Agreement</p> | <p>RBM; WHO Roll Back Malaria Programme</p> |

Key study findings/conclusions

- these PPPs have facilitated better drug availability, with negligible negative side-effects
NB MDT for leprosy was available free in all study countries pre-PPP
- widely-held conclusion at country and global levels that PPPs have assisted the poor to access necessary drugs, but data limited and indirect.
- PPPs for leprosy, LF, onchocerciasis and sleeping sickness appreciated unreservedly by country level interviewees.
- timelimited elimination programmes are good choices for PPP support – minimise risk of creating unsustainable programmes.

Ownership and support

- MoH/district ownership of programmes
- excellent fit between PPP objectives and national/ district priorities: all diseases seen as serious health problems in endemic districts
- most, though not all, national programmes studied were kick-started or revitalised by drug donation/global programmes
- drug donation is *necessary* but not *sufficient* to initiate and support a successful national programme
- operational support has also been required
- continued support during maintenance phase is critical.

Health impact

- mature national TD programmes (oncho, leprosy) have achieved considerable health impact, subject to insecurity
- for LF and malaria, real health impact will be secured because of numbers of people receiving new/better treatment
- drug donations seen as crucial to results achieved, though difficult to isolate their contribution, given wider programme support, health system issues, and social mobilisation.

Health systems impact: I

- international-level concern about 'hidden' costs not mirrored in Uganda, Sri Lanka or Zambia for TD drug donation PPPs
- no evidence of skewed priorities or of unhelpful diversion of human/financial resources at central, district or community levels
- no evidence of unreasonable conditionalities
- transparent processes which comply with interagency guidelines
- reasonable PPP reporting requirements (as distinct from GHP requirements)

NB: time and financial limits on study data-gathering

Health systems impact: II

Interviewees saw impact as beneficial, eg

- availability of drugs and value of additional resources. Precise estimates of the dollar value of tropical disease drug donations/ discounts not available, but likely to be substantial. PPP/related contributions to operations/ training, eg Novartis and NFSD.
- contribution to national capacity-building, especially for policy development/planning
- impetus for community-directed approaches
- strengthened prevention and diagnostics aspects of malaria control, and new health system elements like pharmacovigilance, in Zambia.

Perceived pharma-specific benefits

- assurance of a sustained drug supply
- consistency of supply (promotes adherence, reduces training costs)
- assurance of big pharma brand quality
- possible stimulus to pharma R&D
- increased pharma attention to formulation and packaging, eg Novartis and Merck

ACT Coartem® for malaria: Zambia only

- the only discounted price PPP for a tropical disease
- high governmental commitment to PPP in Zambia, given resistance concerns
- programme new, GFATM funding, rapid planned scale up
- reasonable conditionalities to prevent diversion
- key challenges: (1) reaching 50% patients seeking malaria treatment in private sector. PPP social marketing experiment; (2) sustainability
- Novartis \$2.2m over 3 years for capacity building.

Summary findings

- Drug donation TD PPPs:
 - very considerable benefit with negligible negative side-effects
 - warmly welcomed by countries in the study.
- Discounted Coartem PPP too recent (less than 1 year) to assess definitively.
- Coordination across tropical disease PPP programmes is in its infancy.
- Sustainability is a concern, especially for Coartem.

Recommendations - 1

Given the potential health benefits of expanded efforts, some suitable group should convene or 'broker' consultation between pharmaceutical companies and public health authorities at national and international level, to explore where new tropical disease donation PPPs/ programmes might be initiated or current ones expanded.

Recommendations - 2

- To achieve elimination, all pharmaceutical companies should commit to continued contribution through drug donations and discounts
- donors should sustain support for some element of operations during maintenance as well as intensive phases of elimination/control, if resurgence of disease is to be avoided.

Recommendations - 3

PPP/programme efforts should be integrated with the district health system from the outset.

Recommendations - 4

Tropical disease drug access PPPs and related elimination and control programmes should collectively explore how different programmes – or individual facets of different programmes – might be more integrated /coordinated at international and country level.

Recommendations - 5

A rapid review in due course of the Coartem® discounted price agreement for malaria to draw on greater experience at country level.

Drug Access PPP Study HIV/AIDS
PPPs:
Botswana, Uganda, Zambia

- Louisiana Lush, DFID

Study approach

- Slightly different from tropical disease PPPs because:
 - Drugs are expensive and have major rich country markets
 - Minimal involvement by international organisations
 - Wanted to look at market impact but limited data

Characteristics of HIV/AIDS PPPs

- Diverse, rapidly developing policy environment
- Range:
 - DAI/AAI
 - Drug donations
 - Not-for-profit pricing
 - Discounted pricing
 - Not enforcing patents
 - Outlicensing
- Limited involvement by international organisations – public partner is national government
- Reliance on intermediaries (eg Axios International)
- Unknown trade offs between price, quality, transaction and distribution costs, adherence and sustainability.

Broader public health environment

- Complex policy issues
 - Developing countries have limited capacity to use TRIPs flexibilities; trade negotiation pressures
 - Limited corporate philanthropic activities at country level
- Appropriate resolution must take into account potential public health impact of different approaches as well as maximising business productivity.

HIV/AIDS PPPs by country

| PPP | Botswana | Uganda | Zambia |
|--|--|---|--|
| Boehringer Ingelheim's Viramune Donation Programme | 2003-07 32 hospitals | 2001 initiated 2003 22/56 districts | 2001 pilot sites 2003 formally initiated 2004 11 districts |
| Pfizer's Diflucan Partnership Programme | 2002 initiated 32 hospitals Early days | 2002 initiated Early days | 2003 initiated Early days |
| ARV discounting initiatives | 2001 AAI Supplied through public sector ARV programme | 1998-2000 pilot DAI; 2001-continuation phase All in private sector | No branded ARV discounting initiatives Generics procured |
| Merck & Co's donation of Stocrin and Crixivan through ACHAP | 2002 initiated through public sector ARV programme | - | - |

Health impact

- Influenced by end price of product
- DAI/AAI catalysed price reductions but generic competition probably had more impact on prices
- Few formal mechanisms for rationing based on equity principles. Uganda and Zambia charging for ARVs. Botswana free.
- Donation programmes potentially more impact:
 - Viramune limited to public sector and increasingly available but depends on other services and may give way to ARV treatment for women.
 - Diflucan currently limited to public sector and sites which can diagnose OC and CM, but little data on impact or equity. Could contribute to quality of life but not public health impact.

Ownership, integration and coordination

- PPPs for AIDS medicines are addressing a high priority issue to governments and donors
- Challenge to integrate, especially with SWAp or PRS processes:
 - fragmentation of AIDS initiatives generally and constantly changing picture
 - most AIDS programmes are in their infancy – not much to integrate with
 - but also need to think about drug procurement processes and lack of MOH expertise in relevant trade policy
- ACHAP exception – explicitly integrated with MOH and with built in hand-over plans.

Health systems impact

- Most initiatives claim to strengthen health systems, ACHAP core objective
- General problems with HR, drug procurement, distribution and leakage, HMIS, public-private provider relations
- PPPs focused on assisting with training, drug management and information collection
 - Axios hired by companies to assist countries
 - ARVs generally procured through completely separate systems
 - Viramune and Diflucan handled by programme managers
- Public private split irrational from patient perspective

Market impact

- Sparse data on comparative impact of different types of HIV/AIDS drug donations and discounts on local markets
- Some limited information on price trends over time in Uganda
- Discounts can contribute to downward pressure on prices
- Donations may rule out local competition, particularly if the public sector perceives an obligation to use a sole source.

Governance

- PPPs generally catalysed by external partners, whose priorities are reflected in their design, objectives and management
- Generally some kind of non-government support was required to get them going
- Botswana more evidence of national ownership than Uganda or Zambia.
- Sustainability and efficiency questions remain unresolved.

Key benefits: discounting initiatives

- Discounts enhanced access to HIV/AIDS medicines in 2 / 3 countries through both DAI/AAI and individual company activities
- Modest contribution to treatment programmes in all three countries

Challenges: discounting initiatives

- Fragmentation and coordination, links with funding sources
- Measuring cost-benefit of different approaches at national level
- Limited to public sector but:
 - Much ART is in the private sector
 - Distorts local markets
- Sustainability of initiatives and funding sources

Key benefits: donations

- Viramune contributed to preventing spread of HIV via mother-to-child transmission (after a slow start)
- Diflucan improved quality of life of those living with AIDS
- Merck donation to Botswana credited with
 - contributing to the government decision to launch national treatment programme and
 - strengthening the health system (capital expenditure, human resources).

Challenges: donations

- No precise figures on financial or public health benefit or impact – but likely limited
- Some problems with inappropriate branding in patient education materials in Botswana
- Potential to overwhelm absorptive capacity in the public sector by diverting staff, duplicating financial, monitoring systems and incurring ancillary costs
- Drug requisition process for high value products a particular problem

Recommendations 1

- Problem: Fragmentation of initiatives, funding and conditionalities
- Recommendations:
 - National and international level action
 - Flexible and responsive systems to rationalise procurement
 - Clear evidence of costs and benefits of each approach

Recommendations 2

- Problem: Lack of understanding of the range of options for access to medicine
- Recommendations:
 - Strengthen capacity in poor and middle income countries to assess options, including the role of collaborations with sole source providers
 - International agencies need to step up support and TA
 - Companies and donors to simplify and harmonise discounts and procedures available (within anti-trust constraints) including information on eligibility and conditionality

Recommendations 3

- Problem: Excluding the private sector from initiatives
- Recommendation: Further enhance partnership between public and private sectors in service delivery as ART programmes scale up
 - Recognise potential private sector role
 - Allow access to discounted or donated product
 - Ensure this does not contribute to inequitable public expenditure.

'Access' PPPs: Conclusions

Tropical diseases

- Onchocerciasis/MDP
- Leprosy/GAEL
- Lymphatic filariasis/GAELF
- Malaria/Coartem
- Trachoma/ITI
- Tuberculosis (MDR/RTB)

HIV/AIDS

- DAI (historic)
- AAI (various firms)
- Diflucan
- Viramune
- ACHAP (\$\$\$)

Great variety

'Access' PPPs: Questions



- Who should decide policy regarding donation/discount acceptability, etc?

- Whose interests should be paramount? Over what time frame?

- What are the (theoretical) alternatives? Who would pay for the alternatives?

- How to support countries to evaluate - thoroughly and realistically - the options and their implications?
