Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Selected Low and Middle Income Countries

A Synthesis Report from Studies in Botswana, Sri Lanka, Uganda and Zambia

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Abbreviations

AAI	Accelerating Access Initiative to HIV/AIDS Care
ACHAP	African Comprehensive HIV/AIDS Partnerships
ACT	Artemisinin combination therapy
AMDS	AIDS Medicines and Diagnostics Service (WHO/UNAIDS)
ANC	Ante-natal care
APOC	African Programme for Onchocerciasis Control
ART	Anti-retroviral therapy
ARV	Anti-retroviral drugs
CBOH	Central Board of Health in Zambia
CDT	Community directed treatment
CHAZ	Churches Health Association of Zambia
CPR	Contraceptive Prevalence Rate
DAI	Drug Access Initiative for HIV/AIDS
DEC	Diethylcarbamazine
DFID	UK Department for International Development
GAEL	Global Alliance to Eliminate Leprosy
GAELF	Global Alliance for the Elimination of Lymphatic Filariasis
GDP	Gross Domestic Product
GFATM	Global Fund to Fight AIDS, TB and Malaria
GSK	GlaxoSmithKline
HMIS	Health Management Information System
HSSP	Health Sector Strategic Plan in Uganda
IMR	Infant Mortality Rate
IPPPH	Initiative on Public-Private Partnerships for Health
LF	Lymphatic Filariasis
MAP	World Bank Multi-country AIDS Programme
MB	Multibacillary leprosy
MDA	Mass drug administration
MDP	Mectizan ® Donation Program
MDT	Multi drug treatment
MIS	Management Information System
MMR	Maternal Mortality Rate
MOH	Ministry of Health
MOU	Memorandum of Understanding
MSD	Medical Supplies Division
NFSD	Novartis Foundation for Sustainable Development
NGO	Non-governmental organization
OEPA	Onchocerciasis Elimination Program of the Americas
PB	Paucibacillary leprosy
PELF	WHO Programme to Eliminate Lymphatic Filariasis
PEPFAR	US Presidential Emergency Plan for AIDS Relief
PMTCT	Prevention of mother to child transmission
PPP	Public-private partnership
PRSP	Poverty Reduction Strategy Paper
R&D	Research and Development
SWAp	Sector-wide Approach
TAG	WHO's Technical Advisory Group for the Elimination of Leprosy
TB	Tuberculosis
TFR	Total Fertility Rate
TRIPS	Trade-Related Aspects of Intellectual Property
WHA	World Health Assembly
WHO	World Health Organization
WPESS	WHO Programme to Eliminate Sleeping Sickness

Foreword

by Roy Widdus, Ph.D.
Project Manager, Initiative on Public-Private Partnerships for Health
Global Forum for Health Research

This report provides an overview, with general conclusions and recommendations, from a series of studies of drug access programmes in selected countries, namely, Uganda (the pilot country) plus Botswana, Sri Lanka and Zambia. The studies were initiated by the Initiative on Public-Private Partnerships for Health (IPPPH), supported principally by the UK Department for International Development, and undertaken in association with the Institute for Health Sector Development based in London.

IPPPH was established in 2000, in part to develop a solid evidence base on public-private 'partnerships' for health so that the benefits of such collaboration for populations afflicted by poverty could be maximized and potential risks ameliorated.

IPPPH identified early in its existence the need for the type of study described in this report in response to a range of questions being raised about 'partnerships' addressing drug access in low and middle income countries that included donations or discounted pricing from pharmaceutical companies. Funding was provided by the UK Department for International Development (DFID) with supplementary support from the general contributors to IPPPH, namely, the Bill & Melinda Gates Foundation, the Global Forum for Health Research, The Rockefeller Foundation, and the World Bank.

The study design benefited from wide input, including staff of the World Health Organization and the Study Advisory Committee. Consultant teams were selected for each country with assistance from the Institute for Health Sector Development, London, an organization specializing in evaluation of health systems issues in developing countries. Ultimate approval of the study protocols rested necessarily with the IPPPH (as the agent responsible to the principal funder, DFID), along with the national government counterpart.

Members of the various country consultant teams are independent of the pharmaceutical industry and IPPPH. National team members had no direct programmatic or managerial responsibility for any of the programmes examined. However, in all cases, their knowledge of the respective national health systems and key information sources greatly benefited the studies.

In addition to guiding the study design and protocol development, the IPPPH Secretariat and the Study Advisory Committee offered suggestions for clarification of the draft texts of the country and 'synthesis' reports. The IPPPH Secretariat encouraged the authors of the 'synthesis' report to include general conclusions and recommendations up to – but not beyond – those that were firmly grounded on the information gathered in the country assessments.

IPPPH is pleased to publish the reports of these studies as a major contribution to understanding the nature, benefits, and problems associated with donation or discounted pricing programmes for improving access to drugs to combat diseases in low- and middle-income countries.

These studies add considerably to the previously limited evidence base on the impacts of such programmes at country level. Further questions remain, however. Due to time and resource pressures, it was not possible to include a country where the International Trachoma Initiative was operating; a necessary but unfortunate omission as this is now in a significant scale-up phase. Given the generally positive conclusions on donation programmes, particularly for tropical diseases, it is desirable to systematically consider where existing programmes could be expanded or new ones estab-

lished, always keeping sustainability in mind. Additionally, it remains important to consider the circumstances under which greater integration of these types of programmes might be desirable, feasible and appropriate, at global, national, and district levels. Finally, ongoing efforts are needed to identify how best to document and attribute health impacts of such programmes within broader health efforts.

IPPPH thanks the UK Department for International Development for providing the major portion of resources needed for these studies.

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Executive summary

In 2003–2004, the UK Department for International Development (DFID) funded the Initiative on Public-Private Partnerships for Health (IPPPH – part of the Global Forum for Health Research), in association with the Institute for Health Sector Development (IHSD), to conduct four country studies to assess the health and health systems impact of public-private partnerships (PPPs) for improving access to pharmaceuticals.

The country studies were undertaken in Botswana, Sri Lanka, Uganda and Zambia and examined PPPs supplying donated or discounted drugs for leprosy, lymphatic filariasis (LF), malaria, onchocerciasis, sleeping sickness, and HIV/AIDS (the Drug Access Initiative, Accelerating Access Initiative, the Diflucan® Partnership Programme and the Viramune® Donation Programme.

The specific remit was to examine issues of ownership, integration, coordination, implementation and impact. A key question concerned the degree to which the involvement of multinational research and development-based pharmaceutical companies, as partners in supplying free or discounted drugs, facilitated better drug availability and access by the poor. Further questions included whether the availability of free or discounted drugs distorts decisions on priorities or prices, and the feasibility and sustainability of taking such initiatives to scale.

The report organises its consideration of the PPPs according to whether they address tropical diseases or HIV/AIDS rather than whether the drug itself is donated or discounted. This is because there are more similarities across PPPs (in terms of structure, governance and mode of operation) if they are grouped by disease type than by end price of the product.

Critically, all the tropical disease drugs (except Coartem® for malaria) are cheap, and have no market in rich countries. In addition, all the tropical disease PPPs involve WHO (or APOC) as the major public partner in the PPP, and operate within the context of a wider global or regional partnership. Most are linked to time-limited disease elimination or control programmes. By contrast, all the HIV/AIDS drugs involved in these PPPs are expensive, and have major rich country markets. Further, there is minimal involvement by international organisations in these PPPs. While there are similarities between HIV/AIDS discounting initiatives and the Coartem® discounted price PPP in that the drug is not free, in other respects – most importantly the involvement of WHO – the Coartem® PPP is more like other tropical disease drug access PPPs.

Tropical disease drug access PPPs in Sri Lanka, Uganda and Zambia: major findings

- The involvement of multi-national pharmaceutical companies in tropical disease drug access PPPs has facilitated better drug availability very substantially in the three relevant study countries (Sri Lanka, Uganda and Zambia), with negligible – if any – negative side-effects.
- The widely-held conclusion at country and global levels is that these drug access PPPs have indeed assisted the poor to access necessary drugs. Data to support this remain limited and indirect, but the conclusion seems reasonable given the nature of the diseases, generally high levels of programme coverage and the fact that the drugs are provided free and in unlimited amounts to recipients.
- The major, widely-appreciated benefit of drug donation PPPs lies in the assurance of a sustained, consistent and high quality supply of effective drugs

which governments would mostly struggle to afford. The drug donation PPPs for leprosy, LF, onchocerciasis and sleeping sickness were appreciated unreservedly at country level.

- Other benefits include partner pharmaceutical companies' willingness to invest in packaging and formulations more appropriate to local health system needs, and the recognition that a driving interested party such as a drug access PPP or the drug donation itself can be a stimulus to wider partnerships and programme initiation/revitalisation at global and country levels.
- The only ***discounted price*** drug PPP for a tropical disease offers Novartis' Coartem® for malaria at cost price through WHO. Governmental commitment to the PPP is high in Zambia, since it would have difficulty in financing provision of Coartem®, an effective but expensive drug for the treatment of malaria where resistance is a major concern, in the absence of significant price discounts and support from the Global Fund to Fight AIDS, TB and Malaria (GFATM).
- A key challenge in Zambia is how to reach the estimated 50% of patients who seek malaria treatment from the private sector. Agreement in principle has been reached between the Zambian government, WHO and Novartis to launch an innovative pilot social marketing programme in partnership with the private sector. This is intended to expand access to Coartem® at a reduced price through selected private pharmacies and retail outlets.
- While estimates of the dollar value of tropical disease drug donations/discounts by pharmaceutical companies are not available, they are clearly substantial. In several cases, the PPPs or related foundations – plus wider global partnerships – have provided further finance for operations or training, as well as technical support. For example, Novartis value their planned support to Zambia's malaria capacity building programme at an estimated US$ 2.2 million over three years. In Sri Lanka, the health system has benefited from technical and financial assistance from the Novartis Foundation for Sustainable Development (NFSD) valued at about US$ 1.7 million over 15 years, excluding unquantified drug costs.
- The studies found no evidence that any of these drug access PPPs led to lack of national ownership; distortion of national or district priorities; unhelpful reallocation of human and financial resources at central, district or community levels; or unreasonable conditionalities (e.g. in relation to scope of programme, drug indications, modes of operation or reporting requirements). In the case of Coartem®, there are reasonable conditionalities for the prevention of diversion to unauthorised suppliers. There is a clearly a risk of diversion of Coartem®, and stocks in public facilities and private pharmacies will need to be monitored carefully.
- The PPPs operate transparent processes which comply with interagency guidelines. In most cases, national programme managers deal primarily with WHO and have minimal contact with the participating pharmaceutical companies. The main exceptions are the active involvement of the independent Mectizan® Donation Program (for onchocerciasis and LF) and the Novartis Foundation for Sustainable Development (for leprosy in Sri Lanka), both of which are regarded at country level as supportive and not intrusive. It is too early to assess Novartis' direct support to the Zambia malaria programme.
- Considerable health impact has already been achieved in the study countries by the mature tropical disease programmes for control of onchocerciasis and elimination of leprosy, where the target now in all relevant countries is to secure progress in eliminating small pockets of leprosy at sub-national level. For the more recent tropical disease drug donation PPP/programmes for LF and malaria, real health impact will undoubtedly be secured because of the numbers of people receiving new or better treatment through the PPPs.
- A Ugandan national plan to revitalise sleeping sickness control, using donated drugs, achieved such success in the West Nile District that, in October 2002, MSF France — who had run the programme as a project with its own staff – was able to withdraw support in that area. However, 750 new cases were reported in the district in 2003 (after the study took place). This suggests that, whatever the transitional arrangements, the districts concerned were not in a position to maintain the required level of activity in both surveillance and mopping up of early cases, and highlights the desirability of integrating

project effort with the district health system from the outset.

- In all cases, it is difficult to isolate the specific health impact of the drug access PPP alone, given problems in distinguishing the particular contribution of the drug from other factors, such as wider programme support, health system issues and social mobilisation. Nonetheless, the perception at country level is that drug donations have been crucial to results achieved in terms of coverage and reduced prevalence.
- In implementation, most PPPs are well integrated into services, with programmes following customary national systems for vector-borne diseases. In almost all cases there has been a positive impact on health systems.

  In Sri Lanka and Uganda, interviewees at all levels were adamant that the impact on health systems of tropical disease drug access PPPs, and the wider partnerships, was wholly beneficial. A particular feature has been the contribution to the development of national capacity in the areas of policy and planning, for example, in the application of evidence-based strategies, national mapping of disease prevalence, clear targeting of beneficiaries, the routine use of information for management, and a focus on time-bound outputs and health outcome. Staff at district and facility level welcome the fact that the availability of drugs and some operational funding has enabled them to undertake their functions more effectively, and increased their credibility with the communities they serve. In Sri Lanka, the Novartis Foundation for Sustainable Development has provided extensive technical and financial assistance to the Anti-Leprosy Campaign, including support for a highly successful social marketing campaign and for integration of leprosy services into the district health services.

  In Zambia, interviewees identified several health system benefits, such as strengthened prevention and diagnostic aspects of malaria control because of the high cost of Coartem®, and new health system elements like pharmacovigilance, in addition to provision of the drug itself. Novartis is to provide direct support to Zambia's malaria capacity building programme in relation to training, communications and research. Early problems with distribution of Coartem® to secondary and mission hospitals were not related to the discount programme or its conditionalities and have been resolved, with full integration into the mainstream drug distribution system and Health Management Information System. A key challenge will be to ensure a constant supply of Coartem® as the programme is scaled up.
- Diseases that can be 'eliminated' as major public health problems are good choices for health commodity-focused PPP support because of their time-limited nature, thus minimising the risk of creating a dependency relationship and unsustainable programmes.
- From the country perspective, there appears to be no evident direct commercial benefit for the pharmaceutical companies from the drug donations or any wider support provided. A supporting study at global level[1] suggests that any benefit relates to generalised corporate public relations, better relations with governments and improved staff morale.
- Beyond the tropical disease drug access PPPs, the wider global/regional partnerships and programmes for leprosy, LF, malaria, onchocerciasis and sleeping sickness have an important part to play in providing a stimulus to action at country level and expertise to support it.
- A common finding is that drug donation is necessary but not sufficient to initiate and support a full national elimination/control programme in its active phase for this kind of tropical disease. Support for operational funding is also a prerequisite.
- Similarly, continued operational support – as well as assured drug supplies – during the maintenance phase of most of these programmes is needed, if disease resurgence is to be avoided. Only Sri Lanka seems positioned to take on full responsibility for sustainable programmes in three to four years time.

Conclusions and recommendations

1. The clear finding is that tropical disease drug donation PPPs have provided very considerable benefit with negligible negative side-effects, and have been warmly welcomed by countries in the study. Given the potential health benefits of expanded efforts,

[1] Unpublished manuscript by E. Gardiner, Initiative on Public-Private Partnerships for Health, Switzerland, 2004.

some suitable group should convene or 'broker' consultation between pharmaceutical companies and public health authorities at national and international level, to explore where new programmes might be initiated or current ones expanded.

2. A commitment to continued pharmaceutical company contribution through drug donations and discounts is important to sustainability, as is the preparedness of donors to 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. Partners of all kinds should be prepared to follow the model of those companies which have pledged to contribute for as long as is needed to achieve elimination or control goals.
3. PPP/programme effort should be integrated with the district health system from the outset, a requirement highlighted by the resurgence of sleeping sickness in Uganda following withdrawal of project staff after control had been achieved.
4. The 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 at international and country level.
5. A rapid review in due course to draw on greater experience at country level of the Coartem® discounted price agreement for malaria could be of benefit, since it potentially raises significantly different issues from the tropical disease drug donation PPPs, for example in relation to cost and sustainability, risks of diversion and a pilot in social marketing through the private sector.

HIV/AIDS drug access PPPs in Botswana, Uganda and Zambia: major findings

The overall study conclusion is that pharmaceutical company involvement in enhanced access to drugs for HIV/AIDS is more complex – and problematic – than for tropical diseases. The donation and discounted programs for HIV/AIDS drugs examined in these studies are embedded in an evolving, multi-faceted global debate (related to intellectual property protection, the need to stimulate innovation for new and better products, competition among R&D-based and generic companies, and trade in general) as these issues relate to access to medicines for poor populations. In this debate the poorer countries have often not been given appropriate support to assess for themselves which strategies will maximize the advantages, including assuring public health.

Discount arrangements for high value products can contribute to a downward pressure on prices (in markets where competitor products are also available). However, while donation programmes are greatly valued by recipients, their long-term indirect effects can rule out local competition, particularly if the public sector partner perceives any obligation to use a sole source. The situation with fluconazole in Botswana provides an interesting case in point. The patent has expired, but generic versions are not registered. Therefore, while the public sector benefits from Diflucan® donations, fluconazole cannot be procured in cheaper generic form by the private sector, not even by insurance providers who are purchasing drugs and treatment services for public sector insured employees.

Issues specific to HIV/AIDS drug discounting initiatives

- PPPs to enhance access to HIV/AIDS treatment through discounts on antiretroviral medicines contributed to the expansion of programmes in two of the four study countries. Through the auspices of initiatives such as the DAI and AAI, as well as autonomous company discounting policies, the R&D pharmaceutical industry has lowered prices of medicines for treating HIV/AIDS. Some companies now publish 'cost' (of production) prices for poor countries and other discounts for middle income settings. Outlicensing initiatives have also started.
- However, discounts continue to be fragmented and uncoordinated. Different companies take different approaches to making their prices available – ranging from openly publishing 'cost' prices to depending on bilateral, confidential negotiations. There are large numbers of different ARVs, sources and formulations, and prices change regularly. Furthermore, many ARV programmes are externally financed, with yet more wide-ranging conditions on the procedure for procuring drugs.
- At national level, establishing which offers provide the maximum cost benefit is – in practice – currently not possible. In particular, where there was evidence

available – as in Uganda – it tended to suggest that the main factor stimulating sustained reduction in prices was the presence of generic versions of the medicine at low prices in the market.

- There were widely-held perceptions that benefiting from discounts precludes the use of generics. Lack of overall price transparency meant that governments were not always sure if or when they could negotiate further discounts from companies. There was also an associated low level of trust between the pharmaceutical industry and governments.
- While some discounting initiatives are available to the private sector (especially the corporate sector), the majority are limited to the public sector. The rationale for this is clearly that the initiatives wish to reach the poor, but it creates three problems. Firstly, many patients receiving ART in sub-Saharan Africa currently do so in the private sector – and excluding them while expanding the public sector is likely to add the burden of previously private patients to the existing public sector load. Secondly, the risk of leakage creates an extra burden for the public sector's drug supply and management system. Thirdly, it also distorts local pharmaceutical markets, making it difficult for the private sector to obtain ARVs at competitive prices.
- Overall, in two of the three African countries studied, the contribution of these initiatives to enhanced access to essential HIV/AIDS medicines remains modest. While individuals in sub-Saharan Africa have clearly benefited from reduced prices of branded medicines, it is too early for good information either on the public health impact of ART in general (i.e. preventing further spread of infection), or on the specific contributions of PPPs.

Issues specific to donations

- Drug donations in the HIV/AIDS field have contributed to preventing the spread of HIV (via prevention of mother-to-child transmission) and improving the quality of life of those living with AIDS. Yet, again, there is very limited evidence to quantify this impact or with which to learn lessons on how to maximise benefit and minimise harmful impact on health systems.
- Donations of ARVs for treatment are unusual but, in this study, Merck's donation of Stocrin® and offer of Crixivan® was credited with contributing to the Botswana government's decision to launch their national HIV/AIDS treatment programme. They represent substantial financial support and, in the context of Merck and the Gates Foundation's contributions to the Botswana AIDS programme through the African Comprehensive HIV/AIDS Partnership (ACHAP), also strengthened the health system.
- Pfizer's donation of Diflucan® for the treatment of opportunistic infections is making a substantial difference to the lives of people living with AIDS. Providers and patients widely welcomed this donation. Ordering and distribution are well integrated with the health systems, supported by Axios, and the additional clinical training provided by Pfizer was generally welcomed.
- While PPPs (as with any donor) can expect reasonable publicity at national level, it was striking that facility level staff tended to be unaware of the donated and discounted products. However, caution is needed. For example, the profiling of the donated product in patient information leaflets provided by the Diflucan® Partnership Programme was felt to compromise government generic drugs policy.[1] Monitoring and negotiation are needed to develop mutually acceptable approaches and materials.
- Boehringer Ingelheim's donation of Viramune® for the prevention of mother-to-child transmission has, after a slow start, now expanded in three of the four countries in this study and is reaching significant numbers of mothers and babies, albeit limited to urban locations and with questions relating to resistance. Axios proactively supports the ordering and distribution process.
- They operate in an environment where there is a substantial danger of overwhelming the limited absorptive capacity of national health systems by diverting staff, duplicating financial, monitoring and evaluation systems, and incurring ancillary costs for governments.
- Of particular concern is the impact of the drug requisition process of HIV/AIDS donation initiatives and their significant reporting requirements. These

[1] This concern was being considered by the Pfizer Clinical Advisory Team at the time of publication.

stem from the high value of the drugs involved, which necessitate accurate prediction of demand and maximum security of distribution. Of the two HIV/AIDS donation initiatives, the Viramune® Donation Programme appeared to have made efforts to make these requirements reasonable – including appointing Axios to assist governments in the process – whereas the Diflucan® Partnership Programme's requirements – particularly the condition that all facilities have to report satisfactorily for any facility to receive shipment – remained onerous.

- Finally, it is important not to overstate the contribution of these donation programmes which, to date, remain limited in scope and have distributed rather small quantities of essential medicines compared to the need in poor populations.

Overall conclusions and recommendations

1. **The fragmentation of initiatives, funding and conditionalities** is the critical issue which needs to be addressed by all involved in HIV/AIDS treatment and care. This research found that the picture from country level was extremely confused and that the impact of the multiplicity of programmes spread throughout the health system. Lack of integration is related to the novelty of HIV/AIDS treatment programmes in general, the political profile they have received, the high market value of the products involved, and the role that multinational pharmaceutical companies have played. It is reflected in lack of clarity particularly around drug procurement, requisition and distribution processes, and monitoring and evaluation systems.

   At national and international levels, flexible and responsive systems are needed to rationalise fragmented ARV procurement, based on clear evidence on costs and benefits of different supply sources as well as feasible mechanisms for estimating demand. At national level, coordinated and integrated monitoring and evaluation systems are needed which incorporate the requirements of national drug management systems, international funding agencies and multinational pharmaceutical companies.

2. **Lack of understanding of the range of options regarding access to medicines** and low capacity to compare and contrast alternatives within the range that best suit particular national needs is a key finding. The countries in this study showed:

   - no, or extremely limited, capacity to assess intellectual property and trade issues as they relate to health;
   - limited involvement of health policy makers in formulating trade policies or trade negotiations (and limited capacity to do so, as above);
   - minimal or total lack of support from international organizations on the issues where intellectual property protection and trade affect public health;
   - limited or lack of capacity to set and enforce policies regarding registration among branded and generic medicines;
   - confusion as to whether certain options (e.g., accepting branded drug discounts) precluded other options, such as registering generic products;
   - low level of trust between the pharmaceutical industry and governments;
   - limited capacity to ensure procurement pooling and procedures that would yield the best prices;
   - limited capacity to conduct assessments comparing the cost-utility of different drug options; and
   - limited information and guidance from international organizations on the prices, quality, sources and cost-utility of different drugs, diagnostics, and treatment modalities.

   Actions are needed on many fronts to strengthen the capacity in low and middle income countries to assess all options regarding access to medicines, including the role and nature of collaborations with sole source suppliers. Current activities of international agencies (WHO/AMDS, WIPO, WTO, UNCTAD, World Bank) are insufficient and the health of poor populations is being neglected. International agencies should also review the currently fragmented efforts to collaborate on validating sources and bulk procurement mechanisms to assist poorer countries. Both pharmaceutical companies and international agencies should take steps to simplify and harmonize the discounts and procedures available to some countries, including information and eligibility for the different schemes they offer and clear information on the conditionalities of dif-

ferent schemes. In Botswana, for example, there was a perception that take-up of donation and discount schemes may be linked to use of the companies' branded products only, although this was not the case.

3. **Excluding the private sector from most initiatives** lacks grounding in the reality of health service delivery in sub-Saharan Africa. For patients, having to shop around to receive drugs under different names and formulations, or at varying prices, from several sources – all while sick with AIDS – is undermining any achievable quality of care.

   Every effort should be made to find ways to enhance partnership between public and private sectors in service delivery as ART programmes scale up.

1. Introduction

This report provides a synthesis of the findings from four country studies[1] designed to assess the health and health systems impact of public-private partnerships (PPPs) for improving access to pharmaceuticals in relation to tropical diseases and/or HIV/AIDS, where pharmaceutical companies are involved as partners in supplying free or discounted drugs. It examines issues of ownership, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of these commodity-focused 'access' PPPs as distinct from other comparable programmes where drugs are competitively procured.

The country studies were undertaken in Botswana, Sri Lanka, Uganda and Zambia and examined PPPs supplying drugs for leprosy, lymphatic filariasis, malaria, onchocerciasis, sleeping sickness, and HIV/AIDS – the Drug Access Initiative (DAI), the Accelerating Access Initiative (AAI), the Diflucan® Partnership Programme and the Viramune® Donation Programme).

Each study team analysed relevant literature and data, and undertook interviews at national, district and facility level. Depending on country circumstances and the number of PPP programmes being studied, from three to eight representative districts were visited in each country.

This report also reflects findings from a review of how these PPPs operate at global level, how they relate to broader partnerships in which they participate and how they relate to the countries examined.[2]

In total, the study findings are based on interviews with more than 250 individuals in countries and approximately 40 at global level. They include: representatives of ministries of health in a wide range of posts including Directors General, disease programme managers, medical stores and distribution personnel; a variety of relevant national bodies; district officials; clinicians; public and private sector pharmacists; clients; medical supplies organisations; NGOs; academic institutions; WHO at country, regional and global levels; UNAIDS; UNICEF; development partners, including bilateral aid agencies; pharmaceutical companies, an associated independent donation program and an associated foundation.

[1] K Caines et al., *Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries: Uganda Pilot Study*, Initiative on Public-Private Partnerships for Health, Switzerland, 2003.

N Druce et al., *Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries: Botswana*, Initiative on Public-Private Partnerships for Health, Switzerland, 2004.

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[2] Unpublished manuscript by E. Gardiner, Initiative on Public-Private Partnerships for Health, Switzerland, 2004.

2. Background and approach to the studies

Background

In a vicious cycle, poverty is a major cause of health inequity in developing countries, and ill-health perpetuates poverty. Many health problems among populations disadvantaged by poverty have been neglected because of lack of commercial incentives, or have proven intractable when tackled by the public sector or NGOs independently.

In recent years, a number of public-private partnerships (PPPs) have been established to tackle particular health problems with specific products or technologies. One group of PPPs addresses access to pharmaceuticals critical to treatment or control of diseases disproportionately or uniquely affecting the poor in developing countries. This category of partnerships for drug access is usually based around the provision of products that are donated or heavily discounted (usually a 'sole source'). They entail a multi-partner effort at field level to ensure the distribution and proper use of the medications.

These drug access partnerships are in many instances the only initiatives likely to be mounted for some diseases, especially those that do not rise high on the political visibility scale (e.g. lymphatic filariasis and sleeping sickness) as compared with HIV/AIDS, tuberculosis, and malaria that have attracted global attention. They are accepted by the governments of countries to which they are offered, and by the populations reached, for the health benefits they provide. For HIV/AIDS, which by contrast enjoys high visibility, they offer one means of accessing lower priced or donated product.

However, drug access PPPs have raised a number of questions, mostly relating to their integration with, and impact upon, the broader development of health services in countries in which they operate. The key research question is the degree to which the involvement of multinational R&D pharmaceutical companies in some stage of drug supply and delivery facilitates better drug availability and access by the poor. Further questions include whether the availability of free or reduced price drugs distorts market prices or priority setting at the country level, and the feasibility and sustainability of taking such initiatives to scale.

This range of questions becomes of greater importance as the number of targeted partnerships in particular countries increases and as countries have to prioritise their use of resources within the context of Debt Relief, Sector-Wide Approaches (SWAps) in health, and multi-sectoral Poverty Reduction Strategic Papers (PRSPs). Issues of integration and coordination with these country-specific programmes as well as overall implementation and impact need to be addressed at all levels within countries – national, regional, district and community.

Studies of the impact of PPPs addressing access to pharmaceuticals in four low income countries

The UK Department for International Development (DFID) has funded the Initiative on Public-Private Partnerships for Health (IPPPH – part of the Global Forum for Health Research), in association with the Institute for Health Sector Development (IHSD), to conduct a series of studies across a range of drug access partnerships and countries. Following a pilot study in 2003 in Uganda, three further studies were undertaken in 2004 in Botswana, Sri Lanka and Zambia.

This report provides a synthesis of findings from all four studies, which are part of an ongoing IPPPH programme of activities related to the overall goal of assessing public-private collaboration to improve access to pharmaceuticals for those disadvantaged by poverty.

Objectives of the studies

OBJECTIVES OF THE STUDIES

To assess the health and health systems impact in the selected countries of public-private partnerships for improving access to pharmaceuticals in relation to tropical diseases and/or HIV/AIDS, where pharmaceutical companies are involved as partners at some stage of design and/or implementation. To examine issues of ownership, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of these access PPPs as distinct from other comparable programmes where drugs are competitively procured.

In Sri Lanka, to assess whether the country is benefiting from all PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.

Key issues for examination in all four countries have included:

- The respective roles of PPP programme partners, governments and local interests in the partnership at global and country level, including developing programme proposals, decision-making, conditionalities and governance, their motives and interests in being involved, and levels of support/funding.
- The extent of the PPP programme's integration with national disease programmes and broader health planning.
- The programme's involvement in, and the effectiveness of, any coordinating mechanisms (formal and informal) with other PPPs at all levels, and any consequences of the PPP programme studied for other PPPs (e.g. in terms of creating opportunities or barriers for other PPPs).
- Evidence available of the impact on (a) coverage and (b) health, including the impact of any inclusion in the PPP programme design of efforts specifically to reach poorer populations, women and children, and measurement of coverage by socio-economic status, rural/urban mix, gender and age.
- The impact of the PPP programme on health systems, including the outcome to-date of any specific PPP programme objective to strengthen health systems. This would include perceptions of impact on: use of staff time; staff skills; drug ordering and delivery systems; planning and monitoring systems and management information systems (MIS/HMIS); and government-NGO working relationships.
- Views on the optimal scale of the programme's operations within the country, and any plans for taking the programme to scale and for longer-term sustainability.
- Identification of the specific benefits and challenges, if any, arising from the involvement of pharmaceutical companies in disease-specific PPPs.

Approach to the studies

In line with the views of a technical consultation meeting held in January 2003 to advise on study design, these were rapid and largely qualitative country studies making extensive use of semi-structured interviews with key informants and collection and analysis of pre-existing data. Limitations on funding and time precluded primary data collection, for example, on the health impact of PPPs.

The 2004 studies in Botswana, Sri Lanka and Zambia were also informed by findings from the review at supranational level of how the specific drug donation or discount price programmes operate at global level, how they relate to broader partnerships in which they participate and how they relate to the countries examined.

The country studies mostly lasted for two weeks. They adopted a layered approach to evaluation, covering the country context and the disease control policy before assessing the individual partnership programmes. Fieldwork included interviews about each programme at national, regional (where appropriate), district and health facility levels. Interviews were supplemented by an analysis of global, national and district programme strategies, plans and reports, together with wider literature.

All study team members were independent of the Initiative on Public-Private Partnerships for Health and the pharmaceutical industry.

More detailed information on the conduct of the studies is given in Annex 2.

3. Country contexts

The four countries in this study – Botswana, Sri Lanka, Uganda and Zambia – were selected to gain some geographical and socio-economic contextual variations as well as to represent as wide a sample of public-private partnerships as possible. Uganda and Zambia are both very poor, with average incomes under US$ 350. Sri Lanka is slightly better off while Botswana is a middle income country with a per capita GDP of US$ 3,100.

HIV/AIDS notwithstanding, the three African countries all have rapidly growing populations while Sri Lanka's is more stable. Literacy is highest in Sri Lanka, and in all countries except Botswana it is higher for men than for women. Public expenditure on health care is low for all four countries, ranging from 1.5% of GDP in Uganda to 3.8% in Botswana.

Reflecting this, in all four countries, especially Sri Lanka, private health care expenditure is a significant proportion of the total. Uganda and Zambia are both highly indebted, poor countries and heavily dependent on external donors in the health sector. These do-

Table 1. Key socio-economic indices

	Botswana	Sri Lanka	Uganda	Zambia
Population (millions, 2001)	2	19	23	10
Average annual population growth rate (%)	3.0	1.1	3.5	2.8
Per capita income (US$)	3,100	850	330	320
Illiteracy rate (% ages 15 and above, 2001)	25 M 19 F	5 M 11 F	22 M 42 F	14 M 27 F
Public expenditure on health (% of GDP, 2000)	3.8	1.8	1.5	3.5
Private health expenditure (% of total health expenditure)	37	51	30	38

Source: World Bank (2003) *World Development Indicators 03*. Washington, DC: The World Bank.

Table 2. Key health indices[1]

	Botswana	Sri Lanka	Uganda	Zambia
Life expectancy (years at birth)	39 M 38 F	70 M 75 F	43 M 43 F	37 M 38 F
Infant Mortality Rate (IMR = deaths per 1,000 live births)	80	17	79	112
Maternal Mortality Ratio (MMR = deaths per 100,000 live births)	480	60	505	870
HIV prevalence (% of adults)	38.8	<0.1	5.0	21.5
Total Fertility Rate (TFR = births per woman)	3.9 (2001)	1.9 (2000)	6.9	5.2 (2001)
Contraceptive Prevalence Rate (CPR = % of women 15-49)	—	70	25	26
Access to safe water (% of households)	95	75	52	64

Source: World Bank (2003) *World Development Indicators 03*. Washington, DC: The World Bank.

[1] In order to maintain consistency in socio-economic information on each country, these figures are taken from World Bank standard statistics on countries rather than from the national reports.

nors include traditional bilateral and multilateral funds as well as new sources of funds such as the Global Fund to Fight AIDS, Tuberculosis and Malaria. Sri Lanka is less donor dependent and Botswana is a middle income country in which the government is the major funder of health services.

These socio-economic factors are reflected in the health indices. Health outcomes in Sri Lanka are very good compared to its level of development. Infant and maternal mortality rates are low, and the country has not so far been hit hard by the HIV pandemic. Birth rates have declined steeply and the majority of households now access safe water.

In the African countries in the study, the picture is much bleaker, even in relatively well-off Botswana. HIV has hit all three countries hard and, while Uganda is renowned for having turned around its HIV epidemic, Botswana and Zambia have extremely high adult prevalence. Infant and maternal mortality rates remain high – and indeed in Botswana and Zambia, infant mortality has risen recently as a result of HIV, while life expectancy has declined.

Country participation in drug access PPPs

A particular concern of the study terms of reference in relation to Sri Lanka was whether the country is being offered, or taking advantage of, partnership in all relevant PPPs by comparison with African countries. The study team concluded that it is.

Sri Lanka is already participating in the only two drug access PPPs for tropical diseases from which it would currently benefit – those for leprosy and lymphatic filariasis. Onchocerciasis, sleeping sickness and trachoma are not endemic in the country. Malaria is a major health problem, being tackled by an intensive malaria control problem using GFATM funding. However, in the absence of drug resistance problems, less expensive drugs than Coartem® remain effective at present. Careful monitoring of resistance is desirable in case of future need to access Coartem®.

There is a strong case for Sri Lanka to make an application for free anti-TB drugs from the Stop TB Partnership's Global Drug Facility (GDF).[1] The Novartis Foundation for Sustainable Development (NFSD) has made clear its intention to offer the Sri Lankan Department of Health Services a package of support for social marketing, training etc., under its drug donation agreement with WHO, if the government successfully applies to the GDF. The availability of donated drugs and the offer of wider support are both likely to be of real benefit to Sri Lanka.

Currently, funding for anti-retrovirals in an HIV/AIDS programme starting in Sri Lanka in July 2004 is being provided by a World Bank grant. There is clear opportunity for exploring the place for drug donations/discounts in the coming years.

In Zambia, the study team found some indications that the availability of support from the range of drug access PPPs may not be as widely known as is desirable. Nonetheless, consideration is being given to exploring the need for further support from such PPPs. A 2003 survey found cases of lymphatic filariasis in three of 16 districts surveyed. Further epidemiological investigation has been recommended to inform any future government decision on whether Zambia should apply for donated drugs for lymphatic filariasis. WHO has expressed interest in assisting the government to assess national prevalence of sleeping sickness, to determine whether an application for donated drugs would be appropriate.

[1] An application has subsequently been made to the GDF (August 2004).

4. The drug access PPPs

This section discusses the range and nature of the drug access PPPs studied.

Range of drug access PPPs studied

The study sought to cover as many drug access PPPs involving research and development-based pharmaceutical companies as was possible in four country field studies. In the event, all current such PPPs were examined at least once at country level, with the exception of the International Trachoma Initiative, in which none of the four study countries participates.

The PPPs studied cover drugs for leprosy, lymphatic filariasis, malaria, onchocerciasis, sleeping sickness, and HIV/AIDS (the DAI and AAI, the Diflucan® Partnership Programme and the Viramune® Donation Programme).

Further details of the PPPs, key partners and the route of drug provision are given in Annex 3.

Table 3. Drug access PPPs studied

DISEASE	Drug donation/discounted price PPPs	Related global/regional initiatives
TROPICAL DISEASE PPPs		
Leprosy	■ 1999 WHO/Novartis Agreement to donate Multi Drug Therapy (MDT) until 2005 to help eliminate leprosy; the Agreement is now to be extended to 2010.	■ Global Alliance to Eliminate Leprosy (GAEL) ■ WHO Leprosy Elimination Project
Lymphatic Filariasis	■ 1998 WHO/GSK Agreement to donate all the albendazole required for elimination of LF. ■ 1998 Merck commitment to donate all the Mectizan® required for as long as required to eliminate LF in African countries where onchocerciasis and LF co-exist.	■ Global Alliance for the Elimination of Lymphatic Filariasis (GAELF) ■ WHO Programme to Eliminate Lymphatic Filariasis (PELF)
Malaria	■ 2001–2011 WHO/Novartis Coartem® Public Purchase Agreement.	■ Roll Back Malaria Partnership ■ WHO Roll Back Malaria Programme
Onchocerciasis	■ 1987 Merck/ Mectizan® Donation Program (MDP) commitment to donate all the Mectizan® (ivermectin) required for as long as required to eliminate onchocerciasis as a public health problem.	■ African Programme for Onchocerciasis Control (APOC) ■ Onchocerciasis Elimination Program of the Americas (OEPA)
Sleeping Sickness (Human African Trypanosomiasis)	■ 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.	■ WHO Programme to Eliminate Sleeping Sickness (WPESS)

Continuing page (14) ***HIV/AIDS*** *HAART*

Table 3 continued

DISEASE	Drug donation/discounted price PPPs	Related global/regional initiatives
HIV/AIDS PPPs		
HIV/AIDS HAART	■ Since 1998, five companies (Boehringer Ingelheim, Bristol Myers Squibb, GSK, Merck, Roche) negotiate with governments for price reductions and discounted medicines to treat HIV/AIDS. Since 2000, Abbott and Gilead have also joined. ■ Since 2002 some companies have announced price reductions for poor countries or other differential price formulas. ■ Since 2002, Merck donation of Stocrin® and Crixivan® through ACHAP to Botswana	■ DAI: 1997–2001, pilot phase in Chile, Cote D'Ivoire, Uganda and Vietnam ■ AAI 2001–present, scaling up to nearly 80 countries, with 19 having signed formal agreements.
HIV/AIDS Opportunistic Infections	■ Pfizer's Diflucan Donation Program launched in 2001 to provide treatment with fluconazole for cryptococcal meningitis and oesophageal candidiasis.	—
HIV/AIDS PMTCT	■ Boehringer Ingelheim's Viramune Donation Program (2000–2005) donates nevirapine single dose monotherapy to prevent mother-to-child transmission of HIV	—

Donation and discounted price PPPs

Table 4 illustrates the nature of the PPPs studied, and whether they donate drugs or provide them at discounted prices (including at cost).

In almost all drug access PPPs for tropical diseases, pharmaceutical companies donate drugs free rather than offer discounted prices. Reasons for this bias to donation may include the fact that they generally relate to global elimination initiatives, with some presumption of a time limit for the most intensive activities. In addition, the presumption is that these PPPs should benefit the very poor.

Table 4. Donation and discounted price PPPs studied

	Local market tropical diseases	'Global' market HIV/AIDS
Discounted price PPPs	Coartem® for malaria	HIV/AIDS drugs DAI AAI
Donation PPPs	PPP drugs for: Leprosy Lymphatic filariasis Onchocerciasis Sleeping sickness	Diflucan® Partnership programme Viramune® Donation Programme Merck's donation of Stocrin and offer of Crixivan trough ACHAP in Botswana

Local or global market

In the case of onchocerciasis and lymphatic filariasis, the pharmaceutical companies concerned (Merck & Co. and GlaxoSmithKline) made an unlimited commitment from the outset to donate as much of the drugs as is needed, for as long as is needed, to achieve control or elimination. In the case of leprosy and sleeping sickness, the companies (Novartis, Aventis and Bayer AG) put a time limit on free supplies.

In addition, the donated tropical disease drugs have no market in developed countries and therefore little commercial value, (although in Sri Lanka local commercial sales of GSK's albendazole as an anti-helminthic have fallen following the free mass drug administration of the company's donated albendazole for lymphatic filariasis). Novartis does not make MDT for leprosy commercially available.

The notable exception to this pattern of drug donation rather than discounts for tropical diseases is Coartem®, a fixed-dose artemisinin combination

therapy (ACT) for uncomplicated malaria. In 2001, WHO and Novartis signed an agreement to make Coartem® available at cost through WHO for use in the public sector of malaria-endemic developing countries. Only Zambia[1] of the countries studied was purchasing Coartem® through this agreement, with support from GFATM funds.[2]

For HIV/AIDS PPPs, the product and market characteristics are different from those of tropical disease PPPs in two key ways. Firstly, the drugs involved are highly priced and of significant value to developed country markets as well as developing country markets. Most ARVs are still under patent protection in many countries (although often not in sub-Saharan Africa), although there is rising competition from generic manufacturers. Secondly, access to medicines for HIV/AIDS treatment and care has received unprecedented political profile, as a result of which pharmaceutical companies have been subjected to considerable external pressure to reduce prices.

The majority of PPPs in HIV/AIDS are drug discounting rather than donation programmes. They generally involve price negotiations and contractual relationships between companies and national governments rather than via international organisations. Of the countries studied, Uganda and Botswana had or were currently participating in formal relationships between government and pharmaceutical companies for discounted HIV/AIDS drugs. Zambia opted not to participate in drug discounting schemes until the Southern African Development Community approves it – which has yet to happen. In Sri Lanka, HIV/AIDS is a new problem with fewer than 400 known HIV-positive individuals and therefore no need for major treatment programmes.

There are two global donation programmes in the HIV/AIDS area: the Viramune® Donation Programme – which since 2000 has donated nevirapine for preventing mother-to-child HIV transmission – and the Diflucan® Partnership Programme – which since 2001 has donated fluconazole for treatment of opportunistic infections. These donated products are limited to the public sector. Three of the study's four countries – Botswana, Uganda and Zambia – were benefiting from these donation programmes. In addition, in Botswana, as part of its unique African Comprehensive HIV/AIDS Partnership (ACHAP) with the Government of Botswana and the Bill & Melinda Gates Foundation, Merck has donated the ARVs Stocrin® and Crixivan® to the Botswana government for use in its HIV/AIDS treatment program, known as MASA, since it was started in 2002.

PPPs for tropical disease drugs

While the Mectizan® Donation Programme was established for use against onchocerciasis 17 years ago, most of the tropical disease drug access PPPs studied are relatively new, dating from 1999 onwards. In several cases, it is too early to assess health impact at country level.

All five tropical disease PPPs have to be seen within the context of wider global or regional programmes, i.e., the global alliances to eliminate leprosy (GAEL) and lymphatic filariasis (GAELF); the WHO programmes to eliminate leprosy (WHO Leprosy Elimination Project), LF (PELF), and sleeping sickness (WPESS); the global Roll Back Malaria partnership and the WHO Roll Back Malaria Programme; and the African Programme for Onchocerciasis Control (APOC) and the Onchocerciasis Program of the Americas (OEPA).

These programmes help raise the profile of what have generally been 'neglected' diseases; extend the reach of the drug donation/discount agreements; and provide broader support for disease control/eradication, such as in-country programme funds, technical expertise, political support and research. Even so, these diseases mostly lack the visibility and political clout associated with HIV/AIDS. The nature of the historic

[1] Malaria is a major public health problem in Sri Lanka but the Novartis/WHO agreement on discounted prices for Coartem is not relevant at present because there is no multi-drug resistant malaria and less expensive drugs are currently effective. The Government of Botswana is aware of the Coartem® programme, but has similarly not yet identified a need for introducing the drug. The Uganda MoH is currently (July 2004) pursuing a policy change to adopt Coartem® as the first line treatment for malaria, following rapidly emerging resistance to chloroquine and sulphadoxine-pyrimethamine, the regimen in place at the time of the Uganda study. The Uganda proposal and budget submitted to the GFATM (4th round) is based on Coartem® as the drug of choice.

[2] Over the previous three years from April 2004, 20 countries – seven of them in Africa – had updated their treatment policy to include artemisinin combination therapy (ACT) as first line and second line treatment of malaria. The GFATM has become the largest financier of ACT in countries fighting malaria (Factsheet Coartem, GFATM website).

and current relationships between the individual drug access PPPs and the related global programmes varies somewhat, but tends to be close and symbiotic.

WHO plays a major role in these broader global programmes and is the primary public partner for all tropical disease drug access PPPs except in relation to onchocerciasis, where national governments deal direct with both APOC and the Mectizan® Donation Program.

Pharmaceutical companies handle their contributions to the partnerships at corporate level or through company-funded but independent bodies (e.g. the Mectizan® Donation Program and the Novartis Foundation for Sustainable Development). Pharmaceutical company field offices may occasionally be involved on a voluntary basis for relationship-building, but have no commercial link to the PPPs.

Processes for all tropical disease drug access PPPs operating in the study countries (Sri Lanka, Uganda and Zambia) were found to comply with Interagency Guidelines for Drug Donations and for price discounts of single-source pharmaceuticals:[1] see Annex 4.

The PPPs' application procedures have transparent review processes conducted by independent technical experts who recommend drug recipients to WHO or the company concerned. In the case of Mectizan®, Merck established and funds the independent Mectizan® Expert Committee to review and approve applications on behalf of the company. In the case of GSK's albendazole for LF, the partners have established Regional Programme Review Groups as application review and decision-making bodies with WHO acting as the Secretariat.

Outside PPP structures, a "Donor Coordination Group" of pharmaceutical companies was formed to address issues related to onchocerciasis, trachoma, malaria and LF drug donations and to learn from each other's programmes. Now known as the Partnership for Disease-Control Initiatives, the group aims to share experiences and to look for opportunities for collaboration that might reduce the burden programmes can sometimes impose on resource-scarce communities and governments.

PPPs for HIV/AIDS drugs

Developments in pharmaceutical company policy in relation to HIV/AIDS medicines for poor countries have been rapid and diverse. In 1997, UNAIDS initiated efforts to encourage the pharmaceutical industry to reduce prices for their antiretroviral medicines (ARVs) for treating HIV/AIDS. In 1998, a pilot programme – the DAI – was launched by UNAIDS in partnership with five (later six) pharmaceutical companies. Importantly, UNAIDS and WHO have never been involved in price negotiations themselves under this programme – its purpose was to stimulate and catalyse price negotiations between governments and the pharmaceutical industry for ARVs. It was piloted in four countries, of which only one – Uganda – has been formally and publicly evaluated. In 2000, the DAI pilot phase was followed by the AAI at UNAIDS, and the programme expanded gradually to involve a large number of countries in some form of communication – although far fewer have actually concluded agreements.

In November 2001, formal responsibility for AAI activities was transferred from UNAIDS to WHO but implementation was not actively promoted as a general strategy by WHO after the decision to implement the 3 by 5 campaign. Nevertheless, the AAI has never been formally dismantled and R&D companies are still willing to supply countries with brand name drugs at discounted prices under the AAI banner (including Botswana in this study). Discounted prices are extended to the private sector (especially the corporate sector) in some countries by some companies. Since May 2000, 80 countries have expressed interest in AAI. In 39 of these, national plans to improve access to care have been, or are being, developed. These plans have been used as a framework for dialogue with the pharmaceutical companies, and consequently, by 2002, 19 countries had concluded agreements for the supply of ARV drugs with individual companies participating in the AAI.[2] Since then, at least one other country – Botswana – has entered the AAI.

In the intervening period, several companies have launched their own initiatives, including:

[1] *Interagency Guidelines for Drug Donations*, Revised 1999 (WHO/EDM/PAR/99.4) and *Guidelines for price discounts of single-source pharmaceuticals* (WHO/EDM/PAR/2003.3): see Annex 4.

[2] UNAIDS, Accelerating Access Initiative, Widening Access to Care and Support for People Living with HIV/AIDS. Progress Report. June 2002.

- drug donations (for example, Pfizer's Diflucan® Partnership Programme or Merck's donation of Stocrin® and offer of Crixivan® through the ACHAP partnership to Botswana)
- not-for-profit pricing, sometimes publicly quoted (Abbott, Boehringer Ingelheim, Bristol Myers Squibb, GSK, Merck and Hoffman La Roche)
- discounted pricing (Merck) and
- not enforcing patents in any developing country (Hoffman La Roche).

Recently, the international community has been promoting the concept of out-licensing, with Boehringer Ingelheim and GSK negotiating agreements with Aspen PharmaCare in South Africa to manufacture ARVs and Merck Sharp & Dohme providing a licence to Thembalami Pharmaceuticals to manufacture a generic version of efavirenz for South Africa and the Southern Africa Development Community.

None of these initiatives formally involves any international public sector organisation – the public partner of the PPP is always national government. Nevertheless, some rely on other intermediaries, including Axios International – a service company providing support for procurement and distribution of branded HIV medicines in poor countries and aiming to set up a 'one-stop-shop' to facilitate rational drug management processes. This is a potentially important role since the wide variety of initiatives, each with different conditions, makes it difficult to compare prices. However, the picture is set to change yet again under WHO's 3 by 5 initiative which is launching new proposals for work with the pharmaceutical industry, especially to develop fixed dose combination therapies using branded medicines.

In the HIV/AIDS field, other than humanitarian motives, the incentives for pharmaceutical companies to participate in PPPs are to enhance their public image in relation to drug access, which has received a battering in the international media, and to test out new business models of high-volume, low price marketing of HIV/AIDS drugs, in markets where there is competition from generic producers. Major concerns remain around protecting intellectual property and markets in rich countries as these new business models emerge.

For countries, the incentives to expand ARV procurement are growing as more funds for HIV treatment become available and pressure mounts to achieve high treatment targets under WHO's 3 by 5 initiative. Nonetheless, the rationale for procuring through drug access partnerships is less clear since in the countries in this study, generally where there was a similar generic version available, even the discounted prices of branded medicines remained higher than generic prices. The picture is further confused by the wide range of funds and initiatives to support poor countries' purchasing HIV medicines and ongoing disputes over procedures to ensure adequate product quality.[1] Some of these funders may not allow procurement of generic medicines so give a clear incentive to national governments to participate in initiatives that reduce prices in other ways. Others will allow international competitive tenders for procurement and therefore will likely result in generics being purchased. Above all, the trade-offs for national programmes between price, quality, transaction and distribution costs, adherence and sustainability for different sources of HIV/AIDS medicines remain completely unknown.

PPPs in a broader global public health environment

The drug access PPPs under study here are embedded in a wider environment encompassing issues of pharmaceutical innovation, intellectual property protection, competition among innovator companies, competition between these companies as a group and 'generic' drug producers, product pricing, international trade, respective responsibilities of governments rich and poor, and commercial organizations, and even human rights.

Nevertheless, survival of R&D-based pharmaceutical companies rests overwhelmingly on profitability, which in turn rests principally on revenues from innovation, largely in affluent markets, and these on protection of intellectual property generated with company investment. Hence, actions to preserve or enhance profitability, or deter competitors, are to be expected from both R&D-based and generic companies.

The globalization of intellectual property protection under the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs) recognized the need for flexibilities to be available especially to poor nations to protect public health. Some R&D-based phar-

[1] Including but not limited to the Global Fund to Fight AIDS, Tuberculosis and Malaria, Presidential Emergency Plan for AIDS Relief, the Clinton Foundation, World Bank MAP2.

maceutical companies, and some governments of countries with major R&D-based industries, have promoted policies under which use of these flexibilities would be more restricted, although others supported the Cancun agreement that led to the resolution of the debate over Doha paragraph 6 for certain diseases. Certain governments have also promoted bilateral trade agreements that would limit use of certain options for access to medicines. These policies by major pharmaceutical companies and certain governments have been challenged by some observers as contrary to the need of poor countries for access to medicines.

As well as maintaining profitability, major pharmaceutical companies need to preserve a 'license to operate'. This comprises a policy environment that is not unduly restrictive of their actions, and a belief among shareholders and to some extent the general public (who vote for policy makers), that the company is doing business generally in an ethical fashion that serves the public interest. Expectations that companies will address humanitarian needs through corporate social responsibility appear to be increasing. Programmes that promote drug access for the poor undoubtedly help companies preserve a better 'image'; however humanitarian motivations and internal staff morale are also cited as major motivations for drug access PPPs.

Actions of the pharmaceutical industry overall regarding access to drugs for the populations in poor countries can therefore be seen as to some extent contradictory. At the global level, some companies have promoted policies that would restrict developing country capacity to utilize TRIPs flexibilities to assist access to medicines, while in some countries and for some diseases a few companies have undertaken programmes that enhance access, albeit as yet on a relatively limited scale compared to the need.

The appropriate resolution among competing interests between developing country access to medicines and pharmaceutical company profitability, and among motivations within governments (rich and poor) and companies, is beyond the scope of this analysis. This caveat should be borne in mind while considering the results presented in this report.

5. The tropical disease drug access PPPs at country level

Comparative findings on health impact

Tropical disease drug access PPPs were operating in Sri Lanka (for leprosy and LF), Uganda (for leprosy, LF, onchocerciasis and sleeping sickness) and Zambia (for leprosy and malaria) but not in Botswana.

Programme coverage and performance against targets

Table 5 (see page 20) summarises national programme coverage and performance against targets, on the basis of available information at the time of the studies.

Overall, the health impact of the tropical disease drug access PPPs as mediated by the national disease programmes has been, or is potentially, very considerable. There are some variations from programme to programme.

In all three countries, leprosy programmes are long-standing and can point to substantial achievements. National coverage with MDT[1] and elimination of leprosy at national level both antedated the 1999 WHO/Novartis agreement for the donation of MDT. With the assistance of the PPP, coverage has been maintained and the national prevalence rate of leprosy reduced. The target now for all study countries is to achieve elimination at sub-national level, against the WHO definition of the elimination of leprosy as less than one patient per 10,000 inhabitants.

Insecurity has been a key issue in delaying elimination in all three countries. In Sri Lanka in 2003, the only two districts[2] with higher rates were in the conflict-affected Eastern Province, and in Uganda the majority of districts still to achieve elimination were affected by insecurity. Problems with access and the state of the health system affected two further districts in Uganda. The remaining pockets of higher prevalence in Zambia are attributed to refugee migration from neighbouring countries in conflict.

Only Uganda of the study countries is participating in the PPPs for onchocerciasis and sleeping sickness. In both cases, total geographical coverage of the communities at risk had been achieved at the time of the study. For the onchocerciasis programme, the next challenge is to raise the percentage for annual treatment of those eligible in at risk communities from a national average of 80% in 2002 to the APOC target for 2005 of over 85%.

The current picture on sleeping sickness is less happy. A national plan to revitalise sleeping sickness control was launched in Uganda in 2001 when the Aventis drug donation was made available. The West Nile District was brought sufficiently under control that, in October 2002, MSF France – who had run the programme as a project with their own staff – were able to withdraw support to the trypanosomiasis control programme in that area. However, in 2003, 750 new cases were reported in the West Nile District, with reported high levels of resistance to melarsoprol. This figure became available after the June 2003 Uganda study in this series. It suggests that, whatever the transitional arrangements in the West Nile, the districts concerned were not in a position to maintain the required level of activity in both surveillance and mopping up of early cases, and highlights the desirability of integrating project effort with the district health system from the

[1] Sri Lanka and Zambia received free MDT before the 1999 agreement from the Novartis Foundation and WHO/Nippon Foundation respectively. Uganda and, at an earlier stage, Sri Lanka were assisted in purchasing MDT before the agreement by leprosy NGOs.

[2] In Sri Lanka in 2003, only two districts had rates above elimination level of 1.0 patient per 10,000 inhabitants: Batticaloa and Ampara districts in the conflict-affected Eastern Province, with rates of 1.1 and 1.2 respectively, down from 2002 figures of 3.0 (Batticaloa) and 2.7 (Ampara).

Table 5. Coverage and performance against targets on tropical diseases

Disease PPP	Sri Lanka (2004)	Uganda (2003)	Zambia (2004)
Leprosy PPP with Novartis-donated MDT since 1999.	■ Total national coverage with MDT achieved in 1983. ■ Elimination at the national level achieved in 1995 (five years ahead of the earlier WHO target of 2000). ■ 2003 national prevalence rate of 0.68 against a WHO elimination target of <1 per 10,000. Only two districts did not meet the target (with rates of 1.1 and 1.2/10,000). Priority campaign underway in conflict affected areas.	■ Total national coverage with MDT achieved in 1994. ■ Elimination at the national level achieved in 1994 (six years ahead of the earlier WHO target of 2000). 2002 national prevalence rate of 0.4 against WHO elimination target of <1 per 10,000. Nine districts did not meet the target.	■ Total national coverage with MDT achieved in 1991. ■ Elimination at the national level achieved in 1999. ■ 2000 national prevalence rate of 0.68 against a WHO elimination target of <1 per 10,000. Only two provinces did not meet the target (with rates of 1.3 and 3.3/10,000).
Lymphatic Filariasis PPP with GSK-donated albendazole since 1998. Merck MDP donated Mectizan® since 1998 in African countries where LF/ onchocerciasis are co-endemic.	■ Elimination at the national level achieved in 2003. ■ National 2003 microfilaria rate of 0.09%, (a reduction from 0.15% in 2002 and 0.21% in 2001) against a WHO standard for elimination of 0.1%. However, in some small areas, 2003 rate still exceeded 0.2%. Annual MDA of albendazole +DEC in all endemic areas since 2002.	■ Mapping of LF in Uganda's 50 possible endemic districts began November 2002. ■ Pilot MDA of albendazole + Mectizan® in two districts in 2002, where treatment coverage of 70% of total population was achieved, against a target of 80%. Security problems affected MDA in Lira district.	Not participating in PPP.
Malaria 2001 WHO/Novartis agreement to supply Coartem® at cost.	Not applicable.	Not participating in PPP.	■ Coartem® first used 2003. Coverage in 28 pilot districts by March 2004. Aim to scale up to all 72 districts in Zambia by end 2004, with GFATM funding.
Onchocerciasis Merck MDP donated Mectizan® since 1987.	Not applicable.	■ Target of 100% geographical coverage of endemic districts achieved in 2001 and sustained. National target of 80% treatment coverage of affected communities being met. Now aiming for APOC target of 85% by 2005.	Not applicable.
Sleeping Sickness Aventis donation from 2001–2006 of funding and drugs; Bayer donation of funding and drugs from 2002-2007; Bristol Myers Squibb donation of drug raw materials.	Not applicable.	■ Number of cases increased rapidly 1999-2003. Target of 100% geographical coverage of the 14 endemic districts achieved 2003. Govt. has set target of reducing incidence to <2 per 100,000 at parish level. NB. Post-study 2003 reports of 730 cases and resistance to melarsoprol.	Not participating in PPP.

outset. Moreover, there was a new outbreak of sleeping sickness in Eastern Uganda.

Experience in study countries of the other drug access PPPs – for lymphatic filariasis (LF) and malaria – is more recent.

In Sri Lanka, national mass drug administration (MDA) of albendazole with diethylcarbamazine (DEC) for LF was started in 2002, so to date there have been only two rounds. It is too early to demonstrate the impact of the drug donation, given the long potential life cycle of the filiaria worms. The recent marked downward trend in LF cases is encouraging but began be-

fore the use of albendazole. In 2003, elimination of LF as a public health problem was achieved at national level in Sri Lanka.[1]

In Zambia, health personnel perceived evident benefit from the Coartem® initiative for patients presenting in health facilities since they no longer risked resistance to the first line drug for treating uncomplicated malaria. The GFATM has described artemisinin combination therapy (ACT) drugs as, in some ways, "the ARVs of malaria: known to bring people back from the brink of death, making people feel better almost immediately and killing the parasite so that the patient no longer becomes a carrier of the disease, but still very expensive". ACTs have a 95% cure rate and no documented resistance to date.

The majority of the programmes examined were already operating at full scale in endemic areas, subject to security problems. The exceptions are the PPP-assisted programmes for lymphatic filariasis in Uganda, and for the supply of Coartem® for malaria in Zambia,[2] which had each been operating for less than a year at the time of the studies and were still building to scale. The Government of Zambia aims to accelerate its programme so as to provide Coartem® in all districts by the end of 2004.

The overwhelming majority of interviewees in Sri Lanka, Uganda and Zambia judge drug donations as crucial to the results achieved by the more mature elimination programmes in terms of reduced prevalence.

Measurement of coverage by socio-economic status, age and gender

There are no routine socio-economic data on tropical disease PPP programme clients in Sri Lanka, Uganda or Zambia, and evidence of the impact on equity is limited and indirect.

The widely-held view at country and global levels is that these drug access PPPs have indeed assisted the poor to access necessary drugs, given the nature of the diseases, generally high levels of programme coverage, and the fact that the drugs are provided free and in unlimited amounts to recipients.

In Uganda, the study team was told that these tropical diseases afflict the poor in particular; subsistence farmers, herdsmen or fishing communities resident in remote areas, and those in the urban fringes where the disease vectors are a part of the habitat, and where susceptibility is exacerbated by poor sanitary and environmental conditions, overcrowded housing, and poor access to social services. Since over 60% of the rural population live below the absolute poverty line, achieving high coverage with mass treatment is considered the most cost-effective approach to reaching the poor.

In Zambia, both MDT and Coartem® are provided free to patients in public health facilities, although neither leprosy nor malaria are part of the basic health package. The Coartem® programme is directed at those most vulnerable to malaria,[3] especially those living in rural communities, many of whom are poor. A key challenge is how to reach the estimated 50% of patients who seek malaria treatment from the private sector. Agreement in principle has been reached with the Zambian government, WHO and Novartis to implement a pilot social marketing programme in partnership with the private sector. This is intended to expand access to Coartem® at a reduced price through selected pharmacies and retail outlets. The programme is planned to begin in three districts in October 2004 and will scale up gradually over two years.

In Sri Lanka, the mass drug administration of albendazole and DEC for LF is targeted at the total population in the endemic areas, excluding only children under two, pregnant and lactating women, and the very sick. Grass roots level health workers maintain contact with poor people and those living in remote areas, and work from lists of householders to seek to ensure participation.

The child rate is a key indicator for ongoing leprosy transmissions and is closely monitored. In Sri Lanka, new cases among children under 15 as a percentage of total newly-detected cases for the year rose from 10.07% in 2002 to 11.48% in 2003, though the actual number of cases remained broadly the same (223 and 221 respectively). Figures from one district with 10% of Sri Lanka's total population demonstrated no sustained

[1] In 2003 Sri Lanka had a national microfilaria rate of 0.09%, (a reduction from 0.15% in 2002 and 0.21% in 2001) against a WHO standard for elimination of 0.1%.

[2] In March 2004 Coartem® was available free in public facilities in 28 out of Zambia's 72 districts.

[3] Sulphadoxine-pyrimethamine (SP) is used for prevention in pregnant women and for treating pregnant women and children under two years or below 10 kg, since Coartem® is contra-indicated in these two population groups.

marked imbalance between genders among its leprosy patients.

In summary, considerable health impact has been achieved in the study countries by the mature tropical disease programmes for control of onchocerciasis and elimination of leprosy, where the target now is to secure progress in eliminating small pockets of leprosy at sub-national level. Advances made in sleeping sickness in Uganda have unfortunately been reversed. For the more recent tropical disease drug donation PPP/programmes for LF and malaria, real health impact will undoubtedly be secured because of the numbers of people receiving new or better treatment through the PPPs. In general, this has not yet been documented since the programmes are so new.

In all cases, it is difficult to isolate the specific health impact of the drug access PPP alone, given problems in distinguishing the particular contribution of the drug from other factors, such as wider programme support, health system issues and social mobilisation.[1] Nonetheless, the perception at country level is that drug donations have been crucial to reduction in prevalence and have assisted the poor to access necessary drugs.

Comparative findings on the sustainability of health impact

Country priorities and ownership

One concern that has been expressed about drug access PPPs of this kind, especially drug donations, is whether they have the potential to distort government priorities in the selection of the programmes and the allocation of human and financial resources to implement them. The studies in Sri Lanka, Uganda and Zambia concluded that there is no evidence that the tropical disease drug access PPPs examined have caused such problems.

In Sri Lanka, the Director General of Health Services stated that, as a matter of general policy, the government would not accept a drug donation of any kind without being clear that it related to government priorities and that the government was likely to be able to sustain it. In practice the government had run anti-leprosy and anti-filariasis programmes for decades. Indeed, all three countries had had long-standing leprosy programmes attracting external charitable support.

In Uganda, evidence suggests that the national disease programmes for LF, onchocerciasis and sleeping sickness were kick-started or revitalised by the drug donations plus the broader global/regional partnerships. Nonetheless, government ownership and priorities appear strong. Irrespective of drug donations, the tropical disease programmes concerned are clear national or district priorities included in key policy documents.[2] During the mid-term review of the Health Sector Strategic Plan completed in April 2003 shortly before the Uganda study, partners in Uganda's health sector-wide approach (SWAp) called for increased attention to these elimination programmes.

In Zambia, the Coartem® programme for malaria is a high priority of the government. The Ministry of Health/Central Board of Health made the policy change from chloroquine to Coartem® as the first line drug for treating uncomplicated malaria in November 2001. Chloroquine was immediately withdrawn from all health facilities and sulphadoxine-pyrimethamine used in the interim until Coartem® became available. This national policy decision, which has been supported by WHO and the GFATM, reflected the magnitude of the malaria burden in the country, high resistance to chloroquine and emerging resistance to sulphadoxine-pyrimethamine.

The conclusion of the individual study teams is that, in all countries studied, there is an excellent fit between the objectives of the drug access PPPs operational there and both national and local priorities and plans in relation to these tropical disease programmes. In Uganda one bilateral agency partner said: "Rather than skewing government priorities, [the donation PPPs] enable government to do what it would like to do".

[1] For example, the Sri Lanka study found that the health impact on leprosy is likely to relate both to the use of donated MDT and also to a range of other activities, such as social marketing activities and the integration of leprosy services into general health services (both supported by the Novartis Foundation for Sustainable Development).

[2] At national level, the Uganda National Minimum Health Care Package specifically includes diseases targeted for elimination such as onchocerciasis and leprosy. The Health Sector Strategic Plan 2000/2001–2004/2005 (HSSP) makes clear that districts have the flexibility to add district-specific priorities such as sleeping sickness, bilharzia (schistosomiasis) and filarial hydrocele of the testes. In each district visited by the Uganda study team, the relevant programme was included in the district plan.

Governance and conditionalities

In all cases, governance of, and decision-making within, PPP-assisted national tropical disease programmes was found to rest firmly at national level, accepting the need to comply with criteria for the global partnerships.

In general, there was minimal direct interaction between governments and the pharmaceutical company partners. In all three countries, the prime interface was with WHO or, for onchocerciasis, APOC plus the Mectizan® Donation Program.

The studies identified three exceptions to this lack of pharmaceutical company involvement at country level on the tropical disease front.

The only direct company involvement is planned support from Novartis to capacity-building for the malaria programme in Zambia, following the country's recent introduction of Coartem® as first-line treatment.

The other two examples relate to organisations which are independent of, though funded by, their founding pharmaceutical company (Merck and Novartis respectively). One is the Mectizan® Donation Programme, which has taken a more active stance in visiting Uganda periodically. The other is the Novartis Foundation for Sustainable Development (NFSD) which has provided a 15-year programme of support for the Anti-Leprosy Campaign in Sri Lanka. Their continued direct liaison with study country partners may stem from the fact that MDP had already established links with Uganda before the advent of APOC (the regional partnership) and NFSD with Sri Lanka considerably before the global WHO/Novartis agreement on the donation of MDT for leprosy. In each case, the relationship is regarded by MoH programme managers as helpful and not intrusive. In Sri Lanka particularly, the NFSD is regarded by health officials and clinicians alike as an excellent partner which has helped foster innovation and improvement.

From the country perspective, there appears to be no evident direct commercial benefit for the pharmaceutical companies from the drug donations or any wider support provided. A supporting study[1] at global level suggests that any benefit relates to generalised corporate public relations, better relations with governments and improved staff morale.

Importantly, the studies found that any conditionalities specified for the tropical disease drug access programmes were reasonable. In general, conditionalities relate to issues such as scope of programme, drug indications, modes of operation and reporting of adverse reactions. In the case of Coartem®, there are also reasonable conditionalities for the prevention of diversion to unauthorised suppliers. There is a clearly a risk of diversion of Coartem®, and stocks in public facilities and private pharmacies will need to be monitored carefully.

One study issue that proved problematic is international level concern about the possible hidden operational costs associated with drug access programmes. To elucidate the issue, it would have been preferable to undertake more detailed original data gathering than was possible within the time and resource constraints of these studies. The overwhelming view of country level interviewees in Uganda, Sri Lanka and Zambia was that this is not a justified concern in relation to the tropical disease drug access PPPs operating there and that associated costs are not inflated by external requirements from pharmaceutical donors.

The nature of the reports for the tropical disease drug access PPPs themselves was not seen as unduly onerous. Reporting requirements for the wider global partnerships were regarded as detailed but manageable and acceptable. Examination of the documentation supported this view. While there was evidence in Uganda that HMIS reports tended to be supplemented by specific programme reports, MoH programme managers felt strongly that routine HMIS data were not sufficient for their own programme management purposes.

Health systems impact

Another implicit concern of the terms of reference for this study was that drug access partnerships of the kind studied might have a deleterious impact on the broader health system of participating countries. On the contrary, in Sri Lanka and Uganda, interviewees at all levels were adamant that the impact of tropical disease PPPs was wholly beneficial. In Zambia, the team were told of several health system benefits; some problems with drug ordering and distribution systems – unrelated to PPP conditionalities – have been resolved. These issues are explored in more detail below.

[1] Unpublished manuscript by E. Gardiner, Initiative on Public-Private Partnerships for Health, Switzerland, 2004.

Against the background of the findings above on national and district disease priorities, the study teams found no evidence of unhelpful reallocation of human and financial resources at central, district or community levels with the tropical disease PPPs. While there were some programme-specific staff, especially in central units, none of the districts visited needed to recruit additional staff to manage these tropical disease programmes as a result of the drug donations. Staff at district and facility level welcomed the fact that the availability of drugs and some operational funding had enabled them to undertake their functions more effectively, and in many cases increased their credibility with the communities they serve.

Strengthening health systems is explicitly an integral aim of the new generation of partnerships for health such as APOC, the Global Alliance for the Elimination of Lymphatic Filariasis and the leprosy 'Final Push' programme. All advocate for integration of programmes into the mainstream of primary care activities.

The Uganda study found evidence that tropical disease PPPs and programmes have contributed towards national capacity development in the areas of policy and planning, for example, in the application of evidence-based strategies, national mapping of disease prevalence using tools such as GIS, clear targeting of beneficiaries, the routine use of information for management, a focus on time-bound outputs and health outcomes, and a greater consciousness of the need for programme sustainability. Provision of donated MDT freed funds from the German Leprosy Relief Association previously used for drug purchase to pay for additional staff, delivery trucks, etc.

In Sri Lanka, the health system has benefited substantially from technical and financial assistance from the Novartis Foundation for Sustainable Development (NFSD). Interviewees reported that initial governmental misgivings about the involvement of a Foundation related to a major pharmaceutical company were rapidly dispelled by working with the NFSD. There is general consensus that the Foundation has provided an external stimulus to anti-leprosy activities, helped raised awareness, played an instrumental part in bringing various key groups together and winning their confidence, and contributed to a fresh and more focused consideration of leprosy control.

The NFSD's most notable achievements have been support for an innovative and extremely successful social marketing campaign, and for the challenging process of integrating leprosy services into the general health services. In addition, it has fostered the physical and economic rehabilitation of leprosy-affected people, including through training surgeons, leprosy health inspectors and physiotherapists and teaching patients to care for their own disabilities; improvements in methods of monitoring and record-keeping;[1] and the development and implementation of a plan for leprosy control in the conflict-affected North East of Sri Lanka. Successful approaches developed in the leprosy programme provide lessons for other parts of the Sri Lankan health service – particularly in terms of social marketing and of approaches to record-keeping and analysis, including software development. Lessons about stigma and compliance are particularly relevant to the Sri Lankan TB programme which is seeking to build on the leprosy experience.

NFSD is unlikely to replicate its very intensive involvement in the Sri Lankan Anti-Leprosy Campaign in more than a very few countries because of the substantial human, financial[2] and other resource costs. Nonetheless, WHO Geneva confirms that innovative approaches developed in Sri Lanka with NFSD support have been trend setting and have paved the way for solutions that have been adopted by many countries.

In the Zambia study, health professionals perceive several health system benefits from the introduction of Coartem®, including a new consciousness of the need to strengthen the prevention and diagnostic aspects of malaria control because of the high cost of the drug; and new health system elements like pharmacovigilance, which will eventually be expanded to anti-retroviral therapy for HIV/AIDS.

Novartis itself is to provide direct support[3] to Zambia's malaria capacity building programme in relation to training, communications and research. The main

[1] Improvements in methods of monitoring and record-keeping in leprosy services in Sri Lanka include the development of a computerised database, and design of new patient cards and reports.

[2] Valued at US$ 1.7 million, excluding unquantified drug costs, over 15 years.

[3] Valued at US$ 2.2 million, excluding unquantified drug costs, over 3 years.

thrust of the support will be training 300 frontline health workers from health centre level all over the country in malaria case management, diagnosis, treatment and choice of drugs. Other components include educational materials for patients and caregivers, communications activities for the general public, and some research activities.[1]

Novartis is also assisting the National Malaria Control Programme (NMCP) in improving its practices on the basis of its experience with Coartem®. Since Zambia is one of the first countries to handle Coartem® in bulk, it is serving as a model to share best practices with other countries intending to implement ACTs as first line treatment.

Some early problems with supply of Coartem® to secondary and mission hospitals were not related to the discount programme or its conditionalities. The introduction by the NMCP of a distribution mechanism that did not use normal channels, and lack of consultation between programme and drug supply staff, hampered the smooth introduction of Coartem® into the health system. Drug management and distribution are now fully integrated into the mainstream drug distribution system and Health Management Information System. A key challenge will be to ensure a constant supply of Coartem® as the programme is scaled up. Novartis is providing consultancy support to improve current practices in stock management and drug forecasting.

In relation to leprosy, all districts in Zambia visited by the study team had adequate stocks of MDT for their small numbers of patients. Some health facilities run by the Churches Health Association of Zambia (CHAZ) had reported stock outs in 2002. This was a concern since CHAZ provides health services to 30% of the overall population and to 50% of the rural population in Zambia. However, the problems appear to have been related to internal organisation and logistics, rather than to the drug access PPP, and steps have been taken to address them.

Integration with national systems

In all three countries, the PPP-supported programmes follow customary national systems for programmes relating to control of vector borne diseases.

However, that approach itself varies between countries with full integration into general health services in Sri Lanka, a bias to project mode in Uganda, and in Zambia a mostly integrated approach but with a dedicated malaria control programme at central level. The study teams concluded that the approach in each case had been determined by the Ministry of Health concerned and was not influenced by the drug access PPP.

In Sri Lanka, leprosy and LF programmes are now fully integrated with the decentralised general health services. The integration of leprosy services in 2001 posed major planning, operational and human change management challenges[2] and was substantially supported by the Novartis Foundation for Sustainable Development. It has so far been a positive experience: expertise has been developed at district level, effective networks have been created, and patients have more choice and easier access.

In Uganda, the MoH has typically operated in project mode for such programmes (e.g. in relation to financing, management, drug distribution and reporting).[3] Comparison between the drug donation PPPs and the Schistosomiasis Control Initiative, which provides funding for procurement rather than drugs, suggests few substantive differences in the rather vertical operation of the programmes. Better coordination across these tropical disease programmes and greater integration within the district health systems is desir-

[1] Research will include studying the health seeking behaviour of the public; and monitoring pregnancy registers, with the primary objective of evaluating the safety of Coartem® and sulphadoxine-pyrimethamine in pregnant women with symptomatic malaria. Their infants will be followed up to 12 months.

[2] The 2001 leprosy integration exercise entailed, amongst other things, reorienting and motivating large numbers of doctors and other staff in some 1,000 health institutions, producing a special leaflet for Ayurvedic practitioners on leprosy recognition and referral, and a formidable logistical operation to supply all health facilities with MDT and other supplies such as specially designed patient forms and registers, patient information and posters. A professional advertising campaign was used to create awareness of the availability of treatment at all health facilities as well as overcome residual stigma attached to leprosy. A special campaign was developed for the Tamil community in Sri Lanka, and a 'think leprosy' campaign targeted health care providers.

[3] The study noted debate among Ugandan MoH programme managers about whether disease elimination programmes are best served by the intensive dedicated oversight characteristic of projects, or whether sustainability demands a shift to full integration at all levels. As a matter of practicality, expert advice to the study team was that MOH consideration of distributing all donated drugs through the National Medical Stores rather than through MOH programme managers should be left until major organisational and systems changes at the stores had bedded down.

able.[1] Nonetheless, the Uganda study found no evidence to suggest that these issues were affected by the involvement of a pharmaceutical donor as compared with any other donor and noted that several of the global tropical disease programmes encourage integration.

In Zambia, the National Malaria Control Programme (NMCP) is run as a separate specialist unit at central level, to coordinate policy and implementation. However, most health system elements, including drug distribution and service delivery, are fully integrated with the district health system. Many other African countries also have separate NMCPs, and this is not a consequence of the Novartis/WHO PPP for discounted Coartem®. Both the malaria and leprosy programmes in Zambia use a slightly adapted Ministry of Health drug ordering system for all drugs obtained through WHO, as requests additionally pass through (respectively) the National Malaria Control Programme and the TB/Leprosy Control Programme.

Mobilisation of funding

Several interviewees noted the sheer value of the additional resources brought to health. While it has not proved possible to access estimates of the dollar value of tropical disease drug donations/discounts by pharmaceutical companies, they are clearly substantial.

In some cases, the partnerships have provided further finance for operations or training, as well as technical support.

There is no estimate of total resources mobilised on the back of the drug donation programmes in all three countries.

There are, however, examples of significant contribution. In Zambia, Novartis value their planned support to Zambia's malaria capacity building programme (described above) at an estimated cost of US$ 2.2 million over three years.

Two million courses of Coartem® at a total cost of US$ 3.3 million were ordered on the basis of a letter of credit from the Global Fund to Fight AIDS, TB and Malaria (GFATM), following approval in GFATM Round 1. The GFATM notes that Zambia aims to supply all its 72 districts with ACT by 2004 with further grant money from Round 1.

In Sri Lanka, donation of MDT drugs for leprosy has been supplemented by an extensive programme of wider support from the Novartis Foundation for Sustainable Development (NFSD) over 15 years. The Foundation estimates that, from 1988-2003, it provided funding support of about US$ 1.7 million, excluding unquantified drug costs. The Sri Lanka study report notes that NFSD financial support was significant but fell short of flooding the system with money which would probably have had a non-sustainable effect on the programme and a deleterious effect on other programmes.

In addition, Sri Lanka receives an annual sum of US$ 26,000 for base leprosy control costs from Emmaus (a charitable organization based in Geneva), and external financial support for its mass drug administration for LF. In 2002, the latter amounted to US$ 67,000,[2] mainly for social mobilisation activities.

Sustainability

There is a common view that, even for the mature programmes, sustainability for at least some years to come is a critical challenge if comprehensive elimination/control of these diseases at national and sub-national levels is to be secured and maintained. The lesson of history, illustrated vividly in the full Uganda study report, is the vital need for continued operational support as well as assured drug supplies during the maintenance phase of these programmes, if disease resurgence is to be avoided.

Findings on sustainability vary between programmes and countries:

- Sri Lanka is planning to take on full responsibility for sustainable leprosy and LF programmes in approximately three to four years, given support for appropriate donor exit strategies in the interim.
- In Uganda, the study team found that the onchocerciasis and leprosy programmes were making encour-

[1] "There is considerable overlap in the prevention and management of these [neglected] diseases emphasising the need for combined programmes which are integrated into existing education and health structures, particularly primary health care. There is no role or need for expensive disease-specific vertical programmes". Working Paper 1: Consequences of Neglected Diseases and Tools to Fight Them, International Workshop on Intensified Control of Neglected Diseases, Berlin 10–12 December 2003.

[2] US$ 47,096 from WHO Geneva and US$ 20,000 from the LF Support Centre at the Liverpool School of Tropical Medicine.

aging moves towards sustainability in terms of assuming financial responsibility, and greater integration with the district health systems. However, it also noted that, in the light of the financial shortfall then facing Uganda's health sector, the cumulative demands could tax central and local government, even given a clear recognition of the priority attached to the programmes.

- The Zambia study team found that national commitment to providing Coartem® for malaria was strong, but noted reported past concerns among some donors about the sustainability of the programme, because of the relatively high cost of the drug. Novartis' discounted price under the PPP is US$ 2.40 per adult treatment, (plus WHO and Medical Supplies Limited handling fees) compared with a private sector price in Zambia of US$ 12.00. However, even the discounted price is still relatively expensive compared with the superseded (because no longer effective) policy of chloroquine treatment which was very cheap at US$ 0.20 per treatment. Grants from GFATM are likely to sustain procurements for the next 3–5 years. In the longer term, sustainability will depend on inclusion of Coartem® in the national health budget and support from Zambia's traditional development partners.

  Given its success in reducing prevalence rates, the leprosy programme in Zambia is now small. The existing close collaboration between the government and NGOs should ensure the sustainability of the programme.

Key perceived benefits of tropical disease drug access PPPs studied

The tropical disease drug donation PPPs, under which drugs for leprosy, LF, onchocerciasis and sleeping sickness are provided free and in unlimited amounts, were universally and enthusiastically welcomed by study interviewees at country levels.

The sole discounted price drug access PPP, offering Coartem® for malaria at cost through WHO, is also warmly supported by the government of Zambia.

Perceived benefits of tropical disease drug access PPPs include the following:

- The key benefit of the drug donation programmes for leprosy, lymphatic filariasis, onchocerciasis and sleeping sickness is that they provide a guaranteed supply of effective, user-friendly drugs which governments of the countries concerned would mostly struggle to afford.

  Historically no other donors seem to have been able or willing to fund drugs for national coverage of these diseases other than leprosy.
- Zambia would have difficulty in financing provision of Coartem®, an effective but expensive drug for the treatment of malaria where resistance is a major concern, in the absence of significant price discounts and GFATM support. The Novartis/WHO PPP, together with GFATM support, has assisted Zambia in adopting and implementing its new policy.
- The ultimate benefit is the actual and forecast health impact of the disease programmes supported by the drug access PPPs. Health impact has been very positive in the more mature programmes. As noted above, the widely-held view in Sri Lanka, Uganda and Zambia is that the poor are benefiting in particular.
- National programme managers appreciate the assurance both of drug quality, from using branded drugs from major manufacturers, and of a regular, sustained supply in the amounts required for the term of the donation. Consistency of supply of the same drug is felt to promote patient adherence and reduce training costs.
- Interviewees appreciated the responsiveness to problems of the pharmaceutical companies participating in the PPPs.

  For example, dermatologists occasionally need additional supplies of clofazamine to treat severe *Erythema Nodosum Leprosum* (ENL) reactions in leprosy, and had been cutting up the MDT blister packs with consequent wastage of other drugs. Under an additional agreement with WHO, Novartis are now donating clofazamine alone for this purpose. The company has also invested significantly in more resilient blister packaging after difficulties with clofazamine instability because of climatic conditions.
- In general, there is a perception of increased company sensitivity to formulation and packaging.

  Novartis' introduction for leprosy of a user-friendly MDT calendar blister pack with easy to swallow capsules is widely felt to have enhanced

compliance. New packaging of six packs in one box facilitates the integration of the programme into primary health care through the use of the Accompanied MDT approach.[1] For onchocerciasis and LF, Merck has substituted 3mg for 6mg Mectizan® tablets to avoid the need to break the tablets in half for lower doses. The tablets have been repackaged in 500-tablet containers to assist mass distribution, though this can now pose difficulties for communities with smaller needs.

- A driving interested party such as a drug access PPP or the drug donation itself can be a stimulus to wider partnerships and programme initiation/revitalisation.

  One interviewee noted: "APOC would not have been created without donation of the drugs" under the Mectizan® Donation Programme. In Uganda it was argued that, without the Mectizan® Donation Programme and APOC, there would have been no Ugandan National Onchocerciasis Control Programme. Similarly, GSK's donation of albendazole is reported to have catalysed the creation of the Global Alliance for the Elimination of Lymphatic Filariasis (GAELF), which in turn stimulated DFID and the Bill & Melinda Gates Foundation to provide operational monies for lymphatic filariasis elimination.

Key outstanding challenges

Some challenges remained at the time of the studies:

- Formally two of the tropical disease drug donation programmes had time limitations at the time of the studies: for leprosy MDT until 2005 (the global programme target date for validation of the elimination of leprosy) and for sleeping sickness drugs until 2006/2007. This was a matter of some concern in ministries of health. A continued supply of donated or discounted drugs for all programmes was seen as vital to the sustainability of the programme.

  However, Novartis has subsequently indicated that their donation of MDT for leprosy will be extended from 2005 to 2010, and Aventis is currently identifying generic companies with whom they can work and transfer technology for producing the drugs post 2006/2007. There are no patent issues because the sleeping sickness drugs concerned are off-patent or the patent is owned by WHO.
- There are well-recognised problems in scaling up to full coverage.

  Most of the tropical disease programmes examined have successfully handled this transition.

  However, Zambia still faces a very substantial logistical challenge in scaling up provision of Coartem® from 28 pilot districts in March 2004 to all 72 districts in the country. The original plan target was for full coverage by 2006 but the National Malaria Control Centre have suggested that they will accelerate going to scale by the end of 2004. The GFATM understands that Zambia aims to supply all districts with ACT by 2004 with further grant money from its Round 1. In the longer term, sustainability will require the government to include Coartem® in the national health budget.
- Operational costs are not always sufficiently funded, though interviewees do not see this as the responsibility of the pharmaceutical companies.

  For example, in Uganda lack of funding may prove a constraint in particular to the planned rapid roll-out of the national programme to eliminate lymphatic filariasis.[2] Equally, the five-year time limit for APOC (non-drug) support may raise a sustainability issue for the onchocerciasis programme in Uganda, both nationally and in districts.
- There are also particular challenges which relate not to the drug access PPPs themselves but to successful elimination programmes generally as they reach the endgame.

  One challenge of success is how to keep the disease – for example, leprosy – at the forefront of public and staff attention when the number of cases falls to very low levels. Another is a motivational challenge related to staff, as the commitment and coordination needed to secure sub-national elimination in the most intractable areas is confronted by the reality that at least some of the individuals concerned may be working themselves out of a job.

[1] The Accompanied MDT approach has not been adopted in Sri Lanka.

[2] Sri Lanka receives some financial support for its LF mass drug administration and social mobilisation from WHO and from the Liverpool Lymphatic Filariasis Support Centre.

- The multiplicity of tropical disease drug donation PPP programmes in Uganda raised the issue of coordination and collaboration across programmes, given considerable overlap in prevention and management of some diseases.

  Action on this front was very much in its infancy. At the time of the study, integrated community directed treatment (CDT) for onchocerciasis, schistosomiasis and intestinal helminths was being planned in six districts. Discussions were underway between the National Onchocerciasis Control Programme, the Programme to Eliminate Lymphatic Filariasis and the Schistosomiasis Control Initiative on how best to integrate activities such as training, supervision, advocacy, registration and drug distribution. In both Uganda and Zambia, leprosy is integrated with the TB control programme.

6. The HIV/AIDS drug access PPPs at country level

Since the late 1990s, programmes to deliver ARVs in poor countries have expanded steadily globally. As of June 2004, 440,000 people living with AIDS in developing and transitional countries are receiving ART.[1] National public health systems' capacity to deliver effective ART have also been strengthened, within the framework of global initiatives, and many mission and other not-for-profit agencies are providing services in partnership with the public sector. The availability of ART in private for-profit health services in poor countries has also grown.

Alongside this expansion in treatment access, the price of essential HIV/AIDS medicines has fallen substantially – and in June 2004, the average price per person per year for first line ART was estimated to be US$ 484.[2] In addition, the number and range of initiatives to reduce brand name drug prices have grown. R&D-based pharmaceutical companies which manufacture ARVs have shifted policy and most now supply discounted product to at least some countries. There are also two donation programmes for HIV/AIDS related medicines.

Comparative findings regarding health impact

The health impact of HIV/AIDS PPPs is strongly related to the end price of the product. Where drugs are donated – and are free to the end user – they can potentially reach large numbers of people even in the poorest countries but as price rises, demand falls. In Uganda and Zambia, at the time of the study, patients on ART were required to pay full or partial costs respectively of drugs and associated tests, and the vast majority of discounted branded ARVs remained out of reach to the poor.[3] As a result, the earlier discounting initiatives benefited mainly relatively wealthy populations in these countries: typically, they met the needs of either those who already contributed towards their health care costs, and could now afford to pay for longer or for more expensive tests and treatment, or those who previously could not afford full costs of treatment – but now could. In Botswana, by contrast, where ARVs were fully subsidised by the public sector and free to the end user, they were more likely to be accessible to the poor – although there were suggestions that other problems inhibited the access of some.

To the extent that the DAI and AAI helped to catalyse price reductions among R&D pharmaceutical companies and facilitate countries' price negotiations with them, it has contributed to expanding ARV treatment programmes and had a health impact. In its absence, it may have taken longer to establish that ART delivery is possible in resource poor settings and to generate the political and financial resources needed to make it happen on a national scale. Nonetheless, it is also important not to overstate the contribution of the DAI and AAI, in the context of generic price competition, large global funding increases and intense advocacy by other organisations. Overall, therefore, the study found that the contribution of discounting or donation initiatives to the widespread availability of essential HIV/AIDS medicines in two of the three African countries in this study remained limited in relation to the total number of people in need of treatment.

Information on the impact of these initiatives on equity and the extent to which they reach the poor is generally scarce or not available. Viramune® is being

[1] WHO (2004) *3 by 5 Progress Report: December 2003 through June 2004.* Geneva: World Health Organization.

[2] WHO (2004) *3 by 5 Progress Report: December 2003 through June 2004.* Geneva: World Health Organization.

[3] During mid 2004, after fieldwork was completed, both Uganda and Zambia announced that ARVs would in future be provided free to all within the public sector.

Table 6. Initiation and coverage of HIV/AIDS drug access partnerships

Programme and Goal	Botswana (2004)	Uganda (2003)	Zambia (2004)
Boehringer Ingelheim's Viramune® Donation Programme To improve access to nevirapine free of charge for the prevention of mother-to-child transmission of HIV-1 in developing countries.	■ Initiated in 2003 for five years to 2007. ■ Available in 32 hospitals. ■ In 2003, 36% of pregnant HIV-positive women access the programme.	■ Initiated 2001. ■ Slow to scale up. ■ 2003 – 22/56 districts. ■ Numbers or impact data not available.	■ Pilot sites since 2001. ■ Initiated formally in 2003. ■ 2004 – 11 districts. ■ May-October 2003 – 1,968 adult and 1,434 baby doses given.
Pfizer's Diflucan® Partnership Programme To make fluconazole available, free of charge, for public sector AIDS patients with cryptococcal meningitis or oesophageal candidiasis.	■ Initiated in 2002 in 32 government or government-supported facilities. ■ Too early to measure impact.	■ Initiated 2002. ■ Training in five sites in Kampala, 10 regional and five TASO sites. ■ Too early to measure impact.	■ Initiated 2003. ■ Training in 10 MOH and 11 Mission sites. ■ Too early to measure impact.
Anti-retroviral therapy discounting initiatives DAI and AAI: Abbott, Bristol Myers Squibb, Boehringer Ingelheim, Gilead Sciences, GlaxoSmithKline, Hoffman La Roche, Merck & Co, in partnership with UNAIDS, WHO. To make HIV/AIDS drugs more affordable and accessible in developing countries and to improve technical collaboration and to develop national capacity to deliver care, treatment and support. Other pharmaceutical company discounting initiatives have various independent but related goals.	■ In 2001, negotiations with five companies involved in AAI. ■ Supplied through public sector programme. ■ Supplied in line with public sector ARV programme coverage to public facilities and government supported facilities.	■ Pilot DAI 1998–2000. ■ Coverage increased from <400 to >1,700. ■ Continuation phase since 2001. ■ May 2003 – 10,000 people on treatment. ■ All in private sector – equity issues.	■ No branded ARV discounting initiatives active. ■ Generic ARVs procured through international competitive tendering and available in the public sector.
Merck & Co.'s donation of Stocrin® and Crixivan® through ACHAP To provide drugs as a component of ARV treatment programme in addition to technical and financial contributions to support effective use of ARVs.	■ Initiated 2002 following decision on national treatment protocol. ■ Supplied in line with public sector programme scale up. ■ Approx 55% of patients on ARVs were using Stocrin® as part of first line therapy.	—	—

made available through the public sector at ante-natal care (ANC) sites and should in theory reach all women who attend – which in all these countries is a high proportion. However, expanding effective prevention of mother-to-child transmission programmes depends on a wide range of complex and sensitive services – including identifying and testing pregnant women and ensuring safe infant feeding options, both of which have proved challenging in resource-poor environments. Thus, in Uganda, the scale up was slow outside major urban centres and in Zambia the programme had not yet expanded beyond pilot sites run by NGOs – again mainly urban. These were reaching small numbers of women at particular sites but did not represent a coordinated effort to reach the poorest women. In Botswana, the PMTCT programme was offering free Viramune® throughout the public sector but this was not extended to the (large) private sector.

The Diflucan® Partnership Programme is also limited to the public sector, although there is increasing acknowledgement that, given the large role of the private sector in treating people living with HIV/AIDS, this may be too restrictive. The drug is free to all and well received by most providers but, as for Viramune®, there are no data on who is receiving it and whether it is truly reaching the poor through this system. In particular, it is currently only being provided at sites which have the capacity to diagnose oesophageal candidiasis and cryptococcal meningitis. In Botswana, this includes primary hospitals but in Uganda and Zambia it means only tertiary hospitals in provincial capitals that have a limited catchment population.

The ARV programme in Botswana is aiming to give all eligible people free access to treatment. By contrast, Uganda and Zambia will have great difficulty meeting demand due to financial and health system constraints. Neither has agreed formal mechanisms for rationing who should get access to ART and, at the time of the study, both were charging patients for some or all of their treatment costs. As the countries scale up their efforts rapidly under international targets (30,000 people in Uganda and 100,000 in Zambia by 2005) access to treatment will grow, but there are serious equity concerns around the coverage of treatment centres – to date mostly in tertiary hospitals – and the introduction of co-payments by patients for either the drugs (Uganda) or the associated CD4 and toxicity tests (Zambia). To the extent that these programmes are supported by PPPs in the future, they should be a focus of concern around equitable allocation of resources. Importantly, it is evident that equity considerations within the targeted countries have not been factored into the plans of the R&D pharmaceutical industry.

The broader public health impact of ARV access remains an open question, since little is currently known about the impact of ARVs on transmission dynamics. Having said this, while the impact of PPPs in this area on the future course of the disease is potentially significant, in reality those PPPs that promote ARVs for treatment are currently of very limited scale in most countries. The impact of the availability of Viramune® for PMTCT will be constrained by intensifying pressure to provide triple therapy to pregnant women rather than single dose monotherapy, in order to avoid complications from maternal resistance to nevirapine.

The Diflucan® Partnership Programme, by contrast, has the potential to contribute significantly to the duration and quality of life of those living with HIV/AIDS, and should be supported in order to expand access through activities at lower health system levels. However, there is no evidence that treating cryptococcal meningitis or oesophageal candidiasis themselves will interrupt HIV transmission and therefore its impact on the wider course of the disease is likely to be small.

Comparative findings regarding the sustainability of health impact

Ownership / Integration / Coordination

HIV/AIDS is the foremost development problem facing all the African countries in the study, and efforts to mitigate its impact are of the highest priority. HIV/AIDS initiatives now benefit from considerable national political support and are mainstreamed throughout economic and health sector plans. HIV/AIDS also receives substantial external resources from traditional bilateral and multilateral donors as well as new sources such as the Global Fund for AIDS, Tuberculosis and Malaria, the US Presidential Emergency Plan for AIDS Relief (PEPFAR) or the Gates-Merck & Co.'s ACHAP in Botswana. During the past five years, this support has shifted focus from emphasising prevention of HIV transmission to caring for and treating those living with HIV and AIDS. PPPs to enhance access to medicines are therefore addressing an issue that is of high priority to both governments and international donors.

Nonetheless, tremendous challenges remain for programmes to integrate their activities both with each other and with government ministries of health and National AIDS Council plans. Where a country, like Uganda, has introduced strong health sector donor coordination and sector-wide planning (SWAp), traditional donors mainly try to fit in with the process. In the HIV/AIDS field, the picture is much more complicated – partly because older HIV/AIDS donors, such as USAID, have always opted not to participate in donor coordination mechanisms and partly because newer donors, PPPs among them, tend to set themselves up outside them. As a result, in Uganda a special Global Fund project management unit has been set up in the MOH, while the PEPFAR initiative is coordinated in the Office of the President, with neither so far being directly linked to the health SWAp structures.

In Zambia, government coordination mechanisms in both the Ministry of Health and the National AIDS Council are weaker than in Uganda. Here HIV/AIDS PPPs are entering an even more complex environment, where there is poor central control over new initiatives and weak communication between centre and periphery around potential sources of support for expanding access.

In Botswana, ACHAP provides perhaps the only example of a PPP which has attempted to integrate

Table 7. Ownership and partners of HIV/AIDS drug access partnerships

	Botswana (2004)	Uganda (2003)	Zambia (2004)
Boehringer Ingelheim's Viramune® Donation Programme	MOH/CMS NACA Boehringer Ingelheim Axios	MOH/NACP UNICEF Boehringer Ingelheim Abbott Axios	CBOH National AIDS Council USAID UNICEF International NGOs Axios
Pfizer's Diflucan® Partnership Programme	MOH/CMS NACA Pfizer Axios	MOH/NACP Pfizer Axios	CBOH CHAZ Pfizer Axios
Anti-retroviral therapy discounting initiatives	AAI MOH/CMS NACA Participating companies	DAI MOH/NACP Joint Clinical Research Centre UNAIDS Geneva Medical Access Unlimited Participating companies	—
Merck donation of Stocrin® and Crixivan® through ACHAP	MOH MOF NACA M Local Government ACHAP Merck	—	—

N.B. A list of abbreviations used is given at the beginning of this report.

itself fully with government planning, policy and implementation processes. Initiated in 2000, and incorporating a donation of Stocrin®/efavirenz (and Crixivan®/indinavir sulfate) from Merck, ACHAP provides an innovative model. Once government has made a decision to take forward a proposal, and it has been approved by ACHAP, access to ACHAP's financial and technical resources can enable programme start up and implementation in a much shorter time period than would be possible under normal procedures. Its results-based approach, and streamlined operating procedures have made it a useful mechanism through which government is able to implement initiatives quickly. Furthermore, the government is firmly committed to taking over responsibility for these functions when the partnership expires. While the model was criticised for bypassing some procurement procedures, it also enabled swift deployment of resources to respond to a national emergency that was prioritised by the president.

Among the other HIV/AIDS PPPs examined in this study, none particularly stands out as having made significant effort to integrate with existing planning and coordination mechanisms. Most were established in the period prior to large scale up of HIV/AIDS treatment programmes. At least one company – Boehringer Ingelheim – has expressed surprise at the initial lack of interest in its offer of free Viramune® and subsequently contracted Axios to support governments with the programme's application and reporting requirements. Pfizer has also requested Axios to assist in the distribution of Diflucan® and undertakes its own training activities.

For ARVs, the UNAIDS/pharmaceutical company DAI had played a role in catalysing ARV access in Uganda and the AAI banner was being used by companies in their discounting initiatives in Botswana. However, despite the long history of calls to introduce a more coherent framework for discounts and donations at international level, the wide range, large number and constant turnover of other pharmaceutical industry discounted price, donation and out-licensing global initiatives is highly complex to follow at national level. In this context, an international competitive tendering approach may fit better with national priorities for the most efficient means of purchasing

large volumes of drugs, assuming the legal framework and source of funds allow it.

None of the countries had gone through any formal process of declaring HIV/AIDS a national emergency in order to access generic versions of patented drugs via compulsory licensing, and there was very little evidence that domestic policy makers were thinking about whether their national legislation had been adapted to enable them to invoke this flexibility within TRIPS. On the other hand, neither were there any examples of attempts by the pharmaceutical industry to protect their intellectual property in the face of increasing generic product market domination.

In sum, given the rapidly-changing global policy environment around HIV treatment options, both national governments and the pharmaceutical industry might rightly claim to have experienced great difficulty with either retaining ownership or coordinating and integrating their efforts to enhance access to drugs. While most HIV/AIDS related PPPs profess the desire to integrate more with existing systems, two factors prevent it: firstly, there is currently not very much to integrate with – *most HIV/AIDS treatment programmes are in their infancy*; and secondly, the picture at national level constantly changes as new resources become available, making it near impossible to decide *what to integrate with* as programmes expand. Having said this, the study obtained no evidence that the phar-

Table 8. Health systems impact of HIV/AIDS drug access partnerships

	Botswana (2004)	Uganda (2003)	Zambia (2004)
Boehringer Ingelheim's Viramune® Donation Programme	■ Implementation scaling up through government hospitals and ANC clinics. ■ Drugs ordered from Axios and distributed through national supply system. ■ Treated as schedule 1 drug with separate dispensing register to distinguish from NVP for treatment.	■ Implementation phased according to HIV problem. ■ Training by NACP. ■ Drug distribution outside government system by Surgipharm, Medical Access Unlimited, Joint Medical Stores, NACP. ■ Separate MIS to meet international donor requirements.	■ Implementation phased from pilot sites to district distribution. ■ Training at pilot sites. ■ Drug distribution by CBOH and direct to some projects. ■ Separate MIS with Axios assistance.
Pfizer's Diflucan® Partnership Programme	■ Implementation throughout public sector hospitals. ■ Drugs ordered by CMS from Axios and fully integrated with national system. ■ Treated as schedule 1 drug with monthly named patient information from facilities to Pfizer.	■ Plans to expand to all district/ NGO hospitals/ health centres. ■ Pfizer/government training and materials. ■ Drug supplies fully integrated. ■ Treated as schedule 1 drug with monthly patient information from facilities to Pfizer via Axios.	■ Plans to expand along side ART. ■ Pfizer/government training and materials. ■ Drug supply through CBOH and CHAZ. ■ Treated as schedule 1 drug with monthly patient information from facilities to Pfizer via CBOH/ CHAZ and Axios.
Anti-retroviral therapy discounting initiatives	■ Implementation according to national scale-up plans. ■ Drugs procured by CMS from companies, usually via South African offices and distributed through national supply system.	■ Accreditation of sites according to clinical, laboratory and pharmaceutical management capacity. ■ Drugs procured by Medical Access Unlimited and distributed by Joint Medical Stores. ■ Separate MIS.	Not used.
Merck donation of Stocrin® and Crixivan® through ACHAP	■ Implementation within national ARV programme. ■ CMS forecasts needs based on monthly facility reports and orders from ACHAP/Merck. ■ Treated as schedule 1 drugs and distributed within national supply system.	Not available.	Not available.

maceutical industry initiatives were any worse than others among the expanding multitude of external programmes for HIV/AIDS.

Health systems impact

Managing new and highly complex HIV/AIDS treatment and care programmes provides challenges for all the national health systems in this study. Acknowledging this, most of the initiatives studied claimed to be helping to strengthen health systems and one, ACHAP, had this as a core objective. The areas of the health system most likely to be affected by HIV/AIDS treatment programmes are human resources, drug procurement and distribution systems, health management information systems, and relations with the private for-profit and not-for-profit sectors.

Throughout the health sector, there is a huge shortage of skilled staff for delivering HIV/AIDS treatment and care. Problems with training, retention, motivation and remuneration inhibit effective workforce management. Furthermore, the rapid expansion of HIV/AIDS treatment and care is likely to hinder effective implementation of a wide range of other health services. To some extent, the HIV/AIDS PPPs studies were attempting to overcome these constraints. Pfizer had assisted all study countries with training programmes for clinical and pharmacy staff in the use of Diflucan®.

The DAI in Uganda was credited with expanding clinical training in ARV use. ACHAP in Botswana has helped the ARV programme to streamline recruitment and capital development processes. However, because these activities take place outside normal working routines and training programmes are not synchronised between initiatives, they can also contribute to the overall problem. However, this problem is typical of all projects and there was no indication that the situation was worse because these were driven by pharmaceutical companies.

While drug management systems, like human resource management, are also weak in these countries, the feedback on the contribution of HIV/AIDS PPPs was less positive. On the one hand, the impact was often limited since at the time of the study, the programmes were all small scale. On the other hand, transaction and opportunity costs for national drug procurement and distribution systems meant that wholly separate arrangements were usually put in place for ARVs. For example, in Uganda under the DAI, ARVs were procured entirely outside the Ministry of Health by the Joint Clinical Research Centre, and were distributed directly to the private wards of participating facilities. Donated Viramune® was handled by the programme manager in the Ministry of Health. Only Pfizer had opted to use the district-based drug distribution system, and this was creating serious challenges due to onerous reporting requirements and reported leakages.

The Zambian situation was similar with Viramune® being handled through a national programme manager, outside the normal system. With Diflucan®, the programme was in its very early stages but was attempting to shift to the Central Board of Health's normal procurement and distribution system. In Botswana, by contrast, drugs are all procured and distributed through Ministry of Health systems into which donated or discounted products are fed. Few confirmed cases of leakage were reported in any of the countries although it remains a major concern to drug discounting and donation programmes, especially where the product is differentially priced in the private sector.

All study countries had fairly minimal health management information systems which could not pick up sufficient information for programme needs. All the HIV/AIDS PPPs had therefore established separate mechanisms for gathering the information they required, usually as part of the drug need projection and requisition process. In a few cases, such as Diflucan® in Uganda, the information requirements were reported to be onerous. In most, however, they were not thought to be unreasonable.

Relations between public and private sectors in the HIV/AIDS area are currently fraught with difficulty, not least in the area of access to medicines. Prices of critical products can vary hugely between sectors, depending on where the drugs are purchased, whether they are branded or generic versions, whether they have benefited from any form of initiative, and what kind of mark-up the provider adds. Both Diflucan® and Viramune® specify that their programmes are limited to the public sector. Under the DAI in Uganda, drugs were available only in the private sector – and patients were paying for them. By contrast, under the AAI in Botswana, discounted drugs were available only in the public sector (and government-supported mine facili-

ties) – and even publicly financed medical insurance schemes were excluded. Pharmaceutical companies generally include NGOs in their definition of the public sector; the mission sector delivers substantial services in Uganda and Zambia and is included in all three African countries. While the study was in progress, ways of making access to HIV/AIDS medicines across public and private sectors more coherent were under discussion in all three countries. This is a priority since currently from the patient's perspective, who gets access to what, at what price, remains something of a lottery.

The constraints imposed by the health system context on the further implementation and scaling up of these initiatives are substantial. Given current and projected funding trends, it is unlikely that a PPP approach will contribute greatly to enhancing access to ARVs. Some global pharmaceutical companies have moved on and started outlicensing their products to local manufacturers – although the impact of this approach on price needs to be carefully monitored. Viramune® for preventing mother-to-child transmission is already losing favour to more sophisticated triple therapy, as evidence suggests that single dose monotherapy leads to the rapid development of resistance, particularly with nevirapine. Fluconazole (Diflucan®), on the other hand, while not the preferred treatment for acute cryptococcal meningitis,[1] is recommended for the lifelong maintenance phase and for treatment of oesophageal candidiasis. Donated product saves the cost of generic purchasing and efforts to scale this initiative up and to reach lower level service delivery points are critical.

Market impact

This study would have liked to examine data on the comparative impact of different types of HIV/AIDS drug donations and discounts on local markets for these medicines. Unfortunately, information of this nature was almost entirely absent – a problem which has important implications for national decision makers. Some limited information on price trends over time as new initiatives emerged was available in Uganda, demonstrating key price reductions both as a result of discounts negotiated under the DAI and after generic products became available (Table 9).

Table 9. Number of patients on ARVs and costs in Uganda (1996–2001)

Year	Number of patients accessing ARVs in accredited centres	Average cost of HAART (US$ per month)
1996	100	942
1998	400	800
1999	700	550
2000	1400	400
April 2001	1693	110

Source: Review of the DAI in Uganda, UNAIDS/MOH/WHO; 2001.
N.B. Between October and November 2000 (respectively before and after the introduction of generics into the market), prices of various branded drugs fell by 24–84%, with more than half falling by over 50%.

Discount agreements can contribute to a downward pressure on prices (in markets where competitor products are also available). However, while donation programmes are greatly valued by recipients, their long-term indirect effects can rule out local competition, particularly if the public sector partner perceives any obligation to use a sole source. The situation with fluconazole in Botswana provides an interesting case in point. The patent has expired, but no applications for generic registration have been made. Therefore, while the public sector benefits from Diflucan® donations, fluconazole cannot be procured in cheaper generic form by the private sector, not even by insurance providers who are purchasing drugs and treatment services for public sector employees.

Absolutely critical questions remain over the impact of HIV/AIDS PPPs on drug prices to service providers and end users. For ARVs, it is essential that further careful research is undertaken into the relative merits and challenges of different models of drug regulation, procurement and distribution, including their impact on equity of access in public and private sectors.

Comparative findings regarding governance

The findings from this study suggest that HIV/AIDS PPPs are generally catalysed by external partners, and that their priorities are reflected in the design, objec-

[1] WHO currently recommends amphotericin B.

tives and management of national programmes. In general, for HIV/AIDS, these priorities overlap with those of national governments. However, except in Botswana, there was little evidence of national ownership – for example, generally some form of non-government additional support for training, drug management or reporting was required to get the programmes moving. In Uganda and Zambia, there was little to suggest that national governments are in a position to play a leadership role in coordinating drug procurement and distribution, or to judge the most efficient means to ensure maximum effectiveness of such systems, or regulate others to do so. In Botswana, the government did procure branded drugs effectively, but it had not been able to assess carefully the extent to which these drugs represented value for money.

These issues raise questions over the sustainability of discounted branded product initiatives for enhancing access, particularly in the context of expanded resource availability through multiple sources, each with a different set of conditionalities around procurement, and the increasing availability of cheaper generic sources of product. They should also give cause for further reflection on the rationale for public sector engagement with such initiatives, given their lack of evidence for sustained impact on access to medicines among the poor.

Key perceived benefits and challenges of HIV/AIDS PPPs

In sum, drug donations and discounting initiatives were generally welcomed as providing expanded (if still limited) access to otherwise unaffordable medicines – and in the process contributing additional resources to starved systems. Some PPPs are making huge efforts to strengthen weak health systems by transferring essential clinical skills and guidelines, and improving drug management.

Issues specific to HIV/AIDS drug discounting initiatives

- PPPs to enhance access to HIV/AIDS treatment through discounts on antiretroviral medicines contributed to the expansion of programmes in two of the four study countries. Through the auspices of initiatives such as the DAI and AAI, as well as autonomous company discounting policies, the R&D pharmaceutical industry has lowered prices of medicines for treating HIV/AIDS. Some companies now publish 'cost' (of production) prices for poor countries and other discounts for middle income settings. Outlicensing initiatives have also started.
- However, discounts continue to be fragmented and uncoordinated. Different companies take different approaches to making their prices available – ranging from openly publishing 'cost' prices to depending on bilateral, confidential negotiations. There are large numbers of different ARVs, sources and formulations, and prices change regularly. Furthermore, many ARV programmes are externally financed, with yet more wide-ranging conditions on the procedure for procuring drugs.
- At national level, establishing which offers provide the maximum cost benefit is – in practice – currently not possible. In particular, where there was evidence available – as in Uganda – it tended to suggest that the main factor stimulating sustained reduction in prices was the presence of generic versions of the medicine at low prices in the market.
- While some discounting initiatives are available to the private sector, the majority of these PPPs limit their activities to the public sector. The rationale for this is clearly that the initiatives wish to reach the poor, but it creates two problems. Firstly, much of the ART in sub-Saharan Africa currently takes place in the private sector – and excluding this while expanding the public sector is likely simply to add the burden of previously private patients to the existing public sector load. Secondly, it distorts local pharmaceutical markets, making it difficult for the private sector to obtain ARVs at competitive prices.
- Overall, the contribution of these initiatives to enhanced access to essential HIV/AIDS medicines remains modest. The big risks for HIV/AIDS programmes are the extent to which drug discounts (and donations) continue to be available in the medium term, how they influence the market conditions and therefore incentives for generic companies to provide supply at even lower prices, and the sustainability of external funds to procure ARVs.

Issues specific to donations

- Drug donations in the HIV/AIDS field have contributed to preventing the spread of HIV (via prevention of mother-to-child transmission) and

improving the quality of life of those living with AIDS. Yet, again, there is very limited evidence to quantify this impact or provide lessons on how to maximise benefit and minimise harmful impact on health systems.

- Donations of ARVs for treatment are unusual but, in this study, Merck's donation of Stocrin® and offer of Crixivan® were credited with contributing to the Botswana government's decision to launch their national HIV/AIDS treatment programme. This donation also represents substantial financial support – although precise figures are not available.
- Merck and the Gates Foundation's contributions to the Botswana AIDS programme through ACHAP were also widely credited with strengthening the health system, especially in the critical areas of capital expenditure and human resources.
- Pfizer's donation of Diflucan® for the treatment of opportunistic infections is making a substantial difference to the lives of people living with AIDS. Providers and patients widely welcomed this donation. Ordering and distribution are well integrated with the health systems, supported by Axios, and the additional clinical training provided by Pfizer was generally welcomed.
- While PPPs (as with any donor) can expect reasonable publicity at national level, it was striking that facility level staff tended to be unaware of the donated and discounted products. However, caution is needed. The profiling of products in continuing medical education and patient information provided by PPPs can compromise government drugs policy. For example, the DPP's patient information materials provided in Botswana are technically not in line with the national generic drug policy's principles (and those of WHO), because they omit the generic name of the drug. Now that fluconazole is off patent, any brand preference developed among consumers or prescribers could compromise prospects for generic substitution, if the DPP donation should cease or government decide to make alternative plans for procuring the drug.
- Boehringer Ingelheim's donation of Viramune® for the prevention of mother-to-child transmission has, after a slow start, now expanded in three of the four countries in this study and is reaching significant numbers of mothers and babies, albeit limited to urban locations and with questions relating to resistance. Axios proactively supports the ordering and distribution process.
- Like discounting initiatives, donation programmes target the public sector in these countries and therefore should be accessible to the poor. However there is currently almost no effort to gather the required evidence to evaluate and analyse their health, health systems or equity impact. This situation should be remedied urgently.
- Despite the more positive picture in relation to the donation programmes, they operate in an environment where there is a substantial danger of overwhelming the limited absorptive capacity of national health systems by diverting staff, duplicating financial, monitoring and evaluation systems, and incurring ancillary costs for governments.
- Of particular concern is the impact of the drug requisition process of HIV/AIDS donation initiatives and their significant reporting requirements. These stem from the high value of the drugs involved, which necessitate accurate prediction of demand and maximum security of distribution. Of the two international donation initiatives studied, the Viramune® Donation Programme appeared to have made efforts to make these requirements reasonable – including appointing Axios to assist governments in the process, whereas the Diflucan® Partnership Programme's requirements – particularly the condition that all facilities have to report satisfactorily for any facility to receive shipment – remained onerous.
- Finally, it is important not to overstate the contribution of these donation programmes which to date remain limited in scope and have distributed rather small quantities of essential medicines compared to the need in poor populations.

7. Summary conclusions and recommendations

This report synthesises findings from four country studies undertaken in Botswana, Sri Lanka, Uganda and Zambia to examine PPPs supplying drugs for leprosy, lymphatic filariasis, malaria, onchocerciasis, sleeping sickness, and HIV/AIDS (the DAI and AAI, the Diflucan® Partnership Programme and the Viramune® Donation Programme).

The report separates its conclusions on PPPs according to whether they address tropical diseases or HIV/AIDS rather than whether the drug is donated or discounted. This is because there are more similarities across PPPs (in terms of structure, governance and mode of operation) if they are grouped by disease type than by end price of the product.

Critically, all the tropical disease drugs (except Coartem®) are cheap, and have no market in rich countries. The issue of market distortion does not arise in relation to the current donation PPPs for tropical diseases, and artemether-lumefantrine (Coartem®) is at present the only fixed dose combination of its kind. In addition, all the tropical disease PPPs, including the Coartem® discounted price PPP, involve WHO (or APOC) as the major public partner in the PPP, and operate within the context of a wider global or regional partnership. Most are linked to time-limited disease elimination or control programmes.

By contrast, all the HIV/AIDS drugs involved in these PPPs are expensive, and have major rich country markets. Further, there is minimal involvement by international organisations in the PPPs. While there are similarities between HIV/AIDS discounting initiatives and the Coartem® discounted price PPP, in that the drug is not free, in other respects – most importantly the involvement of WHO – the Coartem® PPP is more like other tropical disease drug access PPPs.

Tropical disease drug access PPPs in Sri Lanka, Uganda and Zambia

Conclusions

Infectious and parasitic diseases remain the primary cause of death worldwide (World Health Report, 2000). The so-called "neglected diseases" affect the very poor in particular. Building on the example of longer-standing PPPs such as the Mectizan® Donation Programme, the last few years have seen the establishment of a range of tropical disease drug access PPPs allied with disease-specific global or regional partnerships, dedicated to accelerating the reduction of this burden of communicable disease. In several cases, the overall goal of elimination or control of the individual disease has been ratified by the World Health Assembly with the collective endorsement of Member States.

The overall conclusion of these studies is that the involvement of multi-national research and development-based pharmaceutical companies in tropical disease drug access PPPs has facilitated better drug availability very substantially in the three relevant study countries (Sri Lanka, Uganda and Zambia), with negligible – if any – negative side-effects. In most cases, national programme managers deal primarily with WHO and have minimal contact with the participating pharmaceutical companies. There is no indication of any specific challenges arising from the involvement of pharmaceutical companies, and several instances of benefits beyond the donation or discounting of drugs, e.g., in contributions to capacity-building.

Diseases that can be eliminated as major public health problems are good choices for health commodity-focused PPP support because of their time limited nature, which minimises the risk of creating a dependency relationship. Where donated drugs are provided free and without time limit to countries, sustainability

problems are reduced – though not eliminated, given the cost of operations. Drug donations that do not raise major market issues locally or in rich countries, nor require complex infrastructure, have proved particularly straightforward to handle.

Governments and clinicians very much welcome the drug access PPPs. Without them, the countries studied would generally struggle to afford the drugs.[1] The widely-held conclusion at country and global levels is that these drug access PPPs have assisted the poor to access necessary drugs.

Considerable health impact has already been achieved in the study countries by the mature tropical disease programmes for control of onchocerciasis and elimination of leprosy. For the more recent tropical disease drug donation PPP/programmes for LF and malaria, real health impact will undoubtedly be secured because of the numbers of people receiving new or better treatment through the PPPs. Regrettably, advances made in sleeping sickness in Uganda have been reversed.

In implementation, most PPPs are well integrated into services, with programmes following customary national systems for vector borne diseases. In almost all cases there has been a positive impact on health systems. The studies found no evidence of unreasonable conditionalities; impaired national ownership; distortion of national or district priorities; or unhelpful reallocation of human and financial resources at central, district or community levels.

Recommendations

1. The clear finding is that tropical disease drug donation PPPs have provided very considerable benefit with negligible negative side-effects, and have been warmly welcomed by countries in the study. 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 programmes might be initiated or current ones expanded.
2. A commitment to continued pharmaceutical company contribution through drug donations and discounts is important to sustainability. So too is the preparedness of donors to 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. Partners of all kinds should be prepared to follow the model of those companies which have pledged to contribute for as long as is needed to achieve elimination or control goals.
3. PPP/programme effort should be integrated with the district health system from the outset, as highlighted by the resurgence of sleeping sickness in Uganda following withdrawal of project staff after control had been achieved.
4. The 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 at international and country level.
5. A rapid review in due course to draw on greater experience at country level of the Coartem® discounted price agreement for malaria could be of benefit, since it potentially raises significantly different issues from the tropical disease drug donation PPPs, for example in relation to cost and sustainability, risks of diversion and a pilot in social marketing through the private sector.

HIV/AIDS drug access PPPs in Botswana, Uganda and Zambia

For HIV/AIDS the overall conclusion is that pharmaceutical company involvement in enhanced access to drugs is more complex and problematic than for tropical diseases. While individuals in sub-Saharan Africa have clearly benefited from reduced prices of branded medicines, there is very little information on public health impact of ART in general – and none on the specific contributions of PPPs or similar initiatives.

Drug donations in the HIV/AIDS field have contributed to preventing the spread of HIV (via prevention of mother-to-child transmission) and improving the quality of life of those living with AIDS. Yet, again, there is scant evidence to quantify this impact or to

[1] As background, the Uganda study report records a resource envelope (excluding private spending) of US$ 9 per capita, compared with an estimated minimum of US$ 28 required to fund the Uganda National Minimum Health Care Package. The Zambia report notes a deficit for delivery of the Basic Health Care Package of US$ 9 per capita, translating into a national deficit of US$ 90 million.

learn lessons on how maximise benefit and minimise harmful impact on health systems.

Conclusions

There are three broad areas of concern:

1. **The fragmentation of initiatives, funding and conditionalities** is the critical issue which needs to be addressed by all involved in HIV/AIDS treatment and care. This research found that the picture from country level was extremely confused and that the impact of the multiplicity of programmes spread throughout the health system. Lack of integration is related to the novelty of HIV/AIDS treatment programmes in general, the political profile they have received, the high market value of the products involved, and the role that multinational pharmaceutical companies have played. It is reflected in lack of clarity particularly around drug procurement, requisition and distribution processes, and monitoring and evaluation systems.
2. **Lack of understanding of the range of options regarding access to medicines** and low capacity to compare and contrast alternatives within the range that best suit particular national needs. In the countries in this study, the studies found:
   - total lack of or extremely limited capacity to assess intellectual property and trade issues as they relate to health;
   - limited involvement of health policy makers in formulating trade policies or trade negotiations (and limited capacity to do so, as above);
   - minimal or total lack of support from international organizations on the issues where intellectual property protection and trade affect public health;
   - limited or lack of capacity to set and enforce policies regarding registration among branded and generic medicines;
   - confusion as to whether certain options (e.g., accepting branded drug discounts) precluded other options, such as registering generic products;
   - low level of trust between the pharmaceutical industry and governments;
   - limited capacity to ensure procurement pooling and procedures that would yield the best prices;
   - limited capacity to conduct assessments comparing the cost-utility of different drug options; and
   - limited information and guidance from international organizations on the prices, quality, sources and cost-utility of different drugs, diagnostics, and treatment modalities.
3. **Excluding the private sector from most initiatives** lacks grounding in the reality of health service delivery in sub-Saharan Africa. The formal private sector currently provides a large proportion of HIV-related care while informally many of those practising in the public sector also have private practices. The division between the two in the context of a massive human resource crisis in the health services of these countries is particularly imprudent. Creating two different markets for these high-value products also promotes leakage and arbitrage. Above all, for patients, having to shop around to receive drugs under different names and formulations, or at varying prices, from several sources – all while sick with AIDS – is not optimal quality of care.

Recommendations

1. At national and international levels, flexible and responsive systems are needed to rationalise fragmented ARV procurement, based on clear evidence on costs and benefits of different supply sources as well as feasible mechanisms for estimating demand. At national level, coordinated and integrated monitoring and evaluation systems are needed which incorporate the requirements of national drug management systems, international funding agencies and multinational pharmaceutical companies.
2. Actions are needed on many fronts to strengthen the capacity in low and middle income countries to assess all options regarding access to medicines, including the role and nature of collaborations with sole source suppliers. Current activities of international agencies (WHO/AMDS, WIPO, WTO, UNCTAD, World Bank) are insufficient and the health of poor populations is being neglected. International agencies should also review the currently fragmented efforts to collaborate on validating sources and bulk procurement mechanisms to assist poorer countries. Both pharmaceutical companies and international agencies should take steps to simplify and harmonize the discounts and procedures

available to some countries, including information and eligibility for the different schemes they offer and clear information on the conditionalities of different schemes. In particular the position of donations and discounts vis-à-vis registration of generic products needs clarification.

3. Every effort should be made to find ways to enhance partnership between public and private sectors in service delivery as ART programmes scale up. Recognising that the private sector could play and is playing an essential role is the first step. Designing drug discount and donation programmes which take their needs into account is an important next stage. Such programmes must, however, also ensure that they do not contribute to inequitable public expenditure.

Annexes

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ANNEX 1

Study Terms of Reference

Impacts of Public-private partnerships addressing access to pharmaceuticals in selected low income and middle income countries: Botswana, Sri Lanka, Uganda and Zambia

Background

The health consequences of poverty lead to major health inequities for poorer populations in developing countries. Many health problems among populations disadvantaged by poverty have been neglected because of lack of commercial incentives or have proven intractable when tackled by public sector or NGOs independently.

In recent years, a number of collaborations have arisen to tackle specific problems. These are usually targeted to specific products, diseases or technologies.

One particular group of these public-private partnerships (PPPs) addresses access to pharmaceuticals (usually drugs) that are critical to treatment or care for tropical diseases which disproportionately or uniquely affect the poor in developing countries. This category of partnerships for drug access is usually based around the provision of products that are donated, heavily discounted or in some way subsidized by their producer (usually a 'sole source'). They entail a multi-partner effort at field level to ensure the distribution and proper use of the medications. These access partnerships are in many instances the only initiatives likely to be mounted for some diseases, especially those that do not rise high on the political visibility scale (e.g. lymphatic filariasis, trachoma and sleeping sickness compared with HIV/AIDS, tuberculosis, and malaria). They are accepted by the governments of countries to which they are offered, and by the populations reached, for the health benefits they provide.

Other types of public-private partnership have been established to encourage pharmaceutical companies to reduce the prices of (and sometimes donate for free) drugs which treat diseases which exist in both rich and poor countries – for example, HIV/AIDS. Here, the multi-partner initiative generally focuses on negotiating different (or tiered) prices across markets – with the most preferential prices reserved for public sector services in developing countries which are assumed to be accessed by the poorest. These types of initiative have generated more controversy due to the difficulties of establishing what are considered to be 'fair' prices in different markets and the problem of arbitrage – or leakage between those markets. Furthermore, they are more difficult than the drug donation programmes above to classify as 'PPPs', since they are not necessarily distinct from normal government purchaser-pharmaceutical provider contracting processes (such as NHS bulk purchasing arrangements) and are heavily influenced by the presence (or not) of generic equivalent products in the market.

Both types of public-private partnership raise a number of questions, mostly relating to their integration with, and impact upon, the broader development of health services in countries in which they operate. The key question is the degree to which the involvement of multinational pharmaceutical companies in some stage of drug procurement and delivery facilitates better drug availability and access by the poor. Further questions include whether the availability of free/reduced price drugs distorts decisions on priorities or prices and what the feasibility is of taking such initiatives to scale, and their sustainability. This range of questions becomes of greater importance as the number of targeted partnerships in particular countries increases and as countries have to prioritise their use of resources within the context of debt relief, Sector-Wide Approaches (SWAps) in health, and multi-sectoral Poverty Reduction Strategic Plans (PRSPs). Issues of integration, coordination, implementation and impact need to be addressed at all levels within countries – national, regional, district and community.

The UK Department for International Development (DFID) has funded the Initiative on Public-Private Partnerships for Health (IPPPH), part of the Global Forum for Health Research, to conduct a series of studies across a range of access partnerships and countries.

Phase I, 2003: Pilot study in Uganda

A pilot study to assess the health and health systems impact of public-private partnerships for improving access to pharmaceuticals in a selected low income country was undertaken in Uganda in May 2003. It covered tropical disease programmes for leprosy, lymphatic filariasis, onchocerciasis and sleeping sickness, and three HIV/AIDS PPPs: the UNAIDS Drug Access Initiative/Accelerating Access Initiative, the Viramune® Donation Programme and the Diflucan® Partnership Programme. The study also pilot tested a study protocol and research instruments for further studies. A full report on the pilot study has been published.

Phase II, 2004: Three further studies in Botswana, Sri Lanka and Zambia, plus a synthesis paper and dissemination

DFID is now funding IPPPH to:

- **Undertake three further country studies** including at least two studies of HIV/AIDS PPPs and two of selected tropical disease PPPs. The countries – Botswana, Sri Lanka and Zambia – were selected with close DFID involvement to ensure that, together with the Uganda study, the maximum number of global drug access partnerships is examined, including major active tropical disease partnerships. The study in Sri Lanka will specifically examine whether the country is benefiting from all PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.
- **Examine supranational level issues** including how the specific drug donation or discount price programmes operate at global level, how they relate to broader partnerships in which they participate, and how they relate to the countries examined.
- **Prepare a synthesis paper** of all the work and conclusions, including the pilot study. The purpose of the synthesis paper is to compare and contrast for policy makers the potential implications, cost, benefits, and risks of drug donations and discounted pricing schemes for contributing to expansion of access to appropriate treatment or control of diseases that primarily afflict poor populations. The synthesis shall also note for policy makers, pharmaceutical companies, and other actors (such as NGOs or funders) operational options that can maximize health and health system benefits and reduce any potential undesirable impacts of such arrangements.
- **Develop and implement a dissemination strategy**, which will communicate the key findings, conclusions and recommendations of the studies to a range of relevant audiences including national policy makers, bilateral and multilateral aid funders, pharmaceutical companies and non-governmental agencies.

Objectives

The studies are part of an ongoing IPPPH programme of activities related to the overall goal of assessing public-private collaboration to improve access for those disadvantaged by poverty to life-saving pharmaceuticals. A key overall objective of the programme is to contribute to the identification of good practices that maximize health benefits for the poor and minimize problems and unintended negative consequences for health systems.

The specific objective of the current studies is to assess the health and health systems impact in the selected countries of public-private partnerships for improving access to pharmaceuticals in relation to HIV/AIDS and to tropical diseases, where pharmaceutical companies are involved as partners at some stage of programme design and/or implementation.

The studies should map the key features of the PPPs, and examine the relationship between the specific drug donation or discount price programmes, the broader partnerships in which they participate and the countries examined.

At country level, the studies will examine issues of ownership, regulation, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of these access PPPs as distinct from other comparable programmes where drugs are competitively procured (for example, the World Bank's MAP, the GFATM or generic purchas-

ing activities). They will review the PPPs in relationship to country health systems and the broader context, both vertically (e.g. how the PPPs relate to pharmaceutical policies, donor/funding issues and broader partnerships) and horizontally (e.g. perceptions and impacts of the partnership from both PPP and government perspectives).

Key issues for examination should include:

- The respective roles of PPP programme partners, governments and local interests in the partnership at global and country level, including developing programme proposals, decision-making, conditionalities and governance, their motives and interests in being involved, and levels of support/funding.
- The extent of the PPP programme's integration with national disease programmes and broader health planning.
- The programme's involvement in, and the effectiveness of, any coordinating mechanisms (formal and informal) with other PPPs at all levels, and any consequences of the PPP programme studied for other PPPs (e.g. in terms of creating opportunities or barriers for other PPPs).
- Evidence available on the impact on (a) coverage and (b) health, including the impact of any inclusion in the PPP programme design of efforts specifically to reach poorer populations, women and children, and measurement of coverage by socioeconomic status, rural/urban mix, gender and age.
- The impact of the PPP programme on health systems, including the outcome to-date of any specific PPP programme objective to strengthen health systems. This would include perceptions of impact on: use of staff time; staff skills; drug ordering and delivery systems; planning and monitoring systems and MIS/HMIS; and government-NGO working relationships.
- For ARVs, the effects of different models of drug supply on regulation, drug procurement and drug distribution. In addition, their impact on equity of access and product availability/prices in both public and private sectors.
- Views on the optimal scale of the programme's operations within the country, and any plans for taking the programme to scale and for longer-term sustainability.
- Identification of the specific benefits and challenges, if any, arising from the involvement of pharmaceutical companies in disease-specific PPPs.

Outputs

The outputs for this second phase of activity will be:

- Findings from a review at supranational level of the relationships between specific drug donation or discount price programmes, broader partnerships, and the countries examined to be made available to country team members before the country studies begin.
- Individual reports on the three further country studies in Botswana, Sri Lanka and Zambia.
- A synthesis paper covering all the work to-date.
- Wide and effective dissemination of the products. This is likely to require tailoring for different audiences (e.g. national governments and partners, pharmaceutical companies, global programme partners/managers, DFID and other agencies).

Methods

Rapid assessments: These are rapid assessments rather than detailed studies. Documentary, quantitative evidence should be obtained wherever available. However, it is recognised that these are likely to be largely qualitative studies making extensive use of semi-structured interviews with key informants. Given funding and time limitations, the studies will not undertake significant original data gathering.

Country studies: The precise range of programmes will vary from country to country.

Fieldwork in each country will be undertaken in a two-week visit by a team of international and national consultants. Undertaking the work in a two-week visit will require effective pre-visit preparation and the prior development of base documentation on the country context and the individual PPP/programmes.

The country studies should adopt a layered approach to evaluation, covering the country context and the disease control policy before assessing the individual partnership programmes. Fieldwork will include interviews about each programme at national, regional (where appropriate), district and health facility levels. Criteria for selection of districts should include:

- Active implementation of those PPP programmes being studied, ensuring that each programme is visited in at least one district. HIV/AIDS programmes should be examined in the capital and at least one contrasting district.
- Regional and socio-economic representation.
- Security and accessibility, within the timescale of the study.

Fieldwork should include interviews about each relevant programme at national, regional (where appropriate), district and health facility/community levels.

Study oversight

Technical advice on the study protocol and the draft reports for Phase II will be provided by a Study Advisory Committee established in Phase I of the study. For this second phase of activities, the Advisory Committee will operate through conference calls and e-mail.

A Steering Committee composed of Roy Widdus (IPPPH), Karen Caines (Team Leader, IHSD) and Veronica Walford (IHSD), will be responsible for the day-to-day implementation of the overall project, periodically keeping the designated representative of the sponsor informed of progress and seeking guidance as necessary.

ANNEX 2

Scope and Conduct of the Study

Study components

The study contains a number of components:

- a pilot country study in Uganda in 2003;
- three further country studies in 2004 in Botswana, Sri Lanka and Zambia, informed by a review of how the specific drug donation or discount price programmes operate at global level;
- a synthesis report in 2004.

Team members for all components of the study were independent of the Initiative on Public-Private Partnerships for Health and the pharmaceutical industry.

The Initiative on Public-Private Partnerships for Health is deeply indebted to the governments of Botswana, Sri Lanka, Uganda and Zambia for their support and contribution to the study.

The pilot study in Uganda 2003

Fieldwork for the pilot study was undertaken in Uganda in May 2003 and covered drug access PPPs for leprosy, lymphatic filariasis, onchocerciasis, sleeping sickness, and HIV/AIDS (the DAI and AAI, the Diflucan® Partnership Programme and the Viramune® Donation Programme). One specific objective of this study was to pilot test in Uganda a study protocol and research instruments addressing critical benefit and health system impact questions in preparation for further studies.

Core elements of the study protocol included:

- information-gathering, both before and during the fieldwork, about the selected public-private partnerships at international level, the country context and the relevant national disease control programmes;
- the adaptation of an information collection tool to target consistent information across the partnership programmes, both nationally and internationally;
- the development of three tailored questionnaires as guides for semi-structured interviews in relation to the tropical disease partnership programmes at national level, the HIV/AIDS programmes at national level and in specialised centres, and all programmes at district level;
- semi-structured interviews at national level with a wide range of interests;
- visits to five districts representing different socio-economic and epidemiological profiles. Each of the PPPs studied was examined in at least one district and some in several districts;
- identification and analysis of relevant quantitative data wherever possible;
- during the course of the study, the team developed criteria for assessing the impact of global public-private partnerships on national health systems; a framework for recording the PPP programme objectives and performance; and a framework for recording the cycle of drug ordering, storage and distribution for each programme.

The study team was:

- Karen Caines (Study team leader), Institute for Health Sector Development, London
- Julie Bataringaya, Health Consultant, Uganda
- Louisiana Lush, London School of Hygiene and Tropical Medicine, London
- Grace Murindwa, Ugandan Ministry of Health
- Hatib N'jie, Institute for Health Sector Development, London and former WHO Representative to Uganda.

The study was overseen by Roy Widdus, Project Manager, IPPPH, supported by a Study Advisory Committee:

- Penny Grewal, Switzerland
- John Gyapong, Ghana
- Stephen K. Lwanga, Uganda
- Mwele Ntuli Malecela-Lazaro, Tanzania
- Stefanie Meredith, France
- Pieter H. Streefland, The Netherlands
- Veronica Walford, United Kingdom
- Roy Widdus, Switzerland.

Country studies in Botswana, Sri Lanka and Zambia 2004

Three further country studies were undertaken in 2004 in Botswana, Sri Lanka and Zambia.

Each of these studies used the same study protocol and study materials,[1] tailored to local circumstances, developed in the pilot study. Materials included:

- minimum data requirements, with possible sources, for the country context, the national disease control policy and the specific PPP programme
- likely key informants
- generic introductory letter to key informants
- interview questionnaire for tropical disease PPPs (national level informants)
- interview questionnaire for HIV/AIDS PPPs (national level informants)
- interview questionnaire for use at district/community level
- criteria for assessing the impact of PPP programmes on national health systems
- framework for recording PPP programme objectives and performance
- framework for recording PPP programme drug ordering/procurement, storage and distribution arrangements.

Each study team analysed relevant literature and data, and undertook interviews at national, district and facility level. Depending on country circumstances and the number of PPP programmes being studied, from three to eight representative districts were visited in each country. Districts were selected on the basis of: active implementation of the PPP programmes, ensuring that each programme was visited in at least one district; regional and socio-economic representation; and security and accessibility within the timescale of the study.

These studies were informed by a global level review conducted by Elizabeth Gardiner, London Business School, of how the specific drug donation or discount price programmes operate at global level, how they relate to broader partnerships in which they participate and how they relate to the countries examined.[2]

Sri Lanka study

The study covered drug access PPPs for leprosy and lymphatic filariasis, and examined whether the country is benefiting from all PPPs for which it is eligible, or should be eligible by comparison with other countries participating in the PPPs.

Fieldwork was undertaken in Sri Lanka in March 2004 and included visits to three districts.

The study team was:

- Karen Caines (Study team leader), Institute for Health Sector Development, London
- Dr Palitha Abeykoon, Member of the Sri Lankan National Health Advisory Council.

Zambia study

The study covered drug access PPPs for leprosy, malaria and HIV/AIDS (the Diflucan® Partnership Programme and the Viramune® Donation Programme).

Fieldwork was undertaken in Zambia in April 2004 and included visits to four districts.

The study team was:

- Qhing Qhing Dlamini (Study team leader), Health Development Consultant, Swaziland
- Louisiana Lush, London School of Hygiene and Tropical Medicine
- Martin Auton, Independent Consultant on the Management of Medicines in Public Health, South Africa
- Patrick Nkandu, Health Consultant, Zambia.

[1] The protocol and tools are contained in the report on the Uganda pilot study: K Caines et al., *Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries: Uganda Pilot Study*, Initiative on Public-Private Partnerships for Health, Switzerland, 2003.

[2] Unpublished manuscript by E. Gardiner, Initiative on Public-Private Partnerships for Health, Switzerland, 2004.

Botswana study

The study covered only PPPs to improve access to drugs for HIV/AIDS related conditions, in contrast to the other countries where PPPs also address tropical diseases not prevalent in Botswana.

Fieldwork was undertaken in Botswana in May 2004 and included visits to eight districts.

The study team was:

- Nel Druce (Study team leader), Institute for Health Sector Development, London
- Dr Joyce Kgatlwane, MOH official for Botswana's Essential Drugs Action Programme
- Dr Ilavenil Ramiah, Research fellow, Harvard School of Public Health, USA
- Otsetswe Mosime, management consultant based with KPMG in Botswana.

Synthesis report

This report synthesises the findings from all four country studies, and a global level review.

In total, the study findings are based on interviews with more than 250 individuals in countries and approximately 40 at global level. They include representatives of Ministries of Health in a wide range of posts including Directors General, disease programme managers, medical stores and distribution personnel; a variety of relevant national bodies; district officials; clinicians; public and private sector pharmacists; clients; medical supplies organisations; NGOs; academic institutions; WHO at country, regional and global levels; UNAIDS; UNICEF; development partners; pharmaceutical companies, an associated independent donation programme and an associated foundation.

Draft reports of the three 2004 country studies and of the synthesis were reviewed by a Study Advisory Committee:

- Jens Byskov, Denmark
- John Gyapong, Ghana
- Stephen K. Lwanga, Uganda
- Veronica Walford, United Kingdom
- Roy Widdus, Switzerland.

Detailed reports on the individual country studies, including the pilot study,[1] have been published separately from this synthesis report.

[1] K Caines et al., *Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries: Uganda Pilot Study*, Initiative on Public-Private Partnerships for Health, Switzerland, 2003.

N Druce et al., *Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries: Botswana*, Initiative on Public-Private Partnerships for Health, Switzerland, 2004.

K Caines et al., *Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries: Sri Lanka*, Initiative on Public-Private Partnerships for Health, Switzerland, 2004.

QQ Dlamini et al., *Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries: Zambia*, Initiative on Public-Private Partnerships for Health, Switzerland, 2004.

ANNEX 3

Table of HIV/AIDS and tropical disease drug access PPPs

I. Tropical disease Drug Access Partnerships

Disease	PPP partners		Drug flow	Related global initiatives
	Primary public partners	Primary private partners		
Leprosy	WHO, national governments	i) Novartis. Donation programme managed for Novartis by Novartis Foundation for Sustainable Development. 1999 WHO/Novartis Agreement on Multi Drug Therapy (MDT) donation due to end in 2005 (the WHO target date for elimination) but Novartis/ NFSD is to extend its donation programme to 2010.	Novartis donates drugs to WHO for allocation and distribution to endemic countries. Novartis does not make MDT commercially available; it supplies WHO with sufficient stocks for all patients in the world.	i) *Global Alliance to Eliminate Leprosy (GAEL)* Members: WHO, the Nippon Foundation/ Sasakawa Memorial Health Foundation, the ministers of health of endemic countries and Novartis/the Novartis Foundation. Associate Members: DANIDA and the World Bank. ii) *WHO Leprosy Elimination Project*.
Lymphatic Filariasis	WHO, national governments	i) GSK. 1997 WHO/GSK agreement to donate all the albendazole required for elimination of LF, plus funding. ii) Merck/MDP (see *Onchocerciasis*). 1999 Merck commitment to provide all the Mectizan® required for as long as required for LF in African countries where onchocerciasis and LF are co-endemic.	WHO-appointed Regional Programme Review Groups review applications for albendazole. Extended MDP Mectizan® Expert Committee approves donations for Mectizan® and albendazole where LF and onchocerciasis are co-endemic. GSK and MDP ship donated drugs to countries for distribution through community-based treatment programmes.	i) *Global Alliance for the Elimination of Lymphatic Filariasis (GAELF)* Members: WHO, GSK, representatives from endemic country ministries of health, donor groups, academia and NGOs. ii) *WHO Programme to Eliminate Lymphatic Filariasis (PELF)*.
Malaria	WHO, national governments	i) Novartis 2001 WHO/Novartis Coartem® Public Purchase Agreement.	Given request/payment by governments and approval by WHO, Novartis sells Coartem® at cost to WHO which delivers it to countries.	i) *Rollback Malaria* Members include WHO, UNICEF, UNDP, World Bank, bilateral and multilateral donors, private sector, academia, private foundations and NGOs.

Disease	PPP partners		Drug flow	Related global initiatives
	Primary public partners	Primary private partners		
Onchocerciasis	National governments	i) Merck/ Mectizan® Donation Programme (MDP) for donation of Mectizan® (ivermectin) since 1987. NB. No formal agreement with WHO or any other body. Mectizan® is not available commercially, though the same drug marketed as Stromectal is available in countries where it is registered. This excludes most African countries where onchocerciasis and LF are endemic.	Independent Merck-funded Mectizan® Expert Committee reviews/approves applications from MoHs, NGOs, local health organisations. The MDP housed at the Task Force For Child Survival and Development oversees applications, ordering and shipment of the drug to applicant country programmes.	*African Programme for Onchocerciasis Control (APOC)* Members include participating countries, WHO, bilateral and multilateral donors, private foundations and NGOs. The World Bank is the fiscal agent, and WHO the executing agent. *Onchocerciasis Elimination Program of the Americas (OEPA)* This is supported by PAHO, Inter-American Development Bank, a consortium of NDGOs and participat ing countries.
Sleeping sickness	WHO, national governments	i) WHO/Aventis MOU: donations of pentamidine, melarsoprol, eflornithine, plus funding 2001–2006; ii) Bristol Myers Squibb: raw materials for one year eflornithine supply, plus funding; iii) WHO/Bayer MOU: 2002–2007 donations of suramin, nifurtimox, plus funding.	Pharmaceutical companies provide drug donations to WHO which determines allocations and, in collaboration with MSF, distributes them to endemic countries.	*WHO Programme to Eliminate Sleeping Sickness* Members: WHO, Aventis, Bayer, Bristol Myers Squibb, MSF Drugs for Neglected Diseases Initiative, governments of Belgium and France.

II. HIV/AIDS Drug Access Partnerships

Disease	Public-private partnership	PPP partners			Drug flow
		Primary public partners	Primary private partners	Other participants	
HIV/AIDS HAART	Accelerating Access Initiative (AAI)	National governments and NGOs purchasing HAART	Abbott, Boehringer Ingelheim, Bristol Myers Squibb, Gilead Sciences, GlaxoSmithKline, Merck, Roche	UNAIDS and co-sponsors (WHO-AMDS/EDM, UNFPA, UNICEF, World Bank)	UNAIDS (now WHO-AMDS) facilitated the introduction of national governments to pharmaceutical companies for ARV purchases. Prices initially negotiated bilaterally but subsequently some companies published discount or at-cost prices for low income countries to access. Drugs delivered to national partner.
	Merck donation of Stocrin® and Crixivan® through ACHAP	Government of Botswana	Merck	None	Donation initiated in 2002 following decision on national treatment protocol. Drugs supplied from Merck USA to Botswana in line with public sector programme scale-up.

Disease	Public-private partnership	PPP partners			Drug flow
		Primary public partners	Primary private partners	Other participants	
HIV/AIDS Opportunistic infections	Diflucan® Donation Programme	National governments, NGOs	Pfizer	Axios	After review and recommendation by Axios, Pfizer delivers drug to public partner.
HIV/AIDS Prevention of mother-to-child transmission (PMTCT)	Viramune® Donation Programme	National governments, NGOs	Boehringer Ingelheim	Axios Private health care providers	After review and recommendation by Axios, Boehringer Ingelheim delivers drug to public partner or private health care providers.

ANNEX 4

Compliance with interagency guidelines for drug donations at country level

Checklist for compliance with Interagency Guidelines for Drug Donations, Revised 1999 (WHO/EDM/PAR/99.4)	DIFLUCAN®		VIRAMUNE®		LEPROSY		LYMPHATIC FILARIAIS	STICCRIN AND CRIXIVAN (ACHAP)
	B	Z	B	Z	S	Z	Z	B
All drugs should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent of the recipient.	Y	Y	Y	Y	Y	Y	Y	Y
All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Drugs, unless specifically requested otherwise by the recipient.	Y	Y WHO	Y	Y WHO	Y	Y	Y	Y
The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those of drugs commonly used in the recipient country.	Y	Y	Y	Y	Y	Y	Y	Y
All donated drugs should be obtained from a reliable source and comply with quality standards in both donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used.	Y	Y	Y	Y	Y	Y	Y	Y
No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.	Y	Y	Y	Y	Y	Y	Y	Y
After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year.	Y	Y	Y	Y	Y	Y	Y	Y
All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Non-proprietary Name (INN) or generic name, batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.	Y	Y	Y	Y	Y*	Y	Y	Y
As much as possible, donated drugs should be presented in larger quantity units and hospital packs.	Y	Y	Y	Y	Y	n/a	Y	Y

Note: B = Botswana; S = Sri Lanka; Z = Zambia. Data for Uganda are not available.

* All drugs that are imported are labelled in English in Sri Lanka. ** It is agreed that the government will clear from the port.

*** Under Merck's pricing policy for its ARVs Stocrin and Crixivan, Botswana would be eligible for Merck's "no-profit" prices: US$ 600/yr for Crixivan, US$ 500/yr for Stocrin 200mg capsules, US$ 346.75 for Stocrin 600 mg tablets.

	DIFLUCAN®		VIRAMUNE®		LEPROSY		LYMPHATIC FILARIAIS	STCCRIN AND CRIXIVAN (ACHAP)
	B	Z	B	Z	S	Z	Z	B
All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.	Y	Y	Y	Y	Y	Y	Y	Y
Recipients should be informed of all drug donations that are being considered, prepared or actually under way.	Y	Y	Y	Y	Y	Y	Y	Y
In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.	??	N	??	N	Y	Y	Y	***
Costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.	Y	Y	Y	Y	Y**	Y	Y	Y

Checklist for compliance with guidelines for price discounts of single-source pharmaceuticals (WHO/EDM/PAR/2003.3)

	COARTEM®	ARV AAI DISCOUNTS
	Z	B
1. The discount programme should aim to assist countries in promoting access The discount agreement should aim to assist countries in their efforts to achieve equitable and sustainable access to essential health care, including essential medicines. The programme should not be mainly promotional in character, nor should it be designed primarily to increase market opportunities for the company involved to the detriment of others.	Y	Y
2. The eligible population should be selected on the basis of agreed criteria The countries and patient populations for which the pricing offer is made should be jointly selected on the basis of agreed justifiable criteria, such as health needs, expression of interest, political commitment, economic status, health system infrastructure and potential for sustainability.	Y	Y
3. The product should be registered for the relevant indication in the country of destination	Y	Y
4. The medicine should be recommended in a recognized clinical guideline The medicine should offer a cost-effective and safe treatment for the disease, and be recommended by an officially published WHO treatment guideline or included in the WHO Model Formulary. The medicine should preferably be included in a national or organizational treatment guideline and in the national list of essential medicines.	Y	Y

	COARTEM®	ARV AAI DISCOUNTS
	Z	B
5. The discounted price should be compared with prices of equivalent medicines The discounted price offered should be compared with the prices of the generic and therapeutic equivalents legally available on the world market.	N	No written agreements but offers in line with company offers (public)
6. Distribution and other costs should be estimated and funding assured Current and future additional funding requirements for the product and its transport, distribution, training and use should be estimated in advance and the funding should be assured. This also applies to additional costs to national and international organizations involved, such as meeting costs, travel costs and country visits.	?	Y
7. The scope of the offer should be clearly specified The scope of the discount (e.g., geographical areas, patient categories, products, volume and duration) should be clearly specified. If the discounted price is limited in scope or in time, these limitations must be clearly defined, and the needs of other patients and the long-term sustainability of the programme must be addressed.	Y	Y
8. Diagnostic and clinical guidelines must be promoted, and treatment facilities available Diagnostic criteria and clinical guidelines for the effective use of the medicine must be defined and promoted. Health workers must have been trained and a supervision system must be in place. Diagnostic and treatment facilities must be available or be developed.	Y	Y
9. Systems for supply and reporting must be defined The systems for supply, distribution, monitoring and reporting must be defined in advance. These systems should not create an undue burden for all concerned and should, as far as possible, be integrated within existing systems.	Y	Y
10. The content of the discount agreement should be public Information regarding the content of the discount agreement and the experiences with the programme should be accessible to the public.	Y	No written agreements but prices in line with public company offers

The aim of the Initiative on Public-Private Partnerships for Health is to increase the effectiveness of public-private collaboration, particularly by helping those seeking to develop health products, or to improve access to such products needed to fight neglected diseases and other health problems in developing countries.

Created in 2000 in Geneva, Switzerland, the Initiative on Public-Private Partnerships for Health is sponsored by the Bill & Melinda Gates Foundation, the Rockefeller Foundation and the World Bank. It operates under the aegis of the Global Forum for Health Research, an independent international foundation helping to correct the 10/90 gap in health research, from which it also receives support (www.globalforumhealth.org).

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