Initiative on Public-Private
Partnerships for Health

Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries: Uganda Pilot Study

REPORT OF A PILOT STUDY ON THE IMPACT OF SELECTED PUBLIC-PRIVATE PARTNERSHIPS ADDRESSING ACCESS TO PHARMACEUTICALS

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FOREWORD

by
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The Initiative on Public-Private Partnerships for Health (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 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 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 and Melinda Gates Foundation, 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. A team of consultants was selected 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 protocol rested necessarily with the IPPPH as the agent responsible to the principal funder, DFID.

All members of the consultant team are independent of the pharmaceutical industry and IPPPH. Neither of the national consultants had any programmatic or managerial responsibility for any of the programmes examined; however, their knowledge of the Ugandan health system and key informants greatly benefited the study.

IPPPH is pleased to publish the consultant team's report, in its entirety and without modification, as a major contribution to understanding the actual impact at national and field level of these diverse collaborative ventures.

This study can stand alone but is 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 affected by diseases associated with poverty. Additional, carefully selected studies in other countries, designed taking into account the suggestions of the consultant team, are desirable to broaden the evidence base on which ultimately to formulate suggestions for "good practices".

IPPPH thanks the UK Department for International Development for its financial support, and the excellent consultant team, particularly Karen Caines of the Institute for Health Sector Development, and Louisiana Lush of the London School of Hygiene and Tropical Medicine for their outstanding leadership of this study overall and of the HIV/AIDS component, respectively.

Special thanks must go to the many individuals in Uganda who gave generously of their time to the consultant team. We trust the insights of the study, especially into areas needing more external technical and financial assistance, will prove useful to them, as well as the broader international community.

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EXECUTIVE SUMMARY

The UK Department for International Development (DFID) funded the Initiative on Public-Private Partnerships for Health (IPPPH)[1] to conduct a pilot study in Uganda to assess the health and health systems impact of public-private partnerships (PPPs) for improving access to pharmaceuticals in relation to leprosy, lymphatic filariasis, onchocerciasis, sleeping sickness, and HIV/AIDS. The specific remit was 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.

Given its time and resource limitations, this was a rapid and largely qualitative study making extensive use of semi-structured interviews with key informants at national and district levels. Fieldwork visits were made to five districts in Uganda – Hoima, Kampala, Katakwi, Masaka and Soroti – 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. All members of the study team are independent of the Initiative on Public-Private Partnerships for Health and the pharmaceutical industry.

Tropical disease drug access PPPs and national programmes

- Drug donation partnerships are perceived as providing real benefit to the Ugandan national programmes for leprosy, lymphatic filariasis, onchocerciasis and sleeping sickness, all of which are serious public health problems in those districts in which they are endemic. The major, widely appreciated benefit is the assurance of a sustained and consistent supply of free, high-quality drugs with no unreasonable conditionalities.
- In most though not all cases, the national disease elimination programmes have been kick-started or revitalised by the drug donations plus the broader WHO-led partnerships. There is nonetheless a strong sense of national ownership of the programmes, and an excellent fit between the PPP objectives and priorities and plans in Uganda. Onchocerciasis and leprosy are included in the National Minimum Health Care Package, while sleeping sickness and filariasis are designated district-specific priorities. All qualify for funding from the Primary Health Care Conditional Grant. The study team found no evidence of any skewing of national or district priorities, nor of unhelpful diversion of human and financial resources at central, district or community levels.
- National programme managers relate mainly to the WHO-led global partnerships of which the drug donation programmes are part, and have had little if any direct interaction with pharmaceutical companies, except for The Mectizan® Donation Programme. They perceive (rightly or wrongly) greater pharmaceutical company interest in research for neglected diseases like sleeping sickness, and welcome evidence of a willingness to invest in packaging and formulations more appropriate to local health system needs.
- Three of the four programmes are already providing nationwide coverage of endemic areas, subject only to problems caused by recurrent insecurity in some districts; the fourth programme (lymphatic filariasis) was launched only in 2002.
- Considerable health impact has been achieved by the mature programmes. In the absence of routine socio-economic data on the clients, it is assumed in Uganda that these programmes benefit the poor particularly, because the drugs are provided free in unlimited amounts and because these 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 including health).

[1] An Initiative operating under the legal auspices of the Global Forum for Health Research, an independent, international foundation created under the Swiss legal code.

- Support for operations as well as assured drug supplies will be critical in the maintenance, as well as the intensive, phase of these elimination programmes. The onchocerciasis and leprosy programmes are making encouraging moves towards sustainability. However, the ability of Uganda to take on the burden of these programmes has to be seen in the context of a shortfall in funding, notable a resource envelope (excluding private spending) of US$9 per capita per year compared with an estimated US$28 per capita per year required for delivering the government's National Minimum Health Care Package.
- Better coordination across these programmes and greater integration within the district health systems is desirable. The 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 PPPs of which they are part positively encourage integration. Comparison with the Schistosomiasis Control Initiative, which provides funding rather than drugs, suggests few substantive differences in the rather vertical operation of the programmes. Any move to distribute drugs from donation programmes to districts through the National Medical Stores should wait until its current operational changes have bedded down.

HIV/AIDS drug access PPPs

- The Drug Access Initiative (DAI) reduced prices of branded medicines and catalysed the training of health workers, accreditation of facilities and development of secure drug distribution systems. The Accelerated Access Initiative (AAI) has continued to provide access to cheaper branded medicines but its profile in Uganda is low.
- However, the DAI raised expectations about drug access which it was unable to meet. The reduced prices it did achieve were still too high for the vast majority of people and its impact was low. Further price reductions were attributable more to the introduction of generic drugs into the Ugandan market than to the DAI.
- The policy environment for ARVs remains insecure – MOH officials have not yet participated in regulating pharmaceutical markets for these drugs. Neither have they played a strong role in developing an intellectual property regime which will protect public health by ensuring the ongoing availability of generic medicines.
- The Viramune® Donation Programme enhanced the availability of a much needed drug and stimulated prevention of mother to child transmission (PMTCT) expansion. The initiative was welcomed by policy makers and providers, and the involvement of the pharmaceutical company in management of the programme within the Ugandan health system was minimal.
- The programme could be scaled up more rapidly but, although the drug is free, infrastructure and a wide range of services are required. It has the potential to be better integrated into existing drug distribution systems, provided their security measures against diversion improve.
- As for Viramune®, the Diflucan® Partnership Programme is much appreciated by those in the front line of providing HIV/AIDS care. The programme specifically targets the poor and assures unlimited supplies of a quality branded medicine for an unlimited time.
- While Diflucan® distribution is already integrated into the National Medical Stores/district system, security problems have created confusion and delayed regular access to the drug.

Future Studies

- If there is to be another full-fledged study on the Uganda model, the country should be selected carefully as a contrast to Uganda in terms of national organisational capacity and the extent of the role of 'big pharma' in country in the tropical disease programmes. Any such study would also benefit from an extension to examining the role of the WHO-led global partnerships.
- There is scope for further examination of the role of pharmaceutical companies in the market for high value, AIDS-related drugs, pricing and procurement issues, security of drug management, and equity in access to treatment and care.

Abbreviations

AAI	Accelerated Access Initiative
APOC	African Onchocerciasis Control Programme
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Azidothymidine; generic name, Zidovudine; brand name, Retrovir®
CDD	Community drug distributor
CDT	Community-directed treatment
DAI	Drug Access Initiative
DDHS	District Director of Health Services
DFID	UK Department for International Development
GAEL	Global Alliance to Eliminate Leprosy
GAELF	Global Alliance to Eliminate Lymphatic Filariasis
GAVI	Global Alliance for Vaccines and Immunization
GFATM	Global Fund to Fight AIDS, TB and Malaria
GoU	Government of Uganda
GSK	GlaxoSmithKline
HAI	Health Action International
HMIS	Health Management Information System
HPAC	Health Policy Advisory Committee
HSSP	Health Sector Strategic Plan
IPPPH	Initiative on Public-Private Partnerships for Health
JCRC	Joint Clinical Research Centre
JMS	Joint Medical Stores
LF	Lymphatic Filariasis
MAP	Multicountry AIDS Project
MAUL	Medical Access Uganda Ltd
MDA	Mass drug administration
MDP	Mectizan® Donation Programme
MDT	Multi-drug therapy
MEC	Mectizan® Expert Committee
MoH	Ministry of Health
MoU	Memorandum of Understanding
NACP	National AIDS Control Programme
NGDO	Non-governmental Development Organization
NGO	Non-governmental Organisation
NMS	National Medical Stores
NOCP	National Onchocerciasis Control Programme
NOTF	National Onchocerciasis Task Force
NTLP	National TB/Leprosy Programme
OCP	Onchocerciasis Control Programme
PAF	Ugandan national Poverty Action Fund
PELF	Programme to Eliminate Lymphatic Filariasis
PLWHA	People living with HIV/AIDS
PMTCT	Prevention of mother-to-child transmission
PPP	Public-private partnership
SCI	Schistosomiasis Control Initiative
SSA	Sleeping Sickness Assistant
SWAp	Sector-wide approach
TDR	Special Programme for Research and Training in Tropical Diseases
UNMHCP	Ugandan National Minimum Heath Care Package

I: INTRODUCTION

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), usually targeted on specific products, diseases or technologies, have arisen to tackle particular health problems. One group of PPPs addresses access to pharmaceuticals critical to treatment or care for 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, trachoma and sleeping sickness) as compared with HIV/AIDS, tuberculosis, and malaria which have attracted global attention.

However, they have given rise to 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. Other questions concern the feasibility of taking such initiatives to scale, and their sustainability. This range of questions becomes of greater importance as the number of targeted partnerships in individual countries increases and as countries attempt to implement broader approaches such as debt relief, sector-wide approaches (SWAPs) in health, and multi-sectoral Poverty Reduction Strategies (PRSs).

Through evaluating national impacts of existing public-private partnerships for drug access in a number of countries, it should ultimately be possible to develop good practices for such initiatives to maximize health benefits for the poor and minimize unintended negative consequences. The presumption was that this would probably require studies across a range of access partnerships and countries.

The pilot study

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, to conduct a pilot study in Uganda in preparation for a larger study or studies. This study can stand alone but is 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.

Pilot Study Terms of Reference

To assess the health and health systems impact in Uganda of public-private partnerships for improving access to pharmaceuticals in relation to leprosy, lymphatic filariasis, onchocerciasis, sleeping sickness, and HIV/AIDS.

Specifically, 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.

Key issues for examination have included:

- the respective roles of PPP programme partners, governments and local interests in developing programme proposals, decision-making, conditionalities and governance;
- the fit between the programme and national/local priorities and plans or individual needs;
- the extent of the PPP programme's integration with national disease programmes and broader health planning, and identification of the specific benefits and challenges, if any, arising from the involvement of the private sector in disease-specific PPPs;
- the programme's involvement in, and the effectiveness of, coordinating mechanisms (formal and informal) with other PPPs;
- 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;
- the impact of 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 inclusion in PPP programme design of a specific objective to strengthen health systems, and the outcome to date.

Objectives

The objectives of this study were to:

- pilot test a study protocol and research instruments addressing critical benefit and health system impact questions in preparation for a larger study or studies;
- identify issues unique to drug access PPPs in Uganda that include the involvement of pharmaceutical companies at some stage of decision-making and/or implementation.

Method

Details of the study approach are given in Section V of this report. The study was overseen by a Study Advisory Committee and the country fieldwork was undertaken in Uganda from 5-23 May 2003 by two national and three international consultants:

- Karen Caines (study team leader), Institute for Health Sector Development, London
- Julie Bataringaya, Health Consultant, Uganda (from 1 June 2003 employed by WHO)
- 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

All members of the study team are independent of the Initiative on Public-Private Partnerships for Health and the pharmaceutical industry. Neither of the national consultants has had programmatic or managerial responsibility for any of the programmes examined in the study, which benefited - particularly given the tight timescale - from their detailed knowledge of the health system and key informants.

It was recognised in the terms of reference that the study would not be able to examine all relevant partnerships in Uganda in the detail ideally desirable nor encompass community focus group work, given timing and budgetary limitations on the study. These restrictions precluded live data-gathering in the field. In line with the views of a technical consultation meeting held in January 2003 to advise on study design, this was a rapid and largely qualitative study making extensive use of semi-structured interviews with key informants.

Fieldwork visits were made to five districts in Uganda – Hoima, Kampala, Katakwi, Masaka and Soroti – 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.

Acknowledgements

The study team is greatly indebted to all those in Uganda who gave so much of their time and energy to provide key information and thoughtful commentary on the study issues. We are the more grateful, given the many other demands on interviewees during the period of the study. We are particularly appreciative of the contributions - and kindly patience - of Professor Omaswa and his colleagues in the Ministry of Health on whom we necessarily relied for much of the substantive data reflected in this report.

We acknowledge with thanks that we have throughout, (and particularly in Section II on the Health Challenges and Health System in Uganda), drawn heavily on a series of key government documents including the Ugandan National Health Policy, the Health Financing Strategy, the Health Sector Strategic Plan and the very timely report of the latter's Mid-term Review.

II: HEALTH CHALLENGES AND THE HEALTH SYSTEM IN UGANDA

The country context

Socio-economic characteristics
Uganda has a population of almost 25 million, with an average population growth rate of 3.5%. Approximately 11.3% of the country's population is resident in urban centres[2].

From 1992-1997, the country achieved marked economic growth of an average of 6.5% per annum with per capita income estimated at US$ 330 over the period (MoFPED, 1997) along with single-digit inflation. Private sector investment increased from 8.6% of GDP in 1992/93 to 14.6% of GDP in 2001/02. Despite these economic achievements, household incomes have remained low, though there has been an overall reduction in the level of absolute poverty from 66.3% in 1994/95 to 35% in 2000. Poverty continues to be a rural phenomenon, with 96% of the poor living in rural areas in 2000, and regional concentrations in the north and east (MoFPED, 2001). In the North, poverty rose by 8% between 1997 and 2000, leaving two-thirds of its population below the poverty line. Poverty is recognized to be the main underlying cause of the poor health situation within Uganda. Associated factors are the low level of literacy, high prevalence of communicable diseases, emergence of lifestyle diseases, inadequate provision and inequitable distribution of social services and amenities, protracted civil unrest in the North and west of the country resulting in mass movement of populations, and underdevelopment of service infrastructure[3].

Epidemiological information
The leading causes of morbidity and mortality in Uganda are mainly communicable diseases. According to the Uganda Burden of Disease study (MoH 1995), over 75% of the life years lost due to premature deaths were from ten preventable diseases. Perinatal and maternal conditions (20.4%), malaria (15.4%), acute respiratory infections (10.5%), HIV/AIDS (9.1%) and diarrhoea (8.4%) together account for over 60% of the total disease burden. There has also been a marked upsurge in non-communicable diseases including hypertension, diabetes and cancer, mental illness and chronic degenerative cardiovascular diseases.

Table 1: Health indices for Uganda

	1995	2000-2001
Life expectancy (at birth)	52	47
Infant Mortality Rate (IMR)	97	88
Under 5 Mortality Rate	147	152
Maternal Mortality Ratio (MMR)	506	505
Total Fertility Rate (TFR)	6.9	6.9
Contraceptive Prevalence Rate (CPR)	15	25
Access to safe water	48%	51.8%

Source: Uganda Demographic and Health Surveys 1995, 2000-2001

The health system in Uganda

During the 1970s and early 1980s, military dictatorship, economic crisis and brain drain left the health sector depleted and disorganized. When Uganda emerged from conflict in 1986, there were vast needs for basic services in all sectors, especially education and health. In the absence of a coherent health policy, a proliferation of international and national agencies and NGOs developed health projects outside the government system. Uganda has since introduced reforms and policies targeting improvement in economic performance, public sector performance in general and health sector performance through increased efficiency and effectiveness in the delivery of health services.

[2] *Population Census 2002,*Uganda Bureau of Statistics.
[3] *National Health Policy*, Ministry of Health, Uganda, September 1999

Politico-administrative and health system structure
Uganda currently consists of 56 districts, with further subdivision into 167 counties, 930 sub-counties, 4,517 parishes and 39,692 villages. Delivery of social services has been decentralised from central government to districts. Both the Constitution of the Republic of Uganda (1995) and the Local Governments Act (1997) spell out the roles and responsibilities of the centre and the district. Key functions for the Ministry of Health (MoH) include policy formulation, setting standards, and quality assurance; resource mobilization; capacity development and technical support; provision of nationally coordinated services, e.g. epidemic control; co-ordination of health research; monitoring and evaluation of the overall sector performance. District health care responsibilities include implementation of the National Health Policy; planning and management of district services; provision of disease prevention, health promotion, curative and rehabilitative services; vector control and control of communicable diseases; health education; ensuring provision of safe water and sanitation; and health data issues.

In the National Health Policy (1999), the responsibility for delivery of health services was transferred from the district to health sub-district – a near self-contained service zone that brings basic health care, including essential referral services, closer to the community but is not in itself a substantive new administrative unit.

National Health Policy, Health Sector Strategic Plan and the UNMHCP
Accelerating the improvement of the health of the population is one of the key pillars of the Government's Poverty Eradication Action Plan (PEAP). A National Health Policy (1999) and a Health Sector Strategic Plan (HSSP, 2000/01 – 2004/05) with a specific development goal were developed as a collaborative undertaking of the Government of Uganda (Ministry of Health and related ministries), development partners and other stakeholders. A primary theme of the National Health Policy is greater equity, with special consideration for the welfare of the poor, the most vulnerable and the most disadvantaged. With 100 females for every 96 males in the population, it also stresses the need to mainstream gender considerations in the planning and implementation of all health programmes.

Among the more fundamental approaches introduced by the HSSP are the adoption of a sector-wide approach in health, introduction of the Uganda National Minimum Health Care Package (UNMHCP) for all (again with emphasis on poor people, women and children), further decentralisation of health service delivery to the health sub-districts, and strengthened collaboration with the private sector.

In August 2000, the Government of Uganda (GoU) and its Development partners in the health sector signed a Memorandum of Understanding (MoU) to guide the implementation of the HSSP through a SWAp. Currently nine donors (UK, Ireland, EU, Norway, Sweden, Belgium, Netherlands, World Bank, DANIDA) in the health sector have moved to some degree of budget support through the Ministry of Finance, Planning and Economic Development (MoFPED).

The Uganda National Minimum Health Care Package (UNMHCP), one of the HSSP's five programme outputs, consists of interventions that are demonstrably cost effective and have the largest impact on reducing mortality and morbidity. It was designed[4] to be implemented countrywide and delivered in an integrated manner at all levels of the health care system. An important factor for this current study is that the package includes control of communicable diseases such as STD/HIV/AIDS, and interventions against diseases targeted for elimination as a public health problem, such as onchocerciasis and leprosy. The HSSP also makes clear that districts have the flexibility to add district-specific priorities not in the national minimum package, citing sleeping sickness, bilharzia (schistosomiasis) and filarial hydrocele of the testis as examples.

The Mid-term Review Report of the HSSP in April 2003[5] raised an issue about assuring effective delivery of the minimum package, without reintroducing verticality. It described one constraint as that some

[4] UNMHCP designed using data from *Burden of Disease and Cost Effective Study* (1995), the Uganda Participatory Poverty Assessment Project (UPPAP 1998) and analysis of Ministry of Health HMIS.
[5] *Health Sector Strategic Plan 2000/01-2004/05 Mid-term Review Report,* April 2003, Ministry of Health, Uganda

Ministry of Health programmes were not able to separate the roles of facilitator, (appropriate to the national level), and implementer (appropriate to the district level) and therefore continued to undertake activities that rightfully belong to the district or health sub-district levels. Resources provided by the Global Fund to Fight AIDS, TB, and Malaria (GFATM) and GAVI were seen as exacerbating the problem by encouraging the maintenance of vertical service delivery systems. The tropical disease programmes examined in this study have traditionally been managed in a vertical way.

The Mid-term Review also noted that the improved policy environment provided by the National Health Policy and HSSP, the increase in the health resource envelope and the abolition of user charges in March 2001 have all contributed to significant growth in the utilisation of primary care services, particularly by the poor. However, it highlighted the mismatch between the aspirations of the HSSP and available resources, a shortage of trained personnel, an inadequate network of functional health infrastructure and serious shortages in drug supply. Physical access to a health facility remains low, with an estimated 57% of the population living within a 5 km radius of an existing facility. Only 42% of approved posts are filled by qualified staff, with a consequent impact on quality of service. The Review suggests that reports of a massive rise in outpatient attendance following abolition of user fees, and the high level of priority given by rural communities to health centre construction under the highly discretionary Local Government Development Programme, are indicative of large unmet needs for basic health care services.

The private sector (NGOs, private practitioners and traditional medicine practitioners) already plays a very significant role in health care in Uganda. Strengthening collaboration and partnership between the public and private sectors in health to accelerate health care coverage is a key principle of the National Health Policy. GoU financial support to this sub-sector jumped from Ug Shs 1.0 billion in FY 1997/98 to Ug Shs 16.5 billion in FY 2002/03.

Funding for the health sector

In 1998 the Government of Uganda was granted debt relief from donor countries and multilateral agencies under the Highly Indebted Poor Countries (HIPC) initiative. A Poverty Action Fund was set up to mobilize and channel additional funds towards the key sectors, including health, identified in the Government's Poverty Eradication Action plan (PEAP).

Current Government expenditure on health is approx. 9.6% (excluding projects, 12.6% including projects) of total Government expenditure and about 0.8% of Gross National Product (MoFPED, 2002). The sector has benefited from budget growth averaging 9% per annum from 2000/01 to 2002/03. Even so, the resource envelope (excluding private spending) is only US$9 per capita compared with the estimated minimum of US$28 per capita[6] required for delivering the UNMHCP. The low level of health sector funding poses major challenges for government in achieving a more balanced allocation of the health budget – for example, in relation to HIV/AIDS, malaria, and reproductive health versus the tropical diseases which are endemic in only parts of the country but are there the cause of serious problems. As an act of policy, the proportion of the overall sector budget directly allocated for district services, (including not for profit providers), has increased from 32% in 1999/2000 to 54% in 2003/04 at the expense of the central MOH and referral hospitals.

The Global Fund to Fight AIDS, TB, and Malaria (GFATM) will provide additional funding up to a total of US$97.7 million dollars over three years. This funding will be split between the GoU budget and a project funding mechanism, and utilised by both public and private entities at central and district levels. Of the total sum available, US$36.3 million dollars has been confirmed for a project to finance the first two years of the implementation of Uganda's Comprehensive programme for Scaling Up the National Response to HIV/AIDS. A third year HIV/AIDS tranche of US$15.6 million will be disbursed dependent on results.

[6] *The Health Financing Strategy*, Ministry of Health, Uganda, 2002

The shift from project mode to SWAps and budget support, the longer time horizons of commitments for external support and the global initiatives targeting priority diseases - including previously neglected diseases – should help to promote greater sustainability.

Drugs policy, procurement and management

Drugs policy and funding
The HSSP sets out to achieve a comprehensive approach to drugs and medical supplies, including drug policy development, coordinated selection and quantification of needs, procurement, storage and distribution, rational drug use, cost recovery, quality control and drug regulation.

A new National Drug Policy was completed in October 2001 though it has yet to be endorsed, and a 5-year National Pharmaceutical Sector Strategic Plan 2002/3-2006/7 has been developed and costed. Funding for drugs and health supplies has increased from less than US$ 0.8 per capita at the start of the HSSP to US$1.2 per capita in FY 2002/03, which still represents only one-third of the estimated requirement of US$3.5 per capita[7] (excluding the pentavalent vaccine currently donated through GAVI and antiretrovirals (ARVs)). The Mid-term Review concludes that this shortfall poses a serious threat to sustained availability of essential drugs and health supplies, and hence to the delivery of the UNMHCP.

Drug budgets have been decentralized, with guidelines to protect them at all service delivery levels. However, demand for essential drugs far exceeds supply, not least because of the rapid increase in service utilisation following the abolition of cost sharing. Additional funding and a policy recommendation to dedicate 50% of the non-wage budget to essential drugs at the lower levels of care have not been enough to stem high stock-out rates which compromise the quality of care[8]. Resources for drugs (ARVs, antimalarials, anti-TB) have been identified from the World Bank's Multi-country AIDS Project (MAP) and the Global Fund to Fight AIDS, TB, and Malaria (GFATM).

Drug regulation
There are two regulatory bodies in this sub-sector: the National Drug Authority and the Pharmacy Council. The drug regulatory system is to be strengthened through a new Uganda Medicines Control Authority Bill.

Procurement, storage and distribution
Procurement has been decentralised to line ministries but the Mid-term Review finds weaknesses in unfilled posts in the MoH procurement unit, undefined roles between various interested bodies, the lack of a comprehensive procurement plan for the Ministry, and conflicting legislation, particularly in relation to the National Medical Stores (NMS).

The NMS was established with a mandate to procure, store and distribute drugs and health supplies to the entire public sector in Uganda, with an emphasis on a social service rather than commercially oriented role. While the expectation of social good has remained, it is no longer guaranteed business from the public sector and increasingly operates in the market like any private company. Parliament has currently suspended the process of privatization of the NMS initiated under the government's programme of divestiture of public enterprises.

Despite some self-admitted operational difficulties at the NMS and a need to improve its credibility[9], the Mid-term Review finds that various achievements in the procurement and management of drugs can be attributed to the NMS' improved efficiency. It has introduced standard procurement procedures in the interests of transparency, responsiveness to fluctuations in demand, and customer service. The organisation is currently handling some substantial operational challenges, including the transition from a 'push' to a

[7] *The Health Financing Strategy*, Ministry of Health, Uganda, 2002
[8] *Drug Tracking Study*, UPPAP2 report
[9] *Note of Health Supplies Procurement Meeting 19 March 2003*, Ministry of Health, Uganda, March 2003

'pull' (order-based) supply system to districts, distribution to a multiplicity of health units and a major IT upgrading.

There is an argument that ideally all drugs from donation programmes should be distributed through the NMS system to promote integration, though there are divided views about this within the Ugandan Ministry of Health. Whatever the decision of principle, the study team was advised that, as a matter of practicality, consideration of such a move should be left until the new changes in NMS systems have bedded down.

During the study field visit, the NMS was the subject of MOH and public attention over a contract with Landmark Pharmaceuticals (Uganda) Ltd, under which NMS would procure drugs, mainly antiretrovirals, and sell them to Landmark which would be free to re-sell the drugs elsewhere. According to press reports, GlaxoSmithKline, which sells AIDS drugs to Uganda at subsidised rates, warned the NMS against selling its products for re-export. The NMS maintained that discounted drugs were not involved. In the event, the deal was aborted after intervention by the Ministry of Health.

A well-regarded NGO, the Joint Medical Stores (JMS), supplies drugs to mission hospitals and other not for profit providers, plus to some government centres. For example, it serves as the second supplier for government when the NMS is out of stock, though there is need for better linkage between the NMS and JMS over supply forecasts. The JMS has no distribution system and operates on a cash and carry basis.

In addition, a number of private for profit companies import and sell drugs for the private medical system, including branded ARVs. A government health research institution specialising in HIV/AIDS, the Joint Clinical Research Centre (JCRC), also imports drugs directly and has been a market leader in importing generic ARVs. Other health providers such as the Mildmay Centre and the Masaka Healthcare Centre are currently considering importing generic drugs.

III: DRUG ACCESS PPPS IN UGANDA FOR FOUR TROPICAL DISEASES: LEPROSY, LYMPHATIC FILARIASIS, ONCHOCERCIASIS, AND SLEEPING SICKNESS

Scope of the study

Uganda benefits from public-private partnerships for improving access to pharmaceuticals in relation to four tropical diseases: leprosy, lymphatic filariasis, onchocerciasis and sleeping sickness. The International Trachoma Initiative does not operate in Uganda.

In each case, the drug donation programmes established by the pharmaceutical companies are operating within and/or alongside a wider disease-focused global partnership under the aegis of WHO. And again in each case, the Ministry of Health in Uganda has established a national programme, albeit at varying stages of development. The key objective of this country level study has therefore been to assess the health and health systems impact of these four national tropical disease programmes, acting in partnership with the global drug access PPPs. Given strong national ownership of the tropical disease programmes and the general lack of involvement and influence of pharmaceutical companies on local implementation beyond the crucial step of providing free drugs, it has not proved possible to assess the drug donation programmes in isolation at country level.

Since the terms of reference were 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, the study also examined one comparable programme – the Schistomiasis Control Initiative (SCI) - for which Uganda is currently providing the global pilot. The Ugandan national schistosomiasis programme, which is combined with the programme for soil-transmitted helminths, has important similarities to the four study programmes. It is tackling a vector borne disease endemic in some but not all districts of Uganda. There is a national programme, run from the Ministry of Health, and supported by an international partnership. But the key distinction for this study is that "big pharma" is not involved in the SCI, either in programme design or in drug donation. In the case of schistosomiasis control, the global initiative is providing not drugs but funding for national procurement of drugs, as well as for training and operational support[10].

Methods

For the four study programmes, members of the study team:

- analysed global, national and district programme strategies, plans and reports, together with wider literature
- within the Ministry of Health, interviewed the Director-General of Health Services, the Commissioner for National Disease Control/Secretary to GFATM Country Coordinating Mechanism, the Assistant Commissioner for Vector-borne Diseases Control, the individual Programme Managers, and Essential Drugs personnel (see MOH organigram in Annex 4)
- interviewed a range of partners and stakeholders, including multilateral and bilateral agencies, and NGOs (see Annex 3)
- visited district level operations for each programme:
    - leprosy (Soroti District)
    - lymphatic filariasis (Katakwi District)
    - onchocerciasis (Hoima District)
    - sleeping sickness (Soroti District)
    - schistosomiasis (Hoima District)

[10] The Schistosomiasis Control Initiative (SCI) based at Imperial College, London, is supported by a $29.8 million award from the Bill and Melinda Gates Foundation's Global Health Programme. A key objective is to encourage development of a sustainable schistosomiasis control programme in sub Saharan Africa.

Further details on district selection are given in Annex 2.

Background information on the programmes

Detailed information on each of the four core tropical disease programmes studied is given in:

Annex 5: National TB/Leprosy Control Programme
Annex 6: National Programme to Eliminate Lymphatic Filariasis (PELF)
Annex 7: National Onchocerciasis Control Programme (NOCP)
Annex 8: National Sleeping Sickness Control Programme

Table 2(a) below summarises the programme objectives and key conditionalities of the global public-private partnerships.

Table 2(b) summarises the programme objectives and current performance of the national partnership programmes.

Table 2(a): Tropical disease PPP programme objectives and performance
Global PPP programmes

Country: Uganda	Leprosy	Lymphatic Filariasis	Onchocerciasis	Sleeping sickness
Global PPP programme and objective	*Global Alliance to Eliminate Leprosy (GAEL)* Elimination by 2005 by "ensuring that all patients, wherever they may be, will have free and equal access to the most modern treatment available"	*Global Alliance to Eliminate LF (GAELF)* Elimination by 2020 *GSK Albendazole donation* *Mectizan® Donation Programme* Objective is to ensure Mectizan treatment is available to those in need via community-based programmes.	*African Programme for Onchocerciasis Control (APOC)* To bring the disease under control as a public health problem and socio-economic problem throughout Africa. 12-year perspective. *Mectizan® Donation Programme*	*WHO Programme to Eliminate Sleeping Sickness (WPESS)* Elimination of sleeping sickness
Drug donation	Novartis MDT free to all countries until end 2005. Support likely to continue over the maintenance phase	i) GSK: all the albendazole required ii) Merck/MDP: all the Mectizan® required for as long as required*	Merck/MDP: all the Mectizan® required for as long as required	i)Aventis: pentamidine, melarsoprol, eflornithine – 5 years to 2006, plus funding ii) Bristol Myers Squibb: raw materials for 1 year eflornithine supply, plus funding ii) Bayer: suramin, nifurtimox- 5 years to 2007, plus funding
Conditionalities	Nothing unreasonable	Appropriate use of the drugs	Appropriate use of the drugs	Nothing unreasonable

Note: Merck and Co. announced in 1987 a commitment to donate as much Mectizan® as necessary to treat onchocerciasis to bring the disease under control as a public health problem globally. In 1999 the donation was expanded to the treatment of lymphatic filariasis in African countries where onchocerciasis and lymphatic filariasis co-exist.

Table 2(b): Tropical disease PPP programme objectives and performance
National programmes

Country: Uganda	National TB/ Leprosy Control Programme	National Programme to Eliminate Lymphatic Filariasis	National Onchocerciasis Control Programme	National Sleeping Sickness Control Programme
Disease a national /district health priority	Yes Included in national health policy and plan, and in district health plans.	Yes Cited in national health plan, and included in district health plans.	Yes Included in national health policy and plan, and in health plans of affected districts.	Yes Cited in national health plan, and included in district health plans.
National programme objective	Achieve and sustain elimination in all districts by 2005	Eliminate LF as a public health problem via CDT, and ultimately interrupt transmission	Develop sustainable CDTI in all endemic areas; eradicate vector in 2 main transmission reservoirs.	Establish sustainable control, reduce incidence to <2 per 100,000 and prevent spread to virgin areas.
Current national programme initiated	1990	2002	1997	2001
Population at risk	Total population, i.e. 25 million	Mapping underway May 2003.	22/56 districts c.2m people	14 districts; c.5.2 million people at risk
National partners	MOH, districts, German Leprosy Relief Association (GLRA), faith-based NGOs	MOH, districts, communities, WHO, GSK, Merck/MDP	MOH, districts, APOC, Merck/MDP, Global 2000 River Blindness Program, Christophel Blinden Mission, GTZ, Sight Savers Int'nal,	MOH, districts, WHO
Current national budget contribution	GoU already meets operational costs for 50% districts and 100% staff costs.	GoU funding in 2002 for advocacy meetings, drug transportation and supervisory visits.	All staff salaries (except 3 central support staff) and c.20% of non-drug operational costs from MoH budget and PHC conditional grant.	GOU PAF funding of Ug Shs 550m in 2001/2 and 350m in 2002/3. No aggregate budget figures available.
Current national coverage	Total national coverage with MDT, and elimination at the national level, achieved 1994 and sustained to date.	2 pilot districts 2002. Planned scale up to 10 in 2003 (4.2m people) subject to operational funding.	Target of 100% geographical coverage of endemic districts achieved in 2001 and sustained.	Target of 100% geographical coverage of the 14 endemic districts achieved.
Performance against targets	2002 nat. prevalence rate of 0.4, against target of 1, per 10,000. 9 districts not achieved target.	Treatment coverage of 70% of total population in 2 districts to date, against target of 80%	NOCP target of 80% treatment coverage of affected communities being met. APOC target of 85% by 2005.	Target of reducing incidence to <2 per 100,000 at parish level.
Sustainability	Declining no. of cases and clinicians with relevant skills points to integrating detection/treatment in general district system. Integration plan developed; all districts mapped; sensitisation of districts initiated.	Achieving and sustaining full scale coverage for the 5 to 6 years necessary to interrupt transmission is wholly dependent on an assured source of funding. MOH special request to Ministry of Finance for funding for 2003 programme is pending.	Programme is in transition away from APOC operational support (limited to 5 years per district). Phase 1 districts already self sustaining. Some later phase districts including CDTI in 2003/4 work plans. PHC conditional grant, district devt. grant, and NGO support should close the gap. Move to greater PHC integration.	GOU PAF funding (provided for last 2 years in 2001/2 and 2002/3) and transfer of sleeping sickness assistants to Primary Health Care payroll are important steps to sustainability.

Abbreviations:
CDT – Community-directed treatment
MDP – Mectizan® Donation Programme
MDT – Multi-drug therapy
MEC – Mectizan® Expert Committee
MOH – Ministry of Health
NOCP – National Onchocerciasis Control Programme
GOU PAF – Government of Uganda Poverty Action Fund
WR – WHO Country Representative

Key findings

Common characteristics

These four programmes share a number of common characteristics:

- *elimination programmes:* all are global and (with the exception of sleeping sickness) national programmes to eliminate the disease as a public health problem, with some presumption of a time limit for the most intensive activities.
- *free drug donations:* in each case, the drugs are being donated free, not offered at discounted prices. In the case of onchocerciasis and lymphatic filariasis, the pharmaceutical companies concerned (Merck & Co. and GlaxoSmithKline) have made a commitment to supply as much as is needed, for as long as is needed to achieve elimination. In the case of leprosy and sleeping sickness, the companies (Novartis, Aventis and Bayer AG) have to date put a time limit on free supplies though there are indications that Novartis' support for leprosy at least will be extended for the maintenance phase.
- *little direct interaction between government and pharmaceutical partners:* for the Ugandan government, the prime interface is with WHO or WHO/APOC, as the secretariat for a global or regional partnership, rather than with the pharmaceutical company direct except for the Mectizan® Donation Programme's more activist stance in visiting Uganda periodically. This latter may stem from the fact that the Mectizan Donation Programme was established in 1987 and active in Uganda through NGDOs several years before APOC was established as the umbrella partnership for Africa. Overall, however, interviewees have had little, if any, interaction with pharmaceutical company partners.
- *operational funding a prerequisite for a national programme:* a key common finding is that the free drug donation is *necessary* but *not sufficient* to initiate and support a full national elimination programme for these kind of diseases in its active phase. Given Uganda's limited resources, some source of extra-government funding for operational costs has also been required.

  For example, despite the availability of free Mectizan® from 1987 and the development of two national plans, a government-led, integrated Ugandan National Onchocerciasis Control Programme (NOCP) was not implemented until the establishment of APOC in 1996 provided a source of technical and financial support. Similarly, notwithstanding the availability of free albendazole and Mectizan® to treat lymphatic filariasis since 1999, the Ugandan national Programme to Eliminate Lymphatic Filariasis (PELF) was launched in two districts only in 2002 with substantial operational funding contributed by WHO and DFID.

  By contrast, the National Leprosy Control Programme achieved national coverage of multidrug therapy (MDT) in 1994, and indeed elimination at a national level in that year, on the basis of contributions from partners sufficient to fund both drugs and operations. The advent of the free drug donation from Novartis in 1999 enabled the programme to deploy more funds into operational support, including at the centre.

National/district priorities and the health SWAp

All four diseases are serious public health problems in those districts of Uganda in which they are endemic. Ministry and district interviewees are adamant that, irrespective of drug donations, the programmes are clear national or district priorities included in key policy documents. 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) makes clear that districts have the flexibility to add district-specific priorities such as sleeping sickness, bilharzia (schistosomiasis) and filarial hydrocele of the testis. In each district visited, the relevant programme was included in the district plan.

The Health Sector Strategic Plan is being implemented through a Sector-wide Approach (SWAp). The MoU establishing the SWAp partnership calls for budget support as the preferred option. In any event, the

budget development process in Uganda requires that all funding for the sector (Government budget including donor budget support and donor funding through projects) be included in the resource envelope for each budget year. The allocations are made in accordance with priorities agreed upon by the broader partnership.

One of the implications of this arrangement is that many of Uganda's health development partners no longer directly support specific programmes such as those tropical diseases programmes being studied. Nonetheless, the study programmes, as part of the jointly developed common development framework of the SWAp partnership – the Health Sector Strategic Plan, are of direct concern to the partnership. All qualify for support from the Primary Health Care Conditional Grant of the National Poverty Action Fund, which is the main conduit for channelling donor budget support and proceeds of debt relief arrangements such as HIPC 1 and 2.

In order to reduce the high transaction costs of the multiple partnerships for the different national programmes, the SWAP operates through various joint government/partner structures such as the Health Policy Advisory Committee (HPAC), Biannual Joint Review Missions, and Joint Technical Working Groups. Individual inter-agency coordination committees for priority programmes report periodically to HPAC and to the Basic Package Working Group. Although none of the tropical disease programmes for this pilot study feature in the core set of indicators for the SWAP, they are included in the annual reporting by the MOH and are therefore subject to scrutiny by HPAC and the Joint Review Missions. Indeed, during the recent Mid-term Review of the HSSP completed in April 2003, many partners called for increased attention to these elimination programmes.

The study team's conclusion is that, in relation to these four tropical disease programmes, there is an excellent fit between the PPP objectives and both national and local priorities and plans. One agency partner told us *"Rather than skewing government priorities, [the donation programmes] enable government to do what it would like to do".*

Ownership and governance

"Ownership of these programmes rests unequivocally with the Ministry of Health. We are implementing them. There is no issue about skewed priorities", the Director General of Health Services, Uganda Ministry of Health.
Against the background of the SWAp, interviewees unanimously regarded governance of, and decision-making within, these programmes as a national matter, accepting the need to comply with general criteria for the global partnership programmes. In some cases, there are specific governance bodies, for example, the Uganda Trypanosomiasis Control Council and its Technical Committee, and the National Onchocerciasis Task Force whose members are drawn from implementing partners.

In all cases, day to day programme management rests firmly within the Ministry of Health (the Department of Community Health or the Department of National Disease Control) and the districts, operating within the guidelines of the global/regional partnerships. Given the decentralised nature of the Uganda health system, Ministry and district officials undertake joint planning and most of the activities are carried out by districts.

Most external interactions are with WHO as the leader of global or regional partnerships and there is little direct contact with the drug donation companies. This marks a contrast with the newly-launched Schistosomiasis Control Initiative (SCI) where the global director, Dr Alan Fenwick, is at present very actively involved in working with the Ministry of Health programme manager. This is no doubt because Uganda is currently engaged in undertaking the pilot for the overall global SCI programme which aims to assist at least four sub-Saharan African countries to establish nationwide routine control involving identifying districts with heavy infections, providing appropriate health education, and procurement of the required drugs. SCI identifies local and international partners to provide training, and then support the delivery of the drug. SCI itself will monitor the effect of the programme to demonstrate the impact that

treatment can achieve, in particular by recording the reduction in people with heavy infections, the reduction in symptoms, and improvement in nutritional status.

For the four core tropical disease PPPs being studied, respondents in Uganda noted only one substantive example of national intentions being amended after discussion with the global partnership. The Ministry of Health's original proposal to WHO and the Mectizan® Donation Programme in 2000 was that their national Programme to Eliminate Lymphatic Filariasis (PELF) should be launched in three districts (Soroti, Katakwi and Lira). The initial response was a recommendation to start MDA in only one district but, after further exchanges with the Ministry and a country visit, it was mutually agreed that the programme should be initiated in two districts (Katakwi and Lira).

There was no evidence or mention of unreasonable conditionalities specified for the drug donation programmes (eg in relation to scope of programme, drug indications, modes of operation or reporting). The nature of the reports for the drug donation programmes (as distinct from the global programmes) was not seen as unduly onerous. For example, for the onchocerciasis programme, the Mectizan® Donation Programme has a 3-page report with only one mandatory item, the reporting of serious adverse reactions, compared with an annual report to APOC of up to 40 pages. MOH programme managers felt strongly that, where the programmes were included in the Health Management Information System (HMIS), the routine data provided were not sufficient for their own programme management purposes.

Integration with national and district systems

At Ministry level, there is full integration of the four PPP-supported programmes with customary MOH systems for vector control programmes. However, it should be noted that for such programmes, the MOH has typically operated in project mode (eg in relation to financing, management, drug distribution and reporting). As one example, vertical programmes of this kind do not at present advise the MOH's Essential Drugs Management personnel of drug supply figures. A similar vertical approach is taken to other MOH programmes such as TB and EPI, the latter – like the National TB and Leprosy programme -having its own store and distribution system, managed by EPI from the National Medical Stores site.

The SCI - which requires procurement activity, since the Initiative provides the funding for praziquantel rather than the drug itself - is using the National Medical Stores to handle procurement and storage. However, the districts then collect supplies for the Mass Drug Administration from the Stores on the authorisation of the MOH programme manager in the Vector Borne Diseases Control department; supplies are not sent out with the NMS district deliveries. Table 3 gives an overview of the cycle of drug ordering, receipt and distribution for all the tropical disease programmes studied.

During our interviews, there were divided views about the best approach in the future. Some central managers of programmes being funded via the project mode were reluctant to let go what they see as their programmes and hence control of the budget. They argued that control initiatives, when new, need the intensive oversight provided by vertical programmes of this kind. There is a similar argument that the same detailed attention is needed when elimination programmes reach their final, often most challenging, stages.

Table 3: Cycle of drug ordering, receipt and distribution: Uganda, May 2003

Country: Uganda	Leprosy	Lymphatic filariasis	Onchocerciasis	Sleeping sickness	Schistosomiasis (SCI)
Estimation of drug requirements	By programme manager based on returns of the previous year, and drug consumption	By programme manager based on district population estimates, (80% treatment coverage)	By the national NOCP Coordinator based on the census of the communities at risk and drugs dispensed	By programme manager based on district estimates/ returns of the previous year	By national co-ordinator based on census of at risk communities, drugs dispensed & expansion plan.
Application process	By programme manager through WR to WHO HQ	By programme manager through WR to WHO HQ and MDP/MEC	NOTF applies to MDP, for MEC evaluation/approval	By programme manager through WR to WHO HQ Review Cmttee.	Districts apply to VCD/SCI and through to SCI London
Orders for drugs	Annually by programme manager through WR to WHO HQ	MOH programme manager through WR to WHO HQ and MDP	NOTF secretariat to MDP which orders from Merck	MOH programme manager through WR to WHO HQ	With SCI London approval, VCD requests NMS to place an order
Reception of drug in country	WHO	WHO	WHO	Drugs shipped by MSF France and collected from airport by WHO	National Medical Stores (NMS)
Storage	MOH programme manager NTLP Stores	MOH programme manager	MOH programme manager NOTF stores	MOH programme manager	National Medical Stores
Distribution to district level	Quarterly delivery to zonal stores; zonal supervisors deliver to DDHS stores quarterly	Collected from MOH programme manager by DDHS	Collected from NOTF stores by DDHS	Collected from MOH programme manager by DDHS	DDHS collects from NMS with authorisation from National Coordinator. (NB praziquantel may be added to USAID's DELIVER list)
Distribution to community level	-	DDHS Office coordinator delivers to CDTI community supervisors, who distribute to each CDD in their area	District oncho coordinator delivers to CDTI community supervisors, who distributes to each CDD in their area	None	Drugs are issued to teachers and selected CDDs by DDHS and VCD district representatives
Distribution to individuals	Patient collects monthly supply from supervising health unit during monthly visit to the unit	CDTI mass distribution or house to house, according to community preference	CDTI mass distribution or house to house, according to community preference	Only as in-patients in designated treatment centres	By trained teachers and CDD (community wishes respected)
Community involvement in decisions on distribution and choice of CDDs	Little if any choice at the moment	Decision rests entirely with each community	Decision rests entirely with each community	N/A	Community leaders sensitized by trained trainers CDD selected by the communities.
Links with other programmes	Integrated leprosy/TB programme No linkage with other programmes	Integrated CDT for oncho, schisto and intestinal helminths planned in 6 districts.	District Oncho coordinators are district focal point for vector borne diseases. Many CDDs involved in other health activities. Integrated CDT for oncho, schisto and intestinal helminths planned in 6 districts.	None except with related agriculture and veterinary projects	Integrated CDT for oncho, schisto and intestinal helminths planned in 6 districts.

Abbreviations:
CDD - Community Drug Distributor
CDT – Community-directed treatment
DDHS –District Director of Health Services
MDP – Mectizan® Donation Programme
MEC – Mectizan® Expert Committee
MOH – Ministry of Health
NMS – National Medical Stores
NOCP – National Onchocerciasis Control Programme
NOTF – National Onchocerciasis Task Force
SCI – Schistosomiasis Control Initiative
WR – WHO Country Representative

Others, however, felt that sustainability required full integration at all levels. For example, it was suggested that the declining number both of leprosy cases and of clinicians with the relevant skills to treat them, pointed to integrating detection and treatment into the general district system with the appropriate training of those concerned. The national onchocerciasis task force is working towards stronger integration with the national primary health care programme: ivermectin has been incorporated in the current version of the national essential drug list, and discussions about including onchocerciasis in the national Health Management Information System (HMIS) have been initiated.

So far as distributing all drugs from donation programmes through the National Medical Stores is concerned, section II has already noted the pressures currently facing that organisation and the general advice that, as a matter of practicality, consideration of such a move should be left until the new changes in NMS systems have bedded down.

Whatever the outcome, the key finding for this study is that the issues of integration are no different because these are programmes with pharmaceutical company involvement rather than any other donor. On the contrary, the global PPP programmes generally advocate integration.

Impact

Health impact

As foreseen in advance of the country visit, it is difficult to map the programme outcomes in a resource- and time-limited study of this kind. For such information as is available, Table 2(b) above, *Tropical disease PPP programme objectives and performance: national programmes,* summarises performance against targets and Annexes 5 to 8 on the individual programmes give greater detail.

The health impact of the drug access PPPs as mediated by the national disease programmes varies from programme to programme. The leprosy programme is long-standing and can point to substantial achievements, with national coverage and elimination at national level having been achieved as long ago as 1994. However, this antedates the 1999 Novartis free drug donation which is the subject of this study. With the assistance of the Novartis donation, coverage has been maintained and the national prevalence rate of leprosy reduced to 0.42 per 10,000 by the end of 2001 down from 0.9 in 1994 and 17.7 in 1983. It was however still above the target of 1 per 10,000 in nine of the then 39 districts in Uganda. The detection rate of new cases was 0.31 per 10,000 in 2001, down from 0.37 and 0.42 for 2000 and 1999 respectively. The treatment completion rate for both types of leprosy was 69% in 2001, still below the national target of at least 85%.The National Onchocerciasis Control Programme became operational in 1997 with support from the Mectizan® Donation Programme and APOC, building on the significant coverage already achieved by NGDOs, again with Mectizan® Donation Programme support. Total coverage of the communities at risk was achieved in 2001 and has since been sustained. In 2002 the percentage of those eligible being treated annually in at risk communities ranged from 65% to 93%, with a national average of 80%. The target for 2005 is over 85%.

Pharmaceutical company drug donations for sleeping sickness have been available only since 2001 (Aventis) and November 2002 (Bayer AG), though these were preceded by other partnerships, often district-based. Under the national plan to revitalise sleeping sickness control launched in Uganda in 2001, services are now being provided to all 14 districts affected by the disease. The West Nile foci had been brought well under control such that in October 2002, MSF France were able to withdraw support to the Trypanosomiasis control programme in that area. However, an increasing number of new cases is again being reported in the West Nile (data from the follow-up surveillance by Epicentre are yet to be released).

The programmes for lymphatic filariasis and schistosomiasis have each been operating less than a year and are still building to scale so the impact is as yet relatively limited. To date, PELF has held MDAs in only two districts where over 733,000 people were treated. In Lira, some parts of the district affected by insecurity were not covered.

Schistosomiasis and concurrent intestinal helminth treatment is even more recent, having been launched on March 4th 2003. During the first 6 months praziquantel and albendazole sufficient to treat 300,000 children and high prevalence communities will be delivered to the 18 worst affected districts. By the end of May 2003, over 100,000 people had been treated in 7 districts on Lake Albert and the Nile (Adjumani, Arua, Hoima, Kibale, Lira, Moyo, and Nebbi).

Health systems impact
An 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. In the case of Uganda, interviewees at all levels were adamant that the impact was beneficial. The study team found no evidence of any skewing of national or district priorities, nor a consequent unhelpful diversion of human and financial resources at central, district or community levels. While there were some specific staff in central units, none of the districts visited needed to recruit additional staff to manage these tropical disease programmes. Staff in place there 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.

While the PPPHs share the wider difficulties of prioritisation within an environment of severe budget constraints, the drug donation programmes tend to act as stimulus for more equitable allocations for the affected communities from the already strained budgets at both the centre and districts, so long as the diseases remain priority concerns.

Several interviewees noted the sheer value of the additional resources brought to health.. While it is difficult to access estimates of the dollar value of drug donations by big pharma, they are clearly substantial. This must be seen for the greater part as additional funding that would not otherwise have come to the sector. In some cases, the partnerships provide further finance for operations or training, as well as technical support. There is no estimate of the resources mobilised on the back of the drug donation programmes.

One issue that has proved problematic, given the pilot study's tight time limits, is international level concern about the 'hidden' operational costs associated with drug access programmes, eg in relation to reporting load. Ideally it would have been preferable to undertake more detailed live data gathering to elucidate the issue than was possible within the constraints of this study. This report faithfully reflects the views of country level interviewees that this is not a justified concern in relation to the tropical disease donation programmes in Uganda. The diseases are felt to be real national or district priorities, and the associated costs are not inflated by external requirements from pharmaceutical donors.

Health systems strengthening is explicitly an integral part of the new generation of PPPs for health such as APOC, the Schistosomiasis Control Initiative, the Global Alliance to Eliminate Lymphatic Filariasis and now the leprosy 'Final Push' programme. All advocate for integration of programmes into the mainstream of primary health care activities.

CDTI, TB DOTS and Polio eradication have influenced many other programmes in Uganda in their approach to communities. Leprosy is now applying the Accompanied MDT approach, Malaria the Home based Management of Fever, and Reproductive Health is reawakening to Traditional Birth Attendants. This must be seen as capacity development across the system with regard to community empowerment for self health development.

The PPPs for health also contribute 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.

Scale and sustainability

Scaling up
Of the four core tropical disease programmes studied, three (leprosy, onchocerciasis and sleeping sickness) are already providing nationwide coverage of endemic areas, subject only to problems caused by recurrent insecurity in some districts.

The fourth programme, lymphatic filariasis, has ambitious plans for going to scale rapidly to provide MDA in all endemic districts by 2005 – a target population of nearly 9.5 million people[11]. Achieving and sustaining this latter for the 5 to 6 years necessary to interrupt transmission is, however, wholly dependent on an assured source of funding for operational activities in addition to the existing commitments by GlaxoSmithKline and Merck & Co. to donate the necessary supplies of drugs (respectively albendazole and Mectizan®). At the time of the study, the Ugandan Ministry of Finance was considering a special request from the Ministry of Health to fund the planned expansion of the programme to 10 districts in 2003.

The Schistosomiasis Control Initiative plans concurrent scaling up in the 18 worst affected districts. As each District Director of Health Services reports successful treatment in one sub-county, the drug will be available for a second sub county as required. The target for 2003 is treatment of up to 800,000 (50% through schools and 50% through CDD). In 2004, those treated in 2003 will be retreated, and an extra one million included. Monitoring and evaluation of the programme will be by independent assessors.

In interviews, the argument was advanced that a long-term assurance of all necessary donated drugs facilitated the rapid scaling-up of a tropical disease control programme.

Sustainability
Sustainability has different dimensions for the various programmes. As stressed throughout, assured funding for operations to complement donated drugs is a prerequisite for all. This will be assisted by the eligibility of these programmes for funding from the national Primary Heath Care Conditional Grant. The transition of the national leprosy and the onchocerciasis programmes to greater self-sufficiency in operational funding is encouraging, though interviewees saw a continued free drug supply as critical.

The lesson of history from this study is the vital need for continued support during the maintenance phase of these programmes if relapse is to be avoided. Given the financial challenges 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.

There are wider issues. As described above, both the leprosy and onchocerciasis programmes see integration at all levels of these hitherto vertical programmes as a key to long-term sustainability, notwithstanding the challenges posed in terms of training and informed oversight. This is being complemented by moves to greater coordination and collaboration across programmes: leprosy has long since been managed alongside TB, and discussions are underway between the National Onchocerciasis Control Programme, PELF and SCI on how best to integrate activities such as training, supervision, advocacy, registration and drug distribution.

Sustainability for the SCI will be measured by the degree to which a grass-roots demand for treatment has been generated.

Perceived Benefits of Tropical Disease Drug Access PPPs

The tropical disease drug access PPPs operating in Uganda were universally welcomed by all relevant interviewees in the study, who were specifically asked to cite disadvantages as well as advantages.

[11] PELF Annual Report for 2002, Vector Control Division, Ministry of Health, Uganda

Perceived benefits included the following:

- the actual and forecast health impact of the programmes;
- access to free and necessary drugs when neither the MOH nor poor individuals can afford them and when, for three programmes out of four studied, there was historically no other donor(s) able or willing to fund drugs for national coverage;
- in the absence of routine socio-economic data on their clients, it is assumed in Uganda that these programmes benefit the poor particularly , because the drugs are provided free in unlimited amounts and because these 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 including health). In the Uganda Participatory Poverty Assessment Report (the first published in 2000 and the second in 2002), the poor indicated ill-health was the most significant cause of, and contributor to, poverty;
- the assurance of a sustained supply for the term of the donation: *"The key is regular, sustainable supply"*;
- for Mectizan® (Merck) and albendazole (GSK), a guaranteed supply of as much as is needed, for as long as is needed to underpin full-term elimination programme plans;
- consistency of supply of the same drug which promotes adherence and reduces training costs. This is more difficult to achieve with repeated procurement from varied sources and with different tablet forms;
- the assurance of quality from using branded drugs from major manufacturers;
- the stimulus to partnerships and programme initiation/revitalisation. The benefits of having a driving interested party such as a PPPH can be seen with the Mectizan Donation Programme. One interviewee noted, *"APOC would not have been created without donation of the drugs".* And as argued above, without the Mectizan Donation Programme and APOC, there would have been no Ugandan National Onchocerciasis Control Programme;
- the *perceived* stimulus to pharmaceutical company R&D for some of these neglected diseases. In spite of wider concerns about a 10/90 disequilibrium in funding R&D for drugs for diseases of developing and developed countries, interviewees in Uganda expressed the view that now there is the prospect of new, safer and more efficacious drugs, because the companies have been sensitised;
- the perceived increase in pharmaceutical company sensitivity to packaging and formulation. For example, the leprosy programme manager feels that Novartis' introduction of a calendar blister pack with easy to swallow capsules for leprosy has demonstrably enhanced compliance. New packaging of 6 packs in one box facilitates the planned integration of the programme into primary health care through the use of the Accompanied MDT approach. Similarly Mectizan® has changed from 6mg to 3mg tablets to avoid breaking 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.

Outstanding Challenges

Some challenges remain:

- for most programmes, operational costs are insufficiently funded. This may prove a constraint in particular to the planned rapid roll-out of the national programme to eliminate lymphatic filariasis. This was not, however, seen by interviewees as the responsibility of the pharmaceutical companies;
- two of the drug donation programmes currently have time limitations. For sleeping sickness, until 2006, and for leprosy in 2005 (the global programme target date for validation of the elimination of leprosy), though the fifth meeting of the WHO Technical Advisory Group on Leprosy has recommended that WHO should continue to supply MDT drugs free of charge during the maintenance phase. Support from Novartis seems likely to continue. Equally the five year time limit for APOC (non-drug) support raises a sustainability issue for the onchocerciasis programme, both nationally and in districts. There is an acceptance at central and district levels of the need to be self-sustaining, as evidenced by the

contributions being made to two most developed programmes, for leprosy and onchocerciasis. However, the ability of Uganda to take on the burden of these programmes collectively has to be seen in the context of the shortfall in funding noted in section II – notably, a resource envelope (excluding private spending) of only US$9 per capita compared with the estimated minimum of US$28 per capita required for delivering the Minimum Health Care Package;

- coordination across the individual tropical disease programmes is only now just getting off the ground.

Summary conclusions

This was a rapid, largely qualitative study, relying heavily on semi-structured interviews and with limited scope for detailed examination of the programmes on the ground.

Within those limits, the study found that the drug donation partnerships provide real benefit to the national elimination programmes, a point made repeatedly by interviewees in Uganda. The study team found no evidence of any skewing of national or district priorities, nor a consequent unhelpful diversion of human and financial resources at central, district or community levels.

The major, widely appreciated benefit is the assurance of a sustained and consistent supply of high-quality drugs with no unreasonable conditionalities. In most, though not all cases, the national programmes have been kick-started or revitalised by the drug donations plus the broader WHO-led partnerships – without forfeiting government ownership or priorities. During the recent Mid-term Review, SWAp partners called for increased attention to these elimination programmes.

Three of the four programmes are providing coverage to endemic areas nation-wide, subject to security problems; the fourth was launched only in 2002. Significant health impact has been achieved, particularly by the more mature programmes (leprosy and onchocerciasis), and the assumption is that the poor in particular have benefited because of the nature and distribution of the diseases and the fact that the drugs are free and unlimited.

Interviewees highlighted some tangential benefits of having pharmaceutical companies specifically as partners, notably a willingness to invest in packaging and formulations more appropriate to local health system needs and (rightly or wrongly) a *perceived* greater interest in research for neglected diseases like sleeping sickness. The Mectizan® Donation Programme apart, whose approach was seen as supportive, programme managers have dealt with primarily with WHO and have had little, if any, interaction with pharmaceutical companies direct.

The main concern is about resources for operations. Historically, effective - generally locality-based - control programmes have foundered after the end of project support. The onchocerciasis and leprosy programmes are making encouraging moves towards sustainability of operational funding, though the more recently-launched lymphatic filariasis programme currently lacks firm commitments. Assured drug supplies and support for operations will be critical in the maintenance, as well as the intensive, phase of these elimination programmes.

There are other issues for further development, notably the desirability of better coordination across these programmes and greater integration within the district health systems. However, the study found no evidence to suggest that these issues were affected by the involvement of a pharmaceutical donor as compared with any other donor. Indeed, several of the global PPPs of which they are part positively encourage integration. Comparison with the Schistosomiasis Control Initiative, which provides funding rather than drugs, suggests few substantive differences beyond the practical requirement of its using the National Medical Stores to procure the drugs.

IV: DRUG ACCESS PPPS IN UGANDA FOR HIV/AIDS

Scope of the study

Global public private partnerships for enhancing access to medicines for treating HIV/AIDS and associated opportunistic infections have burgeoned in the last five years. They have been stimulated by growing international concern over the lack of access of people living with HIV/AIDS in the South to life-prolonging but expensive drugs. While there are similarities between these HIV/AIDS programmes and those for tropical diseases addressed in the previous section, there are two key differences. First, both the drugs and the programmes are relatively new – anti-retrovirals were discovered only in the early 1990s and triple therapy in 1996 – and programmes to enhance access to them in resource poor settings only started in 1997. Second, they involve price reductions or donations of drugs which remain under patent and continue to have a high value in the North. Both these factors had significant impact on the way the programmes interacted with the health system in Uganda.

Our study of HIV/AIDS programmes was initially informed by a similar set of concerns around issues of ownership, integration, coordination, implementation and impact as was the study of tropical disease programmes. In the study, three partnerships were examined in detail: the Drug Access Initiative of UNAIDS in partnership with five pharmaceutical companies; Boehringer Ingelheim's Viramune® Donation Programme; and Pfizer's Diflucan® Partnership Programme. They are presented below separately, rather than comparatively as for the tropical disease programmes, since their objectives, scope and establishment vary substantially. In addition, a set of issues requiring further research is identified.

Methods

For these three programmes, in addition to the tropical disease programme related activities (some of which overlapped), the team:

- analysed global, national and district HIV/AIDS programme strategies, plans and reports;
- within the Ministry of Health, interviewed the AIDS Programme Manager as well as officials responsible for treatment, and prevention of mother-to-child transmission (PMTCT);
- interviewed a range of partners and stakeholders, including multilateral and bilateral agencies, and NGOs, with interests in HIV/AIDS treatment policy (see Annex 3); and
- visited district level operations for each programme in Kampala and Masaka districts; in addition in the tropical disease districts, where there were HIV/AIDS treatment services, these were assessed.

Background to the programmes in Uganda

Details of the establishment and activities of the programmes at global level and in Uganda are given in:

Annex 9: HIV/AIDS Drug Access Initiative and Accelerated Access Initiative
Annex 10: Viramune® Donation Programme
Annex 11: Diflucan® Partnership Programme.

Table 4 below summarises the establishment of the programmes in Uganda, including the date of programme initiation, the objectives, the scope and timescale and the approach to drug procurement, handling and storage.

Table 4: Establishment of HIV/AIDS PPP Programmes in Uganda

Programme	Date of programme initiation	Objectives	Scope and timescale	Drug procurement, handling and storage
UNAIDS DAI/AAI	DAI was a pilot project from 1997 to 2001, and then went through transition to expansion phase which continues today.	To increase access to ARVs in Uganda through reduced prices and capacity development	Initially in five hospitals in Kampala; now scaling up nationwide –23 accredited as of November 2002.	Currently branded drugs only: delivered and procured through Medical Access and stored at the Joint Medical Stores.
Viramune®	Initial offer made 2000; programme commenced in 2001 in Uganda	To provide Viramune® free for preventing mother-to-child transmission of HIV.	National programme within the public sector and NGOs. Limited to five years. No information on number of centres with drug available or doses delivered.	Drugs delivered through Surgipharm to Medical Access at the Joint Medical Stores and then to the PMTCT manager in the MOH NACP; Abbott tests handled by UNICEF.
Diflucan®	Pfizer commenced donation in Uganda in 2002.	To provide Diflucan® free for the treatment of cryptococcal meningitis and oesophageal candidiasis for public sector patients.	National programme within the public sector and NGOs for unlimited time and cost. No information on number of centres with drug available or doses delivered	Drugs stored and distributed to districts by National Medical Stores, with routine district supplies.

Drug Access Initiative (DAI) / Accelerated Access Initiative (AAI)

Ownership and programme rationale in Uganda

The Drug Access Initiative (DAI) in Uganda was launched as a pilot study of the international partnership with full cooperation from the Ugandan government in 1997 and became operational in 1998. The programme goals were: (i) to establish a system for preferential pricing in a developing country; and (ii) to see whether it was possible to deliver ARVs in a resource-poor setting. In interviews, all respondents reported that the Ugandan government had already decided to provide ARVs on a limited scale and was receiving small quantities through research projects.

The DAI pilot project finished in 2001 and, while the Accelerated Access Initiative (AAI) was established to extend the initiative to other countries, in Uganda a transition phase transferred the activities of the joint MOH/UNAIDS project manager to an official in the MOH National AIDS Control Programme (NACP). Since then, the involvement of Uganda in the AAI has been negligible – they continue to rely on some of the systems (especially drug procurement) established under the DAI but no longer have any direct relationship with UNAIDS in this area.

Until recently, there was little evidence that senior management at the MOH was prioritising expanded access to ARVs, given their severe resource constraints. Until 2001, HIV/AIDS programmes were addressed in the National Operational Plan of the AIDS Control Programme of the MOH which did not include ARVs. HIV/AIDS policy is now driven by the National Strategic Framework for HIV/AIDS developed under the auspices of the Uganda AIDS Commission. The framework recognises the benefits of ARVs in the context of a comprehensive package of care and treatment for people living with HIV/AIDS, although it makes no commitment actually to provide ARVs. This will change with funds from the existing World Bank MAP project and subsequently the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Treatment using these resources will be phased in, starting with PMTCT plus (treating new mothers as well as preventing transmission to their babies).

Governance
The DAI in Uganda was overseen by a National Advisory Board, chaired by the army Chief Medical Officer with Dr Mugyenyi, Director of the Joint Clinical Research Centre (JCRC)[12], as secretary. The Board was mandated to develop the government's HIV-related drug policy, estimate needs for drugs, develop rational prescribing, distribution and use guidelines and recommend minimum requirements for accreditation of health centres.

Implementation
To implement these objectives, under the National Advisory Board there were three standing committees for policy and financing, care and practice, and vertical transmission. They also determined criteria for patient participation, made recommendations on how to scale up the programme and started to regulate private sector ART. These committees were strongly influenced by staff from the JCRC, who had the most experience with ARV delivery. After the DAI project finished, the MOH took full responsibility for developing national guidelines and facility accreditation but progress has been quite slow.

At the same time, the pharmaceutical companies involved at international level established a not for profit company – Medical Access Uganda Ltd (MAUL) – to manage drug purchases in partnership with the National Advisory Board. While Medical Access procured and distributed drugs from participating multinational pharmaceutical companies at subsidised costs, the Joint Medical Stores was responsible for storing the drugs. The Director of Medical Access liaised with the MOH on demand for products and then negotiated orders for products from the pharmaceutical companies. He would also arrange supply and distribution of products directly to participating treatment centres.

Integration of HIV/AIDS PPPs with the health system: policy and planning stage
A coordinator and a communication specialist were appointed jointly by UNAIDS and the MOH to establish and implement treatment under the new programme but their activities were largely outside the Ministry. After the DAI, responsibility for this work was transferred into the MOH offices, while technical assistance on HIV care passed from UNAIDS to WHO. According to a Ministry of Health/WHO rapid assessment conducted in November 2002, 22 facilities had been accredited and one other was providing services. Of the 23, 18 were fully operational; 13 were in Kampala and the remaining 10 in regional centres. A number of private physicians also provide ARVs independently.

The MOH is currently in the process of publishing a new ARV treatment policy for Uganda (draft in April 2003).

Service delivery stage
Table 5 compares elements of the integration of service delivery across the three HIV/AIDS programmes, including accreditation criteria and process, training, drug distribution and management information and monitoring.

The DAI helped to establish an institutional framework for delivering ARVs and also achieved its goal of reduced prices for ARVs. It was launched in five centres - one semi-private research institution, three private not-for-profit and only one public sector health facility (Mulago Teaching Hospital). The US CDC assisted with prescription and dispensing records, developed monitoring systems and laboratories, and research facilities also improved greatly.

[12] The JCRC (Joint Clinical Research Centre) was established by the Ministry of Defence, Ministry of Health and Ministry of Education (Makerere University) in the mid 1990s as a specialist HIV/AIDS treatment centre in Kampala. It treats a range of patients not just military and is the largest single provider of ART in Uganda to date. It also procures, imports and dispenses generic ARV drugs.

Drugs were reported to be rarely out of stock and usually as a result of funding gaps rather than distribution problems. After the DAI, debate over the most efficient mechanisms for drug procurement, handling and distribution revolved around the need to guarantee low prices and avoid creating monopolies. Nevertheless, the government acknowledged its weak capacity for managing such complex supply systems and Medical Access continues to be the main source for branded ARVs.

Table 5: Service delivery issues of HIV/AIDS PPP programmes in Uganda

Programme	Accreditation criteria and process	Training	Drug distribution	Management information and monitoring
UNAIDS DAI/AAI	Adequate clinical expertise, access to laboratory facilities, psychosocial support and counselling facilities, and good drug management procedures.	Comprehensive quality care for PLWHA, including treatment of opportunistic infections as well as ART. Attempts were made to integrate training for ARV delivery with existing AIDS programme training under the NACP.	Established entirely outside government systems using sophisticated drug management software developed by Medical Access for use at the JMS, in pharmacies and at all referral centres. Drugs can be redistributed between treatment centres. Appropriate storage and delivery of drugs is monitored.	Separate management information system in participating facilities. The data collection form contains a unique patient identifier as well as a range of socio-demographic and clinical information.
Viramune®	Phased implementation according to magnitude of HIV problem, human resources and physical infrastructure, geographical equity, and presence of NGO partners.	All conducted by the NACP for health centres and NGOs.	Handled entirely separately – facilities must go directly to the national programme manager to obtain supplies, bypassing both the NMS and the districts.	Separate from the HMIS in order to meet the requirements of both the international donation programme and the MOH programme manager.
Diflucan®	Phased implementation to cover 5 Kampala City hospitals, 10 regional hospitals and 5 TASO treatment centres, followed by all remaining district and NGO hospitals, followed by all health centre IVs.	Pfizer has assisted the government with training courses and materials for diagnosis and treatment of opportunistic fungal infections for clinicians and other health professionals.	Drug supplies are fully integrated into the NMS and district system. But there have been problems of leakage.	The contract with Pfizer specifies patient tracking information along with drug utilisation and reporting, supervision and destruction guidelines for expired product.

According to a review of the DAI published in September 2001, providers reported finding the management information form onerous (MOH/UNAIDS/WHO 2001) although for the purposes of programme monitoring more information than is routinely available in the HMIS is necessary. Nevertheless, the review also found that data were rarely analysed because of limited capacity or computers.

At the end of the DAI, according to the review, problems persisted in the following areas: lack of coordination between staff in hospitals about the availability and price of ARVs; poor communication between ARV delivery sites and peripheral health centres; and reliance on private hospital wings for ART (MOH/UNAIDS/WHO 2001). Furthermore, there were delays in the implementation of a more comprehensive package of care for PLWHA, including treatment of opportunistic infections. This has to some extent been ameliorated since the advent of the Diflucan® Partnership Programme.

Another criticism has been the failure of the project to engage with the private sector in its provision of ARVs. ARVs are available in the market in Uganda through a range of sources and it is known that various private medical providers are offering such services. Until the recent draft ARV policy which will cover all facilities providing services, there had been no serious attempt to regulate or even monitor this sector in order to maximise proper use of the drugs and develop consensus on treatment practices.

Impact on health and the health system
Only limited data are available on health impact of the drug access initiative through a review conducted by the CDC in late 2000 (MOH/UNAIDS/CDC 2000). No evaluation of subsequent ARV programmes has been published and in the scale up phase since 2001, only limited monitoring information has been collected so that currently there are few data on the status of ARV provision in Uganda.

Prior to the DAI, fewer than 400 patients had accessed ARVs, the majority through the JCRC. During the course of the project, this number expanded to 912, of which just under half were receiving care at the JCRC and the rest at Nsambya, Mildmay, Mulago and Mengo hospitals, all in the Kampala area. By the time of the evaluation, 1,700 patients had received treatment at seven sites. All patients paid for their drugs, either themselves or through their company or other sources. The majority were relatively wealthy, urban and well educated, and just under half were women. A small number of children was also treated. After the DAI, the number of people accessing ARVs expanded more rapidly to around 10,000, although by November 2002, it was estimated that this represented less than 1% of those living with HIV/AIDS or 3% of those potentially in need (meeting criteria for treatment) (MOH/WHO 2002). Further details on these patients can be found in Annex 9.

The health system impact of the early DAI was limited since so few facilities were providing ART. During the later phase, as operations were scaled up, a range of activities took place including clinical training and capacity building, development of laboratory facilities and the implementation of improved record keeping systems. In addition, an accreditation scheme was introduced for facilities although, according to the review in 2001, uptake was slow and awareness among physicians even in accredited facilities of the availability of cheaper drugs was low (MOH/UNAIDS/WHO 2001). Key problems identified in the 2001 review included clarifying the role of peripheral health centres in referring and monitoring ARV eligible patients and funding for laboratory tests (which the CDC had provided during the DAI).

The study also undertook a case study of current ARV activities at the Masaka Healthcare Centre located within the Masaka Regional Hospital in the Masaka District which has the highest HIV prevalence in Uganda among the adult population over 15 years old. The Masaka Healthcare Centre is funded and operated by UGANDA CARES, a partnership of the MOH, the Uganda Business Coalition on HIV/AIDS, and the AIDS Healthcare Foundation/ Global Immunity, working with the Masaka District Council and local partners (see case study below). The explicit objective of the UGANDA CARES initiative is to provide ARVs to the socio-economically disadvantaged, and the centre is one of very few in Uganda to provide ARVs free. It is in its early days and is providing a demonstrable benefit to PLWHA, although numbers are still very small. Of the 100 patients on ARVs in February 2003, 51 of 80 adults being treated were female, while 5 of 20 children were female. Demand is rising rapidly as people learn of the programme and, despite formally agreed eligibility criteria, the centre is facing potentially problematic issues of how to select those patients to receive treatment.

Sustainability and equity
The system introduced under the DAI was sustainable but highly inequitable – it acted simply as a mechanism for securing preferential prices which were then available for those who could afford them. However, since the national average per capita income is only US$26 per month, the prices of even the cheapest ARVs are beyond the vast majority of Ugandans. The DAI did make some effort to expand access to the programme through community based information campaigns led by a communication consultant – and these are seen as having been successful in sensitising the community - but at the same time they may simply have raised expectations about drug availability which were subsequently dashed by the ongoing high prices. Access to ART in Uganda at even the prices now available will not be affordable to the government for the foreseeable future and is therefore dependent either on out-of-pocket payments, for which there is a tiny but slowly growing market in Uganda, or donor funds.

External funds for ARVs have been available through the World Bank's MAP project for a short time and more have been allocated through the Global Fund to Fight AIDS, Tuberculosis and Malaria, although few of the resources in the first round have been allocated to ARVs. Expansion of access to ARVs under these donor projects, while more equitable, raises more questions about sustainability than previously under the DAI.

Case Study: UGANDA CARES MASAKA HIV/AIDS HEALTHCARE CENTRE

UGANDA CARES Initiative

The Masaka Healthcare Centre for HIV/AIDS at the Masaka Regional Hospital is funded and operated by UGANDA CARES - a partnership of the MOH, the Uganda Business Coalition on HIV/AIDS, and the AIDS Heathcare Foundation/ Global Immunity, working with the Masaka District Council and local partners. The Centre was accredited and opened in February 2002, providing free ARVs. The total annual cost per patient is US$800.

At present, it uses only branded drugs, purchased mainly from Medical Access. The Medical Director regards discounted drug prices as having been essential to the Centre's viability. Consideration is now being given to purchasing generics.

Objectives

1. provide standard ARV treatment to socio-economically disadvantaged people living with advanced AIDS
2. demonstrate that ARVs can be delivered effectively in resource-constrained settings in the developing world
3. identify determinants for treatment success and the quality and cost-effectiveness of using ARVs
4. develop a replicable and scalable model of HIV/AIDS clinical care appropriate to the safe and effective provision of ARVs in resource-constrained settings.

Patient Eligibility for Treatment and Care

- *resident in Masaka district*
- *ambulatory*
- *coming from a stable social network/family*
- *ARV treatment naïve*
- *adults: CD4+ count of 200 cells/mm^3 or less*
- *children: CD4+ count of 25% of normal range per age or less*
- *children to have caretakers able to take responsibility for, consent to and supervise their treatment*
- *no active major opportunistic infection*
- *must be referred through TASO Masaka, Kitovu Mobile Homecare Service, Masaka Hospital VCT Unit or AIDChild orphanage*
- *a known address/location for follow-up*
- *must consent to treatment and comply with treatment and follow-up procedures*

CURRENT ACTIVITIES

The Centre provides:

- free standard triple combination ART
- treatment of opportunistic infections and prophylaxis against *pneumocystis carinii* pneumonia (PCP) and toxoplasmosis until CD4+ count exceeds 200 cells/mm^3
- baseline and ongoing lab testing/monitoring
- treatment education and counselling
- patient follow-up and support services provided by TASO Masaka and Kitovu Mobile Homecare Services.

The Centre operates an outpatient clinic two days per week. Patients who require hopsitalisation are admitted to the Masaka Regional or Kitovu Hospitals.

At February 2003, 100 patients were on ARVs:

- 80 adults (51 female, 29 male)
- 20 children (5 female, 15 male).

Patients are invited to make a voluntary monthly contribution of 2,000 Ug sh (currently about US$1).

Patient Monitoring and Follow-up

Patients are monitored weekly for the first 4 weeks, fortnightly for the next 4 weeks, then monthly if clinically stable and responding to the regimen.

Monitoring and Follow-up Parameters

Clinical	- body weight - patient activity - general condition
Immunological	- CD4+ count
Adherence	- clinic attendance - prescription refills - supervision - missed dosages

Response to Treatment

- *av. CD4+ count increase of 259 cells/mm^3, from 51 to 310, after 1 year of treatment*
- *av weight gain of 11.3 kg, from 45.3 to 56.6 kg, for 76 patients treated longer than 6 months*
- *improvement in activity status: av. Karnofsky Performance score rose from 75 to 95 after 4 months treatment*
- *resolution of opportunistic infections, except Kaposi's sarcoma, in most patients after 6 weeks treatment*
- *av time to cessation of PCP and toxoplasmosis prophylaxis of 5 months*
- *11 patients died*
- *adherence rate exceeds 95%*

Current Challenges

- **excess demand: the VCT Unit has registered a 17-fold increase in clients over the first year**
- **accessing resources to fund scaling up and opening similar centres in other districts**

Source: UGANDA CARES 1st Year Progress Report; interview with Dr Bernard Okongo, Medical Director, Masaka Healthcare Centre

Viramune® Donation Programme

Ownership and programme rationale in Uganda
The Viramune® Donation Programme was initially owned by Boehringer Ingelheim as a global drug donation programme. Uganda's early participation was expected since Mulago Hospital has been the site of the clinical trial which established Nevirapine as an effective preventive measure against mother-to-child transmission of HIV[13]. Furthermore, previous activities in PMTCT existed in partnership with UNAIDS and UNICEF and a range of other organisations[14]. In 2002, Abbott announced the donation of its Determine HIV tests, opening up the possibility of expanding HIV voluntary testing and counselling significantly. The government has now stated clearly a policy intention of PMTCT which is in line with the National Health Policy and is part of the minimum national health care package.

Governance
The PMTCT programme was originally established in partnership with UNICEF with the goal of reducing infant mortality in Uganda through the implementation of a comprehensive package to reduce transmission of HIV from mothers to their babies. The Viramune® Donation Programme is coordinated from within the MOH, as part of its PMTCT programme within the NACP and in accordance with an implementation plan for the period 2001-05. The programme is under the direction of a national technical committee which meets monthly.

Implementation
An implementation plan was developed in response to the donation and has been phased in across the country, depending on capacity and the existence of other partners (NGOs) which can support programmes. The new programme was initiated in 2001 and by December 2002, 22 out of 56 districts were implementing PMTCT services. In addition to Viramune® distribution, the programme covers voluntary counselling and testing, community support and sensitisation, comprehensive care for pregnant mothers and a monitoring system.

Integration of HIV/AIDS PPPs with the health system: policy and planning stage
The planning stage is handled entirely within the MOH NACP and includes the dissemination of policy guidelines on treatment and infant feeding, publication of training manuals, and development or coordination and supervision mechanisms for PMTCT activities.

Service delivery stage
The programme is currently strongly vertical (see Table 5). There are no immediate plans to integrate drug management into the National Medical System (NMS) system, although this was felt by several interviewees to be preferable. The rationale for this is that, to date, small numbers of drugs are being used and, given their high market value, security issues and lack of confidence in the ability of the NMS to prevent leakage have prevented integration. In addition, the programme needs to be able to monitor the use of the drugs and NMS is unable to provide this level of detail. As noted earlier, the NMS are also in the course of a major operational change management programme which suggests that now is not an opportune moment to take on additional challenges.

The MOH plans to integrate the Viramune® programme with existing service delivery systems at facility level. To undertake this, many facilities will need to be upgraded and the programme is still very much under development.

[13] One dose to the mother at the onset of labour and one dose to the baby within 72 hours reduces HIV transmission by 50% compared to a short course of Zidovudine.
[14] Under this 2 year pilot project from 1999, 1,000 women were to receive Zidovudine for PMTCT using the institutional framework of the DAI and obtaining drugs free from GlaxoSmithKline through that programme. UNICEF procured test kits and infant formula in parallel. However, initially, even in Uganda there was little response because of the enormous difficulties of implementing sufficient testing, counselling, post-natal care.

Impact on health and the health system
Very little evidence exists on the impact of the Viramune® Donation Programme which has not yet had any formal evaluation. On the one hand, there are many clear indications that the drug is extremely useful and necessary, and that it is much simpler to administer than the alternative longer AZT (Zidovudine) regimen. Furthermore, the programme is credited with stimulating local partnerships and strengthening voluntary counselling and testing systems. On the other hand, anecdotal reports suggest that the programme has been slow to scale up and has not met expectations in numbers of people accessing the new drugs. In particular, costs associated with distributing free drugs can be higher than anticipated, and the lack of human resources and the space for counselling have proved major constraints.

Sustainability and equity
For the Viramune® Donation Programme, sustainability is an issue since the donation is for a limited five year period only (as for the Abbott test kits) and the costs of distribution of the drug must be met from some source. Nevertheless, respondents generally felt that the advantages of even temporary access to drugs far outweighed any longer term disadvantage of weak sustainability. The government has made no commitment to date to long term funding for PMTCT although it appears in the National Health Plan and some of the gaps may be filled using GFATM money.

Diflucan® Partnership Programme

Ownership and programme rationale in Uganda
The Diflucan® Partnership Programme developed internationally out of negotiations between Pfizer and the government of South Africa. The programme in Uganda was initiated in 2002 after an offer of free Diflucan® from Pfizer. Nonetheless, the government and service providers interviewed all welcome the drug and clearly feel ownership in terms of their clinical needs. The Diflucan® Partnership Programme was received extremely positively by service providers: '*one of the best things that has ever happened to us*'. Diflucan® use for opportunistic infections fits with government HIV/AIDS comprehensive care policy.

Governance
Unlike other HIV/AIDS programmes, the Diflucan® Partnership Programme was established in Uganda through a memorandum of understanding directly between Pfizer and the MOH. HAI, an NGO, reported that initial negotiations between the government and Pfizer over the contract were difficult because of the stringent conditions which Pfizer required for drug management and control systems.

Implementation
The donation programme is managed by the MOH NACP while drugs are supplied by Axios International (which manages the international partnership) to the NMS and from there into the district distribution system. Axios International also manages the application and monitoring processes on behalf of Pfizer. KPMG has been engaged to audit the programme by Pfizer in consultation with the government.

Integration of HIV/AIDS PPPs with the health system: policy and planning stage
The Diflucan® Partnership Programme is in a very early stage and is fairly well integrated with government systems, although it has experienced some teething problems.

Service delivery stage
See Table 5 for a summary of the integration of service delivery under this programme. According to a preliminary evaluation for which a draft summary of findings was available in March 2003, there was a number of initial problems. A confusing variety of treatment guidelines from a range of sources are available. Training programmes have also emphasised clinical aspects over drug management issues and have, to date, covered only 25% of current Diflucan® sites.

Drug supplies are fully integrated into the NMS and district system and volumes remain small to date so at the moment the system is manageable. However, at facilities covered in the evaluation as well as in our interviews, there was considerable confusion over how to requisition the drug as well as over the requirements for parallel registers and other prescribing/dispensing documentation. Some of the confusion may be the after-effects of an early diversion of drugs from the system which led to the introduction of highly restrictive security measures, including a requirement for the Director General personally to sign all requisitions for donated Diflucan®. Other confusion at facility level arose over how to handle and prescribe fluconazole from different donation programmes, including through an earlier World Bank STI project.

Impact on health and health system
The evaluation of the Diflucan® programme was too early to cover its impact on health. Its impact on the health system is harder to judge. Some respondents[15] were concerned about the hidden costs of dealing with donated drugs: although very difficult to measure, these might in reality be higher than the cost of purchasing generic fluconazole on the open market. It did not prove possible to resolve this within the timescale of the study.

[15] HAI, Danida technical assistant in the pharmacy department, and JCRC

Sustainability and equity
The Diflucan® programme was considered by all interviewees to be equitable and highly effective at making available a necessary drug for all. Sustainability is not an issue since the drug is to be donated free for unlimited time.

Complex unresolved issues

It became clear during the course of this brief project that there were a number of areas where further, more in depth consideration of the impact of HIV/AIDS global programmes on health and the health system was necessary. These related to:

- their novelty and the interests of multinational pharmaceutical companies in their outcomes;
- the complexities of pharmaceutical pricing and procurement in such new markets;
- adequately securing distribution of high value commodities to avoid re-export to Northern markets; and
- the lack of clear objectives around equity, selectivity of patients and human rights.

Interests of multinational pharmaceutical companies in enhancing access to HIV/AIDS care
The prices of branded drugs fell dramatically in Uganda under the DAI and subsequently, reflecting the commitment of multinational pharmaceutical companies and the preferential prices they made available. However, important questions remain over the way the DAI programme was operationalised and what its subsequent effects have been. Medical Access was established by the pharmaceutical industry but as a Ugandan NGO, which allowed the companies not to deal directly with the government and, at least initially, to maintain confidentiality on costs and prices offered. What have been the advantages and disadvantages of such a separate agency, since existing private pharmacies clearly can and do import ARVs (and Diflucan®) at prices nearly as low (10-15% higher) as those obtained by Medical Access[16]? To what extent was it acting in the interests of the government and people of Uganda or of the pharmaceutical industry? If it was independent (as it claims), why did Medical Access not access generic as well as branded drugs as soon as they became available[17]?

These questions are linked to the legislative and political environment in Uganda, which have been unclear in this area. For example, generic ARVs were introduced by the JCRC with only a provisional import license from the National Drugs Authority but without proper legal arrangements. Currently, the JCRC rather than Medical Access remains the largest importer of ARVs, mostly generics. While HIV/AIDS has been declared a 'national emergency' (so compulsory licenses can be issued according to World Trade Organisation rules), no information was readily available at the MOH on what patents there were in Uganda[18] and no licenses had actually been issued. To date there is no evidence that any legal action has been taken to ensure patent laws are respected in the import or production or ARVs.

Uganda is also in the process of ratifying a new intellectual property bill, despite being exempt from WTO intellectual property agreements until 2016 as a very poor country. HAI conducted an analysis of the intellectual property policy and concluded that this bill is partially a response to US government pressure to meet conditions to expand their trade relationship[19].

Procurement and pricing issues
Throughout the DAI, drug prices were negotiated by UNAIDS in Geneva with participation by Medical Access, the Uganda MOH and the JCRC after they started to import generic drugs in November 2000.

[16] One respondent cited figures 10-15% higher than those available from Medical Access.
[17] According to their interview, they are now planning to procure generic ARVs.
[18] In March 2001, patent rights had been provided in Uganda for Zidovudine, Lamividine and Combivir.
[19] Under the African Growth and Opportunity Act (AGOA), countries which would like access to a programme of reduced tariffs on agricultural and textile exports to the US must comply with a range of conditionalities, including the introduction of TRIPs-compliant measures.

Prices fluctuated considerably due to political shifts at international level but also because of the depreciation of the Uganda shilling against major foreign currencies (Table 6). This inhibited the involvement of many Ugandan service delivery institutions which do not have the financial security to take on price fluctuation risks. It also created stock problems resulting from rapid shifts in demand in response to price changes.

Table 6: 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.

In addition, 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%.

In the post-DAI period, drug prices have continued to be set largely according to local market conditions. Those branded drugs where there is also a generic version are much cheaper than those where generics are not available, both through Medical Access and in the private sector (Table 7 shows the overlap of branded and generic ARVs). As a result, for regimens involving branded drugs, prices can vary substantially – in March 2001, prices for one month of treatment ranged from USh155,500 (d4T/ddI/Nevirapine) to USh872,000 (Combivir/Nelfinavir). Generic medicines are much cheaper. Triomune, a generic drug produced by Cipla in India, is a single tablet containing a triple therapy regimen and is by far the cheapest treatment option – it has become the de facto first line regimen. By November 2002, the cost of one month of Triomune ranged from USh55,000-75,000 and for Combivir/Efavirenz from USh163,000-255,000[20].

Understanding of the economic complexities of these markets – what drives supply and demand and how to maintain stocks of drugs in rapidly fluctuating price conditions for patients with a chronic disease lasting many years – is weak. There is no obvious parallel in other areas of health care in poor countries, where such high value commodities are available to different people through different mechanisms at different prices. Yet the picture is set to increase in complexity with the arrival of major new funding sources.

At the time of the study fieldwork, there was a sense of Uganda being on the brink of a major shift towards generics, currently imported mainly by the JCRC. Medical Access, the Mildmay Centre, the Masaka Healthcare Centre and a private supplier all reported giving active consideration to importing generics in addition to the Ministry of Health's developing plans for purchasing generics with GFATM funds.

[20] In November 2002, there were approximately USh1800 to US$1.

Table 7: Brand and generic ARVs available in Uganda

Brand ARVs (total 18)	Generic ARVs (total 9)
Retrovir® (Zidovudine, AZT)	Zidovudine
Epivir® (Lamivudine, 3TC)	Lamivudine
Stocrin® (Efavirenz, EFV)	Efavirenz
Videx® (Didanosine, ddI)	Didanosine
Viramune® (Nevirapine, NVP)	Nevirapine
Zerit® (Stavudine, d4T)	Stavudine
Combivir® (3TC+AZT, CMB)	Duovir (3TC+AZT)
Crixivan® (Indinavir)	Indinavir
Fortovase® (Saquinavir soft gel)	Triomune (d4T+3TC+NVP)
Invirase® (Saquinavir hard gel)	
Norvir® (Ritonavir)	
Viracept® (Nelfinavir)	
Ziagen® (Abacavir)	
Kaletra® (Lopinavir/Ritonavir)	
Trizivir® (Combivir + Ziagen)	
Hivid® (ddc)	
Rescriptor® (Delarvidine)	
Hydrea® (Hydroxyurea)	

Source: Draft Report on Rapid Assessment of Access to ART in Uganda. 2002, MOH/WHO

Drug security and distribution systems

For the HIV/AIDS programmes with their high value commodities, one of the burning issues for pharmaceutical companies and drug distribution systems is how to procure, import, handle, store and distribute the drugs cheaply, effectively and securely. The variety of sources for branded and generic medicines at different prices creates incentives for serious leakages both within Uganda and across its borders, as well as for re-export to rich countries. Several scandals have beset the NMS and other elements of the drug distribution system[21]. In our interviews, such criticism of the programmes as we found focused on the way they create incentives for corruption and pilferage by distorting markets.

There is also confusion among providers and ultimately patients over what they can expect to receive for free, what they must pay for and therefore what treatment they can afford. The government is now reportedly starting to regulate the market but questions remain around how to create disincentives for leakage and arbitrage and who should pay the associated costs of secure and efficient drug management systems when the current system evidently does not have the capacity to address all these problems.

Patient perspectives: equity, selectivity and human rights

Finally, the three HIV/AIDS programmes varied considerably in the degree to which they were equitable. In terms of pure financial affordability, the DAI never aimed to improve equity in access (except at the most global level) and essentially met the ARV needs of a small section of the Ugandan upper and middle classes. The Viramune® and Diflucan® programmes by contrast, by offering free drugs, are potentially highly equitable. However, in addition to price affordability, access to drugs is determined by a host of other factors which have not been the main concern of this study but which are crucial to understand, especially as the programmes are scaled up. Clearly, decisions are taken over who should be allowed to receive drugs but there is no current guideline or regulation of the process, let alone public discussion of who might be the best groups of the population to prioritise. The Masaka case study already demonstrates the difficulties of selecting patients to receive these drugs and this will increasingly become a national issue, given the limited numbers to be treated even with GFATM funds.

[21] The Diflucan® programme was afflicted early on by leakages into the private market, apparently from the districts and health centres. This has led to the DG having personally to sign all requisitions. As noted in section II, at the time of our research the NMS was the subject of MOH and media attention over a contract to supply HIV/AIDS drugs including ARVs to a private Ugandan pharmaceutical company for them to sell on. The deal was aborted after MOH intervention.

Conclusions and key findings on the HIV/AIDS programmes

- The Drug Access Initiative and its successor, the Accelerated Access Initiative, worked well within their limits. The DAI itself was a pilot project – it was not integrated and should not have been. Despite this, it catalysed the training of health workers, accreditation of facilities and development of secure drug distribution systems. In addition, it did achieve reduced prices of branded medicines from multi-national pharmaceutical companies.
- However, critics point to inequity in access because the reduced prices they achieved were still too high. As a result, it raised expectations about drug access which it was unable to meet. Furthermore, the later, more substantial price reductions in autumn 2000 may have been attributable more to the entry of generic drugs into the Ugandan market courtesy of the JCRC than to any efforts under these initiatives.
- The DAI had a significant impact on the policy environment – it highlighted what could be achieved as well as the limitations. However, to date MOH officials have not engaged in regulating pharmaceutical markets or developing an appropriate intellectual property regime.
- The key finding on the Viramune® Donation Programme is that it has enhanced the availability of a drug which is much needed for PMTCT and thereby stimulated the development of PMTCT programmes. The initiative has been welcomed by policy makers and providers and the involvement of the pharmaceutical company is minimal. It has also stimulated local partnerships with NGOs, other pharmaceutical companies, and UNICEF.
- Criticisms suggested that it should be scaled up more rapidly through focused attention to human resources, space for counselling, and district coordination of associated activities. The drug is free but the programme to use it requires infrastructure and a wide range of services. There is potential to integrate the programme better with existing drug distribution systems, provided their security measures improve.
- As for Viramune®, Diflucan® is much appreciated by those in the front line – and in particular has no viable alternative for treating two life-threatening and common opportunistic infections. The programme specifically targets the poor and is available only through public sector facilities. It assures unlimited supplies of a quality branded medicine for an unlimited time.
- While Diflucan® distribution is already integrated into the NMS/district system, security problems have created confusion and delayed regular access to the drug.
- As noted earlier, the study's time constraints precluded quantified live data gathering to elucidate in more detail the issue of the 'hidden' operational costs associated with drug access programmes, eg in relation to the reporting load. This is clearly more of an issue for HIV/AIDS drugs, given the tight tracking and reporting regimes, and deserves further examination – though even here, service provider interviewees with one exception took the view that the requirements were not unreasonable.
- In addition to these findings on the programmes, the study has posed a range of important questions. Of particular importance is further investigation of the role of pharmaceutical companies in the market for ARVs and other high value AIDS related drugs, pricing and procurement issues, security of drug management, and equity in access to treatment and care.

V: PILOT TESTING THE STUDY PROTOCOL AND TOOLS FOR FUTURE STUDIES

Study objective

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 a larger study or studies.

The Uganda pilot study

The broad approach to the pilot study was set out in the IPPPH study proposal to DFID, considered by a technical consultation meeting on 10 January 2003 and refined in the final study outline (Annex 1) prepared by the study team leader in consultation with team members and approved by Roy Widdus, Project Manager, IPPPH.

The study was overseen by a Study Advisory Committee:

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

Fieldwork for the pilot study was undertaken in Uganda from 5-23 May 2003 by a team of two national consultants and three international consultants:

- Karen Caines (study team leader), Institute for Health Sector Development, London
- Julie Bataringaya, Health Consultant, Uganda (from 1 June 2003 employed by WHO)
- 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.

All members of the study team are independent of the Initiative on Public-Private Partnerships for Health and the pharmaceutical industry. Neither of the national consultants has had programmatic or managerial responsibility for any of the programmes examined in the study, which benefited - particularly given the tight timescale - from their detailed knowledge of the health system and key informants.

The 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 in Uganda and the relevant national disease control programmes – see Annex 12 for references;
- the adaptation of an information collection tool (originally developed by Kent Buse[22]) 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;

[22] Data collection tool appended to Buse (forthcoming): *Governing partnership: a comparative analysis of the organizational and managerial arrangements of 18 global public-private health partnerships and a compendium of PPP organizational profiles.* Commissioned by the Initiative on Public-Private Partnerships for Health. Draft February 2003. Geneva : IPPPH.

- semi-structured interviews at national level with a wide range of interests, using team members supplemented by network contacts to identify key informants;
- visits to five districts (Hoima, Kampala, Katakwi, Masaka and Soroti) representing different socio-economic and epidemiological profiles. Each of the programmes being studied was examined in at least one district and some in several districts (eg the provision of ARVs using discounted drugs in Kampala, Masaka and Soroti) – see Annex 2 for details of district selection;
- 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.

In all, the team examined the issues in semi-structured interviews with over 100 interviewees in Kampala and the five districts visited. A list of interviewees is attached at Annex 3.

Both the protocol and the individual tools served the purpose well and, as refined in the light of experience, are suitable for future use.

Future study protocol and tools

This pilot study was undertaken in preparation for a larger study or studies. In line with the terms of reference, **Annex 13** provides a generic protocol for a future study and the following pilot-tested study materials to be tailored to local circumstances:

Appendix 1: minimum data requirements, with possible sources, for the country context, the national disease control policy and the specific PPP programme.
Appendix 2: likely key informants
Appendix 3: a generic introductory letter to key informants
Appendix 4: an interview questionnaire for tropical disease PPPs (national level informants)
Appendix 5: an interview questionnaire for HIV/AIDS PPPs (national level informants)
Appendix 6: an interview questionnaire for use at district/community level
Appendix 7: criteria for assessing the impact of PPP programmes on national health systems
Appendix 8: a framework for recording PPP programme objectives and performance
Appendix 9: a framework for recording PPP programme drug ordering/procurement, storage and distribution arrangements

The study team's recommendation on future studies

The overall lens for the study was to identify "issues ***unique*** to PPPs that include the involvement of pharmaceutical companies at some stage of decision-making and/or implementation" rather than to examine issues of impact *per se* (though this is a line the study team has crossed on occasion in the interest of completeness or usefulness).

Notwithstanding the development of tools for future studies, the study team feels that there are matters for consideration about replicating the study in precisely the same form in another country or countries:

i) for the tropical disease programmes, the findings of this pilot study suggest little reason for concern in Uganda about most of the questions which prompted the study – their alignment with government priorities, impact upon the wider health system, feasibility of going to scale and fit with broader approaches such as the SWAp and poverty reduction strategy. Where there are issues - around integration with the district system, coordination across programmes and sustainability -, they tend not to be unique to drug access PPPs but to be shared with other comparable programmes.

Uganda's comparative strength in terms of policy-making, planning and partnership in the health sector will be reflected in the general tenor of this pilot study's findings. The latter may therefore not be typical of all countries.

The study team recommends that, before an identical study is launched elsewhere, a rapid assessment of potentially eligible countries should be undertaken to indicate whether the findings are likely to be significantly different from those in Uganda in terms of pharmaceutical company involvement or influence at country level. It should be possible to establish this quickly and cheaply. If there is to be another full-fledged study on the Uganda model, the country should be selected carefully as a contrast to Uganda in terms of national organisational capacity and the extent of the role of 'big pharma'. Any such study would also benefit from an extension to examining the role of the WHO-led global partnerships.

ii) by contrast with the tropical disease PPPs, the situation surrounding PPPs for HIV/AIDS drugs - particularly for discounted antiretrovirals - is complex, not yet mature and evolving very rapidly.

As described in Section IV above, there is no shortage of substantive issues which arise as a result of the drug access PPPs and which pose considerable challenges in Uganda. There are important questions about the role of multinational pharmaceutical companies in Southern markets for ARVs and how their interests interact with those of governments and people living with HIV/AIDS. Related to this, the development of complex market situations for drugs which have high value in the North but varied prices in the South is an emerging trend which is likely to get more complex with the arrival of new funding sources. Understanding and designing secure drug distribution systems which prevent leakage and arbitrage is of the highest priority. Furthermore, the impact of ARV programmes on both drug distribution systems and other areas of the health system (crucially human resources) will grow in the next few years as new resources come on stream and will merit far more research attention. Finally, above all, there is little evidence to date on how national programmes are making rational choices about who should obtain drugs and what priorities of access there should be – again these issues will become more complex as drugs are increasingly available free of charge.

The study team therefore recommends that, timed appropriately and well-selected, multi-country studies could prove illuminating in helping to identify approaches to maximise benefits and minimise negative or unintended consequences. These would be best examined in a targeted study or studies designed to pursue specific policy and system issues in more detail.

ANNEXES

ANNEX 1

Impacts of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries

Pilot Study Protocol for Uganda, May 2003

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 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, 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. However, they 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. Other questions concern the feasibility 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 attempt to implement broader approaches such as 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.

Through evaluating national impacts of existing public-private partnerships for drug access in a number of countries, it should ultimately be possible to develop 'best practices' for such initiatives that maximize health benefits for the poor and minimize unintended negative consequences. This will probably require studies across a range of access partnerships and countries.

The pilot study

The UK Department for International Development (DFID) is funding the Initiative on Public-Private Partnerships for Health (IPPPH), part of the Global Forum for Health Research, to conduct 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, Uganda. It will examine issues of ownership, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of access PPPs as distinct from other comparable programmes. The study is to be completed by 30 June 2003.

It is important to recognize that, because of limited funding and a restricted time frame, the study will not be able to examine all such partnerships in Uganda in the depth of detail that would be desirable under ideal circumstances. Key issues for examination should include:

- the respective roles of PPP programme partners, governments and local interests in developing programme proposals, decision-making, conditionalities and governance
- the fit between the programme and national/local priorities and plans or individual needs
- the extent of the PPP programme's integration with national disease programmes and broader health planning, and identification of the specific benefits and challenges, if any, arising from the involvement of the private sector in disease-specific PPPs
- the programme's involvement in, and the effectiveness of, coordinating mechanisms (formal and informal) with other PPPs
- 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
- the impact of 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 inclusion in PPP programme design of a specific objective to strengthen health systems, and the outcome to date.

Objectives

This study can stand alone but is 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 these and similar initiatives.

The specific objective of this study is to pilot test a study protocol and research instruments in preparation for a larger study or studies. The key process objective will be achieved through design of a study protocol addressing critical benefit and health system impact questions and its implementation in Uganda through in-country work by a team including national and international consultants. The key substantive objective is to identify issues that are unique to collaborations in low-income countries that include the involvement of pharmaceutical companies at some stage of decision-making and/or implementation.

Methods

A technical consultation meeting held by IPPPH on 10 January 2003 advised that the study should adopt a layered approach to evaluation, covering the country context and the tropical disease control policy before assessing the individual partnership programmes. Initial reviews of the country context, the relevant disease control policies and the individual access PPP programmes will be undertaken in March-April 2003. Research instruments including interview guides will be developed and approved in advance by the Study Advisory Panel.

The country fieldwork for this pilot study will be undertaken in Uganda during three weeks in May 2003 by three national and three international consultants. It will examine public-private partnership programmes for improving access to pharmaceuticals in relation to onchocerciasis, lymphatic filariasis, trypanosomiasis, leprosy and HIV/AIDS.

Fieldwork will include interviews about each programme at international level, and at national, district and health facility levels in Uganda. The technical consultation meeting proposed visits in Uganda to 3-4 districts, one of which will be Kampala itself since the capital is the prime location for the HIV/AIDS drug PPP programmes.

Documentary, quantitative evidence will be obtained wherever available. However, the technical consultation meeting anticipated that this is likely to be a largely qualitative study making extensive use of semi-structured interviews with key informants. The mix of interviewees should cover those involved with each programme, eg partners, programme managers, NGOs, the district health team, shopkeepers; and, if possible, others with an informed but less close view, eg Ministry or NGO representatives not involved in the programme. While it is important to cover all stakeholders, the general view of the technical consultation meeting was that the study could not encompass substantial community focus group work, particularly given timing and budgetary limitations.

The report will be finalized by the end of June 2003, following consultation with the Study Advisory Committee. It will contain recommendations on any larger study or studies.

Data Collection: Uganda, May 2003

Data gathering should as a minimum include:
i) *key data on the country context*, particularly general health and health system information, and on national strategies/policies for the individual program diseases.

Possible data sources include:
- national health plan and budget, annual report
- district health plans and budgets, annual reports
- AIDS strategy and plan; performance/progress reports
- relevant individual tropical disease control plans; performance/progress reports
- Essential Drugs List
- publications and grey literature
- semi-structured interviews

ii) *programme specific data*
The study should map the key characteristics of each PPP studied, including:
- program goal, objectives and strategy
- nature of partnership
- program start date, stage of development, future plans
- governance arrangements
- location of secretariat/manager
- dedicated personnel (number of staff and whole-time equivalents)
    - national
    - regional
    - local
- budget and actual spend
- presentation of programme to beneficiaries
- mode of operations
- current scale of operations
- current geographical and epidemiological coverage (including current scale of coverage in relation to planned coverage; coverage by socio-economic status, gender, age, rural/urban location)
- overall performance against targets to date

Possible data sources include:
- program specification and protocols
- program budget
- all program performance/progress reports (activity and budget)
- minutes of any formal steering group or liaison meetings
- relevant country level correspondence
- any published literature

- semi-structured interviews.

Some useful information will probably not be readily available and should ideally be gathered during study fieldwork, for example:

- the approximate amount of time individuals at different levels spend on the program, and shifts from the pre-program profile, with an assessment of the consequences for other work
- the program's impact on preprogram expenditure patterns for the diseases concerned

Draft outline programme for country fieldwork: Uganda, May 2003

A detailed plan for the three weeks of fieldwork in Uganda will be developed in liaison with the Government of Uganda and local consultant team members. The draft outline programme is structured with an initial round of interviews and information-gathering at national level, followed by visits to 3-4 districts and health facilities/pharmacies, then a return to national level for follow-up enquiries and feedback to key parties. One district will be Kampala itself since the capital is the prime location for the HIV/AIDS drug PPP programs.

National level (week 1)

- briefing with local consultants, link person in Ministry of Health (MOH), courtesy calls
- PPP program managers in Kampala
- relevant MOH personnel, eg communicable disease control, HIV/AIDS programme, essential drugs programme, central medical/drug store and distribution personnel, health planning, finance, health and health service information
- 2-3 NGOs involved in PPP program implementation, where appropriate, and 2 NGOs not involved in the PPP programme
- agencies such as WHO, World Bank, UNAIDS, UNICEF, 2-3 bilaterals
- relevant private sector representatives

District and community level (week 2 to mid-week 3)

- courtesy calls
- district health team
- staff at community health facilities
- local NGO representatives
- shopkeepers supplying drugs
- any other personnel involved in program delivery, including drug distribution
- travel to and from, and within, the district

National level (end week 3)

- follow-up queries as necessary
- summarize findings
- report back to key parties

ANNEX 2

Approach to Uganda Pilot Study Fieldwork: Selection of districts

Criteria

The criteria for selection of districts for study visits were:

- first, active implementation of those PPP programmes being studied, ensuring that each programme was visited in at least one district
- regional and socio-economic representation
- accessibility, within the timescale of the study, and security

Districts selected

The five districts selected in consultation with the Ugandan Ministry of Health were Hoima, Kampala, Katakwi, Masaka and Soroti (see map).

Hoima District : ***onchocerciasis*** and ***schistosomiasis programmes***. Main economic activities are agriculture, livestock farming, fishing and small scale business.

Kampala District : ***DAI/AAI, Viramune® and Diflucan® programmes***. The district is home to Kampala city, Uganda's capital and its commercial and administrative centre. ARV clinical trials and services were pioneered in Kampala. The PPP programmes in the study are administered from Kampala.

Katakwi District : one of only two districts which piloted the ***lymphatic filariasis programme*** in 2002. Its key economic activities are agriculture and small scale trading.

Masaka District : ***DAI/AAI, Viramune® and Diflucan® programmes*** in the Masaka Regional Referral Hospital/Masaka Healthcare Centre. Masaka was the epicentre of HIV/AIDS in the 1980s and 1990s, with Uganda's first AIDS case reported in the old Masaka district in 1981.

Soroti District : leprosy and sleeping sickness programmes. Following a recent upsurge of Human African Trypanosomiasis, the Serere Health Centre in Soroti has recently opened for the treatment of sleeping sickness. Lymphatic filariasis is also endemic, though the programme has not yet been initiated here.

*Number of households and population by residence and sex (2002 Population Census***)**

District	**Number of HH**	**Population by Residence**		**Population by Sex**		**Total**
		Rural	**Urban**	**Males**	**Females**	
Kampala	309,093	-	1,208,544	588,433	620,111	1,208,544
Masaka	175,631	692,079	75,680	377,924	389,835	767,759
Katakwi	70,898	299,737	7,295	148,604	158,428	307,032
Soroti	72,138	330,516	41,470	181,399	190,587	371,986
Hoima	69,743	312,548	36,656	176,200	173,004	349,204

Socio-economic status of the districts and budget allocation per capita

District	**Household Consumption Index***	**Ranking**	**PHC recurrent non wage Budget allocation (Ug shs) per capita per annum****
Kampala	102.90	1st	745
Hoima	46.20	7th	950
Masaka	43.00	12th	905
Soroti	34.50	25th	948
Katakwi	30.60	30th	1,002

*The household consumption index is a measure of purchasing power and used as a proxy for poverty (Ministry of Finance Planning and Economic Development 2002) (Highest score 102.90 for Kampala and lowest score 19.7 for Moroto and Nakapiripirit Districts)

**The Primary Health Care (PHC) recurrent non wage budget allocation takes into account population, poverty, presence of Regional Referral and District Hospitals, special health needs and additional funding from other sources such as projects.

ANNEX 3

Acknowledgements and list of interviewees

The study team is greatly indebted to all those who gave so much of their time and energy to provide key information and thoughtful commentary on the study issues. We are the more grateful to all the interviewees listed below, given the many other demands on them during the period of the study. We are particularly appreciative of the contributions - and kindly patience - of Professor Omaswa and his colleagues in the Ministry of Health on whom we necessarily relied for much of the substantive data reflected in this report.

National level

Ministry of Health

1. Prof F. Omaswa	Director General of Health Services
2. Dr. D. Lwamafa	Commissioner of Health Services (National Disease Control)/Secretary, Country Coordinating Mechanism, GFATM
3. Dr. Dawson Mbulamberi	Assistant Commissioner, Vector Borne Disease Control
4. Dr. Elizabeth Madraa	Programme Manager, AIDS Control Programme
5. Dr. Adatu-Angwau Francis	Programme Manager, National TB and Leprosy Control Programme
6. Dr. Ambrose Onapa	Programme Coordinator, Lymphatic Filariasis Control Programme
7. Dr. Richard Ndyomugyenyi	National Coordinator, Onchocerciasis Control Programme
8. Dr. Saul Onyango	National Coordinator, PMTCT, AIDS Control Programme
9. Dr. Elizabeth Namagala	Coordinator ARV Treatment, AIDS Control Programme
10. Mr. Fred Sebisubi	Acting Principal Pharmacist Ministry of Health
11. Mr. Hanif Nazerali	Drug Management Advisor, DANIDA, Ministry of Health

Development Partners

12. Dr. Oladapo Walker	WHO Representative, WHO Country Office, Uganda
13. Dr. Faustine Maiso	Human African Trypanosomiasis, WHO
14. Mr. Joseph Serutoke	NPO, Essential Drugs and Medicines Policy, WHO
15. Dr. Vincent Orinda	Chief of Health, UNICEF
16. Dr. Dorothy Ochola	Coordinator, PMTCT, UNICEF
17. Mr. Harald Dahl	Supply Officer UNICEF
18. Dr. Eva Kabwongera	UNICEF
19. Ms. Caroline Egaddu	UNAIDS
20. Ms. Ros Cooper	Health Advisor, DfID
21. Ms. Molly Martell	Administrator MSF France & Coordinator for Coalition for Access to Essential Medicines

National Organisations

22. Dr. D. Kihumuro Apuuli	Director General, Uganda AIDS Commission
23. Dr. J.C. Lule	Executive Secretary, National Drug Authority
24. Dr. Pito Jemba	Head of Procurement, National Medical Stores
25. Mr. Deo Kimera	Head of Marketing and Operations, National Medical Stores
26. Mr. Nicholas Kyaterekera	Quality Assurance, Corporation Pharmacist, National Medical Stores
27. Ms. Donna Asiimwe	Deputy Manager, Joint Medical Stores
28. Mr. Alan Fenwick	Director, Schistomiasis Control Initiative, Imperial College, London
29. Mr. Sowedi Muyingo	Medical Access Uganda Ltd
30. Mr. Denis Tugume	Administrative Officer, Medical Access Uganda Ltd.
31. Dr. Alex Coutinho	Chief Executive Officer TASO
32. Mr. Stefano Santini	Country Director, CUAMM (Italian NGO active in the North/West Nile)
33. Ms. Assumpta Byarugaba	Uganda Coalition for Access to Essential Medicines
34. Ms. Beatrice Were	Director, National Community of Women Living with HIV/AIDS in Uganda (NACWOLA)
35. Ms Annette Biryetega	NACWOLA

36. Ms. Rosette Mutambi	Uganda Coalition for Access to Essential Medicines
37. Dr. Haumba Samson	The AIDS/HIV Integrated Model District Programme (AIM) Uganda
38. Ms Martine Donaghue	London School of Hygiene and Tropical Medicine (GFATM Tracking study)

Private Pharmaceutical Agencies

39. Mrs Lilian Mukasa	Managing Director, City Pharmacy
40. Mr. Kinny Nayer	Managing Director, Surgipharm Uganda Ltd

Hoima District

41. Dr. Ruyonga Joseph	Assistant District Director of Health Services, Buhaguza Health Sub-District (HSD)
42. Mr. Asumbusa Moses	District TB/Leprosy Supervisor (DTLS)
43. Mr. Byenume Fredrick	District Onchocerciasis Coordinator Hoima
44. Mr. C. C. Asiimwe	District Health Inspector
45. Mr. Fred Gahwera	District Cold Chain Assistant (DCCA) Hoima
46. Mr. Kwebiiha B. Solomon	Assistant District Onchocerciasis Coordinator/Assistant Health Educator, Buhaguzi HSD

Kampala District

47. Dr. Peter Mugyenyi	Director, Joint Clinical Research Centre, Kampala
48. Mrs. Takubwa J. Mpanga	Pharmacist, Joint Clinical Research Centre
49. Dr. Elly Katabira	Associate Dean, Makerere University Medical School/Mulago Hospital
50. Dr. Emmanuel Luyikira	Director, Clinical Services, Mildmay Centre
51. Dr. Maria Nanyonga	Home Care Programme, Nsambya Hospital
52. Sister Christine	Home Care Programme, Nsambya Hospital
53. Dr. E. Kikule	Director/Research Coordinator, Hospice Uganda
54. Dr. Jack Jagwe	Senior Advisor, National Policy, Drugs/Advocacy – Hospice Uganda
55. Mr. Peter Mikajjo	Dispenser, Hospice Uganda

Katakwi District

56. Dr. T. Onyige	Deputy District Director of Health Services
57. Dr. William Komakech	District Director of Health Services
58. M. Alexei Erongu	Vector Control Officer
59. Mr. G. Adakun Okwii	District Assistant Drug Inspector
60. Mr. Samuel Amali	Health Assistant
61. Mr. Jude Anguria	Health Assistant
62. Mr. Pius Ebau	Clinical Officer, Obalanga HC III
63. Mr. Julius Ebiaru	Health Assistant, Toroma Sub-county
64. Mr. Richard Emeru	Rec./Health Management Information Focal Person
65. Mr. Joseph Emodu	Chairperson LC V
66. Mr. John William Emorut	Clinical Officer, Ngariam
67. Mr. Epacu Pantaho	Medical Clinical Officer, Amuria HSD
68. Mr. Francis Okwameru	LC V Secretary of Health
69. Mr. R. D. Idholu Okia	District Health Inspector
70. Mr. John R. Irangolet	Ophthalmic Clinical Officer
71. Mr. Stephen Ntende	Health Assistant
72. Mr. Philip Odeke	District Surveillance Focal Person
73. Mr. Simon Peter Ojamo	Medical Clinical Officer, Katakwi HC IV
74. Mr. Paul Ojilong	Health Assistant
75. Mr. Julius Peter Okello	Assistant Entomology Officer
76. Mr. Benjamin Okiror	Katakwi HC IV
77. Mr. Johnson Oluka	Medical Clinical Officer, Asamuk HC III
78. Mr. Moses Oluka	Health Inspector
79. Mr. Richard Omujal	Medical Clinical Officer, Aketa HC III
80. Mr. Martin Opio	Clinical Officer
81. Mr. John Robert Osakan	Clinical Officer
82. Mr. Joseph Osekeny	Environmental Health Officer

83. Mrs. Jane Achaet	Enrolled Nurse
84. Ms. Anne Grace Osany	Assistant Health Visitor

Masaka District

Masaka Healthcare Centre (UGANDA CARES)

85. Dr. Bernard Okongo	Medical Director
86. Dr. Monica Etima Kizito	Paediatrician
87. Mr. Stephen Mpiima	VCT Manager
88. Ms. Hope Katete	Nurse, Case Manager

Masaka Regional Referral Hospital

89. Dr. Kenya Mugisha	Medical Superintendent
90. Dr. Daniel Mulokora	PMTCT programme
91. Ms. Beatrice Kasisi	Hospital Dispenser

Soroti District

District Health Team Members

92. Dr. Nicholas Okwana	District Director of Health Services
93. Mrs. Anero	LC V Secretary for Health
94. Mr. James Francis Akopan	District Leprosy Control Supervisor
95. Mr. John O. Okello	District TB/L Supervisor
96. Mr. Emmanuel Wakwesa	HMIS Focal Person
97. Mr. Edward Ongwara Egau	District Health Inspector/Surveillance F/Person

Serere Health Centre IV staff

98. Dr. Calvin Epidu	Medical Officer in-charge
99. Mr. Alloysius Oriokot-	Accounts Assistant
100. Mr. Francis J. Alibu	Records Assistant
101. Mr. Alifani A. Lubanga	Dentist
102. Mr. Oluka Enyanu	Clinical Officer
103. Mr. Moses Olobo	Dispenser
104. Ms. Jane Amuso	Enrolled Nurse
105. Ms. Florence Achom	Laboratory Assistant
106. Ms. Norah Ikeba	Enrolled Nurse
107. Ms. T. A. Abego	Nursing Officer

Outside Uganda

108. Ms Sibongile Pefile	Researcher
109. Ms Betty Leach	HAI Africa

ANNEX 4

Ministry of Health organization and staffing for study programmes

The organigram on the following page depicts the macro-structure of the Uganda Ministry of Health. The public-private partnership programmes examined in this pilot study are handled by two departments – the Department of Community Health and the Department of National Disease Control, both within the Directorate of Clinical and Community Health Services.

Responsibility for lymphatic filariasis, sleeping sickness and schistosomiasis - along with plague, rabies and brucellosis - lies with the Vector Borne Diseases Control Division of the Department of Community Health. Staffing levels at 1 August 2001 (MOH Annual Health Sector Performance Report 2000/2001) for this division were:

- Commissioner Community Health Department 1 post – filled (wider duties)
- Assistant Commissioner Vector Borne Diseases Control 1 post – filled (divisional head)
- Principal Entomologist 1 post – filled
- Senior entomologist 1 post – filled
- Senior Medical Officer 1 post – filled
- Entomologists 5 posts – 4 filled
- Pool Stenographer 1 post – filled

The Department of National Disease Control is composed of a number of vertical disease control programmes, including:

- STD/HIV/AIDS Control Programme
- TB/Leprosy Control Programme [NB this is an integrated programme]
- Onchocerciasis Control Programme

Staffing levels in May 2003 were:

- Commissioner National Disease Control 1 post – filled (wider duties)
- Assistant Commissioner National Disease control 1 post – filled (wider duties)

AIDS Control Programme

- Principal Medical Officer 1 post – filled
- Senior Medical Officer 3 posts – filled
- Senior Nursing Officer 2 posts – filled
- Epidemiologists 1 post – filled
- Nutritionist 1 post – filled

Onchocerciasis Control Programme

- Principal Medical Officer 1 post – filled
- Senior Entomologist 1 post – filled
- Senior Medical Officer 1 post – filled
- 1 project Accountant,
- 1 Secretary
- 1 Driver

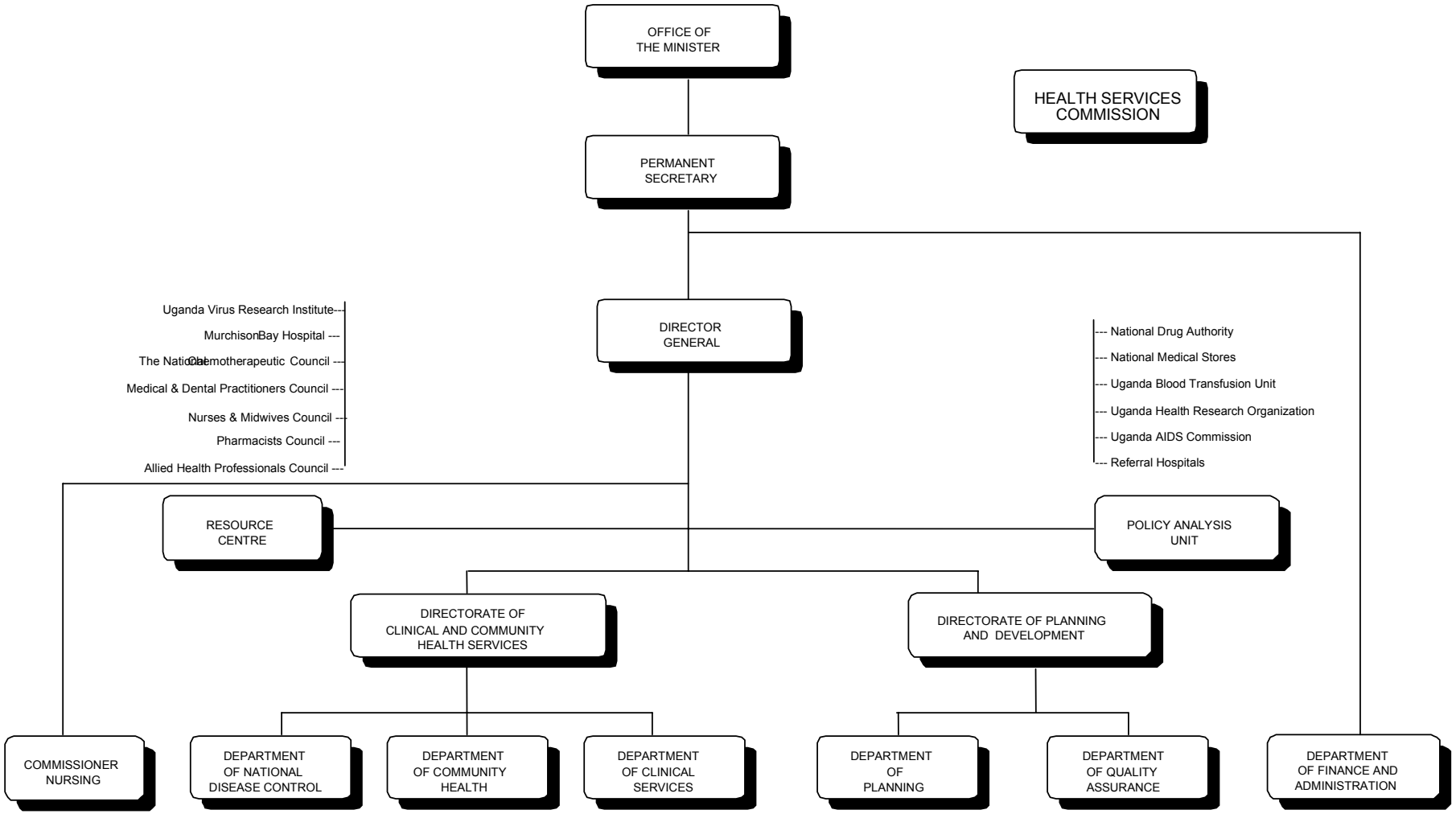
TB/Leprosy Control Programme

- Principal Medical Officer 1 post – filled
- Principal Laboratory Technologist 1 post – filled
- Senior Medical Officer 6 posts – filled
- Senior Laboratory Technologist Grade I 1 post – filled
- Laboratory Technologist 1 post – filled
- Senior Laboratory Technologist Grade II 1 post – vacant
- Laboratory Technicians, 2 posts – filled (salaries provided by GLRA)
- Laboratory Attendants, 2 posts – filled
- Stores Assistant Grade II, 1 post – filled
- Secretary, 1 post – filled
- Drivers, 2 posts – filled

- Cleaner, 1 post – filled
- Security Guard, 1 post – filled

The Department of National Disease Control also covers other vertical disease programmes (Malaria, Guinea Worm Eradication and the Expanded Programme on Immunisation), plus the Division of Surveillance/Epidemiology which is responsible for integrated disease surveillance. National level activities for epidemic and disaster prevention, preparedness and response are implemented by the Department of National Disease Control in collaboration with the Department of Community Health and the Office of the Prime Minister.

MACRO STRUCTURE OF THE MINISTRY OF HEALTH



ANNEX 5

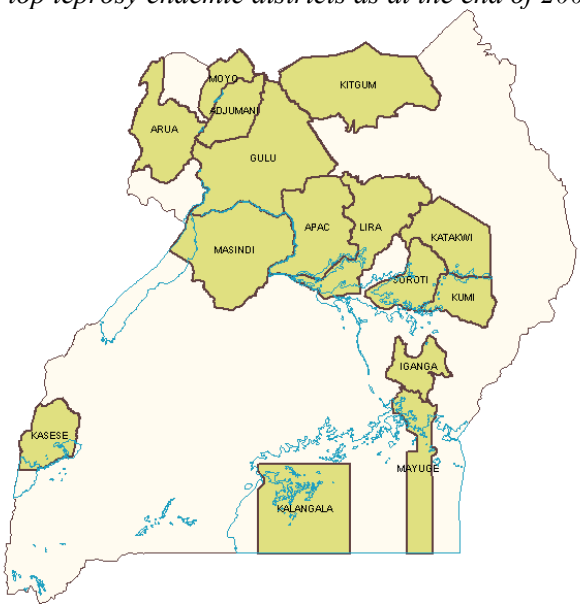
National TB/Leprosy Control Programme (NTLP)

Background

Until recently, Leprosy was endemic throughout Uganda with a national prevalence rate of 17.7 per 10,000 population in 1983 (NTLP Status Report, 2001). Responsibility for the prevention and control of leprosy remained the near exclusive domain of the church-based health service providers. These local Private-Not-for-Profit (PNFP) organizations were closely supported by the German Leprosy Relief Association (GLRA), the Leprosy Mission International, and later by the Italian Cooperation and WHO. The GLRA has been active in Uganda for over 40 years. Leprosy control services were provided through a network of PNFP general health centres and specialized hospitals dedicated to managing leprosy.

Leprosy is one of the priority diseases identified in both the current National Health Policy and the National Health Sector Strategic Plan and is therefore included in the Minimum Health Care Package under "diseases for control, elimination or eradication".

The 15 top leprosy endemic districts as at the end of 2001



In 1990, leprosy control was integrated with TB to become the National TB/Leprosy Control Program (NTLP). It has been operating as a highly vertical programme from the outset. The basic control strategy is the early diagnosis and treatment with WHO recommended multi-drug therapy (MDT). At the end of 2001, the prevalence rate for leprosy in Uganda was 0.42 per 10,000, down from 17.7 in 1983, 2.8 in 1990 and 0.9 in 1994 when the elimination target was first achieved.

Partnerships

The Global Alliance for Leprosy Elimination (GAEL)
In May 1991, the World Health Assembly adopted Resolution WHA44.9 declaring the Year 2000 as the target date for achieving the global elimination leprosy. Between 1995 and 1999, WHO, with support from the Nippon Foundation, Sasakawa Memorial Health Foundation of Japan, began providing free MDT drugs to national leprosy control programmes with the objective of achieving this global target.

While significant progress towards the elimination target was realised, it became evident that elimination would not be achieved by all countries within the target date. In 1998, WHO reported a 76% reduction in the number of registered cases of leprosy between the period 1991-1998, and that 97% of registered cases were receiving MDT provided free through the Organization (WHA51/1998/Rec/3). The global prevalence rate was 1.4 per 10,000 with 24 countries reporting prevalence rates above 1, down from 122 countries in 1984. The WHA resolved to put into effect an accelerated plan (the 'Final Push') for elimination by 2005 (WHA51.15). By 1999, 11 of the most endemic countries recorded prevalence rates above 4.5, with Brazil and India projected as not likely to meet the target by 2005.

In November 1999, on the initiative of WHO, the Global Alliance for the Elimination of Leprosy was formally created during a meeting in Abidjan, Cote d'Ivoire, with the aim of "ensuring that all patients, wherever they may be, will have free and equal access to the most modern treatment available". The partners were the endemic countries, the Nippon Foundation, Novartis, DANIDA and WHO. In that same year, WHO, within the framework of the Alliance, signed a memorandum of understanding with the Novartis Foundation for the provision of free MDT drugs over the period 2000-2005 in pursuit of the "final push" to achieve global elimination. Special attention was to be given to the eight countries (Angola, Brazil, Guinea, India, Madagascar, Mozambique, Myanmar and Nepal) in which much of the remaining burden was concentrated. The Nippon Foundation/Sasakawa Memorial Foundation provided an additional US$24 million as operational support for the final push. DANIDA and the World Bank also work closely with GAEL.

The WHO Technical Advisory Group for the Elimination of Leprosy has been addressing issues related to the final push including easier serological diagnostic tools for leprosy, simpler treatment regimens including new drugs and drug combinations, Accompanied MDT to improve cure rate, uniform MDT for all types of leprosy, and the validation process for elimination. The TAG has also recommended that a formal certification process for elimination was both expensive and unnecessary and should not be pursued by WHO.

Country Level Partnership
The German Leprosy Relief Foundation, Italian Cooperation and WHO were the main supporters of the Ugandan NTLP before creation of the global alliance. GLRA operating through projects supported the Leprosy hospitals, the five national workshops for prosthetics for leprosy patients, three out of the original seven TB/leprosy control zones, as well as technical and operational support to the central programme management office.

National Leprosy Control Programme Objectives
The programme objectives are to:

- achieve elimination in the remaining districts.
- sustain leprosy elimination at national level and in the districts where it has already been achieved.
- improve treatment completion rate to at least 85%.
- strengthen the programme component for prevention and management of disabilities and the physical and socio-economic rehabilitation of those living with disabilities due to leprosy.

Governance Arrangements
The NTLP is based in the Department of National Disease Control of the Directorate of Clinical and Community Health Services of the Ministry of Health. The integrated programme secretariat (which consists of offices, the TB/Leprosy reference laboratory and stores for drugs and other supplies) is located in an annex adjacent to the MoH Headquarters in Kampala. The programme has the following dedicated personnel:

1. Principal Medical Officer/Programme Manager, 1 post – filled
2. Senior Medical Officer/Zonal Supervisors, 6 posts – filled
3. Principal Laboratory Technologist, 1 post – filled
4. Senior Laboratory Technologist Grade II, 1 post – vacant

5. Senior Laboratory Technologist Grade I, 1 post – filled
6. Laboratory Technologist, 1 post – filled
7. Laboratory Technicians, 2 posts – filled (salaries provided by GLRA)
8. Laboratory Attendants, 2 posts - filled
9. Stores Assistant Grade II, 1 post – filled
10. Secretary, 1 post – filled
11. Stores Assistant, 1Post – filled
12. Drivers, 2 posts – filled
13. Cleaner, 1 post – filled
14. Security Guard, 1 post – filled

All posts except item 7 are regular fulltime staff on the central MoH payroll.

In addition, each of the 56 Districts has 1 District Leprosy Supervisor, with some having an assistant.

Mode of operation
The NTLP is directed and managed from the centre by the Programme Manager as a vertical programme. Seven zonal Teams (originally nine), each headed by a Zonal TB/Leprosy Coordinator, support and supervise the cluster of districts under their respective jurisdiction, including supply of drugs and laboratory reagents. The German Leprosy Relief Association provides technical and financial support to the operations of three of the seven zonal teams.

Each district develops its leprosy control plan and budget based on the national plan. Operational Plans are elaborated by each of the health districts where budgets are allocated from the PHC Conditional Grant. Sub-district Health Inspectors are responsible for coordinating leprosy control activities within each county (or constituency in the case of large counties). The Health Centres are supposed to oversee the NTLP activities in the villages within their catchment areas, including support of the Leprosy Attendants.

In practice, much of the work, including confirmation of new cases and initiation of treatment, is undertaken by the itinerant District Leprosy Coordinators and/or Assistant Coordinators. All new suspected cases of leprosy or patients on treatment who need special consultation are given appointments for the scheduled monthly site visit of the District Leprosy Coordinator. After confirmation of new cases by the District Coordinator, details of each new case is entered on a patient card retained in the health unit and subsequently recorded in the district leprosy register.

Drug access
MDT drugs were initially provided to Uganda by the German Leprosy Relief Association through their own funds, later supplemented by WHO and the Uganda office of Italian Cooperation. In the early phase of MDT, prescriptions for patients had to be individually repackaged and dispensed at health unit level from bottles (containing up to 1000 tablets each) of the individual drugs. Between 1995 and 1999 WHO, with funds provided by the Nippon and Sasakawa Foundations, began providing all the MDT drugs needed by the leprosy endemic countries free of charge.

In 1999, under the aegis of the Global Alliance for Leprosy Elimination (GALE), Novartis and the Novartis Foundation for Sustainable Development signed an MOU with WHO to donate MDT worth $30 million free of cost to all countries in need up to the end of 2005. They fund all freight and handling costs to the port of entry and reimburse WHO for the cost of quality assurance batch testing. They are also working with WHO to develop information and advocacy material. In addition, Novartis holds an emergency buffer stock of MDT drugs equivalent to 30% of the estimated global annual requirements in its own stores and at its own cost.

The company has recently introduced new individual 6-blisterpack packets to facilitate dispensing for patients who for good reason may have difficulty in collecting the drugs from a health unit on a monthly basis – this is the Accompanied-MDT approach. They have also redesigned the packaging to withstand

better exposure to atmospheric heat, moisture and physical handling. These developments should facilitate further the logistics of MDT service delivery, increase patient compliance and cure rates, and reduce wastage.

From Uganda's point of view, the effect of free drugs was to release the drug budget of the German Leprosy Relief Association for wider support to the operational costs for both the programme secretariat and a larger number of districts – in fact, to all the districts within the 3 zones they now support.

The Uganda MOH Programme Manager determines the annual national requirements based on the returns of the preceding year and submits the request to WHO Headquarters through the WHO Uganda Country Office. On approval, the drugs are air freighted to Entebbe with the WHO Country Representative as consignee. WHO collects the consignment from the airport and delivers it direct to the TB/Leprosy Programme Manager/office for storage in its central store. Currently, neither the National Medical Stores nor the Department of Pharmaceutical Services of the MoH is involved in the procurement and distribution of leprosy supplies.

The estimated requirements for MDT supplies for each district (drugs, laboratory reagents and other supplies) are packaged and distributed on a quarterly basis to the Zonal NTLP stores, along with the anti-TB drugs and supplies. The NTLP head office has its own delivery truck donated by the German Leprosy Relief Association.

Based on the number of patients registered and projected enrolment rate for each district, the Zonal Coordinator delivers the supplies to the District Director of Health Services, to be taken into the normal inventory of the district medical stores. On a predetermined schedule, the District Leprosy Coordinator delivers the stocks to each of the health units within the district. Because of the small numbers of patients now being seen at the health unit level, supplies are delivered on a patient by patient basis, with the health unit in charge refilling patient prescriptions on a monthly basis. During these patient visits, the health workers reassess the patients, examine and counsel them as necessary, and directly supervise the administration of the first or "killer dose" of the monthly calendar blister pack of drugs. The patient treatment card is updated accordingly.

Reporting and accountability
Each health unit maintains a record card for each leprosy patient. Details of the record card include patient details including sex and age category, type of leprosy diagnosed, presence and level of disability, date of commencement of treatment, number of blister packs dispensed by type, adverse reactions, relapses, defaulting, transfers to or from other centres, and any deaths.

Data from the individual patient cards for each district are compiled on a monthly basis during the visit of the district supervisor and the overall district returns aggregated for the month in the district leprosy control register. These are forwarded to the District Director of Health Services who in turn compiles the quarterly returns for transmission to the National Programme Manager. The data are analysed for programme management purposes and quarterly returns compiled for the MoH; a separate copy is sent through the WHO Country office to the WHO regional office and Headquarters. No separate reporting is made for, nor required by, Novartis.

The system is operating very well and stock-out of MDT drugs for leprosy is reported to have become a thing of the past. There have been no reports of misuse or diversion.

Coverage and performance
National coverage with Multi-drug Therapy was achieved in 1994. In the same year, the global elimination target (prevalence rate of less than 1 per 10,000 population) for leprosy was achieved at national level. There has been a gradual fall in both the prevalence and new case detection rates. At the end of 2001, the national prevalence rate of leprosy in Uganda was 0.42 per 10,000, but was still above 1 in nine (Arua, Adjumani, Moyo, Kitgum, Lira, Katakwi, Kumi, Masindi, and Kalangala) of the then 39 districts in

Uganda. Detection rate of new cases was 0.31 per 10,000 in 2001, down from 0.37 and 0.42 for 2000 and 1999 respectively. The treatment completion rate for both types of leprosy was 69% in 2001, below the national target of at least 85%.

Leprosy is predominantly a disease of the rural and periurban poor. Children below the age of 15 years still account for 10% of all new cases. Some progress has been made towards closing the gender equity gap; currently females account for 54% of all new cases.

The fact that 11.9% of new cases already had visible disabilities and 25% of all new cases had some degree of nerve dysfunction at the time of detection is indicative of the need to strengthen community and health worker awareness of the disease and the availability of free and effective treatment.

The known effects of leprosy on its sufferers go back to biblical times. Untreated, leprosy leads to severe skin lesions that progress to disfigurement of the face and nose requiring patients to cover their faces. The sensory loss that is part of the disease results in frequent injuries that produce serious and incapacitating deformities of both lower and upper limbs. Out of ignorance of the low level of infectivity of leprosy and from historical attitudes, patients of leprosy suffer appalling levels of discrimination even from their communities and family. This frequently condemns them to a life of street begging and total destitution.

In an attempt to improve the welfare of leprosy patients and eliminate discrimination, the national programme is intensifying activities within the component of "physical and socio-economic rehabilitation of those living with disabilities due to leprosy". This entails medical management of deformities including reconstructive surgery, provision of shoes and other physical aides, occupational training, support for income generation, advocacy against discrimination, and social re-integration into their households and communities. The programme has observed that patients that have been successfully rehabilitated make the best advocates in their respective communities.

Out of the original nine leprosy zonal areas, only the North and North West Zones have not achieved the elimination target. These are the regions which have for the past 15 years been plagued by the NRA rebel insurgencies resulting in large populations of refugees and internally displaced persons, in addition to severe disruption of development activities, including health service delivery.

REGISTERED CASES OF LEPROSY BY NTLP ZONES, 2001

(NTLP Status Report, 2001)

LEPROSY SERVICE ZONE	**TOTAL CASES REGISTERED**	**PREV. RATE** (per 10,000)
Kampala	31	0.25
Central	55	0.22
South East	72	0.21
East	166	0.56
North East	3	0.05
South West	54	0.11
West	71	0.37
North	**271**	**1.15**
North West	**192**	**1.26**
Uganda Total	915	0.42

Sustainability

As elimination in all districts becomes closer and the need for sustained surveillance becomes an imperative, NTLP programme management is actively seeking to integrate the programme into routine primary health care activities at district and health sub-district levels. Leprosy mapping of the districts has been completed. Sensitization of the district political and community leadership and of health personnel and other stakeholders in the field has already begun.

The plan is to make MDT drugs available from Health Centre Level 2 up to the referral hospital. The change to decentralize and integrate leprosy control fully poses significant challenges, not least of which is the extensive retraining needs for health workers at all levels of the national health care delivery system. Consultations have been initiated for integrating procurement and distribution into the normal NMS drug distribution system. NTLP is reviewing programme management reporting needs for inclusion into the national HMIS which currently gives figures only for total cases of leprosy.

The number of cases no longer justifies the continuation of leprosy hospitals as specialised facilities, and they have already been transformed into general hospitals with a few wards reserved for those leprosy patients who require admission. The zonal workshops (prosthetics and shoes for leprosy disabled patients) are to be retained for the time being.

As maintaining the elimination target requires early detection and treatment of all cases, efforts to increase self-reporting through community empowerment have become a major preoccupation of NTLP management. Programme activities have been intensified in areas of IEC (with knowledge of the disease and availability of free and effective treatment), advocacy against stigmatisation, social and economic rehabilitation of the leprosy disabled, and reintegration into their communities.

Programme management is concerned that as fewer and fewer cases are seen, specialist knowledge and skills are being lost for ever. The essential focus on the elimination target and on sustaining interest and vigilance within general primary health care will become an even greater challenge as new cases become more and more rare. Another area of anxiety, given the importance of regularity of supply, is the programme's past unhappy experience with the national procurement and distribution system. It is reported that unacceptable delays were encountered in the field as a result of the NMS' operating policy of delaying distribution to districts whenever other items of supply where out of stock at the stores, even when there was a good stock of leprosy drugs.

Government (including district and health sub-district allocations) already funds the operational costs of the program in half the current 56 districts, the rest being supported by GLRA. All programme staff (except a couple in the secretariat) are already on the payroll of the MoH or the respective district local governments. As one of the priorities of the national Health Sector Strategic Plan, leprosy control qualifies for support from the PHC Conditional Grant which is already the main avenue for funding of the program at district and health district levels. Absorbing the operational costs of the programme within the national budget should not be a major obstacle.

The uncertainty of future supply of MDT drugs on expiry of the Novartis commitment at the end of 2005 is yet to be addressed. It is however to be noted that the recent (February 2003) Fifth Meeting of the WHO Technical Advisory Group (TAG) on Leprosy has recommended that WHO "should continue to supply high quality MDT drugs, free of charge to all countries in need, in order to achieve and sustain elimination" **(**WHO/CDS/CPE/CEE/2003.36).

Key conclusions

On the basis of the evidence considered, the country study team found that:

- the elimination of leprosy is a high priority for Uganda with clear ownership of the national programme by both the MoH and the districts
- the availability of free MDT drugs through the Novartis donation has strengthened the national programme by releasing funds for other operational activities such as public information and education about the disease, staff training and supervision and general programme management
- some anxiety remains as to the level of support for drugs to be expected after the end of the present donation programme in 2005
- a plan for devolution through integration into the national PHC system has already been developed and is in an early stage of being implemented

- sustaining the programme should not pose insurmountable difficulty as government and districts are already providing most of its running costs

During interviews, key informants advised that:

- programme managers at both the centre and districts have appreciated the lack of reporting requirements beyond those needed for normal programme management
- there has been no active presence of Novartis in Uganda nor has there been any direct or indirect contact between government officials and the drug donor, as distinct from WHO
- the regular and more dependable supply of drugs has increased the credibility of the programme in the eyes of both the community and health staff
- the improved and colour coded calendar blister pack has improved patient compliance and simplified dispensing by lower unit health personnel
- the new packaging of 6 blister packs in one box should facilitate the planned integration of the programme into PHC through the use of the Accompanied-MDT approach, whereby patients with difficulty in meeting the monthly clinic visits are provided with their full 6 month course

ANNEX 6

National Programme to Eliminate Lymphatic Filariasis (PELF)

Background

Lymphatic Filariasis (LF), caused by microfilaria of w. bancrofti, is a well-known problem in Uganda. Reviews by WHO from the 1940s to the 1970s reported that chronic manifestations, including lymphoedema/elephantiasis, were commonly seen in the Northern, Eastern and Western regions of the country. However, when in 1997 WHO earmarked LF for elimination, there were no baseline data on its endemicity in Uganda. Subsequent baseline community surveys in Katakwi, Lira and Soroti/Kaberamaido districts in 1998/99 showed them to be highly endemic for LF, presenting a serious public health problem. Hydroceles, the most common chronic manifestation in Uganda, was found to have prevalences as high as 28% in males aged 20 years and more.

Highly endemic districts for LF

Mapping of LF in Uganda (funded by WHO for US$ 30,000) to pave the way for a comprehensive national elimination plan began in November 2002. It is targeting 50 out of 56 districts since LF transmission is unlikely to occur in districts over 1500m above sea level. Uncertainty over the quality and use of the kits delayed the start of mapping, and lack of transport for field teams is a constraint[23]. Entomological and antigen surveys have been carried out in the five districts of Busia, Jinja, Kamuli, Kumi and Tororo.

The international partnership

In 1997 a World Health Assembly resolution called for countries 'to strengthen activities towards elimination of lymphatic filariasis as a public health problem'. The following year GlaxoSmithKline and WHO signed a Memorandum of Understanding covering among other things the donation of all the albendazole required for the LF elimination programme. In 1999the Mectizan® Donation Programme of Merck & Co. expanded its existing donation of Mectizan® to the treatment of lymphatic filariasis in African countries where onchocerciasis and LF co-exist. For LF, Mectizan® is administered in tandem with albendazole in a yearly, single dose, two-drug regimen. The ancillary benefits of repeated treatment of entire communities with albendazole should be a dramatic reduction in the intensity of helminth infections,

[23] PELF Uganda Annual report 2002, VCD, MOH, Kampala

major causes of anaemia in women and children and of stunting and inhibited cognitive development in children.

The Global Alliance for the Elimination of Lymphatic Filariasis (GAELF) was established in May 2000 and is envisaged to last at least until 2020. The secretariat is provided by the LF team in WHO, and technical and operational decisions remain the responsibility of WHO. In 2001 GAELF reached its target of achieving MDA coverage of more than 26 million people. The global target for 2005 is coverage of 350 million people at risk.

Programme objectives and strategies in Uganda
Proposals for a national Programme to Eliminate Lymphatic Filariasis (PELF) in Uganda were developed by MOH Vector Control Division in 2000, and approved by WHO and the Mectizan Donation Programme who agreed to provide Mectizan® and albendazole free of charge for as long as required, but with a recommendation to start Mass Drug Administration (MDA) in one rather than three districts as originally proposed by the MOH. After further discussion of this recommendation and a visit to Uganda, it was agreed that PELF should be launched in August 2002 in *two* districts – Katakwi and Lira – with a combined population of more than 960,000.

Objectives
The overall objective of the national PELF is to reduce morbidity due to lymphatic filariasis through community based treatment with a combination of albendazole and Mectizan®, to an extent that this disease ceases to be a public health problem. The ultimate objective is to interrupt transmission. There is also an objective to alleviate suffering and disability.

Target
The target for the programme is for 80% of the total target population to receive the drugs during the MDA.

Strategies
The elimination strategy adopted is to mass treat all eligible individuals with albendazole and Mectizan® once a year for at least 5 to 6 years, in line with the reproductive lifespan of the parasite. This is expected to reduce and interrupt transmission and ultimately prevent the occurrence of new infection. The strategy incorporates a strong component of health education and mobilisation, aimed particularly at morbidity control, to reduce the effects of adult worms that will remain active within the lymphatic system.

Current stage of development and future plans of the national programme

Current stage of development
Preparatory activities prior to the launch included:

- advocacy visits to the two selected districts (October and November 2001)
- sensitisation workshops for district leaders (December 2001)
- training of several cadres including trainers, supervisors and Community Drug Distributors (CDDs – at least two residents per community)
- sensitisation of communities and their leaders
- development of IEC materials
- baseline surveys in sentinel sites in both districts
- delivery of drugs and registers (July 2002):
  - Katakwi: 205,000 albendazole tablets, 615,000 Mectizan tablets and 2200 registers
  - Lira: 535,600 albendazole tablets, 1,607,000 Mectizan tablets and 6,000 registers.

Mass Drug Administration (MDA) was launched in August 2002. In Katakwi it is complete, with a coverage of 74.2% of total population in 664 villages. In Lira, security problems affected coverage: coverage of 76.6% of the population was achieved in 1895 villages (out of 2266 in the district). A total of 733,375 people from both districts were treated, giving coverage of almost 76% of total population. The unit cost per person treated was 200 Uganda shillings, equivalent to about US$ 0.1.

The drugs were well-tolerated, with only three people showing serious adverse reactions; all are fully recovered.

Drug efficacy monitoring has been carried out in Katakwi where the exercise was affected by heavy rains. Some sentinel sites in Lira are still insecure.

Future plans
Plans for small scale disability management trials in Obalanga subcounty of Katakwi and Barr area of Lira), scaling up of PELF and integration with other programmes (schistosomiasis/STH, onchocerciasis and malaria) are being developed.

The programme envisages a rapid expansion in 2003, with eight adjacent districts (Kotido, Moroto, Nakapiripirit, Kumi, Kamuli, Soroti, Kaberamaido and Apac) targeted in addition to repeat MDAs in Katakwi and Lira. The estimated population to be covered during 2003 is 4.2 million in 10 districts. The total population in districts targeted for MDA in 2004 is 7.2 million, and in 2005 9.4 million. However, at the time of this study's fieldwork, operational funding to support the scale of the 2003 roll-out had not been secured (see below).

Conditionalities/principles
The general conditionalities of the Mectizan® Donation Programme apply to the donated drugs for LF. These include:

- observing the treatment criteria, such as providing the drugs to approved districts only, and no treatment of under fives, pregnant women and very sick people
- no payment should be charged
- evidence that financing for the programme is available

Interviewees feel that there are no unreasonable conditionalities.

Nature of partnerships
The National Programme to EliminateLymphatic Filariasis is implemented by Ministry of Health, Local Governments (Katakwi and Lira Districts) and the local communities. The WHO, GlaxoSmithKline and the Mectizan® Donation Programme partnership ensures that the drugs used in the treatment of LF are available and free of charge.

The programme is examining with Uganda Red Cross Society how best to exploit the Red Cross's network in the country.

Governance arrangements
An agreement was signed between the Ministry of Health and the WHO Country Office for the implementation of the national PELF. The programme manager is based in the Vector Control Division of the Ministry of Health and works with support staff (scientists, technicians etc). At district level, the Vector Control Officer or any other relevant officer on the District Health Team serves as the focal person for LF. National and District Coordination Committees to oversee the implementation of the programme were set up at the national and local government levels respectively. Programme staff at Ministry of Health Headquarters conduct joint planning with district officials, but most of the activities are carried out by districts.

Secretariat/Manager
The Programme Manager is located within the Vector Control Division of the Ministry of Health Headquarters.

Dedicated personnel
The personnel carrying out the activities of the programme both at the centre and in the districts are employees of the Ministry of Health and District Local Governments respectively. In addition to the programme's activities, these personnel carry out other activities of the Vector Control Division and District Health Services.

Budget and actual spend
The planned budget for the first round of the Mass Drug Administration in both Katakwi and Lira districts was UShs. 120m. The WHO country office provided US$ 60,000 and DFID provided US$ 40,000 towards the first round MDA. However some planned activities could not be carried out due to lack of funds. The Government of Uganda provided funding for advocacy meetings, transportation of drugs to the districts and supervisory visits.

The estimated cost for the second year of programme implementation in 10 districts is UShs. 700 – 800m., for which the Ministry of Health has made a special request to the Ministry of Finance.

Presentation of programme to beneficiaries
The programme mounted an aggressive advocacy programme to the people in both districts. Sensitisation meetings/workshops were held for district leaders, Local Councils, heads of institutions and health workers in both districts. Communities were sensitised about the programme and then asked to select the Community Drug Distributors (CDDs).

The programme trained Trainers of Trainers (ToTs) in both districts (40 ToTs for Lira and 25 ToTs for Katakwi). The programme also trained 20 supervisors for each health sub-district (140 for Lira and 60 for Katakwi). Trainers at the district level and the supervisors in each district trained the Community Drug Distributors. 2,000 and 6,000 CDDs were trained for Katakwi and Lira districts respectively.

Officials of both districts were consulted about the date for the MDA and chose August 2003 for MDA. During the official launch of the programme in Katakwi District, district political, administrative, technical leadership took the drugs publicly to dispel rumours about bad drugs.

The programme is planning to contract private advertising companies to carry out social mobilisation of communities. The companies will produce posters, pamphlets, radio messages, drama and will also use popular commercial products like Coca Cola and MTN in their campaign.

Mode of operations
To date, only the pilot phase in 2002 has taken place. Districts provide information on population of their districts. The programme manager then determines the estimates for drug requirement, assuming that 80% of the population will need treatment, and submits it to WHO country office, which in turn forwards it to WHO Geneva and the Mectizan® Donation Programme.

When the drugs are shipped to Uganda, the WHO Country Office clears and collects the shipment from the airport and delivers the drugs to the MOH programme manager. The drugs are bulky and last year they were transported to Katakwi and Lira districts by the Ministry of Health direct. Distribution of the drugs within districts was through health units under the supervision of the relevant District Director of Health Services.

Current geographical and epidemiological coverage
The programme covered Katakwi and Lira Districts in 2002, and is planned to expand in 2003 to all the neighbouring districts of Kotido, Moroto, Nakapiripirit, Kumi, Kamuli, Soroti, Kaberamaido and Apac.

Overall performance against targets to date
Overall programme performance is good. During the first MDA, 70% of the total population in both Katakwi and Lira districts received the drugs. This was slightly lower than the desired coverage of 80%. It is planned that more intensive and aggressive IEC campaign will be conducted from this year onwards.

Sustainability measures
GlaxoSmithKline and Merck & Co. have promised free supplies of the drugs for as long as required. The critical key to sustainability lies in securing an assured funding source, ideally from government, to cover the operational costs of the roll-out. At the time of the study's fieldwork, the Ministry of Health had submitted a special request to the Ministry of Finance for funding to support the expansion of the programme in 2003 to cover 10 districts with a total population of 4.3 millions. Successful implementation of the planned rapid roll-out to cover all endemic districts by 2005, followed by maintenance of MDA for 5-6 years to interrupt transmission, will require sustained operational funding.

The programme trained supervisors and Community Drug Distributors who will be utilised during other rounds of MDA. The CDDs are voluntary community workers who will participate in other health activities. There have however been demands from districts for payment of Community Drug Distributors. During the first round of MDA, there were about 8000 CDDs in the two districts. The programme does not have resources to pay incentives to so large a number of community health workers. As the programme scales up, the number of CDDs in the 10 districts will rise to over 26,000, and the issue of incentives will become critical.

Linkage with other programmes
Discussions are underway between the National Onchocerciasis Control Programme, the Schistosomiasis Control Initiative and PELF on how best to integrate some of their activities e.g., training, supervision, advocacy, registration, and drug distribution. At the district level, the Vector Control Officer, who is the focal person for LF, is involved in implementing other vector borne disease programmes. The Community Drug Distributors who were trained for LF are being used for distribution of Homapacks for Home Based Management of Fevers and also participate in most of the community based health programmes.

Key conclusions

- the elimination of lymphatic filariasis is a high MOH and district priority in Uganda in those areas where the disease is endemic. It is included in relevant district plans.
- that said, the national programme to eliminate lymphatic filariasis (PELF) seems to have been kick-started by the drug donation programmes and the Global Alliance to Eliminate LF. While GlaxoSmithKline and Merck & Co have committed to providing free drugs for as long as required, there remains to date considerable uncertainty about provision of sufficient operational funding to go to scale and maintain MDAs for the 5-6 years necessary to interrupt transmission.
- the Global Alliance sought to influence the MOH's programme launch plans; in the event, a compromise proposal was agreed with a launch in two districts in 2002.
- helpful moves towards greater integration with other tropical disease programmes are being developed

ANNEX 7

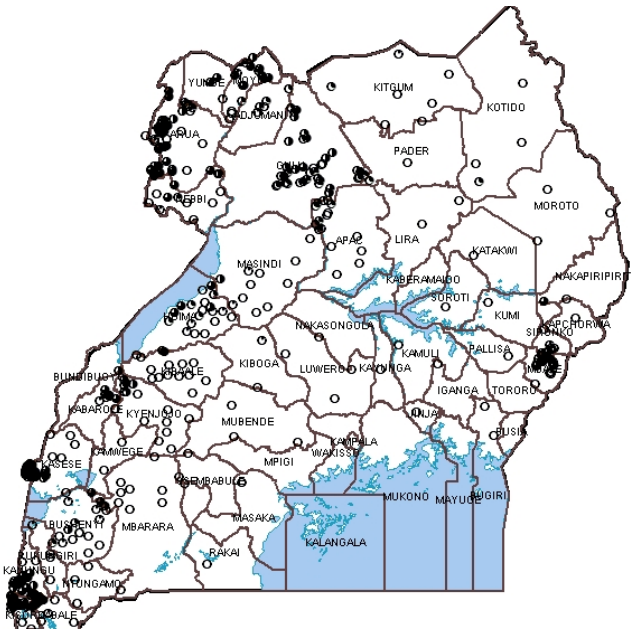
National Onchocerciasis Control Programme (NOCP)

Background

Onchocerciasis is endemic in 22 of the 56 districts of Uganda. It affects mainly the rural poor living in remote areas that are infested with the black fly *(Simulium damnosum)* which transmits the parasite. It is estimated that over 2 million people, concentrated in discrete foci in river valleys within the endemic districts, are at risk. In Uganda, onchocerciasis manifests mainly as a dermatological rather than a blinding disease. A higher than expected prevalence of epilepsy has also been reported in the onchocerciasis endemic districts (Ovugo et al, 1996).

A 1995 multi-country study by the Special Programme for Research and Training in Tropical Diseases (TDR) indicated that dermatological manifestations of onchocerciasis contributed more DALYs lost than onchocerciasis blindness. The skin nodules, intractable itching, de-pigmentation and lymphoedema have been shown to produce significant social and economic costs to the affected individuals and communities.

Onchocerciasis Endemic Districts of Uganda
(Vector Control Department, MoH, Uganda)



There was little organised activity for the control of onchocerciasis in Uganda after the intensive pre-independence vector control efforts, especially around the site of the hydroelectric dam in Jinja, and the limited use of diethylcarbamazine (DEC) for patient treatment. Until recently, efforts to control onchocerciasis remained mostly in the hands of the Non-Governmental Organizations. It is reported that the Uganda Foundation for the Blind, a church-based NGO, introduced Ivermectin treatment in Uganda in 1991 under the aegis of the Mectizan® Donation Program; this was later taken up by the international NGDOs operating in Uganda who by 1994 and 1995 were providing 800,000 treatments per year.

A Draft National Plan was developed in 1994 following a Rapid Epidemiological Assessment which revealed a total of 17 districts affected. The Plan was revised following the more accurate Rapid Epidemiological Mapping of Onchocerciasis (REMO), with support from TDR. The REMO revealed the presence of onchocerciasis in 5 additional districts, bringing the number of affected districts to 22.

Implementation of the national plan was however held up, again for lack of funding. Another proposal for an integrated programme for the control of Lymphatic Filariasis and Onchocerciasis was submitted in August 1996 by the Vector Control Division of the Ministry of Health to TDR, but could not be funded. This funding obstacle was removed in December 1996, when Uganda and Malawi became the first countries to receive approval for funding of their respective national plans by the African Programme for Onchocerciasis Control (APOC).

NOCP Goal and Objectives
The goal of the National Onchocerciasis Control Programme (NOCP) is to achieve the elimination of onchocerciasis as a public health problem in Uganda.

The main objectives of the programme are to:

- develop sustainable Community Directed Treatment with Ivermectin in all the onchocerciasis endemic areas in Uganda;
- eradicate the vector in two of the major transmission reservoirs in Kabarole and Kibaale districts through the application of a safe and effective insecticide.

Programme Targets

- to achieve 100% geographical coverage with Community Directed Treatment with Ivermectin (CDTI) in the affected areas;
- to achieve 80% coverage of the eligible individuals with Ivermectin treatment within affected communities;
- to achieve sustainability of the programme within five years of the onset of implementation.

Nature of Partnerships

Global Level
The Uganda NOCP is being implemented in collaboration with the Mectizan® Donation Program, which gives free and unlimited supplies of Mectizan® (ivermectin), and APOC which provides time-limited technical and financial support for implementing the programme.

Mectizan Donation Program
Merck, Sharpe and Dohme discovered Mectizan® in the mid 1970s as a veterinary de-worming agent. Based on the knowledge that Mectizan® was highly effective in treating microfilaria in cattle and horses, Merck in collaboration with WHO's TDR undertook a series of clinical and laboratory trials on the safety and effectiveness of Mectizan® in human onchocerciasis.

Following successful testing, Merck and Co. announced in 1987 their decision to donate free Mectizan® for the treatment of onchocerciasis for "as long as was needed, wherever needed" (*MDP website*). Before Ivermectin, no really safe and effective drug for onchocerciasis existed. The following year, Merck officially launched the Mectizan® Donation Program (MDP) as a non-profit organization to oversee the donations. In 1998, the program was extended to include lymphatic filariasis in countries/areas where LF was co-endemic with onchocerciasis.

The Onchocerciasis Control Programme or OCP was launched in 1994 by WHO, FAO, UNDP, World Bank and some donor governments to address the heavy burden of river blindness that was obstructing socio-economic development in a large number of countries in and around the Volta River basin of West Africa. The main strategy of OCP was vector eradication through extensive and sustained aerial spraying of the vector breeding sites.

OCP therefore became the first natural partner of the Mectizan® Donation Programme, a relationship that developed to include the NGDO Coordination Committee for onchocerciasis control in non-OCP countries, and later APOC in Africa (see below) and the Onchocerciasis Elimination Program in the Americas (OEPA).

The secretariat of the Mectizan® Donation Program is based in Atlanta, Georgia, and has an independent Mectizan® Expert Committee (with headquarters in Decatur, Georgia) to review all applications for drug donations by the program.

Logistics and management of drug consignments for approved programmes in Africa are handled by the office of the Assistant Medical Manager for Africa, based in Merck, Sharp and Dohme Interpharma in La Celle Saint Cloud in France. This office also manages the Humanitarian Program of MDP (including the approval of requests) which addresses the needs of programmes, hospitals, individual doctors or clinics that care for small numbers of patients in circumstances that do not justify mass treatment.

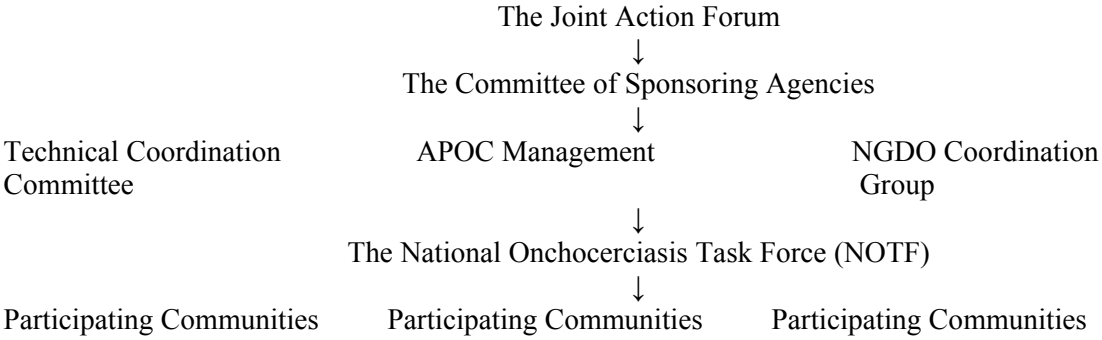
African Programme for Onchocerciasis Control (APOC)
The African Programme for Onchocerciasis Control (APOC) was formally launched in December 1995 with the objective of providing technical and financial support for the elimination of the disease in those onchocerciasis endemic countries in Africa outside the original Onchocerciasis Control Programme (OCP). Its goal is to eliminate onchocerciasis as a public health and socio-economic problem throughout Africa.

Objective
- to establish, within a period of 12 years, effective and self sustainable community-based Ivermectin treatment throughout the endemic areas in the geographic scope of the programme, and if possible to eliminate the vector

Its main control strategy is mass Community Directed Treatment with Ivermectin in affected communities with vector eradication in limited selected foci.

Targets
- by year 2000, Ivermectin delivery projects will have been launched in all endemic areas
- by year 2005, CDTI will have been established in all eligible endemic communities with over 85% of all eligible community members receiving Ivermectin treatment – financial support will have ceased and only monitoring of community based systems will continue.
- by year 2008, all community based systems will have been declared sustainable and all APOC support will have ceased and all residual activities integrated into the national health systems

APOC governance structure:



Partners in APOC include participating endemic countries, WHO, UNDP, FAO, WB, OCP (which hosts the APOC secretariat and provided its first Director a.i. and the current substantive Director), the NGDO Coordination Group and the contributing parties: USA, UK, Germany, the Netherlands, the Kuwait Fund, France, Switzerland.

APOC's Joint Action Forum is made up of the 19 participating countries, contributing parties (donors), the 4 sponsoring agencies (FAO, UNDP, WHO, and World Bank who also make up the Committee of Sponsoring Agencies) and 11 representatives of the NGDO Coordination Group.

The Technical Coordination Committee consists of 10 members on a 3 yearly rotation:
- 5 independent scientists nominated by the Joint Action Forum and appointed by WHO
- 2 NGDO representatives
- 1 representative from the Carter Center
- 1 representative from OCP

APOC Management provides the secretariat and the World Bank acts as Fiscal Agent to APOC.

At the Uganda country level, the National Onchocerciasis Control Programme - operating through the National Onchocerciasis Task Force (NOTF) - is an integral part of the National Health Sector Strategic Plan. It enjoys a strong historical link with those members of the international NGDO Coordination Group for Ivermectin Distribution which operate in Uganda. Partners include:
- Ministry of Health
- participating District Local Governments and the affected communities
- The Global 2000 River Blindness Programme (of the Carter Foundation)
- Sight Savers International
- Christoffel Blindenmission
- World Vision International
- GTZ
- UNICEF
- WHO.

An MoU is signed between APOC and the NOTF for each phase of the national programme, with annual letters of agreement for each successive plan within each phase. Yet another MOU is signed between the NOTF and each participating district.

Conditionalities
As the National Onchocerciasis Control Programme is being implemented with APOC support, it is subject to the guidelines and procedures of APOC and the Mectizan® Donation Program respectively.

For the MDP, there are no conditionalities beyond meeting the criteria for entry into the Mectizan Donation Program. The first application, which goes separately and directly to the MDP and the Mectizan Expert Committee, is assessed on the basis of criteria such as appropriate epidemiological data, capacity to deliver the drug in a medically safe environment, assurance that the drug is used only for the intended purposes, the programme is able to determine drug dosage by weight or height, assurance of adequate storage and distribution systems, monitoring and reporting any severe adverse drug reactions, accurate record keeping and reporting, and to maintain regular treatment cycles in a sustainable manner. The subsequent annual applications go directly only to the Mectizan Expert Committee for review and approval.

The conditionalities for participating in APOC include: drug delivery through community directed treatment, epidemiological mapping using REMO, ability to meet 25% of the operational budget from the outset, gradual phasing out of APOC financial support to achieve 100% local funding of operational costs at the end of year 5 (a sustainability plan is required of each of the participating districts in their fourth year), operation of a special APOC Bank Account with designated signatories, procurement using WHO procedures, clear community ownership and participation, auditing and inspection of the local project accounts, monitoring and reporting as per APOC guidelines.

Programme start date, stage of development, future plans
As noted above, substantial treatment coverage was already being provided by international NGDOs supported by the Mectizan® Donation Program before the launch of the National Onchocerciasis Control

Programme (NOCP). The NOCP was approved in December 1996 and became operational with APOC funding in phases from 1997:

Phase 1	: 4 districts	1997 - 2002
Phase 2:	7 districts	1998 - 2003
Phase 3:	5 districts	1999 - 2004
Phase 4:	6 districts	2000 - 2005

Data from the Project Secretariat indicate that all endemic districts and communities are now fully covered with the necessary community, district and national delivery, support and supervisory structures in place and functional. The programme is now focused on achieving closer integration with other PHC programmes and developing national, district and community sustainability plans including continuing capacity development, and monitoring CDTI coverage and disease prevalence in the communities.

NOCP Governance arrangements

The programme is directed by a National Onchocerciasis Task Force (NOTF) whose membership is drawn from the implementing partners. It is chaired by the Director for Planning and Development of the Ministry of Health, with the Programme Coordinator as Secretary. The NGDO Coalition provides another coordination forum for these key implementing partners.

Each of the partner districts has an Onchocerciasis Coordinator at district level, as well as in each affected Health Sub-District.

Each phase of the APOC project has a separate national proposal or project document and budget by source of funding, and includes the epidemiology of onchocerciasis in the implementing districts, a national plan, and a monitoring and evaluation framework. The proposal must be accompanied by a letter of endorsement from the Government before it is considered by APOC. Once approved, a Memorandum of Understanding (MoU) is signed between NOTF and APOC before any funds are disbursed. Subsequent annual plans and budgets are formalised through an Annual Letter of Agreement from APOC Management.

Each participating district then formulates its own plan of work and budget for approval by the NOTF. A separate MoU is signed between each district and the NOTF, spelling out the obligations and responsibilities of each of the implementing parties. As with the case of the NOTF, each participating district is required to operate a dedicated APOC project bank account, with the Chair of the District Council, the Chief Administrative Officer of the District, and the District Director of Health Services as co-signatories.

Secretariat/manager

The NOCP Secretariat is located in the Vector Control Division of the Department of Community Health, within the Ministry of Health.

Dedicated personnel

The Secretariat consists of the fulltime staff consisting of the National Programme Coordinator, 1 Entomologist, 1 project Accountant, 1 Secretary and a Driver. The Programme Coordinator and the entomologist are staff members of the MoH. The other three members of the secretariat were specifically recruited in support of the project and their salaries have to date been met from APOC funds which will shortly cease. Additional support, including laboratory backup, is provided from within the Vector Control Division. No other new or additional staff has been added at either national or district level as a result of the project.

At District level the District Director of Health Services (DMO) is the Programme Manager, assisted by a Vector Control Officer as Coordinator for the NOCP. They are supported as needed by other district personnel such as the District Health Education Officer. The onchocerciasis related activities are part of their normal schedules of work.

At community level, each participating community selects the appropriate number of CDTI Supervisors and Distributors, all of whom work on a voluntary basis. Most of them are community resource persons with regular jobs such as teachers, Community Health Workers, farmers, housewives, etc. The basic criteria are proven willingness and ability to serve the community, and sufficient literacy to complete the simple tally sheets and registers.

The NOCP does not operate a composite national budget. It uses the APOC format which calls for an annual budget for each phase of the programme, indicating budget allocation by source of funding (MoH, APOC, District, Health Sub-district, NGDO, and the community). The maximum contribution by APOC at year 1 of implementation is 75%, excluding the donated drugs for which no monetary value is assigned in the budgets.

The table below representing the budget summary for the five Phase 3 districts (in their fourth year of implementation) is illustrative. Districts in Phase 1 no longer receive APOC financial support as they concluded their fifth year in November 2003.

Contributor	Year 2003	
	TOTAL Budgeted (US$)	**TOTAL Released (US$)**
The Ministry of Health (MOH)	*2856*	*2856*
The local NGDO(s) (if any)	*No Local NGDO*	*Nil*
The NGDO partner(s)		*5561*
District/LGA		*5398*
Communities		*Not known*
APOC Trust Fund	*102,174*	*40,000*
TOTAL		*53,815*

Financial contributions from lower lever local governments (LCIII) and communities has not proven easy as these are mainly very poor communities with low income and a low tax revenue base for the Sub-county Councils.

Presentation of programme to beneficiaries
Following the creation of APOC, a joint WHO AFRO/APOC/NGDO Office mission visited Uganda in 1996 to sensitise central and local Government, the Uganda NGDO Coalition and other stakeholders on the programme. Other technical visits followed and culminated in a broader sensitization seminar for all actors held in Kasese in November, 1996. Other national sensitization efforts included attendance at the APOC Joint Action Forum and inter-country Meetings on CDTI. A cabinet information paper was later submitted by the Minister of Health.

District Local Governments, health unit personnel and community leaders were in turn sensitised about the proposed programme and its implications for the communities affected. The nature of the partnership, obligations of the respective parties, community ownership and sustainability were emphasised.

NOCP Mode of Operations
For each phase of the programme a separate proposal is submitted by the NOTF for APOC approval.

Concurrently, a series of activities to sensitize the participating district political and health authorities is undertaken by national and district MoH personnel and the partner NGDOs. Mobilization of affected communities includes community selection of the Community Supervisors and Drug Distributors and a decision by each community on the timing and mode of drug distribution - house to house, at fixed points or both. This is followed by training of health unit personnel who in turn assist in training community supervisors and drug distributors.

Flow of Drugs

i. an annual request based on district returns is prepared by the National Programme Coordinator and cleared by the NOTF
ii. initial requests are directed separately to both the Mectizan Donation Program (MDP) for the Mectizan Expert Committee(MEC) using special MDP forms. A separate copy is forwarded to the APOC Secretariat at the same time
iii. each follow-up request is forwarded directly to the MDP/MEC
iv. approved drugs are air freighted to Entebbe Airport by the Merck unit responsible for the Africa Region. MDP pays all charges up to the airport. Government taxes are waived as per prior agreement
v. the consignment of Mectizan® is cleared from the airport by WHO Country Office who deliver it direct to the Programme secretariat in the MOH
vi. the MOH Secretariat delivers each district consignment to the Medical Stores of the respective districts where they are taken into inventory in the normal way
vii. DDHS delivers the supplies to each implementing health unit where they are similarly put into the inventory. Health units (with appropriate authority from the person in charge) may also collect from the District Health Office
viii. the community appointed person (designated community leader, CDTI Supervisor or Community Drug Distributor) collects the drugs for each community
ix. individual CDDs collect their supplies from the Supervisor or designated official at the appropriate time before actual distribution

Reporting

Reporting follows the reverse order with each CDD tallying the number of people treated by dose (which varies between 1 and 4 tablets depending on height of the client), total number of tablets issued out, balance of stock, and explanation for any discrepancies. The totals for each CDD within a community are compiled and sent to or collected by the CDTI Supervisor for a group of villages. The Supervisor checks the returns before compiling the data for his/her area of responsibility. Each supervisor delivers his/her report to the District Onchocerciasis Coordinator who compiles the district figures. District figures are verified by the DDHS before forwarding them to the National Coordinator who in turn prepares the national report for submission separately to the MoH and Mectizan Expert Committee, with copy to APOC Secretariat. Onchocerciasis is currently not included in the National Health Management Information System and reporting, unlike the drug supply line, actually bypasses the supervising health unit and health sub-district.

The 3-page MDP reporting form and the APOC Annual Report (may be up to 40 pages) are the only additional reports resulting from the partnership.

Current Geographical and Epidemiological Coverage

Total coverage of the communities at risk was achieved in 2001 and has been sustained since. Annual treatment of the total eligible averages 1.8 million people per annum (population at risk excluding children under 5, the very sick, etc) with the treatment coverage rate ranging from 65% to 93% with a national average in 2002 of 80%.

29,921 Community drug distributor have been trained in CTD giving an average of 1 CDD for every 43 eligible persons at risk. CDDs are selected by the respective communities or homesteads and generally follow existing clans and kinships. This has facilitated treatment compliance and the voluntarism that is the recommended programme practice with CDDs.

Transmission of onchocerciasis has been successfully interrupted in the two foci that were treated under the programme and entomological surveillance has continued to confirm absence of the black fly in these areas.

Staff and community visited during the field component of this study were all very enthusiastic about the programme. The benefits of the programme were clearly evident. "You should have seen the skins of the people before the programme came here" said one of the CDTI Community Supervisors. "People are able to go about their business, socialise and sleep peacefully without the constant itching and scratching". Their only anxieties were that the younger children who are also exposed are excluded from the programme, and that the river from which they draw water is still swarming with the black flies.

Linkages with other programmes/integration
Like several other national tropical disease control programmes, the programme - though fully owned within the MOH - has until recently been implemented in a vertical manner, even where it was integrated into the district and health sub-district plans. The training, drug supply and reporting systems were separate from the routine systems.

It should be noted however that this was not a condition of the partnership. In fact the initial consignments of Mectizan® were cleared and stored by the National Medical Stores for collection by the respective districts. This was discontinued when the central MoH defaulted in reimbursing the costs incurred by NMS in providing the service.

By contrast, at community level many of the Community Drug Distributors (estimated at about 60%) already act as community agents for various other primary health care programmes such as water/sanitation, EPI, Malaria, Polio eradication, TBA, etc. without impairment of performance or skewed priorities.

Sustainability measures
Collaboration with both MDP and APOC requires assurance of sustainability over the medium term. The NOCP was therefore designed to encourage a progressive shift towards sustainability at all levels. Phase 1 districts have this year commenced operation without APOC funding through increased allocations from the central MoH, district health budgets and support from the NGDO partners. Some risk still exists from sudden withdrawal of some of the supporting NGDOs.

As provided for in the National Health Plan, onchocerciasis qualifies for funding through the Primary Health Care Conditional Grants. Many districts are already using this to support their programmes, as the operational costs of sustaining the programme are relatively small for individual districts. All participating districts are required to develop sustainability plans before the final year of APOC financial support to the operation of their programmes. The MoH has from the 2003-2004 financial year adjusted the formula for allocations of the PHC Conditional Grant to districts to include additional funding for diseases such as onchocerciasis that pose a particular burden to specific districts. Communities continue to provide support (mostly in kind or compensatory relief from communal labour for the CDDs).

The NOTF management is working towards stronger integration with the national primary health care programme through using the national HMIS and drug distribution systems. Ivermectin has been incorporated in the current version of the national essential drug list and discussions have been initiated to include oncho into the HMIS. Supervision from the centre and district is increasingly focusing on the neediest districts, allowing the overseeing health units and health sub-district to take on these functions without much interference.

A recent TDR-funded study[24] has shown that integrating community directed treatment for the control of onchocerciasis, schistosomiasis and intestinal helminths can increase rather lower compliance with CDTI. It

[24] Ndyomugyenyi et al, *Integrated community directed treatment for the control of onchocerciasis, schistosomiasis and intestinal helminths infections in Uganda: advantages and disadvantages*, 2003

is planned to apply the integrated approach to all districts in Uganda where the three parasitic infections co-exist.

Key conclusions

In the first half of the 1990s, the Mectizan® Donation Program was supporting NGDOs in providing substantial treatment coverage for onchocerciasis in Uganda. As early as 1994 the government developed a National Plan for the control of Onchocerciasis but could not proceed with its implementation because of financial constraints. It was a widely expressed view of all the people interviewed, that without free Mectizan from the donation programme **and** financial support from APOC, scaling up of CDTI in a government-led, national programme would not have been possible for some years to come.

The current programme is seen as a clear national priority, particularly for those districts where onchocerciasis is endemic, and is fully owned within the Ministry of Health and the relevant districts.

The national programme is already working towards integrating the programme into the routine PHC system and participating districts are progressively attaining sustainability at the end of their respective 5-year periods of APOC financial support.

A key question for the study was the extent, if any, to which the drug donation programme controlled or influenced national programmes. The presence of MDP has not been intrusive in the Uganda NOCP even at the national level. The Programme Coordinator recalls three visits from MDP in the six years of operation of the programme, and even then, these were primarily to reinforce the need for government commitment to sustaining the programme; the visit of the Director of MDP, Dr Stephanie Meredith, to administer the symbolic 100 millionth dose of Mectizan in Bushicka, in Mbale District in July 1998; and on the logistics of Ivermectin supply and distribution of Mectizan. While these visits were felt to be supportive, the general low profile of MDP was seen as a major benefit rather than a drawback.

ANNEX 8

National Sleeping Sickness Control Programme

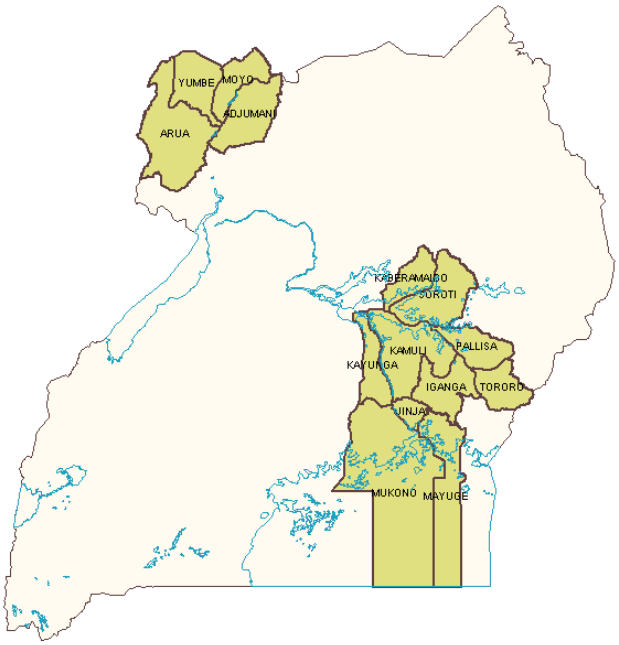
Background

Sleeping Sickness (Human African Trypanosomiasis) has been known in Uganda from the end of the 19th Century. Since then, periodic epidemics have alternated with cycles of intensive disease control and relaxation. Latterly, the political and economic upheavals which beset Uganda in the 1970s and 1980s led to the collapse of social services and tsetse fly control measures. In addition, West Nile exiles returning from Southern Sudan after the liberation war of 1978/79 provoked a sleeping sickness epidemic in that region.

The Ministry of Health established the National Sleeping Sickness Control programme in 1986. With close collaboration between the Ministry of Health and the Ministry of Agriculture and Animal Industry and Fisheries plus strong donor support, sleeping sickness was virtually brought under control. But as a result of the termination of donor support combined with political, economic, behavioural and climatic factors, the disease has re-emerged in Uganda and even spread to previously virgin areas.

Over the last 5 years the number of reported cases in the South Eastern region has continued to increase such that over 400 cases are being reported annually as compared to 32 in 1990. The first case of Sleeping Sickness was reported in Soroti District in 1999, probably as a result of a cattle restocking programme. Serere Health Centre, the only treatment centre for sleeping sickness in Soroti, reported 61 new cases with 3 deaths in 1999; 87 in 2002 and 84 in the first quarter of 2003 alone. As of March 2003, 90% of the Health Centre's admissions are suspected sleeping sickness cases. The rapid spread of the vector and the increasing number of new cases has led to a decision to open two additional treatment centres in the district in 2003. The epidemic is likely to spread to Kumi, Katakwi, Apac and Lira Districts.

Endemic districts for sleeping sickness in Uganda



Programme start date, stage of development, future plans
In the face of these developments, the Ministry of Health in 2000 drew up a plan of action for the revitalisation of the sleeping sickness control in the country. It regards sleeping sickness as a clear national priority, as evidenced by the disease being cited in the national HSSP and by the programme receiving funding from the Primary Health Care Conditional Grant of the National Poverty Action Fund. The national programme is fully owned and managed on a day to day basis by the Ministry of Health and districts. In Uganda there has been no direct pharmaceutical company involvement beyond the drug donation. National programme contacts are with the WHO secretariat for the WHO Programme to Eliminate Sleeping Sickness.

Programme objectives and strategies in Uganda

Objectives
The main objectives of the National Sleeping Sickness Control Programme are to:

- set up sustainable sleeping sickness control,
- reduce the incidence of sleeping sickness to <2 per 100,000 at parish level
- prevent the spread of sleeping sickness to virgin areas
- integrate sleeping sickness into the District Health Services

Strategies
The National Sleeping Sickness Control Programme of the Ministry of Health has over the years been implementing the following strategies for control of sleeping sickness:

- passive and active medical surveillance The main activities in the districts are case finding, case management and surveillance. Treatment for sleeping sickness currently relies on Pentamidine, Suramin, Eflornithine and Melasorprol
- tsetse control in collaboration with the Entomology Division of the Ministry of Agriculture, Animal Industry and Fisheries. The following methods are used in an integrated manner:
    - insecticidal barrier spraying using an environmentally acceptable insecticide (3% dieldrin)
    - deltamethrin pyramidal impregnated traps
    - aerial spraying using endosulfan
    - limited clearing of the Lantana Camara bush, the popular habitat for the tsetse flies in the Busoga Region
- animal reservoir treatment in collaboration with the Veterinary Department of the Ministry of Agriculture, Animal Industry and Fisheries, particularly in the South Eastern Region

Conditionalities
There are no unreasonable conditionalities associated with the WHO Programme or the individual drug donation programmes. The programme has to report on how the last supply of drugs was used, the number of patients treated every month and how many of these are in the last stage of treatment, and it must quantify the requirement for the next supply.

Nature of Partnerships

Global level partnerships
World Health Assembly Resolution (WHA) 50.36 urged countries to coordinate their action for control of trypanosomiasis through a joint OAU/FAO/IAEA/WHO project for global collaboration and coordination of action. Amongst other things, the resolution requested the Director General to "ensure that WHO is able to maintain a sufficient stock of equipment, supplies, in particular drugs and diagnostic reagents to manage the emergency".

The current national control programme is set in the context of a global WHO Programme to Eliminate Sleeping Sickness (WPESS) which has a partnership agreement with three pharmaceutical companies for the supply of free drugs for the treatment of the sleeping sickness:

- in May 2001, Aventis agreed to supply free Pentamidine, Melarsoprol and Eflornithine for five years, plus financial support to strengthen surveillance and control activities. Bristol-Myers Squibb donated sufficient drug raw materials for Aventis to formulate Eflornithine for one year's supply
- in November 2002, Bayer AG agreed to donate Suramin and Nifurtimox for five years and to support studies for a label extension of Nifurtimox for use in treating sleeping sickness

Country level partnerships
A number of development partners have provided substantial support over the years. DfID (ODA) funded a sleeping sickness control programme in the Busoga region between 1985 and 1993. The EU funded a multidisciplinary Tsetse and Trypanosomiasis Control Programme in the South-Eastern region between 1987 and 1993, and another programme implemented by EDF in the West Nile Region ended in September 2002. The Ministry of Health, working in partnership with the affected District Local Governments and in collaboration with WHO country office, is now implementing the programme in both regions.

Governance arrangements
The control of sleeping sickness requires close collaboration between the Ministry of Health and the Ministry of Agriculture and Animal Industry. Government therefore established The Uganda Trypanosomiasis Control Council (UTCC) in 1992, by statute. The statute establishing the council provides for policy guidance relating to Tsetse and Trypanosomiasis control. and spells out the roles and responsibilities of the Ministry of Health (National Sleeping Sickness Control Programme) and the Ministry of Agriculture, Animal Industry and Fisheries (Tsetse Control Department) in collaboration and coordination in the control of sleeping sickness. A Technical Committee of the Council composed of stakeholders implements technical aspects.

Secretariat/Manager
The National Sleeping Sickness Control Programme is managed as vertical programme. It is coordinated and managed by an MOH Programme Manager and assisted by District Vector Control Officers in the affected districts. The Programme Manager and Secretariat were initially located in Jinja but after decentralisation, Programme Management was transferred to Ministry of Health Headquarters Vector Borne Disease Control Division.

Mode of operations
Districts affected by sleeping sickness quantify their drug requirements and submit the requests to the national Programme Manager. The Programme Manager compiles the national requirement and submits it to WHO Country Office which then sends it to WHO Headquarters in Geneva. At WHO Headquarters, there is a Review Committee which reviews the country requests and, once approved, sends them to MSF France in Paris. All sleeping sickness drugs are shipped to countries through MSF France Logistics (supply services) in Bordeaux.

The drugs are collected from the airport by the WHO country office and delivered to the Programme Manager's office at the Ministry of Health Headquarters. The relevant District Directors of Health Services then collect the drugs from the Programme Manager for distribution within the district. The quantities are determined by estimates based on returns of the previous year.

Presentation of programme to beneficiaries
The programme was extensively publicised to the benefiting communities. Aggressive community awareness campaigns were carried out at the beginning of the programme to sensitise the community on the causes, effects, treatment and prevention of sleeping sickness. Communities were sensitised on the importance of treatment and the need to slash bushes, especially lantana camara, around homesteads. Community awareness has waned since the peak of the epidemic in the 1980s.

Communities of each sub-county were organised to form committees to overlook and supervise the tsetse traps and to clear bushes below them. This reduced the incidence of theft of the traps by the communities.

The programme recruited and trained schools leavers as Sleeping Sickness Assistants (SSA). The SSA worked with the Chiefs and helped to outline the roles and responsibilities of communities. They helped to trace infected people in the community, took blood smears for laboratory examination, brought back the results of the examination and followed up treatment.

Current geographical and epidemiological coverage

The National Sleeping Sickness Control Programme is providing services to all fourteen districts with reported cases of sleeping sickness (Arua, Yumbe, Adjumani and Moyo in West Nile Region, where sleeping sickness is caused by Trypanosoma gambiense, and Mukono, Kayunga, Jinja, Iganga, Mayuge, Kamuli, Tororo, Pallisa, Soroti and Kaberamaido in Eastern Region, where sleeping sickness is caused by Trypanosoma rhodesiense). The total number of people at risk of infection with sleeping sickness in Uganda is estimated to be 5.2 million.

Budget and actual spend

The programme has over the last two financial years been receiving funding from the Primary Health Care Conditional Grant of the National Poverty Action Fund (PAF) (i.e. budget support funding). In Financial Year 2001/02, the programme received Shs. 550m, which was used for purchase of equipment, transport for Sleeping Sickness Assistants, supplies for field staff and tsetse traps and for revitalisation of the laboratories. In Financial Year 2002/03, the programme was allocated Shs. 350m. These funds are still inadequate to cater for programme requirements.

Sustainability measures

The story of sleeping sickness in Uganda is a text book example of the importance of sustaining control measures. This requires both drugs and operational funding. So far as the drugs are concerned, assurance - as well as affordability - of a sustained supply is critical.

Rightly or wrongly, study interviewees saw a major benefit of having pharmaceutical companies involved in drug access partnerships as their renewed attention to research and development, given the toxicity of current sleeping sickness drugs and the need for safer and effective alternatives.

The other lesson of history is the vital need for continued operational support. One of the key strategies to ensure sustainability of sleeping sickness programme activities was advocacy for the inclusion of the programme under Uganda's Poverty Action Fund, which was implemented in 2001/2. This is the most sustainable funding under the Budget Support funding arrangement.

The Ministry of Health intends to continue lobbying for the return of the Farming In Tsetse Control Areas (FITCA) project to the Coordination Office for the Control of Trypanosomiasis in Uganda (COCTU). This project was recently transferred to Ministry of Agriculture, Animal Industry and Fisheries with the consequence that the Ministry of Health is currently unable to access any funding from this project.

The Ministry of Health has successfully transferred the payment of salaries for Sleeping Sickness Assistants from Local Governments on to the centralised Primary Health Care payroll. This ensures regular payment of salaries for these critical sleeping sickness field staff.

Linkage with other programmes

The programme is currently run as a typical vertical programme. There are however opportunities which could be used for collaboration and integration with other programmes. The highly trained Sleeping Sickness Assistants have been selected as community health workers in many districts and, as such, are instrumental in implementing community based health programmes. Many are already performing well as community agents for various other primary health care programmes such as malaria (in the distribution of Homapacks for Home Based Management of Fevers), EPI, polio eradication and water/sanitation.

Key conclusions

- in the face of a sleeping sickness epidemic which has spread into virgin areas, the national control programme is seen as a clear national and district priority, as evidenced by funding from the Primary Health Care Conditional Grant.
- the Aventis and Bayer AG donations are limited to 5 years, so there remains uncertainty about the future.
- the vicissitudes of sleeping sickness control in Uganda illustrate the importance of sustained control measures, with the corollary of sustained drug supply and adequate operational funding.
- rightly or wrongly, interviewees feel that the involvement of 'big pharma' in the global partnership has created renewed interest in R&D for this neglected disease.

ANNEX 9

HIV/AIDS Drug Access Initiative (DAI) and the Accelerated Access Initiative (AAI)

International level

Programme start date, stage of development, future plans
The DAI was started 1998 by UNAIDS as a pilot phase in four countries – Uganda, Chile, Cote d'Ivoire and Vietnam. The pilot phase finished in 2000 and in 2001 it changed its name to the Accelerated Access Initiative, still under UNAIDS. In 2002 it shifted to the auspices of WHO and is currently expanding to over 80 countries.

Programme objectives and strategy
The programme was launched in recognition of the growing disparity between rich and poor countries in access to HIV/AIDS related drugs. The objectives are to make HIV/AIDS drugs more affordable and accessible in developing countries and to improve technical collaboration in the development of national programme capacities to deliver care, treatment and support.

Expected benefits: (i) to accelerate sustained access to and use of appropriate, good quality interventions for prevention, treatment and care of HIV/AIDS related illness and prevention of perinatal transmission of HIV; (ii) to work through alliances involving governments, private industry, the UN system, aid agencies, NGOs and PLWHAs; and (iii) to implement public-private cooperation to respond to the needs and requests of countries with respect for human rights, equity, transparency and accountability.

Conditionalities/principles
- Political commitment by national governments.
- Strengthened national capacity for delivering care.
- Engagement of all sectors at national and global level.
- Efficient, reliable and secure distribution systems for medical supplies and other consumables.
- Additional sustainable funding from new national and international sources.
- Continued investment in R&D by the pharmaceutical industry on new treatments for HIV/AIDS and protection of IPRs.

Conditionalities to supply agreements typically are minimal – agreements usually last for one year but leave the buyer the option to buy from other (i.e. generic) supply sources, consistent with regulatory requirements and international agreements.

Nature of donation programme partnership
The founding organisations of the Drug Access Initiative were the UNAIDS Secretariat and five multinational pharmaceutical companies (Boehringer Ingelheim GmbH; Bristol-Myers Squibb; GlaxoSmithKline; Merck & Co. Inc; and F. Hoffmann-LaRoche Ltd). Other partners joined under the Accelerated Access Initiative and included international organisations (UNICEF, UNFPA, WHO and the World Bank) and a sixth pharmaceutical company, Abbott Laboratories.

Governance arrangements
The UNAIDS Contact Group is a forum for representatives of government, PLWHA, NGOs and others including the pharmaceutical industry. It serves to exchange information and views, engage in consultation and articulate needs and expectations from governments and provide advice from UNAIDS and other agencies. The contact group is convened by the UNAIDS Secretariat and co-sponsors and established by the Chair of the UNAIDS Programme Coordinating Board in consultation with members of the Board and the UNAIDS Secretariat.

Roles have been split between the international agencies and pharmaceutical companies. There are three working groups: country support – undertaken by pharmaceutical companies, the UNAIDS secretariat, UNICEF and WHO; communications – all partners; and procurement – UNAIDS secretariat, UNFPA, UNICEF and WHO.

Mode of operations

The DAI was only the pilot phase of what was always intended to be an international activity. Under the AAI, which started in July 2001, governments are informed about the initiative through the UN theme groups. Governments are offered UN input into their planning of care and support for PLWHA and requested to signify interest in the AAI to the UNAIDS representative. The UN country support working group would then organise support for the development of a plan for access to ARV drugs while promoting comprehensive care and informing the government about all procurement options, including information on the availability and costs of generic ARVs. The final plan for access is transmitted by the UN to those pharmaceutical companies from which the government would wish to open discussions on prices and transactions. Discussions involve government and pharmaceutical company representatives and are facilitated by UN staff in the country support working group. Technical support is also provided on a regional basis. Companies also provide training, health infrastructure strengthening and capacity development.

Overall performance against targets to date

Measuring performance

Performance is assessed in relation to:

- *the overall number of treatments delivered*
  As of December 2001, 27,000 people had gained access to ARV therapy through the programme – a 10-fold rise in the number of patients treated. According to industry sources, 35,500 had accessed treatment by March 2002. The proportion of these on triple therapy increased from 1/3 to 2/3 between September 2000 and March 2002 – an increase in quality of treatment. In low and middle income countries, 6 million people are estimated by UNAIDS to be in need of ARV treatment.

- *the number of endemic countries collaborating and their performance*
  As of June 2002: 80 countries had expressed interest, 39 countries had developed plans of action, 22 countries had entered negotiations with pharmaceutical companies, and 19 had successful UN-brokered supply agreements for ARVs. From July 2002, two regional groups have formed to negotiate with pharmaceutical companies with WHO/UNAIDS support: ECOWAS (15 West African countries) and CARICOM (15 Caribbean countries).

- *measures undertaken in countries for sustainability*
  There are no specific measures to report under the DAI/AAI but there have been efforts to fundraise for ARVs from other aid sources, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Also new World Bank offers to finance care and treatment reflects changing attitudes of donors to financing the purchase of ARVs. This is partly the result of UNAIDS' efforts to change perceptions at global level, in combination with reduced prices. All countries participating have also moved to eliminate or waive import taxes and duties on drugs used in HIV treatment.

- *measurement of disease reduction*
  ARVs will not cure HIV/AIDS although they can extend life dramatically and reduce the burden of disease. Boehringer Ingelheim's offer of free Nevirapine, combined with Abbott's free tests from June 2002, for the prevention of mother-to-child transmission is the only element which will really reduce disease incidence.

- *other possible impact*
  The lower prices of ARVs is the most significant achievement of the DAI/AAI – in some cases to 10-20% of prices in the North. The impact of the programme must, however, be estimated in the context of the emergence of competition from generic drug manufacturers, in particular for first line regimens that do not include protease inhibitors. The AAI also brought about transparent differential pricing for poor countries and price reductions continue – Abbott announced further price reductions for two ARV drugs in June 2002. The UN continues to lobby for further price reductions and increased transparency in formularies and prices.

Issues

Value added by partnership (partnership judgement)/criticisms

- coalition building at country level
  A limitation of the partnership has been its focus on governments/MOHs despite intention to engage with other actors – especially NGOs, private medical providers and large employers

- impetus to new thinking and approaches
  The programme has contributed to the development of consensus that it is possible to delivery ARVs in resource poor settings

- provision of new skills to the public sector
  Country by country approach is quite slow and the resources of the UN system have been stretched to respond to demands for assistance. Transfer of responsibility for technical assistance from UNAIDS to WHO in November 2001 will increase UN capacity – regional offices are now building up staff to help and WHO national offices are establishing focal points

- improved monitoring/surveillance
  Progress reports have been presented regularly at the Contact Group and other consultations. There is no structured information collection framework although indicators for care have been developed – pilot testing in Cambodia, Ethiopia and Kenya. These could be used to evaluate the AAI and in HIV surveillance

- capacity strengthening in the public sector
  Public and private health providers have accessed ARVs and gained experience with their use. Generally not supported by national guidelines. The AAI aims to support capacity but responsibility for it is with national governments. Constraints to capacity development – funds etc. – mean that little has happened

- raising profile of specific issue on the national/international agenda
  UNAIDS has contributed to the raising of the issue of treatment of HIV/AIDS on the international agenda, including the UN General Assembly Special Session on AIDS and the negotiation with pharmaceutical companies for the delivery of ARVs to resource poor settings

- use of private sector distribution/marketing channels
  Focus of procurement has been largely only on the drugs of the six participating drugs companies rather than generics. A representative of the generics industry has recently joined the Contact Group and greater efforts are needed to encourage generic competition to lower prices.

Comments
Lack of funds means that the numbers actually receiving treatment remains quite low and prices remain out of reach for most people in poor countries. Procurement solely through domestic financing remains impossible and health systems remain weak – VCT is not widely available for example and qualified staff are in short supply.

World Bank's MAP is providing support for HIV prevention, care and treatment throughout Africa and the first round of GFATM 60% of funding will go to HIV/AIDS. 21 countries will use part of these funds to purchase ARVs.

COUNTRY LEVEL: UGANDA

Assessment of disease in national/district health strategy and plan

HIV/AIDS status in Uganda:

The government policy of openness and political commitment to HIV/AIDS control has created high levels of awareness in the population and features prominently in the national and district health strategic plans.

- HIV infection prevalence rates from antenatal sentinel surveillance sites in 2001 was 6.5%
- Knowledge on preventive practices has also risen to 90% in 2001
- Condom use and age at first intercourse are both rising
- Progressive improvement in accessibility to PTMCT, VCT and ARV services. 24 centres provide PTMCT services, 20 centres provide treatment with ARVs to adults
  (HSSP Mid Term Review Report)

It is estimated that approximately 2 million people are infected with HIV, about 200,000 are expected to be symptomatic and only 8,515 patients are accessing ARVs in Uganda

Goals of the National Strategic Framework for HIV/AIDS activities in Uganda (2000/01 – 2005/06)

- reduction of HIV prevalence rates by 25% by the year 2005/06
- mitigation of health and socio-economic effects of HIV/AIDS at individual, household and community levels
- strengthening the national capacity to respond to the epidemic

Guiding policy documents

National Health Policy (1999)
Health Sector Strategic Plan (2000/01 – 2004/05)
National Operational Plan of the AIDS Control Programme, MoH (1997 – 2001)
National Strategic Framework for HIV/AIDS Activities in Uganda (2000/01 – 2005/06)
National Policy on Antiretroviral Treatment (2003)
National Treatment Guidelines
Prevention of Mother to Child Transmission Scale up Plan (2001 – 2006)
H.E. The President of Uganda's Manifesto (2001 – 2006)

Drug Access Initiative goal, objectives and strategy in Uganda

Goal: To improve and widen access to HIV/AIDS related drugs, in particular ARVs.

Expected outputs:

- An adequate and responsive distribution system to ensure continuous flows of HIV/AIDS drugs (and avoid expiry) would have been developed
- Mechanisms for access to HIV/AIDS-related drugs without disrupting or altering existing Essential Drugs Programmes implemented
- Appropriate information and training to health workers and communities to foster the establishment and improvement of an adequate medical information system provided
- Ultimately make HIV/AIDS-related drugs more available in Uganda

Conditionalities

Guarantee lowest price to end-user. The drugs to be sold only to accredited centres

Nature of partnership

Ministry of Health/UNAIDS

Medical Access Uganda Ltd (MAUL)

Participating Pharmaceutical companies established the non-profit company, Medical Access Uganda Ltd. (MAUL) for the purpose of the Initiative to manage drug purchase in liaison with the National

Advisory Board of the DAI, referral centres and the suppliers. The Board of Directors of MAUL was made up of the representatives of the five ARV patent holders participating in the UNAIDS partnership, who also contributed to its running costs and facilitated management of stocks through the supply of drugs on credit (to a total $75,000 in year one of operations).

NGOs

The Joint Medical Stores were responsible for storing and distributing drugs. The AIDS Support Organisation (TASO), The AIDS Information Centre (AIC) ensured appropriate levels of public awareness as well as make referrals to the next level of health facilities.

Program start date, stage of development, future plans

Launched in November 1997 as a pilot project by UNAIDS and the MoH in partnership with several pharmaceutical companies. The project became operational in August 1998.

Implementation of the following activities:

- Coordination of meetings
- Assessment and accreditation of treatment centres
- Training of health providers
- Development of policy and project document on PMTCT in Uganda
- Liaison with the relevant NGOs, PLWAs and other stakeholders
- Development of appropriate monitoring tools and carrying out monitoring of Initiative activities
- IEC and advocacy for DAI
- Community mobilisation and sensitisation
- Forging collaboration with the private sector/private companies to increase their participation in the management of HIV/AIDS in the workplace
- Collaboration with private practitioners
- Training of data clerks from the treatment centres in stock management software

Future plans:

The DAI was a pilot project designed to be implemented over a two year period and was extended by a further 18 months, running from 1997-2001. A review of the pilot phase was carried out between April 23rd and May 4th 2001 and the final report of the lessons learned was presented in September 2001. The global Accelerated Access Initiative (AAI) is not to be operating as a follow-on project in Uganda although drug procurement activities established under the DAI have continued.

Governance arrangements

Overseen by a National Advisory Board, appointed by the Minister of Health and comprising officials from a range of ministries, social scientists, doctors, the UN AIDS theme group and representatives of PLWHA. The Project coordinator, the manager of Medical Access Uganda and the communication consultant were ex-officio members. The board had three standing subcommittees that dealt with the different aspects of the initiative.

Location of secretariat/manager

Project Coordinator was appointed by the MoH and UNAIDS and was located within the UNAIDS country office.

Dedicated personnel

Project Coordinator DAI located within UNAIDS. IEC (Communications) consultant to support the MoH with the implementation of the initiative. The role was to assist the initiative with internal and external communications.

Budget and actual spend

Finances for the pilot project were administered by UNDP. The coordinator would initiate an activity with a cover letter approved and signed by the CPA with a copy to the Theme Group chairman. UNDP processed the payment for the activity.

Mode of operations

National Advisory Board with 3 subcommittees:
Subcommittee on Drug Policy and Financing

- Develop/review the drug pricing policies for the drug distribution system
- Periodically review the Initiative's drug needs based on reports from the accredited centres and the Non profit company
- Institute and maintain a drugs record/database system
- Explore alternative financing options for the Initiative

Subcommittee on Vertical Transmission

- To harmonise the activities in the country related to mother-to-child transmission to HIV (MTCT)
- To characterise the magnitude of MTCT in the country
- To carry out needs assessment for MTCT activities for selected Maternal and Child Health (MCH) units
- To develop an assessment tool for selected MCH units
- To develop/review recommendations/guidelines for implementation of MTCT activities such as recommendations on breastfeeding and alternative feeds, therapy guidelines and laboratory guidelines

Subcommittee on Care and Practice

- To develop/review national clinical management guidelines for the patients on antiretrovirals and other HIV related drugs
- To develop a training plan relevant to the Initiative in collaboration with AIDS Control Programme/MoH
- To identify and train a pool of trainers
- To conduct follow up and monitor the standards of care
- To review and design new drug regimens

Access to ARVs
Medical Access Uganda Ltd (MAUL,) a non profit organisation. was established to ensure continuous supply of ARV drugs. The ARVs from MAUL are sold to participating treatment centres with the minimum of profit.

Geographical and epidemiological coverage

The Initiative initially selected five health facilities in Kampala to function as referral centres for delivery of ARVs. By the end of the review of the DAI, two additional facilities had been accredited and a third was being evaluated. All the facilities are located in Kampala.
Before DAI, fewer than 400 patients accessed ARVs, by end of the evaluation 1,700 patients accessed ARVs through 7 accredited centres. Since then, in an expansion phase, 23 facilities have now been accredited, and up to 10,000 PLWHA have received treatment, of which 83% now receive triple therapy regimes.

Overall performance against targets to date

In the 2000 CDC evaluation, it was found that most patients accessed drugs at an advanced stage of disease as indicated by WHO staging, prior conditions, CD4+ cell count and viral load. The most common AIDS-related conditions prior to accessing ARVs were tuberculosis and oral candidiasis. Laboratory monitoring was also paid for by the patient until mid 1999 when the US CDC offered to provide viral load and CD4 counts. Most monitoring in Uganda took place at the JCRC. However, even at reduced prices, the costs of drugs and associated laboratory tests remain the major barrier to expanded access. The patients returning for follow-up had reasonably good adherence rates to the drugs although those who did not return were not available to check: the probability of a patient remaining on ART at six months was 77% and at one year was 67%. Of the total, around a third were on two drugs and half on trip therapy (HAART). A substantial proportion of patients changed therapy mainly due to toxicity and virologic failure. As would be expected, greater virologic responses were

obtained from patients on HAARTThe overall probability of survival was 82% at six months and 74% at one year.

Resistance to drugs was tested in Belgium and the UK and was found to be consistent with European and US resistance patterns. However, there are serious concerns with the impact on spread of drug resistance of the scaling up process. The monitoring mechanisms introduced under the DAI will help if they can be disseminated effectively during scaling up.

The role of peripheral centres in referral and monitoring of ARV treated patients was unclear as they received no information on availability and prices of drugs and were not conducting sufficient HIV testing to be able refer patients on for treatment. Counselling on the financial, social and personal implications of ART was hampered by lack of up to date information on prices and availability of different treatment options.

Laboratory monitoring was another problematic area since, at the end of the DAI project, the US CDC terminated its support. Referral centres reported serious problems with laboratory monitoring due to the high costs of CD4 count and viral load monitoring (approximately US$143 per test). This high cost was reported to have deterred those who might be able to afford the drugs alone from enrolling for treatment. In addition, some patients had initiated treatment without proper laboratory monitoring, with implications for toxicity, adherence and resistance. There were also problems with laboratory diagnosis of specific opportunistic infections leading to sub-optimal treatment of these conditions.

Issues

Value-added

- Demonstrated the feasibility of safely introducing ARVs in a low resource setting based on the principle of cost-sharing
- Achieved lower prices of branded ARVs
- Enriching the policy environment addressing issues of access to ARVs, treatment guidelines and standards.
- Enabled capacity building at the participating centres

Criticisms

- The prices of the ARVs supplied by the MAUL are still unaffordable by the majority of the population that need the drugs. Therefore there was no huge impact on the very poor. The expectation was that prices would drop to negligible levels allowing access to almost all the patients needing ARVs.
- The DAI was largely accessed via the public and NGO sector where the issue of privacy was not addressed. Patients would therefore shy away from attending clinics known to treat HIV/AIDS patients.
- Access to ARVs cannot work as a stand alone intervention. There are other issues such as partner notification and disclosure, stigma, psychosocial support, gender and decision making etc.

Comments

The DAI was initially a pilot project for two years. It was extended for six months and thereafter the leadership was transferred to the Ministry of Health under the AIDS Control Programme. The MAUL continues to function as before while the availability of generic ARVs is on the increase.

ANNEX 10

Viramune® Donation Programme

International Level

Programme start date, stage of development, future plans
July 2000, at the Durban International AIDS Conference, Boehringer Ingelheim announced that it would offer Viramune® (nevirapine) free. First supply was to the Republic of Congo (Brazzaville) in October 2000. The next countries to take part were Senegal, Rwanda, Zimbabwe and Uganda. In June 2002, Abbott Laboratories announced that the company would also donate its Determine HIV rapid test.

Programme objectives and strategy
To improve access to Viramune® (nevirapine) free of charge to interested governments for a period of 5 years to developing countries through the Viramune® Donation Programme for the prevention of mother-to-child transmission of HIV. One tablet of Viramune® given to mother during labour and a few drops of Viramune® to the infant within 72 hours will reduce the risk of viral transmission by ~50%. The Determine test is used in programmes to prevent MTCT in Africa and other least developed countries.

Conditionalities/principles
Only for use for preventing mother-to-child transmission and evidence of capacity to do so is required. Otherwise none known.

Nature of donation programme partnership
Straight drug donation programme handled outside any UN agency or auspices with assistance from Axios International.

Governance arrangements
To receive Viramune®, MTCT prevention programmes must complete an application form and go through a review process managed by Axios, as contracted directly by Boehringer Ingelheim.

Secretariat/manager
Axios International was hired in September 2001 to help with application process and overall management of the programme after very few responses were received to initial offer. It advises Boehringer Ingelheim on whether applicants are prepared to use the drug donation successfully. Once approved, a second form facilitates the shipping details. One annual report is required according to a standard template developed by Axios.

Mode of operations
Viramune® is to be made available to interested governments, NGOs, charitable organisation and other health care providers involved in the prevention of MTCT in developing countries. Over 100 countries are eligible to participate – derived from the World Bank classification of economies. Requirements are according to WHO Guidelines for Drug Donations: offers to governments which have expressed interest and have registered the drug for the prevention of MTCT according to local regulations and laws. NGOs, charitable organisations and other providers must also obtain approval from the local government in order to receive the donation.

It is offered to groups providing comprehensive MTCT prevention programmes which according to the UN also include HIV testing, voluntary counselling, appropriate antenatal care, counselling and support for safer infant feeing practices.

Boehringer Ingelheim provides an approved quantity of Viramune® free of charge and will also cover the cost of insurance and shipping up to the point of entry into the country. No additional local handling, tax, duties or distribution costs will be covered.

Overall performance against targets to date

Measuring performance
Performance is assessed in relation to:

- the overall number of treatments delivered
- the number of endemic countries collaborating and their performance
- measures undertaken in countries for sustainability
- measurement of disease reduction
- other possible impact

COUNTRY LEVEL: UGANDA
Assessment of disease in national/district health strategy and plan
(Disease – same as DAI) The MoH elaborated a strategic plan to scale up PMTCT to cover the entire country. The plan has two main components: ▪ The geographical expansion that focuses on establishing at least one implementing site in each district; and ▪ The organisational/functional expansion, which aims as supporting districts to provide services at the Health Sub-District or Health Centre IV levels. Goal: Reducing the current incidence of mother to child transmission by a third by the year 2005/06 (National Strategic Framework for HIV/AIDS activities in Uganda, 2000/01 – 2005/06)
Viramune® Donation Program goal, objectives and strategy in Uganda
Free access to NVP for PMTCT for 5 years
Nature of partnership
MoH. UNICEF, WHO, GTZ, Elisabeth Glaser Paediatric AIDS Foundation, Centre for Disease Control and Prevention (CDC), MSF France, Insituto Superiore di Sanita (ISS) – Rome, Medical Research Council in collaboration with Uganda Virus Research Institute, Médicin du Monde and Plan International, Population Service International
Program start date, stage of development, future plans
Programme initiated in 2001. PMTCT activities were already being carried out in Uganda. In January 2002 only 4 districts were offering PMTCT services and these increased to 22 districts by end of December 2002. The MoH scale up plan aims to cover at least half the country by end of 2002 and to establish at least one implementing site in all districts by the end of 2004.
Governance arrangements
Coordinated by the MoH.
Location of secretariat/manager
Coordinator PMTCT within MoH

Mode of operations
Drug procurement, importing and handling is the responsibility of Surgipharm (a private company representing Boehringer Ingelheim in Uganda). The NVP is then delivered to MAUL stores located within JMS. They supply the drugs to the office of the PMTCT officer in the MOH NACP. The participating centres get their supplies from the coordinator. The monitoring reports are compiled by the coordinator and submitted to Axios International managing the programme on behalf of Boehringer Ingelheim. UNICEF was involved in the Abbott Determine test distribution until recently when Medical Access took it over.
Current geographical and epidemiological coverage
Currently in 22 districts (Annual Report for PMTCT Jan to Dec 2002).
Linkages with other programmes
Donation of HIV testing kits by Abbott Laboratories and infant formula procured by UNICEF.
Issues
Value-added
More women willing to be counselled and tested.

ANNEX 11

Diflucan® Partnership Programme

International level

Programme start date, stage of development, future plans
In 2000, Pfizer made a partnership with the government of South Africa MOH. This is now a mature donation programme and is in the process of expanding to other African countries. As of April 2003, Pfizer has donated Diflucan® to governments and NGOs in Botswana, Ghana, Haiti, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zanzibar and Zimbabwe.

Programme objectives and strategy
The objective is to make the anti-fungal medicine Diflucan® (fluconazole) available to public sector HIV/AIDS patients with cryptococcal meningitis and oesophageal candidiasis who cannot afford treatment. Patients in the private sector cannot benefit from the donation.

Conditionalities/principles
Limited to the treatment of two infections (cryptococcal meningitis and oesophageal candidiasis) for patients in the public sector. Countries with greater than 1% HIV prevalence get priority. It is without dollar or time limits.

Nature of donation programme partnership
Drug donation programme for treating acute infection and preventing relapse for life.

Governance arrangements
None at international level.

Secretariat/manager
Axios International manages the programme application process and drug distribution. They are an independent consulting company with extensive experience in public health implementation programmes in developing countries.

Budget (approx.)
Without dollar or time limits.

Mode of operations
Pfizer provides drug and training of health professionals in the diagnosis and treatment of opportunistic infections.

Overall performance against targets to date

Measuring performance
Performance is assessed in relation to:

- *the overall number of treatments delivered*

3 million free doses of Diflucan® to governments and NGOs, 81,000 prescriptions processed

- *the number of endemic countries collaborating and their performance*

15 countries

- *measures undertaken in countries for sustainability*
- *measurement of disease reduction*
- *other possible impact.*

11,000 health care workers trained in the diagnosis and treatment of opportunistic fungal infections in partnership with the International Association of Physicians in AIDS Care.

Issues

Value added by partnership (partnership judgement)/criticisms

- capacity strengthening in the public sector

Pfizer committed to building capacity in this area – education materials are provided to facilitate effective diagnosis and treatment of fungal opportunistic infections. As the programme expands, regional training initiatives are planned. Materials include inventory management tools, patient support materials, diagnostic wall charts, training-of-trainer kits.

Comments

Initial concerns over prescribing restrictions to cryptococcal meningitis have been allayed by the subsequent addition of oesophageal candidiasis. The main remaining query from a few interviewees focuses on the rationality of establishing dependence on a donation programme of an expensive branded medicine at a time when the patent is about to expire and generic versions will be routinely available very cheaply, given concerns about the hidden costs of handling and reporting for donation programmes.

COUNTRY LEVEL: UGANDA
Assessment of disease in national/district health strategy and plan
(Disease same as DAI) Oesophageal and/or candidiasis are the most common opportunistic infections afflicting people living with HIV/AIDS and cryptococcal meningitis is the second largest cause of death in this group after tuberculosis.
Diflucan® Partnership Programme goal, objectives and strategy in Uganda
Improving access to drugs for opportunistic infections (cryptococcal meningitis and oesophageal candidiasis) for as long as is needed.
Conditionalities
The Diflucan® should be prescribed on the indicated conditions (Cryptococcal meningitis and oesophageal candidiasis) only. Compliance with Pfizer drug monitoring and prescribing systems.
Nature of partnership
Public: Ministry of Health, Uganda Private commercial: Pfizer International
Program start date, stage of development, future plans
Started in 2002 and is available in health facilities countrywide
Governance arrangements
Contract between MOH and Pfizer directly through a Memorandum of Understanding. No international organisations involved.
Location of secretariat/manager
Ministry of Health
Dedicated personnel
National coordinator in the MoH
Mode of operations
The MOH orders the drug from Pfizer's South African plant which then delivers to the NMS. Requisitions for the needed quantities of drugs are sent to the MoH focal person for approval. The approval letter (endorsed by the DGHS) is forwarded to the National Medical Stores. Participating health facilities order the drug from the NMS and the order is then dispatched each month, according to NMS and MOH guidelines for controlled substances. NMS delivers consignment to the district/health facility. Health facilities receive, store and dispense donated Diflucan® following controlled substances regulations.
Current geographical and epidemiological coverage The Diflucan® is available at the National Medical Stores and is distributed countrywide as required by the districts.

Issues
Value-added Availability of Diflucan® to all patients that need it.
Comments Diflucan® is being imported into Uganda in its patent and generic forms (fluconazole) without any restrictions by Pfizer.

ANNEX 12

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ANNEX 13

Generic study protocol and materials for future studies

I: International level

IPPPH will liaise with the relevant public-private partnerships at international level. In addition, the report of the pilot study undertaken in Uganda in May 2003 provides background information on:

- the African Programme for Onchocerciasis Control and Mectizan Donation Programme
- the Global Alliance to Eliminate Leprosy (GAEL)
- the Global Alliance to Eliminate Lymphatic Filariasis (GAELF)
- the WHO Programme to Eliminate Sleeping Sickness
- the Drug Access Initiative (DAI) and the Accelerated Access Initiative (AAI)
- the Viramune® Donation Programme
- the Diflucan® Donation Programme.

II: Country level

Method: A technical consultation meeting held by IPPPH on 10 January 2003 advised that the study should adopt a layered approach to evaluation, covering the country context and the national disease control policy before assessing the individual partnership programmes.

Fieldwork programming: to ensure this layered approach, it may be helpful to structure the fieldwork with an initial round of interviews and information-gathering at national level, followed by visits to 3-4 appropriately selected districts for interviews at district, community and facility level (plus regional level visits where appropriate), then a return to national level for follow-up enquiries and feedback to key parties. The detailed fieldwork plan will need to be developed in liaison with the government and national study team members.

Minimum data requirements: Appendix A (below) specifies minimum data requirements, with possible sources, for the country context, the national disease control policy and the specific public-private partnership programme. Some useful information will probably not be readily available and, wherever possible, should be gathered during study fieldwork, (for example the PPP programme's impact on staffing/staff workload patterns and expenditure patterns).

Documentary, quantitative evidence should be obtained wherever available. However, the technical consultation meeting concluded that this is likely to be a largely qualitative study making extensive use of semi-structured interviews with key informants.

Key informants at country level: Fieldwork should include interviews about each relevant programme at national, regional (where appropriate), district and health facility/community levels. **Appendix B** suggests likely informants.

The following pilot-tested study materials (to be tailored to local circumstances) are attached:
Appendix C: an information collection tool
Appendix D: a generic introductory letter to key informants
Appendix E: an interview questionnaire for tropical disease PPPs (national level informants)
Appendix F: an interview questionnaire for HIV/AIDS PPPs (national level informants)
Appendix G: an interview questionnaire for use at district/community level
Appendix H: criteria for assessing the impact of PPP programmes on national health systems
Appendix I: a framework for recording PPP programme objectives and performance
Appendix J: a framework for recording PPP programme drug ordering/procurement, storage and distribution arrangements.

APPENDIX A

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries: Study Data Collection

MINIMUM DATA REQUIREMENTS

1. Key data on the country context, particularly general health and health system information, and on national strategies/policies for the individual programme diseases

The report should give **a selective summary of key data on the country context**, including:

- demographics
- GDP, per capita income
- poverty data (% of population below the poverty line; geographical distribution)
- epidemiological data
- health sector strategies (including any SWAp)
- health system characteristics
- health sector funding (per capita health spending, % of government spending allocated to health
- drugs policy, regulation, procurement and management.

Possible data sources include:

- country poverty reduction strategy, poverty assessment report
- national health strategy
- national health accounts
- national health plan and budget, annual report
- district health plans and budgets, annual reports
- AIDS strategy and plan; performance/progress reports
- relevant individual tropical disease control plans; performance/progress reports
- Essential Drugs List
- drug procurement, storage and distribution policies
- publications and grey literature
- semi-structured interviews.

2. Programme specific data

The study should map **the key characteristics at country level of each PPP studied**, including:

- programme objectives and strategy
- conditionalities
- nature of partnership
- programme start date, stage of development, future plans
- governance arrangements
- secretariat/manager
- dedicated personnel *(number of staff and whole-time equivalents, where available)*
    - national
    - regional *(as appropriate)*
    - local
- budget and actual spend
- presentation of programme to beneficiaries
- mode of operations
- current geographical and epidemiological coverage (including current scale of coverage in relation to planned coverage; coverage by socio-economic status, gender, age, rural/urban location)
- overall performance against targets to date
- sustainability measures
- linkages with other programmes.

Possible data sources include:

- programme specification and protocols
- programme budget
- all programme performance/progress reports (activity and budget)
- minutes of any formal steering group or liaison meetings
- any programme evaluations
- relevant country level correspondence
- any published literature
- semi-structured interviews.

APPENDIX B

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries: Key Informants

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

This appendix suggests likely key informants. The precise specification may vary from country to country and programme to programme.

National level

- courtesy calls *(as appropriate)*
- any link person in the Ministry of Health (MOH)
- national PPP programme managers
- relevant MOH personnel, eg the Director-General and/or top MOH officers, personnel in communicable disease control, HIV/AIDS programme, essential drugs programme, central medical/drug store and distribution, health planning, finance, health and health service information
- any relevant pharmaceutical company representatives
- key NGOs involved in PPP programme implementation
- relevant stakeholder NGOs not directly involved in programme implementation
- any other partners in the programme at national level
- national representatives of programme clients
- agencies such as WHO, World Bank, UNAIDS, UNICEF, relevant bilaterals
- relevant private sector representatives (profit and not for profit), eg pharmaceutical importers, wholesalers, distributors and retailers
- national drug regulation authority
- researchers

Regional, district and community levels

- courtesy calls
- local government officers with health responsibilities
- district health team
- relevant hospital staff
- staff at community health facilities, hospices, home care programmes
- community health workers/distributors
- staff at specialist HIV/AIDS centers
- local representatives of programme clients
- local NGO partners
- any other personnel involved in programme delivery, including drug distribution
- pharmacists/retailers supplying drugs
- researchers

APPENDIX C

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries

PROGRAMME-SPECIFIC INFORMATION COLLECTION TOOL

PROGRAMME *[name]* (*pharmaceutical company name)* *[disease]*
INTERNATIONAL LEVEL
Programme start date, stage of development, future plans
Start date
Stage of development
Future plans
Programme objectives and strategy
Conditionalities
Governance arrangements
Secretariat/manager
Mode of operations
Measuring performance
Issues
Value-added ▪ ▪
Criticisms ▪ ▪
Comments ▪ ▪

PROGRAMME *[name]* (*pharmaceutical company name**)***
[disease]
COUNTRY LEVEL: *[country name]*
Country programme background/assessment of disease in national/district health strategy and plan
Programme objectives and strategy in [country]
Conditionalities
Nature of partnership
Programme start date, stage of development, future plans
Start date
Stage of development
Future plans
Governance arrangements
Secretariat/manager
Dedicated personnel
- national
- local
Budget and actual spend
Presentation of programme to beneficiaries
Mode of operations
Current geographical and epidemiological coverage *(eg current scale of coverage compared with planned coverage; coverage by socio-economic status, gender, age, rural/urban location)*
Overall performance against targets to date
Sustainability measures
Linkages with other programmes
Issues
Value-added ▪ ▪
Criticisms ▪ ▪
Comments ▪ ▪

APPENDIX D

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries

INTRODUCTION LETTER TO KEY INFORMANTS

[date]

Dear Colleague,

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low and Middle Income Countries: study in [***country***]

The UK Department for International Development (DFID) is funding the Initiative on Public-Private Partnerships for Health (IPPPH), part of the Global Forum for Health Research, to conduct a study to assess the health and health systems impact of public-private partnerships for improving access to pharmaceuticals in *[country]*. Public-private partnerships (PPPs) addressing access to pharmaceuticals are 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.

I am attaching the study protocol and a questionnaire. You will see that the study will examine issues of ownership, integration, coordination, implementation and impact, with a particular focus on the unique strengths and problems of access PPPs as distinct from other comparable programs.

Fieldwork for the study will take place *[date]*. I should be very grateful for your participation, including your time in an interview with study team members. *[Name]* will be contacting you to follow up this letter [I understand that *[name]* has already been in contact with you]. H/she can be contacted on [*details*]

Yours sincerely,

Roy Widdus,
Director of IPPPH

[name]
Study Team Leader

APPENDIX E

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries

QUESTIONNAIRE FOR TROPICAL DISEASE PROGRAMMES: National level informants

Throughout the study, a key objective will be to identify those issues that are unique to public-private partnerships addressing access to pharmaceuticals in low and middle income countries where the pharmaceutical companies partners are involved at some stage of design and/or implementation.

Ownership and programme rationale

- Was the disease a national priority before the programme was initiated? If not, to what extent was there need for such a programme? Is the disease/programme now included in the current national health plan?
- What triggered consideration of the partnership programme in this country? What was the nature of any feasibility study/prior evaluation, and who undertook it?
- How was the decision to launch the programme in this country taken, and by whom? What was the nature of any consultation process?
- What, if any, are the incentives and disincentives for districts and health providers to participate in the programme?
- Are there any conditionalities to the programme? Are they reasonable?

Governance

- What are the governance arrangements for the programme?
- How effectively do they operate, eg in terms of achieving collective ownership and accountability for performance?
- Have arrangements changed over time and, if so, why?
- What are the respective roles of PPP programme partners, the government and local interests in developing programme proposals, decision-making, conditionalities and governance?
- What interaction, if any, has there been with partnership pharmaceutical company representatives?

Implementation and integration

- To what extent is the PPP programme integrated into the general health system? How does it interface with existing systems for
    - planning, finance, and reporting
    - monitoring and evaluation
    - disease surveillance
    - drug ordering, handling and distribution to local level?

  How has this evolved over time?
- Have there been any consequences of the approach taken?
- What are the primary obstacles to integration *(as appropriate)*? What factors improve/assist integration by PPPs?
- In what ways, if any, are the issues of integration different because this is a programme with pharmaceutical company involvement rather than any other donor?
- Has the PPP programme resulted in additional demands or benefits? Have there been any staffing implications? Have there been any budgetary implications?
- What are the plans for sustainability? And further scaling up?

Coordination

- If more than one PPP programmes operate in the district, are there any formal or informal links between them? If so, how useful are those links? What are the links between PPPs and other donor coordination mechanisms?
- What are the consequences (positive or negative) from having multiple PPPs operating in the country?
- Are there any regional coordination mechanisms for this PPP?

Monitoring and evaluation

- How does each PPP measure its effectiveness? Does it have reliable baseline data?
- How far have targets to date been achieved? Are there differences in performance between different districts? If so, why?
- What changes in the operation of the programme have monitoring and evaluation led to? If there have been changes in the operation of the program for other reasons, what and why?

Impact

- Has the programme helped mobilize additional resources, beyond the free product provided by the sponsor? Did the programme substitute for previous funding (government or donor)? What government subsidies or other inputs are required?
- Who has benefited from the programme and how were they selected? Would they have received treatment otherwise?
- What efforts have been made in the programme specifically to reach poorer populations, women and children, disadvantaged groups and rural populations? What impact are these efforts having? Has the PPP program been able to access previously unreached populations *(as appropriate)*?
- What evidence is there on health impact?
- What impact has the programme had to date on the health system (defined as encompassing the public, private and voluntary sectors)?
- Has the programme had a capacity building/strengthening component, and if so, how effective has it been to date?
- What impact has the programme had on drug markets, procurement systems and capacity, and on drug policy formulation?

APPENDIX F

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries

QUESTIONNAIRE FOR HIV/AIDS PPPs: National level informants

Throughout the study, a key objective will be to identify those issues that are unique to public-private partnerships addressing access to pharmaceuticals in low and middle income countries where the pharmaceutical company partner(s) are involved at some stage of programme design and/or implementation.

Ownership and programme rationale

- What triggered consideration of the partnership programme in this country? What was the nature of any feasibility study/prior evaluation, and who undertook it?
- How was the decision to launch the programme in this country taken, and by whom? What was the nature of any consultation process? What happened during the transition from pilot DAI to the scaled up AAI – consultation, feasibility studies?
- What, if any, are the incentives and disincentives for districts and health providers to participate in the programme? How was the ART accreditation process established under the AAI?
- Are there any conditionalities to the programme? What about prescribing restrictions or government tax relief on commodities? Are they reasonable?

Governance

- What are the governance arrangements for the programme?
- How effectively do they operate, eg in terms of achieving collective ownership and accountability for performance?
- Have arrangements changed over time and, if so, why?
- What are the respective roles of PPP programme partners, the government and local interests in developing programme proposals, decision-making, conditionalities and governance?
- What interaction, if any, has there been with partnership pharmaceutical company representatives?

Implementation and integration

- To what extent is the PPP programme integrated into the general health system and the AIDS programme? How does it interface with existing systems for
    - planning, finance, and reporting
    - monitoring and evaluation
    - disease surveillance
    - drug ordering, handling and distribution to local level?

  How has this evolved over time?
- How were drug prices negotiated under the DAI and AAI and how has this process evolved over time? What has been the role of generic drug manufacturers? How was this whole process integrated with other drug procurement activities?
- What are the primary obstacles to integration? What factors improve/assist integration by PPP programmes?
- Have there been any consequences of the approach taken?
- In what ways, if any, are the issues of integration different because this is a programme with pharmaceutical company involvement rather than any other donor?

- Has the PPP programme resulted in additional demands or benefits? Have there been any staffing implications? Have there been any budgetary implications?
- What are the plans for sustainability? And further scaling up?

Coordination

- If more than one PPP programmes operate in the district, are there any formal or informal links between them? If so, how useful are those links?
- What are the consequences (positive or negative) from having multiple PPPs operating in the country?
- What are the links between PPPs and other donor coordination mechanisms?
- Are there any regional coordination mechanisms for this PPP?

Monitoring and evaluation

- How does each PPP measure its effectiveness? Does it have reliable baseline data?
- How far have targets to date been achieved? Are there differences in performance between different districts? If so, why?
- What changes in the operation of the programme have monitoring and evaluation led to? If there have been changes in the operation of the programme for other reasons, what and why?

Impact

- Has the programme helped mobilize additional resources, beyond the price reductions or free product provided by the sponsor? Did the programme substitute for previous funding (government or donor)? What government subsidies or other inputs are required?
- Who has benefited from the programme and how were they selected? Would they have received treatment otherwise?
- What efforts have been made in the programme specifically to reach poorer populations, women and children, disadvantaged groups and rural populations? What impact are these efforts having? Has the PPP program been able to access previously unreached populations *(as appropriate)*?
- What evidence is there on health impact?
- What impact has the programme had to date on the health system (defined as encompassing the public, private and voluntary sectors)?
- Has the programme had a capacity building/strengthening component, and if so, how effective has it been to date?
- What impact has the programme had on drug markets, procurement systems and capacity, and on drug policy formulation? What impact has the programme had on intellectual property regulation policy?

APPENDIX G

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries

QUESTIONNAIRE FOR DISTRICT LEVEL

Throughout the study, a key objective will be to identify those issues that are unique to public-private partnerships addressing access to pharmaceuticals in low and middle income countries where the pharmaceutical company partners are involved at some stage of programme design and/or implementation.

Ownership and programme rationale

- Was the disease a district priority before the programme was initiated? If not, to what extent was there need for such a programme? Is the disease/programme now included in the current district health plan?
- How was the decision to launch the programme in this district taken, and by whom? What was the nature of any consultation process?
- What, if any, are the incentives and disincentives for districts and health providers to participate in the programme?
- Are there any conditionalities to the programme? Are they reasonable?

Implementation

- Who are the partners involved in this programme at district level, and what are their respective roles?
- What interaction, if any, has there been with partnership pharmaceutical company representatives?
- What is the local capacity to test and diagnose before initiating treatment under this programme?
- Has the PPP programme resulted in additional demands or benefits? Have there been any staffing implications? Have there been any budgetary implications?
- What are the plans for sustainability? And further scaling up?

Integration

- To what extent is the PPP programme integrated into the general health system? How does it interface with existing systems for:
    - planning, finance, and reporting
    - monitoring and evaluation
    - disease surveillance
    - drug ordering, handling and distribution to local level?
- How has this evolved over time?
- Have there been any consequences of the approach taken?
- What are the primary obstacles to integration *(as appropriate)*? What factors improve/assist integration by PPPs?
- In what ways, if any, are the issues of integration different because this is a programme with pharmaceutical company involvement rather than any other donor?

Coordination

- If more than one PPP programmes operate in the district, are there any formal or informal links between them? If so, how useful are those links?
- What are the consequences (positive or negative) from having multiple PPPs operating in the district?
- What are the links between PPPs and other donor coordination mechanisms?

Monitoring and evaluation

- How does each PPP programme measure its effectiveness? Does it have reliable baseline data?
- How far have targets to date been achieved?
- What changes in the operation of the programme have monitoring and evaluation led to? If there have been changes in the operation of the programme for other reasons, what and why?

Impact

- Has the PPP helped mobilize additional resources, beyond the price reductions or free product provided by the sponsor? Did the programme substitute for previous funding (government or donor)? What government subsidies or other inputs are required?
- Who has benefited from the programme and how were they selected? Would they have received treatment otherwise?
- What efforts have been made in the programme specifically to reach poorer populations, women and children, disadvantaged groups and rural populations? What impact are these efforts having? Has the PPP program been able to access previously unreached populations *(as appropriate)*?
- What evidence is there on health impact?
- What impact has the programme had to date on the district health system (defined as encompassing the public, private and voluntary sectors)?
- Has the programme had a capacity building/strengthening component, and if so, how effective has it been to date?

APPENDIX H

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries

CRITERIA FOR ASSESSING THE IMPACT OF PPP PROGRAMMES ON NATIONAL HEALTH SYSTEMS

This appendix defines criteria by which the impact of global public private partnerships on health systems may be assessed. Criteria are in three categories – two relating to integration with the nation health system at planning and drug delivery stages respectively and one relating to the degree of involvement of multinational pharmaceutical companies in decision making. Within each category the criteria are defined against three classifications of low, medium and high.

1. Policy and planning stage

National health plan
The degree to which the partnership's objectives fit with the national health plan.
Low: partnership programme not a priority for the health system and not included in the national health plan
Medium: partnership programme mentioned in the national health plan but not a major national priority
High: partnership programme receives sufficient attention in the national health plan to indicate that it is a major national priority

District health plan
The degree to which the partnership's objectives fit with the district health plan.
Low: partnership programme not a priority and not included in the district health plan.
Medium: partnership programme mentioned in the district health plan but not a major local priority
High: partnership programme receives sufficient attention in the district health plan to indicate that it is a major local priority

Financing and budget plan
The degree to which funds for partnership activities will be allocated under the national budget (with inputs from government and donors through basket of funds).
Low: partnership programme not mentioned in the health plan or partnership mentioned in the health plan but is allocated either no additional funding or only project funds.
Medium: partnership programme allocated funding partially through the budget and partially through project funds.
High: partnership programme costs are fully allocated under the sector budget

2. Delivery stage

Procurement
The degree to which the partnership uses MOH customary mechanisms for procurement
**NB Procurement is not an issue for free donation partnerships.*
Low: partnership drugs are procured entirely by partnership staff
Medium: partnership drugs are procured within MOH systems but with partial support from partnership staff
High: partnership drugs are procured entirely within MOH systems

Storage and Distribution
The degree to which the partnership uses MOH customary systems (either primary health care system or disease control programme) for drug ordering by facilities or districts and subsequent dispatch to them.

Low: partnership drugs are ordered and dispatched entirely by partnership staff from port of entry right down to health facility
Medium: partnership drugs are ordered and/or dispatched within the MOH system but with some partnership support to the process
High: partnership drugs ordered and dispatched entirely within MOH routine system

Surveillance
The degree to which the partnership's surveillance requirements rely on MOH customary systems or other arrangements (such as notifiable diseases or antenatal surveillance).
Low: partnership surveillance activities are entirely separate from MOH arrangements and are the requirements of external partners.
Medium: partnership uses routine arrangements but with some limited additional surveillance for external partners.
High: partnership surveillance relies wholly on MOH surveillance and monitoring arrangements

Reporting
The degree to which the partnership's reporting requirements rely on MOH customary systems (including HMIS, monitoring and evaluation, planning and financing reports).
Low: the partnership has its own dedicated reporting arrangements largely for external partners' benefit
Medium: the partnership works within customary MOH reporting arrangements but in addition requires further information for external partners
High: the partnership relies solely on customary MOH reporting arrangements/ information taken from MOH reports

Community workers
The degree to which the partnership's community distribution networks are within the existing health system.
Low: the partnership programme has its own community workers.
Medium: the partnership programme shares community workers with other donation partnerships with related work.
High: the partnership programme uses only MOH employed community workers

Multi-partner effort in service delivery
The degree to which the partnership collaborates with private (not-for profit) providers active in its area of service delivery.
**NB Not all partnerships will find appropriate private providers to work with.*
Low: the partnership uses only its own or public sector service providers
Medium: the partnership collaborates with a few private providers but not widely
High: the partnership works with a wide range of private providers with interests in its area of service delivery

3. Involvement of 'big pharma' at country level

MOH ownership and partnership involvement
The extent to which the MOH takes ownership of the national programme
Low: National programme activities largely driven by the partnership
Medium: MOH takes nominal ownership but partnership plays a substantial role in driving the national programme
High: MOH takes full and active ownership of the national programme

Conditionalities
The number and burden of conditionalities attached by the pharmaceutical company(ies) involved to the use of donated or subsidised drugs.
**NB Beyond the factual position, there is likely to be need for a value judgement on the reasonableness of the conditions.*
Low: there are no conditionalities associated with use of donated or subsidised drugs.
Medium: some minor conditionalities are associated
High: strong conditionalities are attached (such as strict definitions of the conditions to be treated and/or populations who can receive treatment and/or limits to other related drugs which can be procured by the government)

Pharmaceutical company support
The amount of support to programme planning, implementation and monitoring provided by the pharmaceutical company(ies) in addition to donating or subsidising the drugs.
Low: the pharmaceutical company(ies) provides no support to planning, implementation and monitoring of related service delivery.
Medium: the pharmaceutical company(ies) provides limited support to planning, implementation and monitoring of related service delivery.
High: the pharmaceutical company(ies) provides substantial resources or technical support planning, implementation and monitoring of related service delivery

APPENDIX I

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries

A FRAMEWORK FOR RECORDING PPP PROGRAMME OBJECTIVES AND PERFORMANCE

Table (a): Tropical disease PPP programme objectives and performance
Global PPP programme(s)

Country: *[name]*	***[PPP]*** *eg Leprosy*	***[PPP]*** *eg Lymphatic Filariasis*	***[PPP]*** *eg Onchocerciasis*	***[PPP]*** *eg Sleeping sickness*
Global PPP programme objective				
Drug donation				
Conditionalities				

Table (b): Tropical disease PPP programme objectives and performance
National programme(s)

Country: *[name]*	***[PPP]*** *eg Leprosy*	***[PPP]*** *eg Lymphatic Filariasis*	***[PPP]*** *eg Onchocerciasis*	***[PPP]*** *eg Sleeping sickness*
Disease a national /district health priority				
National programme and objective				
National programme initiated				
Population at risk				
National partners				
Current national budget contribution				
Current national coverage				
Performance against targets				
Sustainability				

APPENDIX J

The Impact of Public-Private Partnerships Addressing Access to Pharmaceuticals in Low Income Countries

A FRAMEWORK FOR RECORDING PPP PROGRAMME DRUG ORDERING/ PROCUREMENT, STORAGE AND DISTRIBUTION ARRANGEMENTS

Table…: Cycle of drug ordering, receipt and distribution

Country: *[name]*	***[PPP]*** *eg Leprosy*	***[PPP]*** *eg Lymphatic Filariasis*	***[PPP]*** *eg Onchocerciasis*	***[PPP]*** *eg Sleeping sickness*	***[PPP]*** *eg Schistosomiasis*
Estimation of drug requirements					
Application process					
Orders for drugs					
Receipt of drug in country					
Storage					
Distribution to district level					
Distribution to community level					
Distribution to individuals					
Community involvement in decisions on distribution methods and choice of CDDs					
Links with other programmes					

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