‘Responsibly improving access to ACTs in the private sector’

Report of the MoH-MMV Workshop Series

Munyoyo Resort, Kampala Uganda
September 26 – October 2, 2007

The Ministry of Health (Uganda) and Medicines for Malaria Venture have joined forces in an attempt to address the critical access gap to effective antimalarials in Uganda, and turn the tide of death and disability from this disease. A jointly-convened series of four workshops was held from 26 September to 2 October 2007 to plan an operational research intervention to distribute a subsidised artemisinin-combination therapy (ACT) in 6 districts of Uganda – Kamuli, Pallisa, Budaka, Kaliro, and Soroti (control district) in the eastern region; and Kamwenge, Kabarole, and Mubende (control district) in the western region.

The intervention attempts to demonstrate that universal availability of affordable ACTs will reduce mortality and morbidity from malaria in vulnerable populations in Uganda. It also aims to inform the planned Affordable Medicines Facility, malaria (AMFm) on the core set of supporting country level interventions. For a brief description of the intervention concept go to **Section 1**.

The fourth and final workshop on planning the blueprint for the intervention was inaugurated by the Minister of State for Primary Health Care, the Honourable Emmanuel Otaala, and the CEO MMV, Dr Chris Hentschel. Both the Minister and the CEO noted the urgent and critical need to ensure widespread access to high quality ACTs through the private sector in Uganda. The joint MoH-MMV intervention aims to provide answers to some of the critical challenges so as to facilitate national scale up and extension to other countries. The joint MoH-MMV intervention aims to develop specific learning in this area, which could be scaled up nationally in Uganda and other countries.

Each of four workshops addressed specific issues critical to the draft blueprint of the intervention:

1. The first of these, on 26 September, focused on presentations from the intervention and control districts (with the exception of Soroti District[*]). The district health officials presented their respective district profiles, highlighting the challenges to and opportunities for improvement in malaria care.

   Please click here for agenda and presentations

2. The second, held on 26–27 September, took a “Deep Dive” into the results from the supply and demand baseline surveys conducted over the past four months on:
   a. The antimalarial market, supply chain, and pricing of antimalarials in Uganda
   b. Health-seeking behaviour of malaria patients that govern the demand for antimalarials

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3. On 28 September, the third workshop focused on how to improve market intelligence for the antimalarials market in Africa. This built on the results of the Uganda Pricing Survey and culminated in a discussion on the ways in which stakeholders could coordinate improvements in market intelligence.

   Please click here for agenda, a short report, and session presentations

[*] Was affected by heavy rains and flooding at the time of the workshop

4. The fourth and final workshop on 1-2 October brought together issues presented in the first three workshops, and served specifically to plan the intervention for the distribution of a subsidised ACT in the 6 selected districts.

   Five breakout groups brought a number of suggestions and recommendations to the plenary on predetermined themes to generate consensus and inform the design of an implementation blueprint for rolling out the intervention. The themes included national policy and regulatory preparedness, supply-side issues, social marketing, provider training, and monitoring and evaluation. A summary of the key findings and recommendations are listed in **Section 2**.

   Please click here for agenda, session presentations and breakout group topics and presentations

Each workshop followed a similar structure, with a series of presentations followed by a discussion which brought to light a number of new facts and suggestions.

Participants in each workshop comprised international and national experts with distinguished careers in malaria treatment research and implementation (*Please click here for the participants list*).

This Report summarises the findings of the baseline demand-side and supply-side surveys, and presents a synthesis of the recommendations that emerged from the breakout sessions, highlighting several aspects of the challenges and possible solutions associated with increasing access to high quality antimalarial treatment in malaria-endemic countries.

1. The Concept behind the Intervention

In 2004, the Institute of Medicine published a path-breaking report authored by Kenneth Arrow et al. entitled *Buying Time, Saving Lives*: *Economics of Malaria Drugs in an Age of Resistance.* The report addressed the need to make effective antimalarial drugs more widely accessible and available via a massive global subsidy that would radically lower the cost of new ACTs to that of old, ineffective medicines such as chloroquine.

The idea was to stem the tide of death and disability from malaria by making new effective ACTs available to malaria sufferers at a price they were used to paying for treatment. Its recommendation has been taken up by the Affordable Medicines Facility – malaria (AMFm) which is planning to launch such a subsidy in the near future.

The MoH-MMV intervention in Uganda is also based on this recommendation. Malaria is an all too familiar disease in Uganda and takes a heavy toll. The country has the highest rate of malaria infections in the world - almost 50 infections for every 100 people – over 1500 infective bites/person/year (Okello et al, 2006). Although the government now deploys ACTs in all public sector health facilities and recognizes the failure of chloroquine, ACTs remain inaccessible to the majority of Ugandans. ACTs are too expensive and are not available through drug shops due to their prescription-only status, yet 60-80% of people buy their medicines from such outlets.

To overcome these challenges the intervention will provide a highly-subsidized ACT through the private sector in order to reduce malaria-related mortality and morbidity and to inform national and international policy on the viability of such a measure.

Before launching the intervention in 6 districts in Uganda (and two control districts), the MoH and MMV commissioned baseline surveys on the antimalarial market in Uganda and the health-seeking behaviour of those afflicted with malaria to understand the reality on the ground. The baseline studies were aimed at answering the following questions: Who sells antimalarials? From which type of outlets are the drugs sold? What type of drugs? What

price? From where are the drugs sourced? What drives patient/ caregiver choice of outlet and antimalarial? What is the experience of caregivers with the treatment? How can access to treatment be improved?
Only once the reality is clear can the intervention be designed.

2. Key output and recommendations

Breakout sessions in the fourth, planning workshop held on 1-2 October, addressed the five critical themes on which the blueprint for intervention will be based. These are listed below, and include key recommendations for action.

This section is also available as a PDF here.

2.1 National Policy and Regulatory Preparedness

Key Findings

- The private sector (clinic, pharmacies, drug shops etc.) is the most important source of antimalarials for caregivers. The choice of outlets varies across districts even though the public sector outlets are considered the best source of advice and diagnosis. This anomaly is due to stock outs in public health facilities.
- ACT availability is limited due to high price in the private sector and prescription-only status.
- The proportion of licensed vs. unlicensed outlets selling antimalarials varied considerably among districts. The licensed outlets were typically clustered around trading centres leaving large underserved areas which are presently served by unlicensed outlets.
- Storage conditions are an issue in most retail stores.
- In most outlets the attendant was someone with some health training.

Key issues and recommendations

Enabling policy framework: An enabling policy by the national drug authority (NDA) will be a necessary precondition for improving geographical access to ACTs including:

- Rescheduling ACTs to be over the counter (OTC) medicines and permitting their sale through drug shops.
- Increasing the number of licensed outlets:
  - Facilitating regularization of unlicensed outlets which fall below current standards (e.g. meeting quality standards but have not renewed licence).
  - Reviewing current licensing criteria in terms of:
    - lowering license fees (currently ranging from USD 50 to 70)
    - reducing distance between drug shops,
    - reviewing requirements for qualification especially in rural areas (from nurse or health worker). Learn from Nigeria where the qualification for drug shop operators (PPMVL stores) is secondary education and the Pharmacy Council trains the PPMVL workers.

Supervision: Supervision is critical and should be an integral component of the intervention, particularly in cases when lower-cadre of the staff are licensed. Strong community collaboration will be crucial to getting implementation and regulation moving smoothly. (see experience of Tanzania). The NDA and District Drug Inspectors seem to be viewed by the retailers as law enforcement agents rather than regulators. Government/NDA should encourage the improvement of unregistered drug shops, especially those requiring minor changes.

Storage: Storage conditions will be a major issue in most retail stores which could compromise product quality and integrity. There will be a need to train providers (could be carried out by distributors).

Plan to with draw CQ: The use of CQ and SP for other indications complicates future regulation and the NDA should expedite the change of status of these drugs to prescription only. For example, Tanzania has delisted CQ.

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Need for policy convergence with Home based management of fever (HBMF): There were lengthy discussions on the possible effect of the intervention on community medicine distributors (CMDs) under the home based management of fever (HBMF). CMDs are important providers of antimalarials for under 5s and contribute to improved access to medicines to poor communities. However sustaining CMDs as volunteers, without incentives, is problematic. Options need to be explored for the intervention to complement CMD work. Compelling reasons for allowing CMDs to sell subsidised ACTs, especially for adults, were put forward.

CMDs already provide free antimalarials to children with fever and typically operate in the poor areas with limited private sector coverage. They co-exist with the private sector and will shortly be providing ACTs free of charge for under-fives. If CMDs serving communities living in underserved areas, beyond the reach of public facilities and private outlets are permitted to sell the subsidised ACTs, this would improve access to life saving drugs and also provide a strong incentive for them to continue to operate.

However, there was a concern that CMDs selling ACTs goes against the original concept of providing free treatment to vulnerable age groups. If permitted to sell ACTs for older age groups, there is a risk that the HBMF medicines supplied through the public sector would be sold. Moreover CMDs are considered an extension of the public health services and other programmes (e.g. IMCI, ART, CB-TBDOTS) and are thus prohibited by policy from selling public medicines.

The consensus was that any private sector initiative must address the issues of CMDs and it would be useful to understand the trade-offs between improved coverage and the principle of free treatment in one of the districts. Different models were proposed including:

- CMDs selling to adults while providing free treatment for children with fever.
- Implementation through CMDs alongside the private sector and exploring linkages for mutual support between wholesalers, retailers and CMDs
- Implementation only via the private sector.

2.2 Antimalarial market

Key findings

Outlets stock a wide range of antimalarials but CQ remains the most stocked

- CQ accounted for 23 % of all formulations stocked and ACTs were the least stocked (only 10%).
- CQ and SP were abundant in all sectors including large stocks in the public sector, national medical stores and joint medical stores. Neither is first line therapy for malaria and would not normally be expected in large quantities. The low price and antipyretic effect of CQ, which is lacking in ACTs, is likely to explain its continued popularity among caregivers.
- Coartem® was only available in public / mission facilities. Very limited amounts of leaked public sector Coartem® was found in the private sector.

Significant price differences between effective and ineffective antimalarials

- ACTs and artemisinin monotherapies were the most expensive antimalarials available - 20 to 40 times more expensive than CQ and unaffordable to most patients. The parenteral formulation of artemisinin monotherapy had a significant premium over the oral formulation with prices within the same range as ACTs.
- The final retail price ranges between 2 to 5 times the ex-factory price.
- Prices appear to vary across brands rather than by retail outlets, with the highest prices often charged at clinics which typically include a dispensing fee.
- Margins for pharmaceutical products vary according to therapeutic category but the largest margins are levied at the retail level.

Price is a key driver of antimalarial choice

- Price remains a major driver of choice in Uganda and is a barrier to accessing a complete course.
- Certain monotherapies commanded a high price, and yet were still sold – thus indicating that for some classes, preference prevails over price.
- Only around half the clients reportedly purchased a full course of antimalarials, even when buying low priced medicines. Retail shops typically priced individual tablets rather than the full dose.

Supply chain

- Outlets obtained their supplies locally, regionally and in Kampala.

Key issues and recommendations

Informal sector data needs

Collecting supply side data in the informal sector will be challenging and will require the active support of local leaders. In a few areas the extent and importance of the informal sector could have been underestimated. It will be important to continue to refine the database and develop feedback mechanisms on a “learn as you do” approach. Regular monitoring surveys should be initiated to assess changes in prices and availability of antimalarials.

Need for a maximum recommended retail price to ensure affordability of the subsidized price

Ensuring affordability of the subsidized product for the very poor will be challenging, especially in the absence of price control / consumer protection mechanisms. A maximum recommended retail price (MRRP) should be set, based on cost-plus approach which includes all costs and reasonable mark up at each level in the chain. Ideally the final consumer price should be similar to that for CQ or SP treatment which would facilitate the displacement of these sub optimal treatment options and move the ACT market to a volume based one. The different age-group packs should be priced proportionately to avoid overstocking of one pack.

Efforts should be made to ensure adherence to the maximum recommended retail price such as heightened consumer awareness of the retail price, good availability in most outlets to ensure competition, adequate stocks and consistent / reliable supply. This will help reduce the risk of profiteering. Like other retail prices, post-subsidy retail prices might be expected to vary with location. Clinics are likely to continue their current practice of adding a consultation fee to the subsidized retail price, thus raising the price to patient.

Focus on incentives to ensure wide stocking

The challenge will be to ensure affordability of the subsidized drugs and maintain widespread availability. Prices cannot be imposed due to the free market economy structure in Uganda. Therefore the focus must be on incentives for the distribution chain and the demand side pull through widespread knowledge of the MRRP by consumers. Positive incentives should be provided to distributors to limit leakage and increase availability / sales (e.g., sales targets with bonus). Lessons should be learned from local distributors. Managing the margin/volume for ACTs will be crucial for trade acceptance and functioning of a subsidized product. It will probably be easier to manage import and wholesale margins than retail margins.

Facilitating buy in

Increased sales of subsidised ACT will have an impact on current producers and importers of CQ, SP, ACTs within the liberalised environment in the country. Discussions should be held with these parties to gain their buy-in to the intervention.

Supply chain

The existing supply chain effectively delivers antimalarials to a wide range of outlets. The challenge will be to displace ineffective drugs with the subsidized product. The intervention should use existing supply chain in the areas and minimise direct intervention in existing distribution channels. Reducing the risk of leakage back to Kampala of the subsidized product will be a big challenge. In addition for some new districts, there are no wholesalers and they will have to rely on neighbouring districts, outside the study area for supplies. Underserved areas not covered by the existing supply chain should be identified using the data collected in the baseline survey. The current public sector access definition of a 5 km radius should be used in the gap identification.

Clear selection criteria and transparency

Selection criteria for repackaging and distributors should be developed which ensures competition, minimizes leakage while ensuring adequate reach and quality. For importers the criteria should include: Being on the NDA list , reliability, price, speed, efficiency, maximum lead time for repackaging, approval by original manufacturer. For distributors the criteria should include capacity, infrastructure, reach, commitment to the process, willingness to participate (vs. existing business), ability to avoid leakage, lead times/stock-out, training capacity, M&E and data gathering capacity.

Quantifying drugs requirements

Estimating the required quantities of the subsidised ACTs will be challenging. In principle, consumption data would be the ideal basis for quantification but such data are difficult and expensive to obtain. Data from multiple sources should be used to work out the best estimate and refine over time such as malaria case load data from government statistics, imports of antimalarials which should also factor in wastage due to expiry. Triangulation should be used to confirm quantities and refine over the period of the intervention. MSH and the Clinton Foundation have developed models to estimate drug requirements and have kindly offered to make these available. Buffer stocks will be essential to avoid stock-outs. The initial supplies should be based on a push approach through provision of subsidised ACTs on credit. With time and careful monitoring (e.g. retail audits, new orders) actual demand could be calculated which would guide forecasts. In addition, suppliers should systematically provide volumes and the types of antimalarials sold to study districts.

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2.3 Social Marketing

Key findings

Low rates of prompt health seeking

- High rates of fever were found in all districts, but less than one third of children under the age of 5 years (under 5s) were treated with an antimalarial within 24 hours of fever onset and less than 4% of fevers were treated with an ACT.

Providers and communities continue to believe in CQ effectiveness

- Health care providers and caregivers believe that CQ and SP are effective for the treatment of malaria in under-fives.
- The district staff explained that the dual strategy of providing Coartem® at health facilities and Homapak (CQ+SP) via community medicine distributors (CMDs) was very confusing to both the providers and community. It was suggested that Homapak should be withdrawn from the intervention districts.
- Significant determinants of appropriate treatment seeking behaviour are: self-efficacy (self-confidence to use antimalarials effectively) and socio-economic status (ability to pay)

Subsidy welcomed by communities

- The community is excited at the prospect of effective antimalarials being subsidized at community level and wish for rapid introduction of the scheme.

Key issues and recommendations

Need to explain value add of ACTs

Over the past decade, Uganda has changed first line antimalarials from CQ to CQ+SP and now to ACTs. As expected, there is considerable lag between policy change and provider behaviour. There has also been limited communication around the switch to ACTs. A serious effort should be placed on explaining the move to ACTs, as well as subsidized ACTs, to the community. ACTs also need a more "user friendly" name which is acceptable across the many languages spoken in Uganda.

Need for a fixed dose combination to facilitate compliance

After considerable discussion, and in line with the design of the Affordable Medicines Facility, malaria (AMFm), it was agreed that a WHO prequalified fixed dose combination product would be used for the pilot. Therefore in line with Uganda's current first line treatment the initial subsidized product would be Artemether – Lumefantrine. However, with time, other ACTs that get prequalified would be eligible for provision under the AMFm subsidy.

A differentiated product offering to facilitate choice

The subsidised ACT will have to compete against over 160 marketed antimalarials – many with brand recognition and established consumer preference. Generating demand for the subsidised product will be challenging. The creation of a culturally sensitive umbrella brand and repackaging the product will be vital to differentiate the subsidised ACT from other antimalarials including the public sector offering. This, together with the promotional support for the subsidised product, will encourage the distributors and retail trade to stock the product. A leaked public sector product would otherwise discourage the supply chain from holding the subsidised product.

Promotional efforts will focus on generating demand for the umbrella brand. This will facilitate provider, dispenser and consumer choice. Government ownership of the umbrella brand

(trademark) will be vital to allow its use for other ACTs as they are subsidized. The umbrella brand should be limited to only subsidized ACTs rather than all NDA-registered ACTs as the umbrella brand will stand for affordable and effective antimalarials. The successful experience from Rwanda (using a single name "Primo") and Tanzania (which used a phrase) could guide the process.

Repackaging to facilitate correct dispensing and use

Repackaging will allow the inclusion of locally understandable pictorial information to facilitate correct use of the product. Age-based colour coding will also facilitate correct dispensing of the subsidized product by dispensers, especially those with limited training. This will of course need to be complemented by specific materials for dispensers and caregivers. Although repackaging will add to the cost of the final product it is considered to be indispensable.

Generating demand but with an eye on the budget

An integrated communication campaign should be developed to promote prompt health seeking and above all to generate demand for ACTs via promotion of the umbrella brand. The MRRP must be included in all communications to serve as a reference / anchor price for communities to reduce the risk of profiteering. The campaign should also facilitate the correct dispensing and use of the subsidized drug. The overall costs and reach of the media deployed in the pilot are particularly important to ensure their use during national scale up.

Particular attention should be paid to rural communities as caregivers of sick children often do not know what the best treatment is. Lessons should be learnt from the Nigerian 'role mother model'.

Communications will need to be carried out prior to and concomitant with the implementation of the intervention.

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2.4 Training

Key findings

- Many private sector outlets were owned by trained staff and someone with some health training.
- Choice of antimalarial typically depended on customer demand, price, and recommendation by the provider / dispenser.
- Quality of service to the private sector was considered poor, because providers simply supply what is asked for in the quantities the consumer can afford.
- Retailers typically sold incomplete doses.

Key issues and recommendations

Training in private sector poses particular challenges

Training should be targeted at the wide range of outlets selling antimalarials to ensure correct dispensing and sale of full treatment course. Categories of private providers who need training should be identified, including: owners, dispensers and prescribers each with separate needs and curricula. Different approaches will be needed for each category - cascade district training, mixed (group and on-site follow-up) training and drug distribution network e.g. distributor to retailer training. Given the limited training capacity of distributors in Uganda, this could be included in the selection criteria for distributors. Private sector training will be further complicated by the different educational levels of the participants and their tasks, as well as the fact that time is money and business must go on. Training should ideally

not exceed 2 hours, often only on weekends. Uganda could also learn from Nigeria's experience in working closely with trade associations for in-service training and regulation.

Need to learn from past efforts

The training of the trainers could be carried out by a team which includes public sector health care staff, ideally with NMCP training materials adapted for the private sector. However, lessons need to be learned from the health facility training on Coartem® as a large proportion of health workers do not comply with the policy change even after training. Understanding the reasons behind this reluctance will be critical to ensure the success of future training.

Evaluation of the impact of training

Training cannot be a one-off event and will require support supervision. Although supervision systems exist within the districts, this needs to be strengthened to include the private sector. The effectiveness of the training should be evaluated based on reviews of prescriptions through outlet records and spot surveys e.g. using mystery shoppers. The MoH training of CMDs, will complement the delivery of subsidised ACTs in the private sector.

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2.5 Monitoring and Evaluation

Key findings

- Detailed statistics on the malaria burden (out-patient and hospital admissions) are collected at the various health facilities. The data however need to compiled and analysed to provide a baseline, preferably for the previous five years..

Key issues and recommendations

Monitoring and evaluation critical for the learning process

The monitoring and evaluation system should focus on a limited set of key variables required to make evidence-based decisions during the implementation phase as well as inform future policy decisions. This will also simplify the provision / collection of information from the various sources. Ideally the M&E framework should be harmonised with that of regional initiatives such as the Malaria Market Monitoring and the planned Affordable Medicines Facility, malaria.

Sales data from a sample of outlets by type of category (sentinel sites) will be critical to quantify drug requirements and monitor the success of the intervention. Collecting data from the private sector will undoubtedly be challenging. Mechanisms need to be found to gain the confidence of these sentinel outlets to provide such data and motivate them to do so on a regular basis. This could be complemented with surveys rather that routine passive collection at all outlets. Specific indicators need to be developed to monitor availability at different levels in the private sector by type of outlets. Since the intervention targets all age groups, monitoring impact should be extended beyond school absenteeism to include work absenteeism, as well as population-based measures of disease burden such as parasite rates and anaemia prevalence in primary school going children.

The following data categories should be measured to ensure that the intervention is on the right track and achieving its goals:

- Geographical access
- Trade stocking and dispensing patterns
- Correct use of ACTs
- Safety efficacy and pharmacovigilance
- Financial access
- Equity

- Impact of the subsidised ACT (Parasite rates, anaemia rates, absenteeism from school and work, and in patient facility case load data)

Pharmacovigilance needed to assess potential risks with wider distribution

Although pharmacovigilance and post marketing surveillance are vital, appropriate and effective systems to collect and evaluate such data within sub-Saharan health systems are lacking. Pharmacovigilance should be nonetheless be incorporated into the intervention and should be included within the national rather than intervention context. Important lessons will be learnt from the pharmacovigilance pilot project under the Uganda Malaria Surveillance project. The MoH –MMV intervention should explore possibilities of expanding this pilot to the study areas and link with global initiatives to ensure standardisation and to facilitate causality assessment.

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3. Way forward and next steps

In a follow up discussion with the Ministry of Health senior management, it was agreed that the Task Force Secretariat should develop the detailed blue print with the input of the existing sub-committees of the National Malaria Control Programme. Further analysis on the demand and supply data sets should be carried out to provide a more comprehensive understanding of the antimalarial market. The determinants of compliance should be further analysed as well as the issue of self-efficacy. The following guiding principles should be respected when designing the intervention:

Experiment but only with approaches which can be taken to scale

The pilot offers a unique opportunity to test different approaches such as in training, supervision, and distribution. However, the pilot should inform national and international policy. Therefore, only approaches that can be scaled up or replicated in other contexts should be tested.

Continuing the consultative process is critical

The design of pilot has been informed by a true consultative process since its inception with key stakeholders. This process should be continued and expanded to include the remaining relevant stakeholders such as those involved in the supply chain, associations of medical practitioners and pharmacy operators as well as consumer associations. The success of the intervention will depend on outreach to and inclusion of all interested stakeholders, including public sector, private sector (supply chain) and health sector representatives. This will further strengthen existing partnerships.

Limited interference in the supply chain

Antimalarials are available throughout the country through the private sector. Linking into this distribution network with limited interference should allow valuable lessons to be learnt for the scaling up process.

Need to be pragmatic

Malaria diagnosis remains a major problem in most districts due to a lack of adequate laboratory capacity as well as reliable rapid diagnostic tests (RDTs), especially in high endemic areas (high parasitemia even in asymptomatic people). Moreover every fever is given antimalarials irrespective of the diagnosis due to a number of reasons including limited faith in the diagnostics, limited treatment options. The pilot will continue the current policy of presumptive management of fever. However, the proportion of malaria cases being treated will be ascertained as part of monitoring and evaluation. If non malaria cases are documented to be substantial, modalities for introduction of Rapid Diagnostic tests (RDTs) will be explored

Ensure coordination of demand and supply

Close collaboration and coordination between the different groups involved in generating and meeting demand for the subsidized ACT will be vital to achieve health impact.

Respect the process within the Ministry

The draft blueprint needs to go through the existing procedural processes within the Health Ministry, namely approval by the Case Management Committee and subsequent approval by the Inter-Agency Coordination Committee (ICCM) and the Health Policy Committee (HPAC).

The likely launch date for the intervention is the end half of 2008.

Annexes

1. PDF of Key Output and Recommendations, Section 2
2. Participants