



Aligning ACT Supply and Demand: Short and Long Term Options

Final draft

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ACRONYMS

ACTs	Artemisinin combination therapy
AQ	Amodiaquine
ART	Artesunate or artemether
DFID	Department for International Development
DRF	Drug revolving fund
EC	European Commission
EDL	Essential drugs list
EOI	Expression of Interest
FDA	US Food and Drug Administration
FDC	Fixed-dose combination
GAVI	The Global Alliance for Vaccines and Immunization
GDF	Global Drug Facility of Stop TB Partnership
GF	Global Fund (for AIDS, TB and malaria)
GFATM	Global Fund for AIDS, TB and malaria
IAPSO	Inter-Agency Procurement Services Office
LLIN	Long lasting insecticide treated nets
LTA	Long term agreement
LUM	Lumefantrine
MMSS	Malaria Medicines and Supply Services
MoF	Ministry of Finance
MoU	Memorandum of Understanding
OTECI	Office Technique d'Etudes et de Coopération Internationales,
PAHO	Pan American Health Organization
PR	Principal Recipient (GFATM)
PSM	Procurement and Supply Management (plan)
RBM	Roll Back Malaria
RFP	Request for proposals
SP	Sulphadoxine Pyrimethamine
TB	Tuberculosis
ToRs	Terms of reference
TRIPS	Trade related aspects of intellectual property rights
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
USP	United States Pharmacopeial Convention
WHO	World Health Organization

1. ACKNOWLEDGEMENTS

We would like to thank all the people participating in the informal RBM sub-working group on ACTs (see below) for attention to this important issue, Allan Schapira, WHO/RBM Department and Maryse Dugué, RBM Partnership Secretariat, for initiating our assistance in this process, Billy Stewart at DFID for responding to RBM's request, and all the people who gave us generous amounts of their time during the assignment. (Appendix G).

2. EXECUTIVE SUMMARY

Forty-nine countries have now adopted ACTs in their policy, and 24 are currently implementing it. The rapid increase in forecast demand for ACTs, and the need to match this with increased supplies have led to a number of problems. Although the GFATM financing is there to support ACT scale-up and roll-out, there have been problems in getting final approval of GFATM grants, in getting the supply side to respond quickly to the increase in finance (due to the 18 month cycle between artemisinin planting and finished product availability) and various other country level bottlenecks. Consequently, while a number of countries have expressed their intention to order ACTs, only a small fraction of the GFATM funds approved for ACT purchase has already been translated to actual orders. The potential for a vicious cycle was therefore recognised, since the potential consequence of this lack of orders may be a reluctance of manufacturers to make financial commitments necessary to increase production.

The GFATM has been making efforts to better align supply and demand. In mid-2004, the GFATM created a 'Memo account', an accounting mechanism within the World Bank, which effectively consolidated the funds that would be used for ACT treatments, and sent a clear signal to industry and other partners on the availability of funds for malaria grants in developing countries. In addition, since the problems in early 2005 seemed to stem from countries inability to place orders due to delay in processing and receiving their GFATM funds, the GFATM responded by initiating '6-point restructuring exercise' with the aim of speeding time between GFATM Rounds and actual orders. Simultaneous to the GFATM's re-engineering, stakeholders have been considering whether further, more immediate, mechanisms are needed to align supply and demand. This was the subject of the MMSS presentation at the April RBM Board meeting which focused on an idea to create a "revolving fund", or a non-country specific mechanism to pre-purchase ACTs immediately (i.e. before September 2005, when investment decisions are taken for 2007 supply.)

The aim of this consultancy assignment has been to analyse the existing ACT situation and to consider whether and how restructuring the financing or procurement of ACTs might improve alignment of supply and demand. The report begins by breaking out various short-term (i.e. interventions that could be implemented over the next few months, with the intention to bring 2007 supply and demand into alignment) and long-term (post 2007) options, and describing the situations that would justify selection of the different options. The report then analyses the ACT demand and supply situation, from 3 angles: Has industry and will industry make sufficient investment to meet the financed demand for 2007? Is the financing available to countries to place orders? Will the orders come in to support the financed level of demand?

2.1 The Options

The main short term options include: doing nothing, offering technical assistance to support ACT roll-out, advancing orders/funds to industry either via an umbrella mechanism covering all countries or on behalf of individual countries, and doing so either with or without country approval. There are various sub-options, or mechanisms, by which these main options could be implemented. For instance, if an order/fund advance is justified, it could be done via the drug revolving fund mechanism outlined in MMSS's presentation, or it could be done via a few donors issuing a letter of guarantee to a procurement agent, who would advance the order to industry and expect to be reimbursed by the country when the country is ready to

place its order. It is suggested that one of either of the following two situations would make the need for the short-term advance order/'revolving fund' option unnecessary:

- 1) If there is confidence that industry will go ahead and make decisions/commitment to scale up to the financed demand level for 2007 (conclusion: no short term intervention needed), or
- 2) If the reason countries are not placing orders is related to a more serious and fundamental problem with switching to ACTs – which may prevent the countries from placing orders at all. (conclusion: enhanced technical/policy support would be the way to bring about genuine orders, not a donor-led order advance to industry)

The long-term options primarily focus on whether or not pooled procurement, in advance of needed supply, would be of benefit to aligning supply and demand. It is suggested that regardless of which option is chosen short-term, pooled procurement and placing orders in advance of needed supply would be of benefit to aligning supply and demand. There are various sub-options relating to how the pooled procurement would be organised, however, the major issues with moving to pooled procurement and advance contracting are not so much these design related questions, as an experienced procurement agent can advise on the design issues. The real challenges, which were identified partly through comparing the ACT situation with how procurement works within PAHO and GDF, relate to the perceived benefit to countries to participating in pooled procurement, whether enough countries be willing to participate, and how can the need for tendering in advance of needed supply be practically accomplished, given the way the GFATM financing currently works?

2.2 The Situation Analysis

When this consulting assignment started, it was widely believed that a major problem on the demand side was that countries were held up in GFATM bottlenecks of fund disbursement; that is, either countries had not passed through PSM or they were held up in some other way and therefore did not have the funds with which to purchase in time for September (conclusion: intervention needed). On the supply side, it was also opined that 2007 supply capacity would be insufficient to meet 2007 demand unless manufacturers received a strong signal that orders were coming, or even better, received the actual firm orders. (Conclusion: intervention needed). It was also suggested that, if orders could be placed on behalf of countries (for example, by donors through a drug revolving fund mechanism) by September 2005, that this would encourage manufacturers to make investments needed to scale up 2007 supply.

Whilst it may have been true six months ago that countries could not order largely because they were caught up in the GFATM processes, we found that the majority of countries currently have GFATM finances approved and available for ACT purchase. For artemether/lumefantrine purchase, USD 177 million of GFATM funds has been approved for Coartem purchase. This is money that has been through all GFATM disbursement phases (including approval of the Procurement and Supply Management – PSM - plan) and can be used immediately to place orders. USD 26 million is still held up in the GFATM disbursement process, for various reasons, including yet-to-be-approved PSM plans. For artesunate/amodiaquine, USD 21 million is available now (i.e. PSM approved) for placing orders compared with USD 1.7 million budgeted for ART+AQ where the PSM plan is not yet approved. The majority of these grants received final sign off during the past few months.

On the supply side, Novartis has announced that it will be producing 210 million treatments over this time period. At average prices of \$1.5 per treatment, this

equates to \$315 million of needed budget to buy Novartis's entire production over the two-year period. This means that Novartis will be producing in excess of the GFATM financed demand, and there will be a short-fall of \$80 million to buy the entire production of Novartis over the two-year period. However, this shortfall may be met by i) Novartis sales to the private sector, ii) the ACT portion (not yet decided) of the \$500 million from the World Bank (Booster program) devoted to Africa to fight Malaria over the next 5 years, iii) by new countries winning GFATM grants for ACT procurement in GFATM Round 5, or iv) other donors, (e.g. EC, Bush initiative July 1st 2005 declaration) and v) GFATM Phase II of grants currently in operation. It should also be noted that the shelf life of the artemisinin is approximately 5 years, and time to bring artemisinin to finished product only several months, thereby allowing some flexibility to hold stock for subsequent years if a firm happens to over-contract for supply. As for artesunate/amodiaquine, Sanofi production in 2006 might reach 15 million treatments, and IPCA will soon be producing 2 million treatments (co-blisters) per month (which is a fraction of what they are capable of producing). Cipla produces this product as well. Since GFATM financing covers 235 million over the 2 year time period, the current projected production exceeds the financed demand. Presumably these suppliers are producing to a higher level in order to capture private sector demand, in addition to public sector business.

Even though the financing is clearly available and the manufacturer's projected supply exceeds the GFATM financing, there still remains the question of country orders. Only a small fraction (about 35%) of the \$235 million GFATM funds approved for ACT purchase has entered into the order pipeline. This suggests that the primary issue for focus going forward should not be so much on finance and supply availability, but on identifying the reasons for country reluctance to place orders and meeting country needs, via technical assistance for example.

The appropriate choice of short-term option depends crucially on this contextual detail at country level, and the consultants have not had access to this level of contextual detail. Those who do have access to this contextual detail now have this report, however, and can map out what they know about the context against the options and the justification for choosing each one. The fact that there is sufficient supply relative to financed demand would, however, make a case that a short term intervention, along the lines of a drug revolving fund, is not needed.

The consultants would suggest that, regardless of decisions taken about the short-term, longer-term pooled and advance procurement arrangements should be sought. Also, regardless of whether a short-term option to finance purchase guarantees is chosen, there seems to be enough evidence (albeit in the form of triangulated viewpoints) that enhanced technical/policy support is needed at the country level at this time.

Once decisions are taken about which options best meet the needs of the situation, the appropriate actions and roles (related to the option chosen) can be mapped out.

2.3 Recommended Actions

We would recommend the following short-term actions:

- 1) Investigate the detail of the large potential ACT-consuming countries who have GFATM money, but who do not appear to be planning to order significant quantities anytime soon. The most recent figures (Appendix E) show that this would be Kenya, Uganda, and Nigeria.
 - Do they need technical assistance?

- Do they need assurance that funds will be there to support them after Phase I GFATM grant period ends?
- Do countries understand the link between the signals sent by orders placed now and supply security 18 months from now?

2) Revisit the malaria financing, procurement and information pooling architecture, from an institutional standpoint, to remedy communication problems & potential mission drift. Such a review would need high-level support.

- Which functions need to be performed?
- Where do those functions most logically sit?
- What resources are needed to perform those functions?

If political support cannot be harnessed to look at 3 above, then at the very least, more thought needs to be given to:

- What are the **formal** channels and processes for linking/communicating between groups carrying out different and often overlapping functions?

The recently announced Bush funding for malaria increases the importance of implementing this actionable, since it expands (and complicates) the malaria financing architecture.

3) Number 2 above would help further progress on consolidating and communicating information on the following:

- Consolidated data on ACT funding by all donors for each country
- Consolidated real time data on order status (i.e. at what stage in the order 'pipeline')
- Data on industry production/supply

4) Explore pooled procurement

- The benefit and disadvantages from a country perspective
- Will enough countries be willing to participate?
- How can it be practically accomplished, give the way GFATM financing works? (Could GFATM grants for commodities – ACTs – become grants in kind, as with TB drugs and GDF?)

It is suggested that MMSS, GFATM, WHO and others need to find a forum to discuss these issues in conjunction with endemic countries.

5) It may also be necessary to organise annual regional meetings (Africa, Asia and LA) with Directors of local 'national malaria programme', country procurement director and international players to:

- Communicate the ACT situation in terms of production, procurement, and financing
- Reassure countries on long-term commitment (at least 5 years) from donors (through GFATM, or directly from DFID, USAID)
- Convey a clear message on the benefits of co-ordinated and predictable mechanisms for procurement and financing

Finally, while this report focuses on the situation at a specific point in time with regard to aligning ACT supply and demand, it must be recognised first of all that the situation is continually evolving and secondly, that there are clearly other important issues to resolve if broad access to ACTs is the overarching goal.

3. BACKGROUND

Due to increasing resistance to traditional malaria treatments, WHO recommended that countries change their drug policy to artemisinin-based combination therapy (ACTs), the only available treatments that are fully effective against all strains of multi-drug resistant falciparum malaria. Forty-nine countries have now adopted ACTs in their policy, and 24 are currently implementing it. The rapid increase in forecast demand for ACTs, and the need to match this with increased supplies have led to a number of problems. Before GFATM Round 4, financing need was the primary problem. Then, in GFATM Rounds 1,2,3,and 4, the financing for \$235 million worth of ACTs was approved, and attention shifted to how quickly the supply side could adapt to this significant increase in financing, which, it was presumed, would be reflected very quickly in an increase in demand. However, since there is an 18-month cycle between artemisinin planting and finished product availability, the situation at any point in time is a result of market dynamics and investment decisions made some 18 months prior. And although Novartis secured raw materials for its 2005 production in the absence of either financing or scaled-up demand, and has made investments to produce for 2006 in the absence of any significant orders (although now with the presence of GFATM finance availability), the result for this year is a significant shortfall in supply.

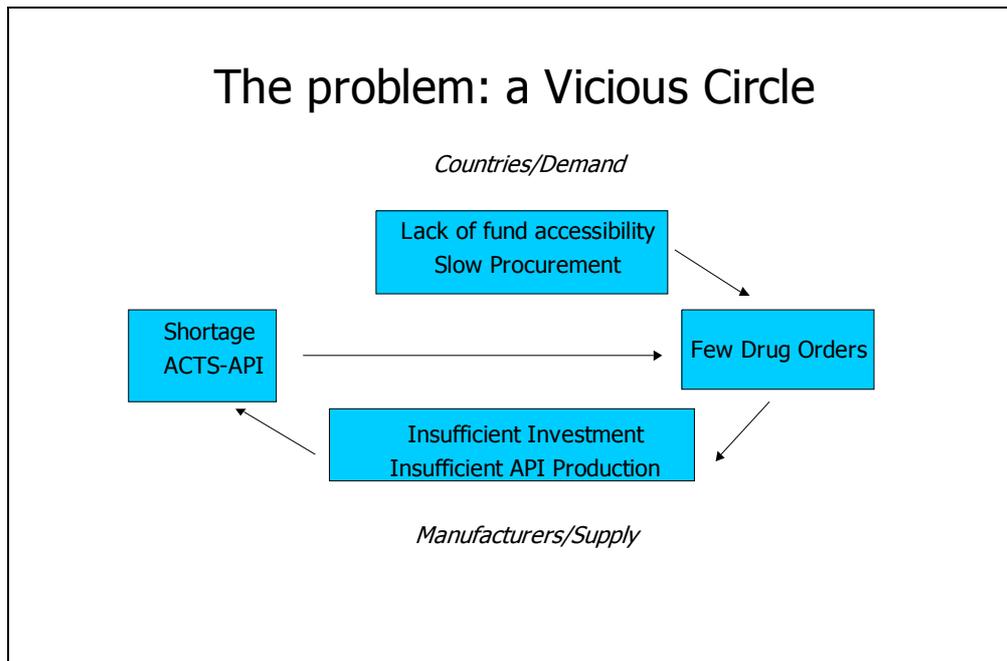
Nothing can be done about the current shortage of Coartem, however, stakeholders are now focused on how to ensure that investment decisions are taken in September 2005 (when planting decisions are taken), which will ensure that sufficient supplies are available in early 2007 as well as how to ensure improved alignment of supply and demand longer term.

Whilst a number of countries have expressed their intention to order ACTs, only a small fraction (about 35%) of the \$235 million GFATM funds approved for ACT purchase has been used to place actual orders. The potential for a vicious cycle has thus been recognised, as the potential consequence of this lack of orders may be a reluctance of manufacturers to make financial commitments necessary to increase production.

Stakeholders in the fight against malaria are therefore working together to increase the availability, affordability and quality of ACTs drugs at this crucial, initial phase.

3.1 MMSS's proposals

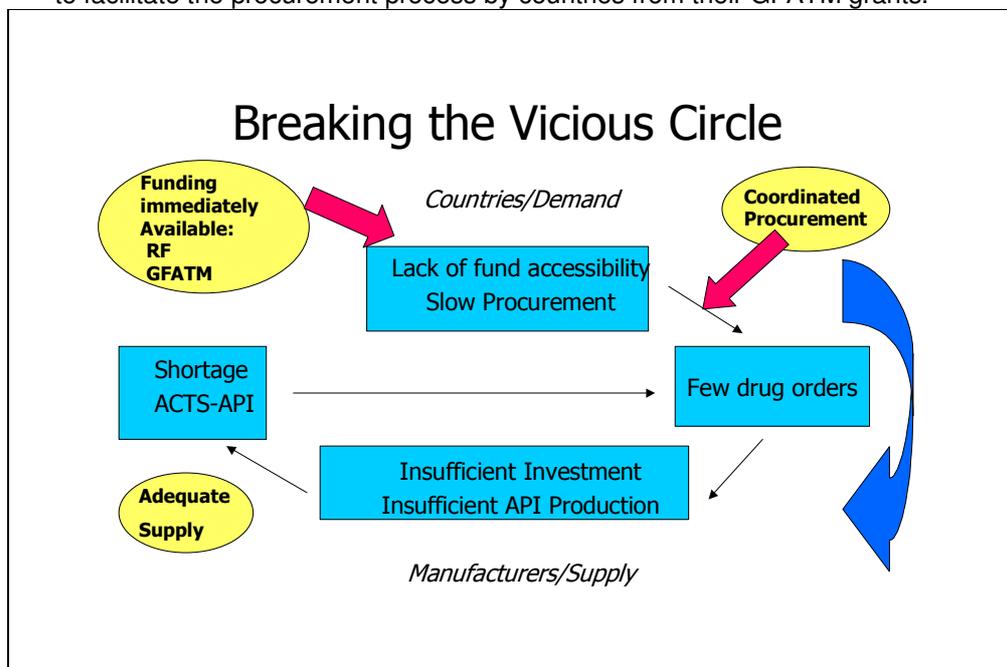
MMSS has been working to find solutions to align supply and demand of ACTs. In April, a presentation was made to the RBM board, which outlines the problem, depicted in the following diagrammed:



Slide source: MMSS

The presentation also offered concrete solutions to remedy short-term problems with ACT supply and demand alignment. Two propositions were made:

1. A “revolving fund”, non-country specific mechanism to pre-purchase ACTs immediately (i.e. before September 2005)
2. A country-specific mechanism, based on a re-engineering of GFATM processes, to facilitate the procurement process by countries from their GFATM grants.



Slide source: MMSS

The operation of the proposal was described as follows:

*An advance of funds would be made in an account ("**revolving fund**"), available to an entity in charge of passing orders **immediately**, for staggered deliveries (**pre-purchase**). Approximately US\$30-50 million is estimated to be necessary to pass sufficient orders up front. The disbursements from this fund would be replaced from the GFATM's memorandum account (or countries' grants) for ACTs, when orders from countries are approved (the fund being then replenished). Countries would opt for being delivered from this mechanism on a voluntary basis. This mechanism would be **temporary**, and funds would revert to the "general pool of funds" of the GFATM after 2-3 years. This initial advance of funds could therefore be made by donors against their pledge to the GFATM, as shown below ("top-slicing" from future commitments).*

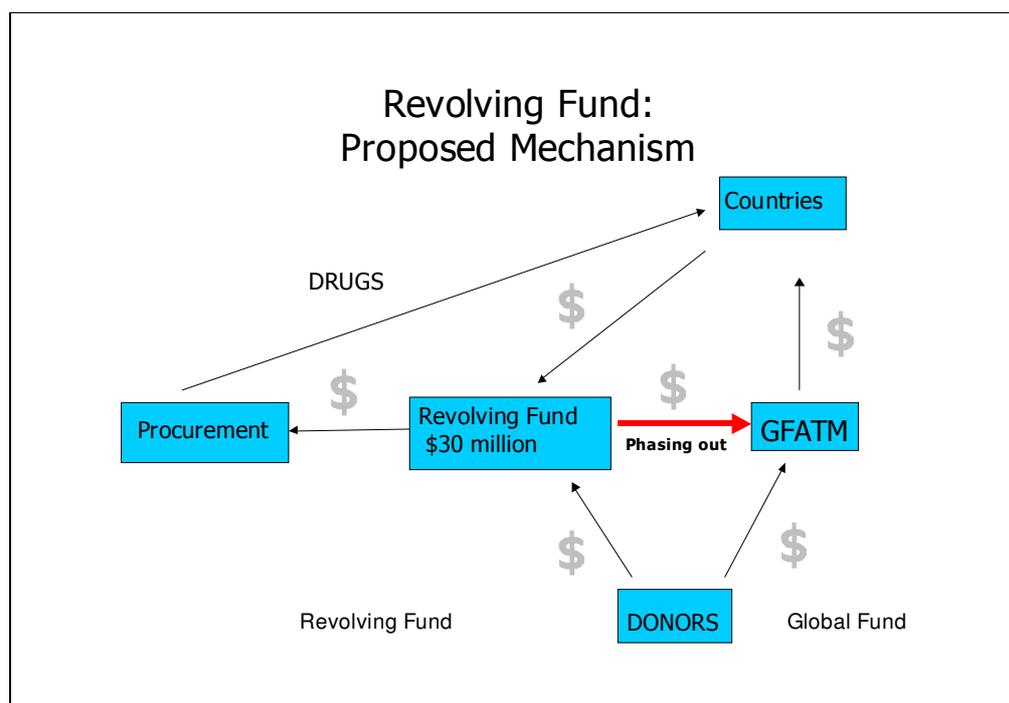
The World Bank could host this fund, as this would facilitate the management and the transfer to the GFATM.

*Another utilization of this fund could be as a **guarantee mechanism** for suppliers, against the difference between orders actually passed and the forecasted demand. The percentage of orders guaranteed has to be defined by negotiation. Another issue is the mechanism to allocate guarantee between manufacturers when several manufacturers are producing the same drug and are pre-qualified (the pre-qualified product having priority over non-pre-qualified ones).*

This process would operate as follows:

- *Step 1: PRs would send a letter to GF/RBM Partnership to indicate their interest in participating in the new procurement process; the letter should indicate that the PR is 1) interested in participating in the new mechanism and 2) that the GF should withhold the PRs funds for ACT procurement which should be used to pay procurement agent(s)/suppliers directly*
- *Step 2: GF would earmark funds for ACT procurement for signed grants and set these funds aside for direct payment to the procurement agent(s)*
- *Step 3: RBM Partnership would work with countries to project ACT requirements for 2 years and coordinate orders for 12 months; these orders may be supplied quarterly, and would be adjusted according to need*
- *Step 4: PRs would place orders with procurement agents and instruct GF to transfer funds directly to the procurement agent.*
- *Step 5: GF would transfer funds directly to the procurement agents (currently UNICEF and WHO for Coartem and agent of choice for other ACTs)*

The advantage of this mechanism is that (i) it does not require the creation of a new system, and (ii) it will facilitate procurement over the medium-term. The inconvenient is that it will not allow to pass immediately large orders, as it still depends on a processes of approval and signature that has proven to be slow, and offers no guarantee for the coming months.

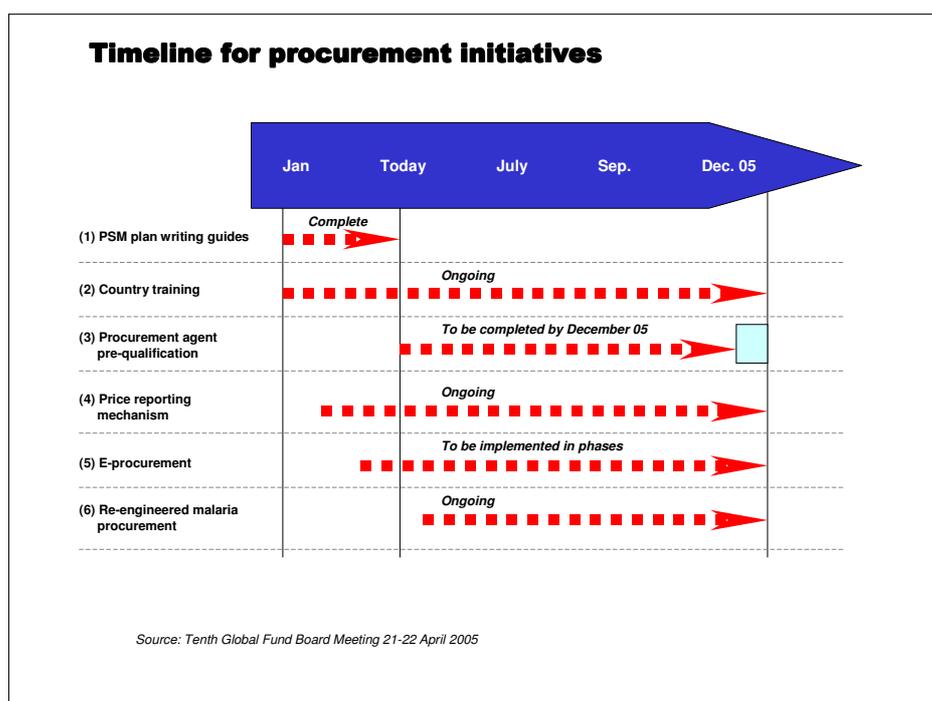


Slide source: MMSS

3.2 The GFATM's work plan

The Global Fund has also been considering what role it might play in aligning ACT supply and demand. In mid-2004, the GFATM created a 'Memo account', an accounting mechanism within the World Bank, which effectively consolidated the funds that would be used for ACT treatments, and send a clear signal to industry and other partners on the availability of funds for malaria grants in developing countries.

Since the problems in early 2005 seemed to stem from countries inability to place orders due to delay in processing and receiving their GFATM funds, the GFATM responded by initiating '6-point restructuring exercise' (diagram below).



Initiatives 1 and 2 are aimed at speeding the grant approval time and helping countries to make the transition to ACTs by helping them finalise their procurement plans. This initiative involves offering Procurement and Supply management (PSM) support and procurement workshops, via partners such as PAHO, the World Bank, USAID, WHO and others.

Initiative 3, 'procurement agent pre-qualification', is aimed at establishing a short-list of agents who are compliant with GFATM procurement rules and guidelines. Countries requiring the assistance of a procurement agent would then be able to make an appropriate selection more easily.

Initiative 4, 'price reporting mechanism' enables countries to share information on prices actually paid for each products and the Global Fund to track expenditure (and delivery conditions) against disbursement.

Initiative 5, 'e-procurement' can be used in conjunction with direct fund transfer to speed up the procurement cycles in the countries, which sometime may take several months to complete (from product-selection to awarding contracts).

Initiative 6, 're-engineered malaria procurement' refers to a changed in financing flow architecture, taking advantage of the possibility for the Global Fund to use direct payments to suppliers and/or procurement agents.

Simultaneous to the GFATM's re-engineering, stakeholders have been considering whether further mechanisms are needed to align supply and demand, and this was the subject of the MMSS presentation described above as well as the reason for this consultancy.

4. INTRODUCTION

The work on which this report is based has been commissioned by DFID, in its support to RBM and MMSS, and is focused on addressing emerging challenges with the demand and supply of ACTs for malaria. Specifically, the work considers whether and how restructuring of financing and/or procurement might ensure more secure alignment of supply and demand, in the short and longer-term.

Specific tasks required of this consultancy, outlined in the Terms of Reference (Appendix C) include:

- a. Finalizing, in collaboration with MMSS, the April proposal on mechanisms to improve financing and procurement of ACTs to ensure short and long-term sufficient availability of quality products to satisfy the demand. This would include the revision of existing drafts on the subject.
- b. Studying existing pooled procurement mechanisms such as the GDF and GAVI, to identify relevant and transferable mechanisms
- c. Facilitation of teleconferences with UNICEF, WHO, MMSS, GFATM, USAID, DFID, WB, MSF and in some cases, industry
- d. Development of a final 10 page document, with
 1. Background
 2. Description of the various options for an advanced purchase/procurement mechanism for ACTs and (possibly reverting to) a guarantee fund, its links with the GFATM, the size of the proposed fund, the phasing out of the fund (timeline and modalities)
 3. Mechanism of coverage of the guarantee fund
 4. Governance, management structure, coordination with procurement agencies
 5. Staffing
 6. Budget

Early in the consulting process, it was suggested that the focus of the consultancy and this report should really be on point number 2 under 'd.' above, with attention given to points 3, 4, 5, and 6 under 'd.' only if the guarantee or revolving fund was found to be the most viable option.

It was also agreed that the consultancy would be undertaken in a participatory manner, with the consultants holding bilateral discussions, as well as facilitating discussion around data needs and options during teleconferences, as appropriate.

5. METHODOLOGY AND APPROACH

The consultants had 14 days allocated for this piece of work. They began with a teleconference in early May with the informal working group who had been meeting to resolve these issues). Bilateral discussions were then held with working group members, as well as other informants, to gather data. Documents were reviewed. Interim findings were presented during the teleconference on May 13th and subsequent T/Cs were held on May 26th, June 2nd and June 16th. (See Appendices D and E for the slides.)

The consultants divided the analysis into two primary streams of investigation:

1) Identifying problems or bottlenecks in supply or demand, which would justify the need and form of any intervention in the procurement and financing options.

This analysis takes on three dimensions:

- Has industry and will industry make sufficient investment to meet the financed demand for 2007?
- Is the financing available to countries to allow them to place orders?
- Will the orders come in to support the financed level of demand?

2) Proposing options for such an intervention, with the choice dictated by the need to solve the problems identified in #1 above. The options are separated into

- Short-term (i.e. interventions implemented over the next few months, with the intention to bring 2007 supply and demand into alignment) and
- Long-term (post 2007).

Subsequent T/C meetings and bilateral discussions were held weekly in June to try to resolve some of the subsequent issues that emerged during the consultancy.

The report was sent to participants of the June 2005 Arusha meeting, organised by RBM and MMSS, and to members of the RBM Board. Feedback received from these groups was incorporated into this final draft.

We will begin this report with work stream number 2 above, elaborating the variety of options, divided by short and long-term.

6. THE INTERVENTION OPTIONS, SHORT AND LONG TERM

6.1 Short Term Options

Short-term options include:

Option	Mechanisms	Justification
A. Doing nothing.		This would be justified if short-term supply and demand were found to be in alignment for 2007.
Advancing funds to industry, prior to actual orders, via a kind of 'umbrella' mechanism that all countries can take advantage of, and which countries command and control . Consideration could be given to whether the GFATM/World Bank 'Memo account' could potentially serve as the source of funds, since countries would be in the driving seat.	<p>The mechanisms, or sub-options, here would be</p> <p>i) Who funds the advance, for example,</p> <ul style="list-style-type: none"> - The country via its Principal Recipient (e.g. via 'retroactive financing') - The procurement agent (as UNICEF does with LLIN) - Donors (e.g. letter of guarantee to a procurement agent) or the DRF/guarantee fund described earlier in the MMSS proposal) - The GFATM <p>ii) How far in advance of the order, or at what stage in the GFATM approval process, the funds can be advanced¹, and</p> <p>iii) Design issues such as % down-payment, and agreements for supply, e.g. a) manufacturers take a down payment but don't manufacture, b) product is manufactured immediately but held at manufacturers' site, c) product is manufactured immediately and sent to country immediately</p> <p>iv) If a drug revolving mechanism is chosen, what should be the fund size,² how long should it exist, how would it be dissolved,</p>	<p>Justified if:</p> <ol style="list-style-type: none"> 1. Delays in placing orders at country level due to bottlenecks in the GFATM financing process, bureaucratic delays at country level (e.g. in going through a tender process), or governance problems causing delays in the order <p>IN COMBINATION WITH</p> <ol style="list-style-type: none"> 2. A belief that industry will not make sufficient investment to increase supply in line with demand projections

¹ The earlier the advance, the more potential incentive effect on industry but the greater risk of over-ordering, causing stock wastage and/or risk of non-repayment. If the advance is made near to the time of the order, there is less finance and stock wastage risk, but the incentive effect may not be much stronger than achieved by strong communication of pipeline and a robust forecasting process.

	<p>where would the fund sit - or who would manage it (e.g. GFATM, WB, procurement agent?)</p> <p>vi) Whether to use a procurement agent to manage the advance, and if so, how many and if one, whom?</p>	
C. Advancing funds to industry, via a kind of umbrella mechanism, applicable to all GFATM countries, but utilised without country approval .	Same as with B – except that under i), GFATM funds could not be used at present, since current GFATM Board Policy does not permit GFATM fund utilisation without country approval	Same as with B.
D. Advance of funds to industry, via a country-specific mechanism to solve particular country challenges	The idea is not that donors would tailor-make a dozen different mechanisms to meet each country's needs (which would be transaction cost heavy). Rather, the idea is that donors tailor-make a mechanism to meet one or two large consuming countries needs, if the justifications above, under 'B' hold true. ³	Same as with B.
E. Enhanced technical/policy support as suggested by MMSS/RBM to accelerate placing of genuine orders		Justified if countries have fundamental problems in making the transition to ACTs – and technical assistance may help resolve the problems.

² Please see Appendix B

³ Given the relatively small number of suppliers at present, one could argue that simply communicating each country's situation at regular intervals to suppliers might have a comparable (and even superior) incentive effect versus a donor-led, mechanistic kind of funds/orders advance, which might not necessarily reflect genuine order intent.

6.2 Discussion

The difference between Options B and C is who is in the driving seat. Countries control the mechanism in Option B, whereas donors control it in Option C. The difference between Options B&C versus Option D is that Option D is done on a country-by-country basis (implicitly with country control) whilst Options B&C are 'umbrella' mechanisms useable by all countries.

The Drug Revolving, or Guarantee fund mechanism, under Options B and C was the subject of the April MMSS concept note and presentations at the RBM Board meeting. The idea is that a drug revolving or guarantee fund would be established to advance funds for orders to industry by August/September, in advance of actual orders received from countries, with the intention of sending a kind of weak incentive signal to industry that orders are coming in, countries are making the change to ACTs, and therefore firms should feel secure to make investment commitments for scale-up. The disadvantages of this option would be the potential for the mechanism to 'take on a life of its own' as a parallel financing mechanism⁴, the fact that the decisions to advance are made without country approval, political unacceptability by some,⁵ as well as questionable incentive effect, given that industry would be more directly incentivised by genuine intention to order, rather than by a mechanistic, donor-led order/fund advancement. The advantage of this option would be speed of getting firm⁶ orders to industry before the September 2004 planting season.

Option B would perhaps be more politically acceptable, but the disadvantage of Option B would be speed. The whole point would be to advance funds to industry prior to September, and it might be difficult to get countries acceptance and participation by that time. In fact, countries may not be interested in participating at all. For instance, it seems that countries have been reluctant to take advantage of the GFATM 'Memo account', allegedly with the belief that it may undermine national systems and capacity and limit ordering and financing flexibilities. The same types of reservations may hold true for participation in such an 'industry advance' scheme.

If it is judged that an intervention is needed in the short term, we would suggest that the best options would be C or D, made possible by a letter of guarantee from a collection of donors to a procurement agent. The advantages of making advances without country authorization (Option C) would be to by-pass the lack of efficient management decisions⁷ that may slow market development. The disadvantage of operating outside country control is that there would be more funding risk, since the advance may be made in cases where the countries do not have a genuine intention to order within the necessary timeframe. On the 'umbrella' versus 'country-specific' dimension, an umbrella mechanism shares the risk amongst multiple countries,

⁴ Some disadvantages of parallel mechanisms include i) increased transaction costs to set them up, keep them running and for countries to figure out how to use the scheme and where it fits within the global architecture, ii) the potential for disjointed decision making, as multiple financing mechanisms develop their own, perhaps un-co-ordinated processes and systems, and iii) the

⁵ Richard Feachem sent a letter to some RBM partners stating that the emphasis should be on solving problems and providing TA at the country level, not creating parallel financing mechanisms to the GFATM.

⁶ Or at least orders that can be backed up with cash. It should be noted that Novartis argued at one T/C that they do not necessarily want a donor-financed DRF to advance funds on behalf of countries. To give them the security they need to continue to make investments supporting scale-up, they would rather see genuine orders from countries, indicating a real commitment that they are making the transition to ACTs.

⁷ For example, various sources have confirmed that some countries have administrative or bureaucratic problems at country level, e.g. lack of realisation that the GFATM funds are now approved and available for placing orders, or a lengthy process for actually putting together a procurement order.

therefore if the amount advanced is 5 million, for example, there is greater chance that this will be repaid (if a DRF mechanism used) or that the letter of guarantee will never be needed (since multiple countries' orders can replenish the procurement agents pre-purchase). On the other hand, if such a mechanism is utilised for a specific country, then there would (should) be very good knowledge about what bottleneck that country is experiencing and the likelihood that bottleneck will be resolved and the money repaid with an actual order.

We suggest that one of either of the following two situations makes the need for interventions B, C & D unnecessary:

- 3) If there is confidence that industry will go ahead and make decisions/commitment to scale up to the financed demand level for 2007 (conclusion: no intervention needed), or
- 4) If the reason countries are not placing orders is related to a more serious and fundamental problem with switching to ACTs – which may prevent the country from placing orders at all. (Conclusion: enhanced technical/policy support would be the way to bring about genuine orders, not a donor-led order advance to industry)

6.3 Long term options

The long-term options centre on procurement choices:

Option	Mechanisms	Justification
A. 'Free market' ordering/tendering by countries, along with stronger organisation of demand and supply information by MMSS, GFATM, industries and RBM. This is the status quo option, although the information co-ordination and demand forecasting mechanism is being continually strengthened, as is the speed and leadership with policy changes		<p>Any combination of the following characteristics makes pooled procurement less necessary:</p> <ul style="list-style-type: none"> i) Market is relatively more mature, making demand forecasting easier ii) Public sector financed portion of market is relatively small, as with reproductive health commodities iii) Manufacturer investment is relatively small (i.e. small minimum efficient scale) iv) Lead-time between investment and product supply relatively short v) Countries have sufficient demand/scale (relative to manufacturer's scale) to conduct efficient procurement of the product at country level vi) Supply market is relatively competitive
B. Information management (as in Option A)+ pooled procurement	<p>Mechanisms, or sub-options, include:</p> <ul style="list-style-type: none"> i) When to move to pooled procurement ii) Is the pooled procurement done with country controlled funds or with other funds, outside of country control iii) If done with country controlled funds, is their participation ('opting in') entirely voluntary or incentivised? iv) Which procurement agent manages the pooled procurement? One or several? How selected? 	<p>Pooled procurement is justified by the converse of the characteristics above.</p>

6.4 Discussion

Because the characteristics of the ACT supply market are not those in the Option A 'Justification' box above, we suggest that pooled procurement would be a useful addition, at this time, to the stronger demand forecasting and information sharing functions already being strengthened.

If the pooled procurement option is chosen, there are a range of design related questions. These include: How far in advance of needed supply should the tender be held?⁸ What should be the contract period of the tender (1 year like GDF or 3 years as with some vaccines)⁹? Whether a percentage down payment is given to manufacturers? How strong is the commitment to purchase (i.e. 40% over 3 years, as la GAVI, or 100% over 1 year, as with GDF)? How is competition managed (both current suppliers and potential entrants in the pipeline)? (e.g. 65/35 GDF model, reserving a percentage for newcomers). What ranges of conditions are covered in the contract? (e.g. delivery, price, quality, packaging). Decisions taken on these design issues will be crucially influenced by the market situation for a specific product and the degree to which information exists to write binding contracts.

The major issues with moving to pooled procurement and advance contracting are not so much the design related questions in the previous paragraph, as an experienced procurement agent can advise on the design issues. The real challenges relate to:

- The perceived benefit to countries to participating in pooled procurement
- Will enough countries be willing to participate? And
- How can the need for tendering in advance of needed supply be practically accomplished, given the way the GFATM financing currently works?

Although we do not yet have clear answers to these questions, our study of PAHO, GDF and GAVI provides some ideas. Please see Appendix A for details on the PAHO, GAVI and GDF models. The key learning points from our review of these models are as follows:

Comparing ACT demand pooling and pooled procurement to vaccines and TB drugs

1. Good demand estimations are the basis of a good contract. Malaria drugs (partly because of clinical manifestations and diagnosis of disease & partly because of the importance of the informal private sector as distribution channel) estimates are more difficult than with TB drugs & vaccines.
2. The importance of a programming function: Both GDF and PAHO have to get involved in the programming side because of the historical lack of prioritisation given to these areas. With TB, people do not continue to take their pills when they start to feel better, whilst vaccines are given to healthy children – so less urgency is felt. In contrast, malaria is well publicised, stakeholders are vocal, and lifesaving treatments exist that work in 3 days. However, the novelty of ACTs, and the lack of public demand would argue for a need for ACT programming support as well, in order to help countries make the transition to ACTs.
3. When GFATM money was approved for TB drugs, raw material producers increased their price. There are few producers, which increases the potential to collude on prices. As with artemisinin, there was also a lag between increase in

⁸ The further ahead the tender, the more assurance industry is given, but the risk of forward contracting is that less information is available.

⁹ The longer the duration of the contract, the more assurance industry has but the risk is less information. It would also be important to structure it in such a way so as not to impede competitive entry (e.g. by reserving a percentage for newcomers).

GFATM funds and an increase in the supply of TB drugs; this was partly attributable to the opportunity cost of space in fermentation tanks. A supply crisis resulted. GDF responded by issuing a new tender. (IAPSO signs LTA with manufacturers for 1 year.)

4. Although the benefits of selecting a procurement agent via competitive tender (a la GDF's selection of IAPSO) are recognised, the benefits need to be weighed against the possibility of slowing down the move to pooled procurement.¹⁰
5. IAPSO's purchase contracts are tightly binding; they promise to buy 100% of the tendered amount over a one year period. This is possible since TB demand estimations are relatively predictable and the programme is growing. Given demand estimation uncertainties with ACTs, the risk of passing tightly (i.e.100%) binding contracts would be higher, and consideration may be given to contracting for only a portion of the expected demand (50% for example).
6. The GDF model, whereby multiple suppliers are awarded a fixed percentage of the total demand estimation for that year, would also make sense for ACTs (esp. ART+AQ). A percentage could be reserved for 'newcomers' as well, in order to incentivise new entry.
7. If GFATM '*recommended*' (as with GDF) countries to enter into pooled procurement for ACTs, would they participate? If not, would it be possible for the commodity-focused portion of GFATM grants for ACTs to become 'grants-in-kind', as with vaccines and TB drugs from the GDF?
8. GFATM funds operate differently from the funds utilised by PAHO & GDF. In the case of PAHO and GDF, the organisation who offers the funds has the power to dictate terms, e.g. by leveraging the grant making & services to drive programming changes and to *require* opting into pooled purchase. How GFATM funds, which are under each country's control, could be leveraged in the same way is a serious *policy* and *practical* challenge, unless the GFATM Board would be willing to take on a more PAHO or GDF-like role of dictating terms or unless countries easily opt-in to pooled procurement.
9. The benefit to countries, from the countries perspective, needs to be given careful thought. At present, countries probably cannot see much obvious benefit to participating in pooled procurement, since prices of the primary product (representing 90% of financed demand in \$ terms) are fixed by the WHO/Novartis MoU. Countries would need to be educated that the supply security benefits are the primary reason to participate in pooled, advance procurement at this point, (although price reduction benefit may also become another advantage of pooled procurement, as more producers enter the market.) This consideration of country benefit also needs to be thought of from the perspective of individual actors making the decision on whether to opt-in to pooled procurement, as health and malaria programme decision-makers may have different perspectives versus people in procurement, finance or political positions, for example.
10. Participation of the big potential ACT consuming countries in demand pooling is essential if the goal is to drive price reductions and security. These countries will not only have the volume that can be leveraged to drive down prices, but they may also have better demand estimation capability, although this has been disputed. An interviewee with PAHO advised: 'Get the 'good' countries first and then 'name the game' with the others'

We shall now move onto the supply and demand situation and whether there is justification for an intervention.

¹⁰ Hugo Vrakking, from GDF, suggests that the minimum time to organise this would be 3 to 4 months and warns that the speed is highly dependent on how quickly legal council can work.

7. SUPPLY AND DEMAND SITUATION: THE NEED FOR AN INTERVENTION

It would probably be helpful to review some of the hypotheses that we were presented with, when we started this work.

- 1) Hypothesis #1: A major problem on the demand side is that countries are held up in GFATM bottlenecks of fund disbursement – either countries had not passed through PSM or they were held up in some other way and therefore did not have the funds with which to purchase in time for September (conclusion: intervention needed.)
- 2) Hypothesis #2: on the supply side, it was opined that 2007 supply capacity would be insufficient to meet 2007 demand unless manufacturers received a strong signal that orders were coming, or even better, received the actual firm orders. (Conclusion: intervention needed)

We set out to investigate the demand and supply side, and the following paragraphs describe our findings.

7.1 (Financed) Demand side

On the demand side, we investigated the level of finance actually available from the GFATM, which is currently the primary financer of ACTs.¹¹

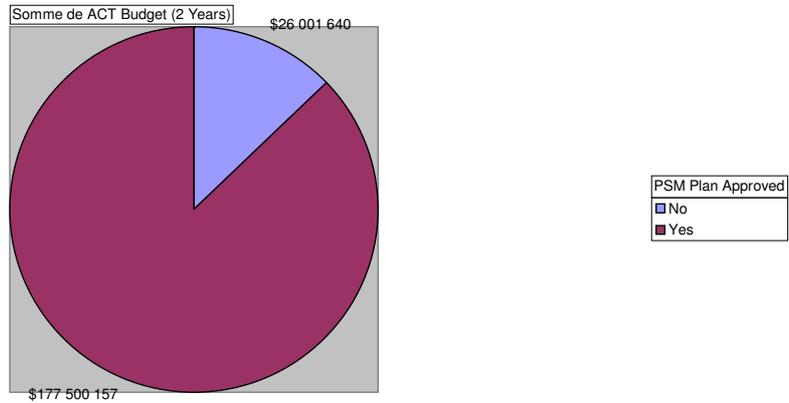
7.1.1 Artemether/lumefantrine

As revealed in the diagram below, USD 177 million of GFATM funds have been approved for Artemether/lumefantrine purchase. This is money that has been through all GFATM disbursement phases (including approval of the Procurement and Supply Management – PSM - plan) and can be used immediately to place an order. USD 26 million is still held up in the GFATM disbursement process, for various reasons, including yet-to-be-approved PSM plans.

¹¹ The level of financed demand may not be indicative of actual health need, which is likely to be much larger. For purposes of comparing supply and demand, it is the GFATM financed demand that is relevant for Coartem, as it would be unrealistic (at current prices) to expect Novartis to produce in excess of the GFATM financed demand. The story with the ART+AQ ACT suppliers may be slightly different, since their prices are lower and they may therefore find more private sector custom in developing countries, thereby making production in excess of GFATM financed demand less risky.

Round(Tous)

Coartem

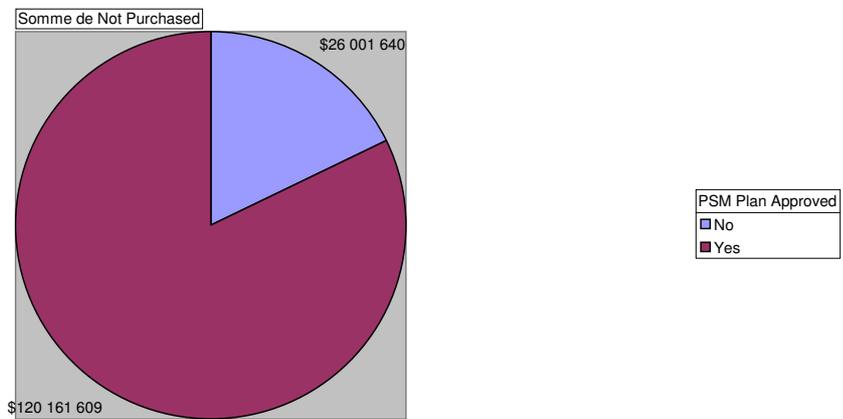


Type of ACT

Almost \$57 million of the \$177 million has already been used to place orders, leaving approximately \$120 million (plus the \$26 million yet-to-be-approved) for future order purchase. The majority of the grants have only recently (mid-2005) been approved, and the \$146 million will need to be utilised (to place orders) within 2 years, i.e. mid-year 2007. Otherwise countries might risk losing the funds if the phase 2 is not approved.

Round(Tous)

Coartem



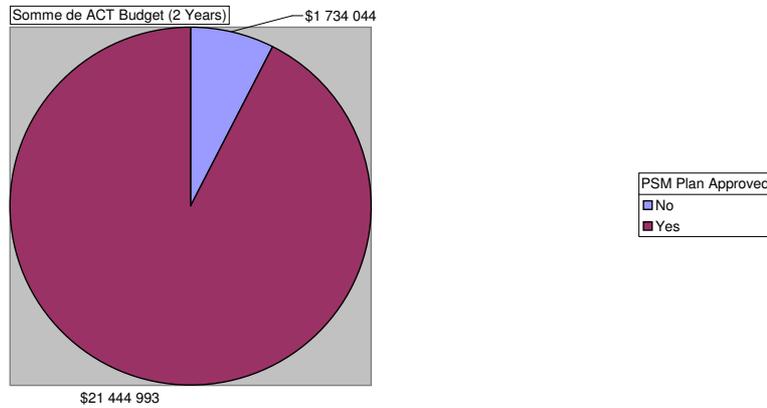
Type of ACT

7.1.2 Artesunate/amodiaquine

The diagram below shows that for ART+AQ, USD 21 million is available now (i.e. PSM approved) for placing orders compared with USD 1.7 million budgeted for ART+AQ where the PSM plan is not yet approved.

Round(Tous)

ART + AQ

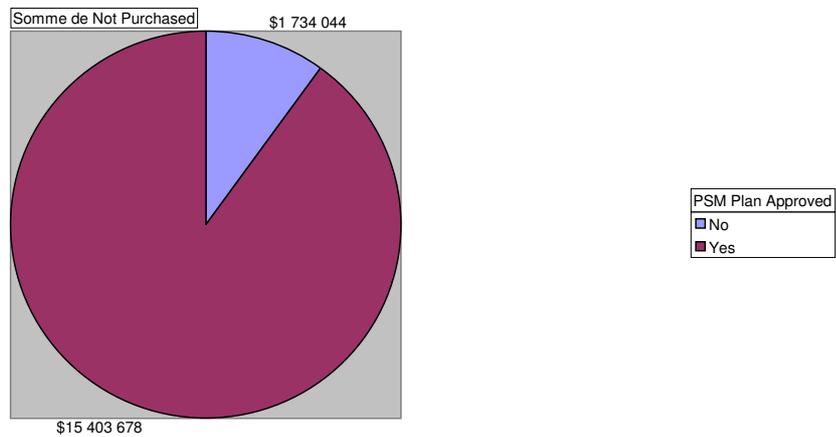


Type of ACT

Of the fully approved 21 million, 15 million has already been used towards placing orders, leaving USD 6 million of ART+AQ to be purchased over a period of 2 years (and a further 1.7 million, once the other countries have completed the GFATM PSM plan process).

Round(Tous)

ART + AQ



Type of ACT

7.2 Demand side conclusion

Whilst it may have been true 6 months ago that countries could not order largely because they were caught up in the GFATM processes, the situation has evolved. The majority of countries currently have GFATM finances approved and available for ACT purchase.¹² These developments may have been partly the result of the GFATM's 6-point re-engineering exercise, aimed at speeding the grant approval time and helping countries to make the transition to ACTs, or perhaps a result of 'learning curve' advantages, as GFATM and countries more quickly go through the disbursement process as a result of learning from previous experience.

7.3 Supply side

We have focused on the principal finished product producers in this section, although there are clearly a number of other producers of finished product and of API for a variety of ACTs.

7.3.1 Artemether/lumefantrine

The supply of the artemether/lumefantrine combination is limited to a single source – Novartis' supply of Coartem.

Coartem supply problems revealed themselves in 2004, spurred by a sudden surge in demand (due to increased GFATM funding and not foreseen UNICEF funding) relative to supply (which had been the result of planting decisions taken 18 months prior). Supply problems were compounded by the failure of one of Novartis's major artemisinin suppliers to deliver the required quantities in a timely fashion, and other bottlenecks in the supply chain.

At the same time, the GFATM significantly increased financing available for ACTs and effectively ring-fenced ACT funds within the 'Memo account' described earlier. Novartis has recently responded to the increase in financing by investing to remedy supply chain bottlenecks, by tightening up their contracts with suppliers, and by diversifying their artemisinin supply base.

As evidence of Novartis's position, actions and commitments, Novartis made the following public statements:

1. From Novartis's Annual report p 62, the report states that 'Commitments (Global Fund) to date exceed USD 1 billion over five years to finance malaria control activities in more than 70 countries'.
2. In a 26 April 2005 media release, Novartis communicated 'its 2006 production goal of 120 million treatments to leading representatives of the WHO, the Global Fund for HIV/AIDS, Tuberculosis and Malaria, African health ministries and other key stakeholders in the battle against malaria at its annual Coartem Advisory Board meeting held last month in Dakar, Senegal.'
3. In a 6 June 2005 media release, Novartis communicated that:
 - a. Novartis partners with East African Botanicals to expand cultivation and extraction of natural ingredient used in anti-malarial Coartem®
 - b. Contracts to purchase extracted artemisinin stimulate cultivation of more than 1,000 hectares of *Artemisia annua* in Kenya, Tanzania and Uganda
 - c. East African Botanicals scale-up efforts boosted by financial and technical support from Novartis

¹² In previous versions of this report, DRC's PSM plan had not been approved, however, as of the end of June, we are told that the DRC's PSM Plan was partially approved for the purchase of drugs and they are tendering.

- d. Local economies benefit from job creation in agricultural and manufacturing sectors

During the June 2nd T/C, the working group compared the financed demand with Novartis's estimated Coartem production until June 2007 (which is the time by which all countries should have exhausted the \$235 million available for the first two years of their GFATM financing).

- 1) The financed demand: Dividing \$235 million by \$1.5 per treatment (an average price taking into account the differential between adult and paediatric prices and average volumes sold) translates to 156 million treatments. This is the financed demand to which we would hope Novartis would produce.
- 2) Novartis's production: However, Novartis has announced that it will be producing 210 million¹³ treatments over this time period. At average prices of \$1.5 per treatment, this equates to \$315 million of needed budget to buy Novartis entire production over the two-year period. This means that Novartis will be producing in excess of the GFATM financed demand, and there will be a shortfall of \$80 million to buy the entire production of Novartis over the two-year period. However, this shortfall may be met by i) Novartis sales to the private sector, ii) the ACT portion (not yet decided) of the \$500 million from the World Bank (Booster program) devoted to Africa to fight Malaria over the next 5 years, iii) by new countries winning GFATM grants for ACT procurement in GFATM Round 5, or iv) other donor, (e.g. EC, Bush initiative July 1st 2005 declaration) and v) Phase II of grants currently in operation. It should also be noted that the shelf-life of the artemisinin is approximately 5 years¹⁴, and time to bring artemisinin to finished product only several months, thereby allowing some flexibility to hold stock for subsequent years if a firm over-contracts for supply.

7.3.2 Generic artemether/lumefantrine

Cipla expects to be making generic Coartem (unspecified quantities) by the end of 2005, and will submit pre-qualification documents to WHO prior to December 2005. The degree to which generic producers will be able to offer substantially reduced prices versus Novartis has been questioned; according to one generic producer, approximately 90% of the cost is in the lumefantrine and artemether API, the price of which is determined by the API suppliers. This leaves the finished product producers with only 10% of the cost with which to try to gain efficiencies, unless generic finished product producers are able to enter into, and manufacture efficiently, the production of lumefantrine or artemether API themselves.

There are several angles from which to consider whether generic Coartem produced in the near-term will be compliant with intellectual property requirements – the patent status of Coartem in the exporting country, the patent status of Coartem in the importing country, and whether Novartis would take action against a company who is believed to be producing generic Coartem outside the bounds of intellectual property requirements. It should be noted that, even if it is legal to produce generic Coartem from the exporting country's perspective, many developing countries have

¹³ 30 million in 2005, 120 million in 2006, and 60 million over the first half of 2007

¹⁴ Industry sources indicate that artemisinin has a longer shelf-life (approximately 5 years) than the derivative form. However, storage may result in a certain degree of degradation, making it necessary to retest and verify the conformity before use, and if necessary retreat by recrystallization.

implemented patent laws prior to the date they are required to do so by TRIPS, and it may therefore not be legal for them to import a generic version of Coartem.

7.3.3 Artesunate/amodiaquine

In 2004, WHO and UNICEF conducted an 'Interim exercise' to select 3 ART+ AQ suppliers, all co-blister drugs, all of whom have GMP approval and none of which have been pre-qualified. The 3 companies who passed this exercise were Sanofi, IPCA, and CIPLA. Prices range was between \$0.45 and \$1.7 per treatment depending on the unit pack size.

For 2005, UNICEF and WHO started conducting a revised 'Interim exercise' and encouraged Chinese and African suppliers to participate in this exercise. The 2005 list should be available by the end of September 2005. Meanwhile, several manufacturers have submitted dossiers for co-blistered artesunate+AQ to the UN prequalification project and several manufacturers are expecting to submit to the dossiers for the fixed-dose combination (FDC) drug by 2006.

Sanofi production in 2006 might reach 15 millions treatments. By the end of 2005, IPCA will be producing 2 million treatments (co-blister) per month (which is a fraction of what they are capable of producing), and has formed a joint venture with Holley Group, assuring their access to artemisinin supply. Cipla and IPCA have stated that they are keen on capturing private sector demand, in addition to public sector business.

7.3.4 Other ACTs

There are other ACT combinations, which combine artemisinin derivatives with mefloquine or Sulfadoxine-pyrimethamine (SP). So far, there was no combination approved for procurement by UNICEF or WHO. The demand for these is rather limited in scale relative to the two ACTs analysed above, nonetheless, several manufacturers are preparing to submit dossiers to the WHO pre-qualification project for these combinations.

7.4 Planting and supply of artemisinin raw material

In our supply side calculations, we have focused on establishing what the expected finished product supply is, since all reports seem to affirm that artemisinin planting is being significantly increased and the finished product suppliers have tightened up their contracts in order to get their requested artemisinin API to meet their finished product projections.¹⁵ For example, both Novartis and IPCA (the two largest producers of ART+LUM and ART+AQ respectively) have backward integrated, in different ways and to varying degrees, into API production, thereby providing more assurance that their requested supply will be provided.

7.5 Supply side conclusion

We should acknowledge that we do not have perfect information on supply side capacity and plans, as we are not sitting within the companies. However, the data we have at this time seems to support the view that there will be sufficient capacity, starting from autumn of 2005, to produce to the current level of financed demand for the ART+LUM and the ART+AQ combinations. We base this view on what we know

¹⁵ Earlier reports done by Steve Jarrett (UNICEF) and Maryse Dugue (MMSS) supported this view, and the June 2005 Arusha meeting unveiled no evidence to the contrary.

about investment decisions taken for 2006 supply, the realisation that it would be undesirable, from an industrial viewpoint, to scale down production significantly after having already made the investments to support scaling-up, and the fact that suppliers have not argued with our view during bilateral and teleconference discussions.

7.6 A full systems perspective to developing the ACT market

We should not just restrict ourselves to talking about how financing and procurement systems need to change in order to better align supply and demand of ACTs. There are other policies that would help support market development as well.

7.6.1 Demand forecasting

Accurate demand forecasting is an essential component to aligning supply and demand. Regardless of which options are chosen for the short and long-term, this area clearly needs strengthening.

7.6.2 Institutional linkages

We would suggest that formal institutional structures and linkages need to be given further thought, since it has become clear during the course of this consultancy that there are still gaps in communication.¹⁶

7.6.3 Market entry barriers

Potential market entry barriers for new ACT suppliers include patent status (may be an issue for Coartem follow-on products), cost of registration in multiple countries, and pre-qualification.

7.6.4 Pre-qualification

The GFATM requires that drugs purchased with GFATM grants must have GMP, however WHO pre-qualification does not become a necessity until at least 2 drugs in the class have been pre-qualified. This applies to 'single and limited source products' to which certain anti-malarials like ACTs belong.

For Coartem follow-on drugs, gaining pre-qualification is relatively easier. This is because Novartis went through the lengthy process of conducting clinical trials to establish safety and efficacy, therefore follow-on products could refer to the originator's clinical trial data to establish safety and efficacy, and simply have to prove level two (or in-vivo) bioequivalence, though this process may be difficult for all but the most advanced Indian firms.

¹⁶ We cite two examples:

- 1) The confusion, between MMSS and GFATM, over what has actually been ordered. At the present time, the confusion is ongoing, with MMSS stating that Novartis has received only 5m of orders, whilst according to GFATM 57 m of orders have been placed for Coartem. During one of the teleconferences, everyone witnessed the debate about whether Tanzania had yet placed an order. According to GFATM, they have placed an order for 34m, whilst MMSS does not recognise such an order. Co-ordinating together to agree the definition of 'an order' would be a starting point, as well as the term 'pipeline' used in MMSS's documentation (Appendix F).
- 2) The lack of understanding amongst key stakeholders about the GFATM's 6 point initiatives, exactly what they involve and the value-added of each.

The situation with the ART+AQ suppliers is different, and more challenging, since there is no originator's clinical trial data to refer to in order to establish safety and efficacy data. In theory, safety and efficacy can be established via good clinical trials using the loose combination. The first amodiaquine combination producer to gain the pre-qualification status will either have to conduct clinical trials or may gain pre-qualification status via reliance on existing literature/data plus a good quality bio-equivalence study. For firms who are primarily generic producers, this is outside their normal capabilities and resources. This may be a challenge for other ACT combinations as well. Sanofi is expecting to be the first with a pre-qualified product, anticipating approval of their ART+AQ co-blistered product by July 2005.

The pre-qualification group at WHO faces a current dilemma. Firms are asking for technical assistance in compiling their dossiers, and the pre-qualification programme has neither the resources nor the mandate to respond to these requests, though they would like to. The pre-qualification programme is charged with assessing the dossiers; therefore aiding specific companies to prepare a dossier about a specific product would be a conflict of interest. This said, the pre-qualification project has done and will continue to do training courses for manufacturers explaining openly what is required, where and why the products fail and also how to overcome the problems. But such trainings are 'general' and addressed to all who want to listen. The pre-qualification project is planning to strengthen pre-submission advice (providing resources will be available) in order to facilitate quality submissions. FDA and EMEA also engage in such pre-submissions advice.

MMSS has been providing more tailored assistance to firms in China, India, and Africa, and is now organizing this technical assistance with partners, such as USP and OTECI. According to MMSS, 'It is definitely NOT the role of the prequalification project to support manufacturers, as there would be obvious problems with conflicts of interest.'

8. THE REMAINING PROBLEM AT COUNTRY LEVEL

Regardless of the available finance and supply, the outstanding problem currently is lack of orders. Only a small fraction (about 35%) of the \$235 million GFATM funds approved for ACT purchase has been used to place actual orders¹⁷, and this is using the optimistic GFATM definition of an order, which means that the GFATM staff have been notified by the principal recipient that an order has been placed. MMSS, on the other hand, defines an order as one that has actually been sent to a manufacturer, and this currently stands at only 5 million (versus 57 million by GFATM definition) for Coartem. So it would seem that the GFATM's order definition kicks in at the beginning of the order cycle, or pipeline, whereas the MMSS's order definition captures what is seen at the end of this cycle/pipeline. Regardless of whether one takes the optimistic GFATM definition of order or the MMSS definition, it is true that many countries have not yet used the GFATM funds available to them, in order to place significant orders.¹⁸

A number of factors may be behind this:

- 1) Information about insufficient supplies of artemether-lumefantrine in late 2004 was likely to have had a negative impact on willingness to place orders. Countries may be looking into other options for short-term supply, not realising that their lack of orders now may reduce incentives for manufacturers to invest for the future.
- 2) There may be a lack of willingness or lack of intent to switch to ACTs, due to insecurity about the sustainability of GFATM funds, for instance. Since the annual cost of the switch to ACTs may represent three times the national annual EDL budget, countries may be understandably concerned about who picks up that bill if i) the country is not successfully evaluated after the first two years of the grant and/or ii) if the GFATM itself is not successful in raising projected funding needs.
- 3) There may be administrative or bureaucratic problems at country level, e.g. lack of realisation that the GFATM funds have now been approved and are available for placing orders, or a lengthy process for actually putting together a procurement order.

At the May 26th T/C, the working group agreed to research these hypotheses, since the actual barriers will substantially affect the form of intervention that would be the most useful.

The GFATM subsequently came back with data (as presented above) that largely refuted the hypotheses above. According to GFATM research, the overall picture is looking very promising, with countries either having just ordered or being on the verge of ordering. If accurate, this would negate the need for any short term intervention along the lines of the short term options proposed above, although there may still be a need to look at risk sharing arrangements and supply security longer term. At the most recent T/C on June 2nd, the group decided that it would be appropriate for RBM and MMSS to research the hypothesis as well so as to triangulate responses.

During recent teleconferences with selected country representatives (meetings called for other purposes but where the subject of ACTs arose spontaneously), other views have arisen:

¹⁷ For Coartem, 28% of the total has entered into the order pipeline and for artesunate/amodiaquine, 91%.

¹⁸ Although it must be noted that the situation, at least from the perspective of news received by the GFATM, has been improving tremendously over the past few months.

- 1) The systems costs to introducing a new drugs may not be adequately financed.
- 2) The Finance Ministry may be concerned about the GFATM grant being for only two years. (GAVI is quoted as an example where a country can be left with the immunization bill after Vaccine Fund financing terminated.)
- 3) There may be pressures by locally based manufacturers to source ACTs from local manufacturers, rather than through WHO.
- 4) There may be reluctance to move to ACTs since the cost would be several times the annual EDL budget.
 - 3) 5) On the subject of the GFATM 'Memo account', there may be concerns about autonomy, i.e. a feeling that national procurement and financial administration is sufficiently developed to the degree that international mechanisms are not needed.

9. THE WAY FORWARD

This report was submitted to members of an RBM sub-working group, prior to a June 16th T/C, with the intention that the group would discuss members' findings from discussions held at country level over the previous two weeks. At that stage, it was hoped that the group could either determine whether additional information would be needed or whether a decision could be made about the short-term options. (It was envisioned that a follow-up meeting would be scheduled to discuss the longer-term options.)

9.1 June 16th T/C

The meeting notes from the T/C on June 16th are as follows:

1. Country situation. MMSS (Maryse Dugue) explained their findings of the actual situation in countries; these findings broadly chimed with the hypotheses in Section 8 of this report. Some countries (e.g. Uganda) look like they may be ordering less than originally forecast under GFATM proposals. We did not however have time to go into each country in detail. Maryse said there might be a need for TA and for policy support. MMSS is currently constrained in terms of its funding to provide policy/technical support. Maryse planned to submit more country information in the coming week. (See Appendix F for what was submitted the subsequent week.)

2. We discussed the process for longer-term discussions. Awa Collseck pointed out that the ACT sub-committee needs to report back to the main coordinating board and a time has been fixed for 29th June. Billy Stewart raised the question of whether we wanted a face-to-face meeting but Awa felt that questions were better to put to the CB.

3. Comments were invited on this report, which not everyone had had a chance to read - comments should have been submitted by Wednesday June 22, so that revisions could be made in time for the bigger CB teleconference on June 29th. We'll make a decision following that on the next time for the ACT group to talk.

9.2 Deciding on the Options

As for the short term 'guarantee' or 'drug revolving fund' options, this report describes the different options, and offers a structured way of thinking about them relative to the demand and supply situation. We have presented some new data on the supply and demand situation, but we have also acknowledged what we do not know. We do not have the time allocation to go into detail at the country level and determine when exactly the orders are expected to come through and what exactly is holding up some countries – we have to rely on the data provided by GFATM, MMSS and other members of the working group for that. The appropriate choice of short-term option depends crucially on this contextual detail at country level, and the consultants have not had access to this level of contextual detail. Those who do have access to this contextual detail now have this report, however, and can map out what they know about the context against the options and the justification for choosing each one. The fact that there is sufficient supply relative to financed demand would, however, make a case that a short term intervention, along the lines of a drug revolving fund, is not needed.

The consultants would suggest that, regardless of decisions taken about the short term, longer term pooled and advance procurement arrangements should be sought. Also, regardless of whether a short-term option to finance purchase guarantees is

chosen, there seems to be enough evidence (albeit in the form of triangulated viewpoints) that enhanced technical/policy support is needed at the country level at this time to help make the ACT transition.

Once decisions are taken about which options best meet the needs of the situation, the appropriate actions and roles (related to the option chosen) can be mapped out.

9.3 Recommended Actions

We would recommend the following short-term actions:

1) Investigate the detail of the large potential ACT-consuming countries who have GFATM money, but who do not appear to be planning to order significant quantities anytime soon. The most recent figures (Appendix E) show that this would be Kenya, Uganda, and Nigeria.

- Do they need technical assistance?
- Do they need assurance that funds will be there to support them after Phase I GFATM grant period ends?
- Do countries understand the link between the signals sent by orders placed now and supply security 18 months from now?

2) Revisit the malaria financing, procurement and information pooling architecture, from an institutional standpoint, to remedy communication problems & potential mission drift. Such a review would need high-level support.

- Which functions need to be performed?
- Where do those functions most logically sit?
- What resources are needed to perform those functions?

If political support cannot be harnessed to look at 3 above, then at the very least, more thought needs to be given to:

- What are the **formal** channels and processes for linking/communicating between groups carrying out different and often overlapping functions?

The recently announced Bush funding for malaria increases the importance of implementing this actionable, since it expands (and complicates) the malaria financing architecture.

3) Number 2 above would help further progress on consolidating and communicating information on the following:

- Consolidated data on ACT funding by all donors for each country
- Consolidated real time data on order status (i.e. at what stage in the order 'pipeline')
- Data on industry production/supply

4) Explore pooled procurement

- The benefit and disadvantages from a country perspective
- Will enough countries be willing to participate?
- How can it be practically accomplished, give the way GFATM financing works? (Could GFATM grants for commodities – ACTs – become grants in kind, as with TB drugs and GDF?)

It is suggested that MMSS, GFATM, WHO and others need to find a forum to discuss these issues in conjunction with endemic countries.

5) It may also be necessary to organise annual regional meetings (Africa, Asia and LA) with Directors of local 'national malaria programme', country procurement director and international players to:

- Communicate the ACT situation in terms of production, procurement, and financing
- Reassure countries on long-term commitment (at least 5 years) from donors (through GFATM, or directly from DFID, USAID)
- Convey a clear message on the benefits of co-ordinated and predictable mechanisms for procurement and financing

Finally, while this report focuses on the situation at a specific point in time with regard to aligning ACT supply and demand, it must be recognised first of all that the situation is continually evolving and secondly, that there are clearly other important issues to resolve if broad access to ACTs is the overarching goal.

APPENDIX A: RELEVANT LESSONS FROM PAHO AND GDF

Rationale for the development of PAHO

- 1) Prior to PAHO, countries placed urgent orders w/o regard to price
- 2) Manufacturers found it difficult to plan production in advance, resulting in frequent stock outs, b/c demand>supply
- 3) In some cases, public confidence in immunization programmes was undermined
- 4) Vaccine investment is large and required far in advance of product availability
- 5) Government is main purchaser (no private outlet for excess supply, should manufacturers over-invest and over-produce); need pooling and assurance for security of supply.
- 6) Disaggregated orders vying for oligopolistic supply; need pooling and co-ordination for price reduction potential and more secure/consistent supply
- 7) DRF gave PAHO leverage to drive better programming, e.g. installing a vaccine budget line in national budgets
- 8) It allowed relationships to be developed with manufacturers that would allow urgent orders to be placed and delivered at short notice
- 9) PAHO appealed to countries b/c it provided a ready & continuous source of funds, which once committed for purchase, become available for commitment again as soon as they're repaid
- 10) Overall, PAHO ensures a good quality vaccine, good prices, technical co-operation for programming and for the cold chain

Model features

- 1) Country payment (DRF replenishment) required within 60 days upon receipt of PAHO's invoice (in practice, this means that countries have 3 to 4 months to pay after receipt of goods)
- 2) Manufacturers are not allowed to sell to PAHO countries for less than the PAHO price
- 3) If a country neglects to pay, they are ousted from PAHO
- 4) The bid/tender is sent out 1 year in advance. Manufacturers know 6 months in advance what they need to produce.
- 5) Allows purchase of vaccines in local currencies (avoid delays and loss from currency exchanges)
- 6) PAHO buys on behalf of member countries
- 7) Charges 3% of cost
- 8) 1 million USD DRF has become 23 million USD
- 9) 19 countries in 1977 grew to 35 by 2002
- 10) actual expenditures grew to 120 million
- 11) 1.4 million in working capital
- 12) PAHO charges countries an average price to maintain equity

GDF

Rationale for GDF

- 1) There was lack of consistent supply of TB meds, with many suppliers exiting the market
- 2) Disaggregated orders vying for oligopolistic supply; need pooling and co-ordination for price reduction potential
- 3) Grants and better pricing gave GDF leverage to drive better programming, e.g. DOTS compliance

Model features

- 4) IAPSO is the GDF procurement agent, chosen by competitive tender. GDF followed a 4 phased process
 - Write and issue an EOI, send to known interested companies and advertise internationally if you wish. (The delay for the EOI expression of interests could be set at one month.
 - Then you will have to develop the text of the tender letter, the criteria for adjudication, and a draft contract.
 - Thereafter you issue a RFP request for proposals. The delay until the closure date is usually 40 days (in EU that is).
 - Then you award the tender, and have the contract signed. Legal council should be involved from the beginning. Depending on 'legal' the whole process will take you at least 3 to 4 months.
- 5) IAPSO issues tenders, normally for 1 year of supply, several months in advance of when product will be required. GDF commits to purchasing 100% of the amount tendered. GDF has never had a situation where they committed to purchasing more drugs than they could use in that year. This is because the programme is growing and expanding. Typically, GDF will purchase 120% of guaranteed quantities in any given year.
- 6) IAPSO typically awards to multiple suppliers for a fixed percentage of the total demand estimation for that year, and in accordance with the bids received. e.g. if there is a large price differential between supplier 1 and supplier 2, then they might award 75% of the total to supplier 1 and 25% to supplier 2; whereas if the price differential is smaller they might award 60% to supplier 1 and 40% to supplier 2.
- 7) The production lead time for TB drugs is approx. 110 days
- 8) Although the tenders are won on an estimated amount, payments are only made to suppliers as and when orders are placed throughout the year
- 9) If countries are using their own money, they may either procure TB drugs via IAPSO or via other mechanisms
- 10) If countries are using GDF grants, it is mandatory to go through IAPSO since the GDF grants are 'grants-in-kind' and arrive in the form of drugs
- 11) If the financing comes from GFATM, GFATM recommends that countries buy through GDF/IAPSO, but they do not require it.

GAVI

- As opposed to GDF guaranteeing purchase of 100% of TB drugs for one year, GAVI commits to buying 40% over 3 years (3-year tenders, e.g. 2004-2006).
- More precisely, UNICEF is the buyer of all vaccines on behalf of the countries that receive grants from GAVI (of which the Vaccine Fund is one of several sources of funding). UNICEF issues firm contracts for both GAVI-supported grants and for UNICEF-funded purchases. UNICEF makes the judgement as to which vaccines and which companies should be subject to firm contracts. The figure of 40% is the percentage of vaccines (by value) UNICEF buys under firm contract (3 years) - this excludes polio vaccine.

APPENDIX B: CALCULATING THE SIZE OF A DRUG REVOLVING FUND

Size of the fund

If the fund handles n purchases per month, the average size of each purchase = S ,
the number of months to repayment = m , and the size of drug revolving fund = X ,
Then $X = Smn$

Assuming¹⁹: $n = 1$, $S = \$5$ million²⁰ and $m = 6$

$X = \$30$ million

The following illustration proves that the formula is true:

	EXAMPLE: $m = 6; n = 1; S = \$5m$			$X = S * m * n = \$30m$			
Amounts in \$ '000	Start	M1	M2	M3	M4	M5	M6
Funds at period start:	30,000	25,000	20,000	15,000	10,000	5,000	-
Movement of funds:							
Start	(5,000)						5,000
M1		(5,000)					
M2			(5,000)				
M3				(5,000)			
M4					(5,000)		
M5						(5,000)	
M6							(5,000)
Funds at period end:	25,000	20,000	15,000	10,000	5,000	-	-
Number of transactions:	1	1	1	1	1	1	1
Transaction size:	5,000	5,000	5,000	5,000	5,000	5,000	5,000
Volume:	5,000	5,000	5,000	5,000	5,000	5,000	5,000

By month 6, the fund would have zero funds at the start of the month, but would start to receive repayment from the country that had relied on the revolving fund in the first month, and so on in Month 7, for the country that had relied on the revolving fund in the second month.

Note that this example is just to illustrate approximate amounts. A more detailed model would need to include financing costs, the revolving fund's operating costs and revenues from commission charged. .

Covering the fund's overheads

The commission charged should cover the overheads, at a minimum. If you want to increase 'n', 'm' or 'S', then you either need a larger initial seed capital or you can grow your working capital by charging a higher commission rate.

¹⁹ Note that there is no particular rationale for the choice of numbers in the assumptions. WHO procurement and MMSS should be able to work together to fill in the most reasonable numbers for the assumptions according to what has been the order history and what is the most likely scenario for future order magnitudes and intervals.

²⁰ This model assumes that manufacturers would need to be paid 100% up-front, when in fact, it may be acceptable to offer a percentage of the total as down-payment or even to pay after receipt of goods.

APPENDIX C: TERMS OF REFERENCE

Terms of Reference for Consultancy Support – Guaranteeing Supply of Effective Anti-Malarial Drugs

BACKGROUND

The widespread resistance of *Plasmodium Falciparum* to conventional therapies has resulted in increased malaria mortality in the past decade. This has led WHO to recommend that countries change their drug policy to artemisinin-based Combination Therapies (ACTs), the only available drug regimens that are fully effective against all strains of multi-drug resistant falciparum malaria. Forty-nine countries have now adopted ACTs in their policy, and 24 are currently implementing it.

The rapid increase in forecast demand for ACTs, and the need to match this with increased supplies have led to a number of problems – meaning that few countries have fully implemented a shift to use of ACTs. A vicious circle has developed including both demand side issues (slow passing of orders for drugs) and supply side ones (lack of investment in increasing production capacity, insufficient cultivation of the raw material from which artemisinin is derived).

While a number of countries have expressed their intention to order ACTs, few firm orders have been passed as of end March 2005. Information about insufficient supplies of artemether-lumefantrine in late 2004 has had a negative impact on procurement. The consequence of this lack of orders is that manufacturers have no incentive to increase production. Any major increase in production has to be planned at least one year in advance and at a fixed period of the year (ideally in September for cultivation of *Artemisia Annuum* in the northern hemisphere), to coincide with the production cycle of artemisinin. Any surge of orders coming late in the year results in potential shortage for the next 12 to 18 months. WHO and UNICEF have made efforts to communicate forecast of demand to manufacturers, but this has little impact if this potential demand is not translated rapidly in orders.

On 20 December 2004, a meeting of RBM Partnership Board members held in Geneva decided to accelerate the finding of a viable solution, and requested the RBM Partnership Secretariat and the GFATM to propose a suitable mechanism. This fed into two presentations made by RBM and by GFATM at the 7th RBM Board Meeting in Geneva on 1 April. Following these presentations the RBM board agreed to develop specific and worked up proposals which would allow donors to allocate funding to a revolving mechanism which would serve to pre-purchase supplies of certain ACTs in 2005 and would develop into a purchase guarantee mechanism for 2006 – thereby sending more robust signals to suppliers of the market, and maximising incentives to expand production.

To develop these proposals consultancy support has been requested. These terms of reference are for that support.

SCOPE

The consultancy has two principle objectives:

1. Finalize, in collaboration with MMSS, the proposal on mechanisms to improve financing and procurement of ACTs to ensure short and long-term sufficient availability of quality products to satisfy the demand.

2. Prepare, in collaboration with WHO's RBM Department (Strategy and Policy Team) a meeting on Production of artemisinin and ACTs (Arusha, early June).

SPECIFIC TASKS

Under objective 1 (mechanisms for financing and procurement), the consultant should complete the following tasks:

- a. The revision of existing drafts on the subject
- b. Studying existing pooled procurement mechanisms such as the GDF and GAVI, to identify relevant and transferable mechanisms
- c. Organization of teleconferences with UNICEF, WHO, MMSS, GFATM, USAID, DFID, WB, MSF and in some cases, industry
- d. Development of a final document (see outputs)

Under objective 2 (meeting on production of artemisinin) the following specific tasks are required:

- a. Finalize agenda in contact with WHO (and UNICEF)
- b. Draft invitations, finalize list of invitees
- c. Contact with invitees
- d. Follow-up for preparation of working-papers
- e. Contact with local organizers
- f. Prepare report on the meeting.

OUTPUTS

Under objective 1, the consultation should work with others to ensure the deliver of a 10-page document, which includes:

- Background
- Description of the various options for an advanced purchase/procurement mechanism for ACTs and (possibly reverting to) a guarantee fund, its links with the GFATM, the size of the proposed fund, the phasing out of the fund (timeline and modalities)
- Mechanism of coverage of the guarantee fund
- Governance, management structure, coordination with procurement agencies
- Staffing
- Budget.

Under objective two the outputs will include a successful meeting and a meeting report of around 10 pages (actual length to be determined at a later stage), including sections as decided at the meeting.

REPORTING

On contractual matters the consultant will report to the Global Health Partnerships team at DFID. The project officer responsible will be Dilip Shah.

For technical matters, to clarify any issues outstanding in these ToRs, and to agree finished outputs the consultant will report to a steering group composed of the DFID GHP team, the Roll Back Malaria Partnership Secretariat and the World Health Organisation.

TIMING

The total contract will be for a period of 29 days, broken down as follows:

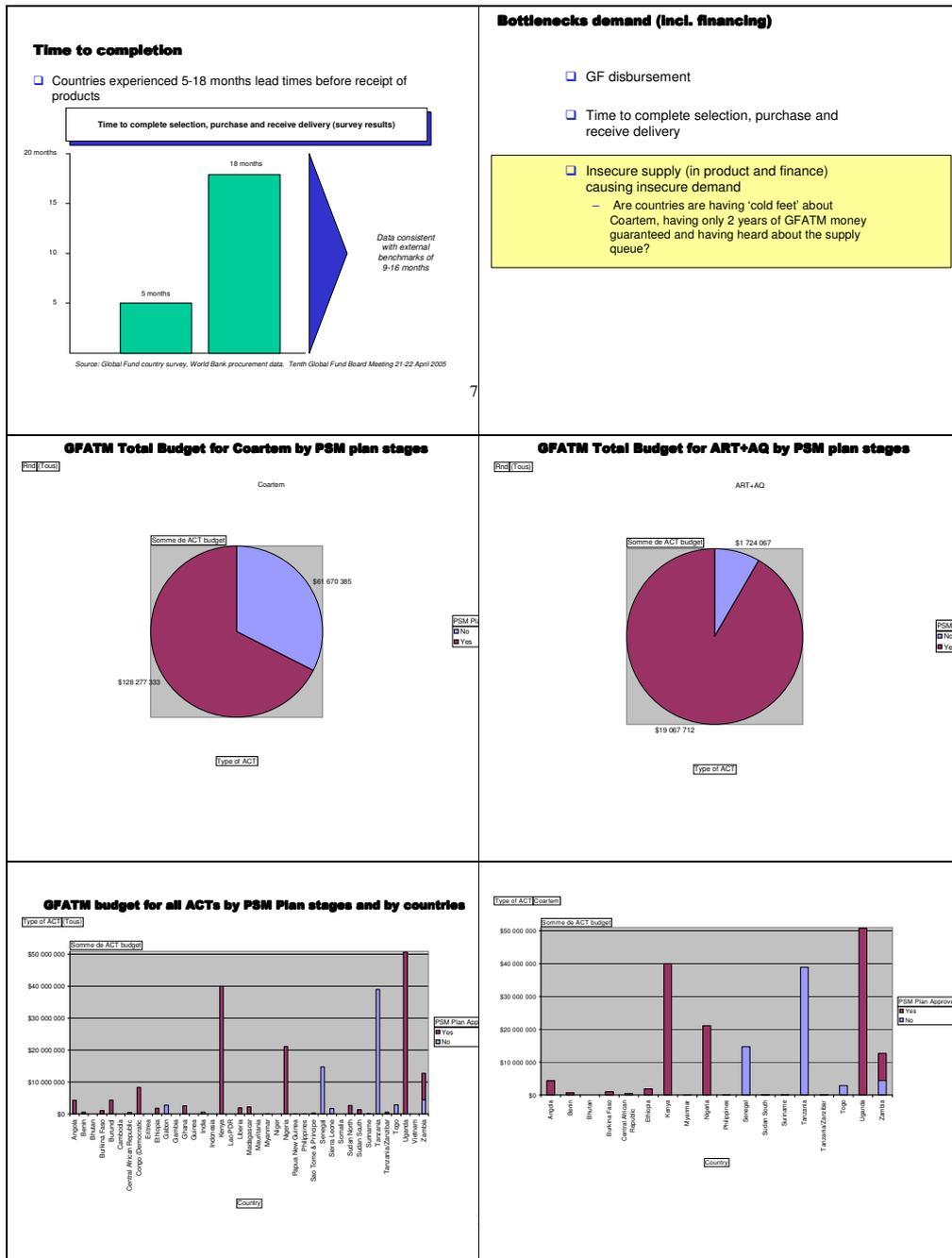
- Objective 1: 14 days of work, partly in Geneva (minimum 5 days)
- Objective 2: 15 days of work, thereof 2 in Geneva, telecommunication for organisation of the meeting.

Billy Stewart
Global Health Partnerships Team
DFID

6 April 2005

APPENDIX D: TELECONFERENCE SLIDE PRESENTATION MAY 13TH

<p>DFID HEALTH SYSTEMS RESOURCE CENTRE</p> <p>ACT Procurement and Finance Options</p> <p>Cheri Grace Michel Grupper May 13, 2005</p>	<p>Presentation Structure</p> <ul style="list-style-type: none"> <input type="checkbox"/> Bottlenecks supply <input type="checkbox"/> Bottlenecks demand <ul style="list-style-type: none"> - Order pipeline <input type="checkbox"/> Financing Options <input type="checkbox"/> Procurement Options <p style="text-align: right;">2</p>
<p>Supply side situation</p> <ul style="list-style-type: none"> <input type="checkbox"/> New entry likely over coming year <input type="checkbox"/> API risk: incomplete contracting environment resulting in backward integration <input type="checkbox"/> Potential entry barriers: Pre-qualification, patent status, registration status, API sourcing and technology of extraction with greatest yields <input type="checkbox"/> Poor forecasting – no consensus <ul style="list-style-type: none"> - (Industry will produce somewhere between the level of actual orders and finance available) <input type="checkbox"/> Where are the orders? 	<p>ACT Options</p>
<p>Bottlenecks demand (incl. financing)</p> <ul style="list-style-type: none"> <input type="checkbox"/> GFATM fund disbursement <input type="checkbox"/> Time to complete selection, purchase and receive delivery <input type="checkbox"/> Insecure supply (in product and finance) causing insecure demand 	<p>Timeline for procurement initiatives</p> <p><small>Source: Tenth Global Fund Board Meeting 21-22 April 2005</small></p>



	<p style="text-align: center;">Finance Options</p> <hr/> <p style="text-align: right;">14</p>
<p style="text-align: center;">'Guarantee' or 'Revolving' Fund</p> <hr/> <ul style="list-style-type: none"> <input type="checkbox"/> Who would fund it? How long would it exist? How would it be dissolved? <input type="checkbox"/> What should be the fund size? <input type="checkbox"/> Where would it sit? (within GFATM/ a procurement agent/ the WB?) <input type="checkbox"/> At what stage would it be used? <ul style="list-style-type: none"> - Earlier = stronger industry incentive effects, but risk of non-payment and stock wastage - Later = Less fund risk, but less incentive effect as well (may not be much different than strong communication of pipeline and robust forecasting process) <hr/> <p style="text-align: right;">15</p>	<p style="text-align: center;">The 'In-between' options</p> <hr/> <ul style="list-style-type: none"> <input type="checkbox"/> Who takes the risk? <ul style="list-style-type: none"> - Country - Principal recipient (retroactive financing) - Procurement agent (as with LLIN) - Donors (eg Letter of guarantee to procurement agent) - Global Fund - World Bank <input type="checkbox"/> How much risk is taken <ul style="list-style-type: none"> - How much time between paying out and getting finance (linked to the stage at which the mechanism kicks in) - What percentage is paid to manufacturer? <input type="checkbox"/> Whether country participation in revised financing or procurement schemes is mandatory (how?), incentivised (how?) or free-for-all? <hr/> <p style="text-align: right;">16</p>
<p style="text-align: center;">Procurement Options</p> <hr/> <hr/> <p style="text-align: right;">17</p>	<p style="text-align: center;">Pooled procurement?</p> <hr/> <hr/> <p style="text-align: right;">18</p>
<p style="text-align: center;">Other procurement questions</p> <hr/> <ul style="list-style-type: none"> <input type="checkbox"/> How 'tight' or binding should the contract be? (influenced by degree to which information exists to write appropriate contracts) <ul style="list-style-type: none"> - LOA & non-binding 'promise to purchase' with credible demand projections & demand building (ADPs) - Pre-set percentages (GDF) but ? quantity commitment, - Minimum quantity commitment (GAVI/UNICEF) (+ pre-set percentages) - Revenue agreements, binding on both price and quantity <input type="checkbox"/> Timing of the tender? 1 year in advance (GDF) or for near term supply. (Further ahead = stronger incentives but less information) <input type="checkbox"/> Duration of the contract? (Longer = more purchase leverage in short term but important to structure in way that induces competitive entry) <input type="checkbox"/> Payment terms? % down, timing of payment <input type="checkbox"/> What range of conditions covered in contract? (delivery, price, quality, packaging) <hr/> <p style="text-align: right;">19</p>	<p style="text-align: center;">Full systems perspective on building a market</p> <hr/> <ul style="list-style-type: none"> <input type="checkbox"/> Pre-qualification <input type="checkbox"/> Transparency about patent status <input type="checkbox"/> Registration <input type="checkbox"/> Building demand and addressing concerns at country level <hr/> <p style="text-align: right;">20</p>

Which mechanism to adopt?

Financial
options

- Risk taken by others**
- Do you believe that industry needs additional incentives?**
 - Is there sufficient production capacity?
 - Are current finance risk sharing arrangements appropriate? How tight should procurement contracts be?
- To what degree and in what timeframe will the '6 initiatives' will be sufficient?**
 - Will GFATM successfully manage the re-engineering?
 - Within what time frame will they be successful?
 - Will countries opt-in?
- Which options will be seen as credible to industry?**
 - The more binding the commitment, the less likely that sponsors will range on ex post (but balance with need to induce new suppliers to enter)
- What is the political acceptability of the options?**
- What options exist within the current architecture?**
- How will various options impact on roles (eg MMS)?**

Risk taken
by industry

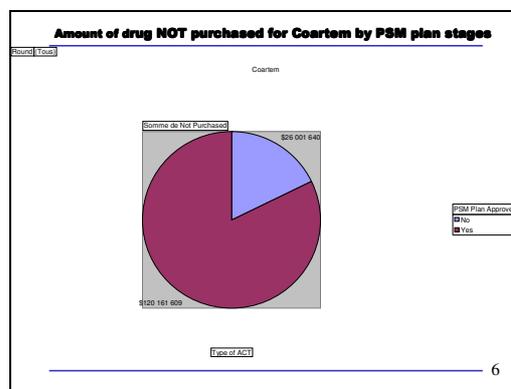
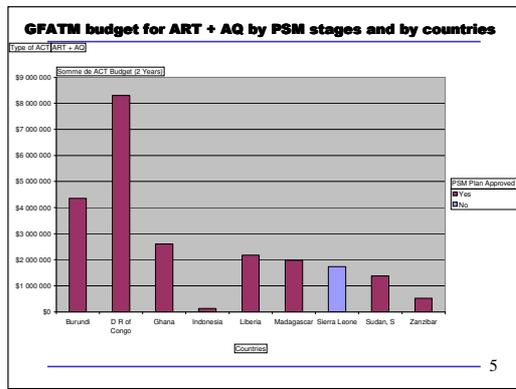
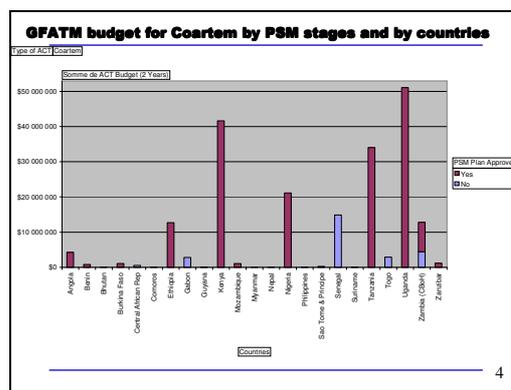
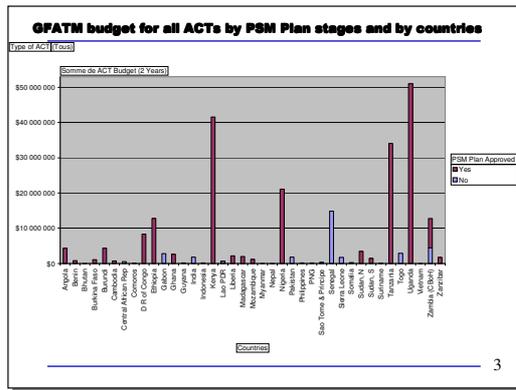
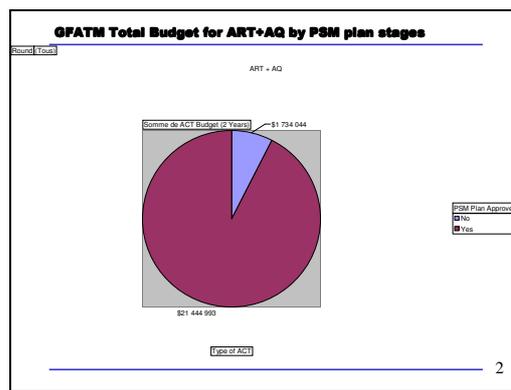
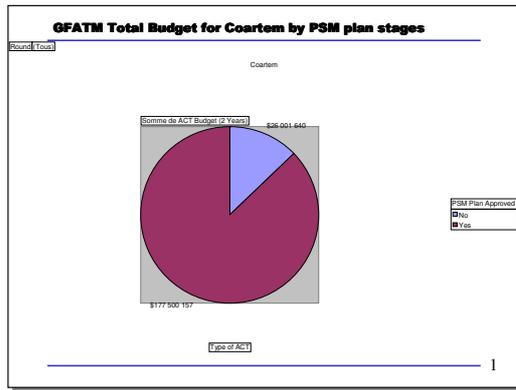
Loose' commitment procurement

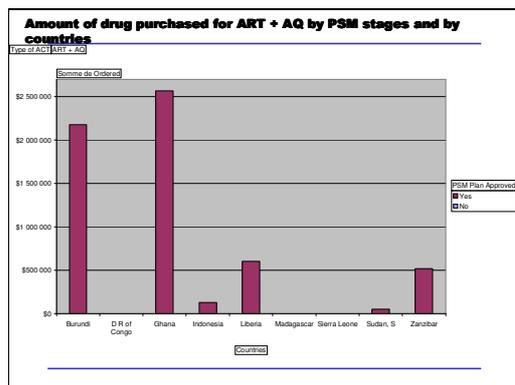
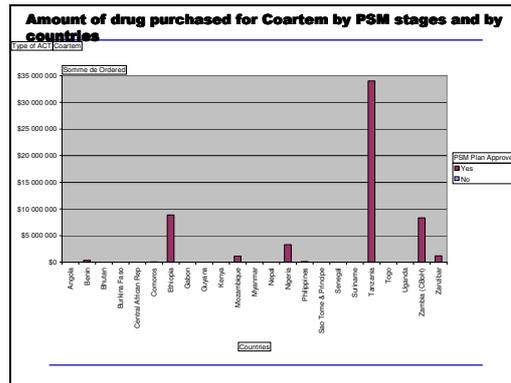
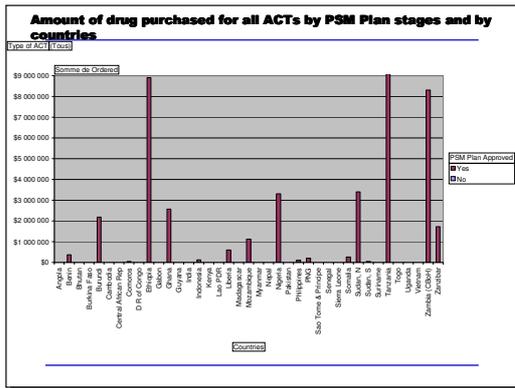
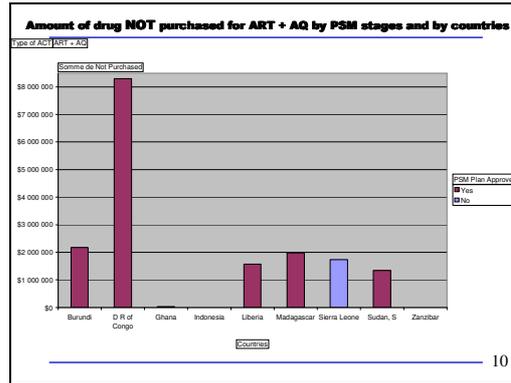
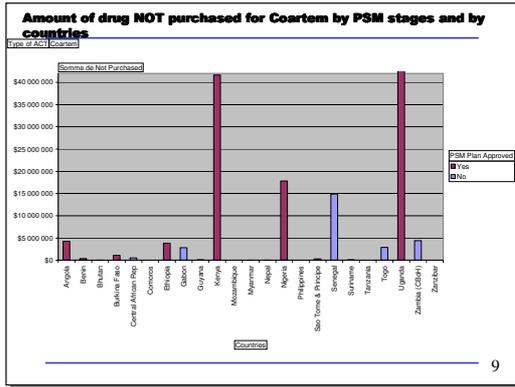
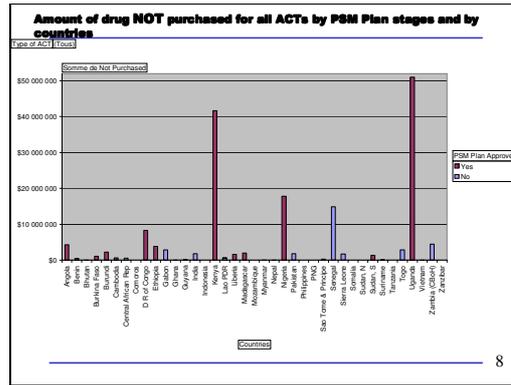
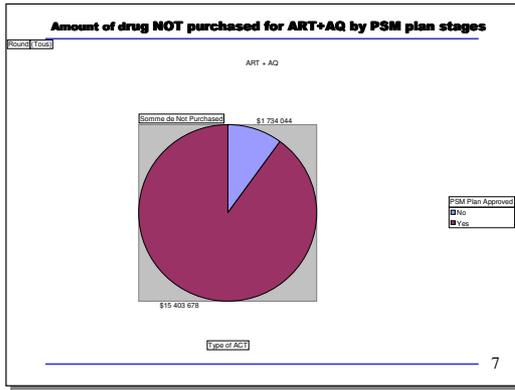
Procurement options

"Tight" or binding procurement

21

APPENDIX E: PSM AND ORDER STATUS ACCORDING TO GFATM DATA AS OF END OF JUNE 2005





APPENDIX F: MMSS COMMUNICATION OF ORDER STATUS, DATED JUNE 27TH

Country	Drug	Qty (million Tt)	procurement ongoing
Angola	Art/L	\$4.3 Mo	submission being prepared, approx. 1.4 Mo treatments, for a 2-years ACTs budget of \$4.3 million
Benin	Art/L		procurement ongoing
Burkina	Art/L	\$1.08	just changed policy, art/L 1st line. Discussions to buy 1st the 2nd line, which is art + AQ. PSM plan validated.
Burundi	Art + AQ	1.6	Has procured already
Cameroon	Art + AQ		No ACT under GFATM
Chad	Art + AQ		no GFATM malaria
Comoros	Art/L	\$42,000	partial delivery already
DRC	art + AQ	6 in 05, 15 in 06	tendering
Ethiopia	Art/L	Budg. 12.7Mo 2 years	procuring (8.9\$Mo) and implementing
Gabon	Art + AQ		no progress, PSM plan still under review
Gambia	Coartem		Will take 12 months to get ready. No second line treatment
Ghana	Art + AQ		Already procured. In the process of having art +AQ in OTC
Guinea			no ACT in the GFATM grant, therefore reprogramming is ongoing
Kenya	Art/L	Budg.\$40Mo, 2 years	slow proc prcs, still no dec whether to merge orders Rd2 and Rd 4. 11 million treatments order expected (pipeline)
Liberia	Art+AQ		already procured partly
Mali	Art + AQ		With their own money. No GFATM for ACTs
Niger	Art/L		no GFATM for ACTs
Nigeria	Art/L	Budg.\$16Mo 2 years	2.5 Mo treatments already ordered
RCA	AQ + SP		Art + AQ is 2nd line, GF not signed
Rwanda	Art/L		small submission received (\$34,000), approved by the TAG
Senegal	Art+AQ	Budg.\$14.8Mo 2 years	GF Rd 4 signed in June. PSM plan prepared with MMSS assistance
Somalia	Art/L ?		SP+?? Ordered. \$260,750
Sudan N	Art + SP	Budg.\$3.9 Mo 2 years	procuring
Sudan S	art + AQ	Budg.\$1.39 Mo	\$50,000 Coartem in the pipeline
Tanzania	Art/L	Budg.\$13MoY1 25MoY2	small order only (\$110,000), submission form received, waiting for fund ransfer
Togo	Art/L	Budg.2.9 Mo 2years	PSM plan not approved
Uganda	Art/L	Budg.\$51 Mo, 2 years	still issues with procurement procedures. Order expected= 17 million treatments for one year
Zambia	Art/L	Rd4 \$ 4.44Mo	waiting for Rd 4 grant to be signed, difficulty with quantification and drug management. Receiving MMSS support.
Zanzibar	artesunate		Art/L is 2nd line

APPENDIX G: PEOPLE CONSULTED

Awa Coll-Seck, Executive Secretary, RBM Partnership Secretariat
Allan Schapira, RBM Department, WHO
Andrea Bosman, RBM Department, WHO
Francoise Mas, Procurement Services, WHO
Kamini Nirmala Mendis, RBM Department, WHO
Maryse Dugué, Malaria Medicines and Supply Service, RBM Partnership Secretariat
Remy Prohom, Malaria Medicines and Supply Service, RBM Partnership Secretariat
Luca Li Bassi, GFATM
Carl Manlan, GFATM
Aika-Ruwa Temu, GFATM
Paul Lalvani, GFATM
Brad Herbert, GFATM
Robert Matiru, GDF
Daniel Kress, Bill and Melinda Gates Foundation
Dennis Carroll, USAID
Billy Stewart, DFID
Hugo Vrakking, GDF
Peter Carrasco, WHO vaccines (former PAHO)
John Fitzimmons. PAHO - WHO/AMRO
Lembit Rago, WHO Pre-qualification
Steve Jarrett, UNICEF
Thuy Huong Ha, UNICEF
Philippe Baetz, Sanofi,
Rene Cazetien, Sanofi
Hans Rietveld, Novartis
Michael Rombach, Novartis
Pradeep Kumar Nambiar, IPCA
Yusuf Hamied, CIPLA
Jean Marie Kindermans, MSF

Jacques Pilloy, OTECI
Members of the RBM Board during two teleconferences in June and July 2005
Various participants who attended the June 2005 Arusha meeting