MMV Access Symposium

Expanding Reach of ACTs in the private Sector: Dialogue with Countries

Accra, Ghana, 1-2 June 2008

Summary Report

The third MMV Symposium 'Expanding Reach of ACTs in the Private Sector: Dialogue with Countries,' was held in Accra, Ghana, on Monday, 2 June 2008. It followed the MMV Stakeholders Meeting and was inaugurated at an opening dinner on the evening of 1 June, with a keynote speech by Dora Akunyili, Director General of the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC). She spoke on 'Challenges to access to ACTs in Africa: A personal view'.

The symposium was ably chaired by Dr Alex Dodoo, President, Pharmaceutical Society of Ghana, and Catherine Hodgkin of KIT, Netherlands. It was attended by a large group of Ghanaian pharmacists, scientists, physicians and regulators as well as representatives of 11 African countries. Representatives of donor organizations, pharmaceutical companies, civil society organizations, fellow product development partnerships, national malaria control programmes, national drug regulators and the WHO participated.

The symposium focused on what needed to happen to ensure roll-out of ACTs. It addressed the issue of affordability and other interventions required to ensure access to ACTs surpasses the 3% of those currently treated.

Symposium Synopsis

Keynote speech: ***Challenges to access to ACTs in Africa: A personal view***	**Dora Akunyili** Director General, NAFDAC, Nigeria Download presentation (*will be available shortly*)

Purpose of the symposium:

- To share an overview of the status of access to antimalarials in Africa
- To share latest thinking on how to expand the reach of ACTs to the poor through the private sector

Introduction to MMV Access Symposium ***Welcome***	**Chris Hentschel** President CEO
Introduction by Co-Chairs	**Catherine Hodgkin** Co-chair **Alex Dodoo** Co-chair

Chris Hentschel, MMV President and CEO, opened the meeting with a special welcome to ADAC members, particularly Awa Marie Coll-Seck who is coordinating so many issues in malaria.

Co-chairs welcomed participants and noted that 11 African countries were represented at the symposium (Burkina Faso, Cote d'Ivoire, Ghana, Kenya, Malawi, Mozambique, Nigeria, Senegal, Tanzania, Zambia, Zimbabwe)

Session 1: Are ACTs reaching people in Africa today?

An Overview – the State of ACT Access	**Jackson Sillah** WHO/IST *West Africa* Download presentation

What has been the impact of policy change to ACTs? What volumes of ACTs have been supplied? Who are they reaching? What are the challenges?

Different phases of adoption and roll-out were presented: policy change, adoption, partial roll-out, national roll-out and roll-out at community level. Countries are at different phases although almost all have now completed policy change and adoption. Problem now is that levels of roll-out nationally are still very low, only 3% on average of children treated are being treated with ACT.

Discussion

Q: What does implementation of ACT really mean?
A: Countries are at different stages of implementation (only in the public sector), and some have rolled out ACTs in only a few districts, some via Community health Workers (CHWs) etc.

Panel discussion on national experiences (1) ***2 countries with relatively high ACT access: Senegal and Uganda***	**Moussa Thior** NMCP *Senegal*, Download presentation **Ambrose Talisuna** Uganda Download presentation

Senegal and Uganda adopted ACTs in 2005 and 2004 (respectively); and deployed in 2006. What has been their experience so far?

Senegal

- Changed policy in 2004: They are using ASAQ.
- Two procurements made to date, 3m doses in Jan 06 and 3m Nov 2007.
- The adult dose is sold in the public sector at 300 FCFA = cost of 1kg rice.
- Cost recovery systems are standard in francophone African health systems, which do not provide medicines for free. In Senegal, ~99% of ACTs are distributed through public sector and only 1% through private sector.
- Significant scale up in public sector across the country. Next stage of scale up was on introduction of Rapid Diagnostic Test (RDT): in last 3 months there has been a fall in number of cases, this is considered to be a major success.
- ACTs not yet available at CHW level as they do not want to make them available without RDTs, and they have not yet made RDTs available at that level – training needs to happen.

Uganda

It takes >52 weeks to go from policy change to implementation of ACTs. Some activities can happen in parallel, but the whole process is long. Several issues emerge: focus on the private sector is not enough, there also needs to be a significant effort to strengthen public sector as well as CHW access. How can older classes of drugs which were widely available be withdrawn without replacing them by something else? In order to get correct dispensing, there needs to be a high focus on training in a very short space of time. What is the best way to achieve this?

Discussion

Q: Senegal is using RDT for home based care, is this correct? What is the Ministry doing to train people to use RDT at home?
A: At the moment, Senegal is only using RDTs and ACTs in public health facilities, so as to avoid using them unsupervised at HBM level. A pilot has been launched in 10 districts to see if distributing RDT and ACT to local CHW will work.

Q: Can you explain a little about the government programme to provide ACT in private pharmacies
A: The private sector procures from another source, and sells at the same price as sold in the public sector. Private sector can purchase from the CAMEG (Central Medical Stores) if they wish, in which case they purchase at the same price as public sector. Prices in Senegal are regulated.

Q: You mentioned that only 1% of ACTs are distributed through the private sector, what is the definition of a private sector outlet?
A: The definition only includes registered private sector outlets. They do not take account the informal sector, which is insignificant in Senegal.

Q: Does Senegal have indication of the side effects of Amodiaquine?
A: Yes, there is an indication that people throw away AQ if it is not in a fixed dose combination. This is why the next procurement in Senegal will be FDC.

Panel discussion on national experiences (2) ***2 countries with relatively recent ACT roll-out : Ghana and Malawi***	**Constance Bart-Plange** NMCP *Ghana* Download presentation **Jack Wirima** NMCP *Malawi* Download presentation

Ghana and Malawi adopted ACTs in 2004 and 2006 respectively; deployed in 2005 / 2007 respectively. What has been their experience so far?

Malawi

- The switch process in Malawi is evidence-based. The country monitors drug efficacy nationally on an annual basis. SP resistance was addressed in two phases – first, the recommended dosage of SP was increased, then a decision to switch to an ACT in 2006, with a review of all alternatives.
- In Nov 2007 Malawi moved to AL. Roll out at the moment is in public sector only.
- Challenges:
  - Countries such as Malawi are at the mercy of funding agencies, which dictate what countries should buy
  - How to get products to move right down to the bottom of the supply chain
  - The number of pills, which can lead to lack of compliance and thus resistance
  - Communication and training are significant investments, can be a drain on resources
  - Messages to the population around the use of SP for IPT while withdrawing it for malaria treatment, leaves confusion as to whether SP is effective or not.
- Need to have access to official ACTs in private sector.
  - Otherwise they will use either poor drugs or monotherapy. Also, the official WHO policy is presumptive treatment; if this is to happen, then Malawi needs products to go down to the lowest level.

Ghana

- Ghana started policy change in 2002 to ASAQ.
- Implementation started in Nov 2005, at which point the training had been completed and stocks were available.
- There was leakage from the public sector even before implementation and slow increase in ASAQ use until 2007. ASAQ was used earlier in the private sector.
- Concern back in 2005 around safety of ASAQ: some high profile cases of adverse events caused general public concern. MoH worked hard to alleviate these concerns but this delayed rollout of the programme.
- Ghana National Health Insurance Scheme was introduced to improve access to treatment by the general population.
- A total of 10.5 m doses ACT procured to date; mainly paid for by GFATM, but in the private sector patients have to pay full cost.
- Government pays for transport and distribution costs. However, there has also been a significant donation by the government of China and by sanofi-aventis.
- The next switch in policy was anticipated in 2007 to allow expansion of access to ACTs. There is concern that more adult doses were ordered so that dispensers could cut up the strips, sell them as child doses and make more profit. This affects both quantification and rational use.
- Private sector buys from local manufacture and direct import, as well as from CMS.

Discussion

Q: Does the Ghana private sector get stocks from CMS at subsidized price or full cost?
A: ACTs from the CMS are sold at the same price to both public and private sectors.

Q: In Malawi, what percentage seeks treatment in private sector?
A: Definition of private sector varies from country to country. In Malawi it includes grocery shops, traditional healers, and CHAM. 60-70% goes first to the private sector.

Q: What is the role of GFATM in Malawi and why is PMI coming to fill in the gaps? Why should the donor make the decision on which drug to choose? The decision should be made based on the country's choice of first line treatment.
A: Malawi was told to buy AL or it would not be funded. It had made a decision and the funding agency should respect that. The first switch decision was not towards AL, but then we were told that if we chose the other product we would not be able to access funds.

Q: How does the adult dose overuse (cutting up to get more profit) affect supply chain, push or pull?
A: At the moment the supply chain is based on a push process, but there is a clear incentive for people to adapt the distribution to maximize profit in Ghana by cutting the adult packs.

Q: What were the reasons for dramatic loss of confidence in ASAQ?
A: A number of highly profiled adverse events were publicized widely. Pharmacovigilance (PV) response for safety – there were adverse events, some products had issues with quality, it was not clear which products were used, not clear whether it was an issue of overdosing, genetics, or other issues. WHO has been very helpful to support PV on AQ to understand the issues. Now there is more confidence and uptake is increasing significantly.

[Comment] People used to access CQ properly, so why are they not accessing ACTs properly? There is a huge price differential between ACT and monotherapy, and if monotherapy is good quality, doctors in Ghana often choose to prescribe / dispense monotherapy, if available. If loose dose combinations are more readily available vs. fixed-dose, as is the case, this also increases use of monotherapy. Patients prefer to have a product for longer duration than more tablets per dose. Ghana has health insurance and national system that allows access to ACTs. A person can walk into a pharmacy and get a product and not pay because he is on health insurance scheme.

Expansion of discussion to other countries: countries input led by **Alex Dodoo**

Discussion

1) General comments

- Discussion on AQ is about side effects – the key is to get a branded product, not a generic. Side effects can be worse than effects of malaria itself. ACTs should be considered within the whole management of malaria.
- To avoid resistance developing to ACTs we need to address issues of poor management, and upgrade teaching and training of staff etc.
- Top professors should be included in policy setting so that they understand what drives policy decisions.
- WHO should produce leaflets about different ACTs to share with all (effectively, treatment guidelines with detailed information about products).
- Need to increase number of African institutions with research capacity.

2) Donors cannot guide choice – country plan is the guiding document. GFATM and USAID are signatories of the Global Health Partnership and should not impose on countries. Country ownership should be paramount.

3) WHO's treatment guidelines are global. There is need to communicate better through the country office as malaria control is not just a global activity. There is a lot of well analyzed country level data which could be shared - need to have solid information systems grounded in the countries.

4) PMI supports national treatment policies and does not push countries to procure certain brands against its wishes. PMI can only procure drugs that are prequalified or ICH standard. PMI supports countries directly by procuring both AL and ASAQ

5) Country ownership is a fundamental principle, but we need to understand what really happens in countries. Need to acknowledge some local limitations and the different influences to which countries are subjected.

6) When linking ACT & RDTs, price must be considered. It will only work if cost of diagnostic is lower than cost of ACT. Diagnostic would have to be lower than subsidized ACT product – in which case RDT will need to use GFATM funding. This means most of the money will be mainly spent on RDT rather than ACT. In Mali, government wanted to have RDT before treatment, but as they had no RDTs the ACTs sat on shelves and government had to do a U-turn and change policy.

7) Concerns were also raised about what treatment option to use if RDT is negative.

Session 2: Grappling with affordability in the private sector

An overview of global approaches by **Alex Dodoo**, Co-Chair

Subsidizing ACTs at the country level

Larry Barat
PMI
Download presentation

The presentation investigates the feasibility of tailoring solutions to affordability on a country by country basis

PMI focuses on 'subsidy plus'. It concerns itself with all aspects of how to get access to affordable ACTs, including training on delivery, supervision, placing of products in the supply chain, subsidizing products, and promoting correct use. Two examples were given:

1) **Rwanda** - distribution through the private sector.
Rwanda has a strong regulatory authority and its antimalarials market is designed as a pull system. PSI did an initial push, to ensure that initial stocks were available, but still needs to see how long the pull system will work.
Challenges –

- Need for different packaging
- Are adults buying the subsidized child dose and under dosing themselves?
- Short shelf-life of the drug.

2) **Tanzania**: ADDOs (Accredited Drug Dispensing Outlets).
Tanzania does not want to see drugs go to unqualified hands – i.e., at community level. *Duka La Dawa Muhimo* serves several needs, not just malaria. Intensive intervention and costly. Only 3 areas in Tanzania being scaled up at the moment.
Challenges –

- Access to non-upgraded product
- Co-existence of other products including SP which is cheaper
- Number of ADDOs is limited
- As ADDOs are self financing, and ACT is more expensive, shop keeper has a higher initial outlay and capital risk cost.

Discussion

Q Are there examples from other countries about alternative sources of procurement such as Rwanda buying through the CAMEG?
A: Yes, several other countries in francophone Africa use this approach.

Subsidizing ACTs at the global level	**Uzo Gilpin** *RBM* Download presentation

How will the Affordable Medicines Facility, malaria (AMFm) work? What are the challenges? How are these being resolved?

The problem: ACTs are more expensive, the issue of resistance doesn't help and very few ACTs are on the market. Availability is also not as good as imagined in public sector. Main issue is affordability.

Response to problem: AMFm – to address availability and affordability across all sectors. It will have greatest impact in the private sector but will help across the board. AMFm will focus on support to first line buyers (government, NGOs, major importers) and on the top of the supply chain.

Drug will cost US$1 but importer only pays 5 cents, AMFm will pay subsidy of 95%. NGO and public sector buyers, drug will be cheaper. Can put drugs in through CMS.

Number of supporting interventions, including training to health professionals and providers, public education, PV and resistance monitoring; look at policy, decide on what level that the ACT can go down to.

How does AMFm fit into a bigger picture? – AMFM is only part of a package of interventions that will make a difference, e.g., LLINs. Need to ensure use of RDTs and improve HMBF. R&D of drugs and vaccines is a part of this. SUFI (Scale Up For impact) is fundamental to the whole image.

Timeline for implementation was presented. Call for countries to continue to include and discuss with RBM Partners.

Intervention : Affordability challenges and how to address them	**Andrew Freeman** GFATM

This intervention asked for discussion on two specific issues.

- Reaching the poor: need to put in place innovative solutions to achieve this and then provide feedback to the GFATM Board
- Access: ACT should reach all those who need them, respecting the regulatory framework and PV.

Discussion on PMI, AMFm and GFATM presentations

Q: What will be the cost to the GFATM of the subsidy?
A: GFATM will not fund directly, as is outlined in the AMFM paper.

Q: Who will be responsible for the training and supporting interventions?
A: RBMP will support but countries need to lead.

Q: How did CQ and vaccines get to be affordable to the consumer?
A: Vaccines are different as these are made available via the public sector and are usually once in lifetime. However, increased competition has helped and could also help bring down prices for ACTs.
A: ACTs, CQ and vaccines are very different products. The cost of production for CQ is significantly lower because it was a much simpler compound and easier to produce, so the price baseline is different – this is not a valid comparison with ACT cost structure.

Comments:

- Big issue is getting drugs physically to the lowest levels – an issue of logistics. This also results in a problem of quantification – if you can't get proper shifting of drugs to where they are most needed you can't get better consumer data. Need to look at quantification in terms of the other interventions such as IRS, LLIN, climate change and the impact on outbreaks.
- We should differentiate between local manufacturers and low quality. Brazil and India have several FDA-qualified manufacturers. They are not seen as low quality and should be seen as positive contributors
- In Zambia public sector is very strong in delivery so people don't need to go to private sector. It's up to people and countries to decide what they do and what to focus on. Global and sub regional support will help if capacity does not exist in country. Inform countries that there is a country consultation in August.
- Many of the issues raised are about health systems – so throw the ball back to GFATM and ask them to support health systems as this will have a significant impact for many countries.
- We should also support manufacturers that provide good quality products, wherever they are. We are not interested in low quality products.
- What happens if the subsidy is removed and countries are not ready to take up the slack – this could be catastrophic.
- Also need to think about diagnostics and LLINs not just think about treatment. Deal with management of the whole system and not just think about drugs.

Concerns were raised about:

- Whether work was being done on cost-effectiveness of ACTs.
- How many countries were making use of the available options and submitting proposals to GFATM for PV, M&E etc.
- Whether the use of private sector is really as widespread as suggested. How far do people need to travel for antimalarials - the situation in different countries. Can we really use assumptions based on a few countries.
- Whether focusing on the formal sector is a relevant approach for achieving access. After all, how many cases of malaria are actually treated in formal institutions? The logic of discussing HBMF was to recognize the fact that people are actually treating at home. The current policy of most countries of institutionalizing ACTs is increasing the gap as majority actually treat at home.
- Vaccines are subsidized by GAVI. ACTs are in a similar situation and need to be subsidized somehow so that countries can afford to buy them.

The discussion has flagged the fact that issues of quality, quantification and country ownership are critical.

The subsidy in action: Insights from the Tanzanian study	**Renata Mendike** NMCP *Tanzania* Download presentation

In a pilot study, Tanzania is providing a subsidized ACT in the private sector. What are the preliminary results? Who is buying ACTs? At what price?

The pilot study in Tanzania was led by Tanzania's Ministry of Health and Social Welfare and implemented by PSI and the Clinton Foundation. The pilot sought to answer the following key questions:

- What is the final price paid by patients for subsidized ACTs?
- What is the effect of a package of accompanying interventions (e.g., SRP, repackaging, social marketing) on end-user price and uptake?
- What is the impact of the subsidy on the purchase and use of ACTs compared to other antimalarials?

Findings:

- Uptake of ACTs has increased rapidly in the target districts since the introduction of the subsidy, with particularly rapid uptake observed among consumers seeking treatment for children under 5
- Retail prices of ACTs are 95% less than before the subsidy and equal to or less than those for the most common alternatives
- The poorest people in these generally poor districts are accessing treatment at shops less frequently, but there has been no significant difference in the purchase of ACTs between the poorest and the best off
- Penetration of ACTs has been slower in more remote shops in the two rural target districts, but prices charged in those shops are not higher
- Treatment-seeking at drug shops for children under 5 has increased in the target districts, while older children remain under-represented
- The rapid increase in sales of subsidized ACTs appears to have contributed to higher overall ACT access in the target districts

Implications of the pilot for other countries:

- A subsidy can cause rapid uptake of ACTs
- The subsidy can be passed to patients
- Interventions are needed to reach remote shops
- SRP is an effective tool but must be set carefully
- Interventions may be needed to reach poorest

Session 3: Beyond affordability…
What else needs to be done?

Increasing points of access (OTC status): The Nigerian experience	**Dora Akunyili** *NAFDAC* Download presentation

Why did Nigeria reschedule ACTs? What are the challenges they faced? Has this improved reach?

- Early 90's, Nigeria started shifting to second line drugs like Fansidar, Halfan, etc.
- Late 90's shift to Artemisinin derivatives to counter resistance
- 2004 ACTs adopted as first line treatment
- HBM introduced to expand coverage of treatment - Caregivers trained
- 2005 switched ACTs to OTCs to improve access
- Training and Enlightenment programmes for medicine suppliers improved knowledge and practices on appropriate use of ACTs by more than four fold
- Progress to severe malaria was reduced by > 50% and overall child mortality by 40%
- By 2007 over 3 million doses were distributed
- Nigeria's newly created Pharmacovigilance Centre is keeping a close eye on SAEs.

Discussion

Q: In anecdotal reports of ACT not working, is this resistance to the companion drug? This could be causing problem in some African countries – WHO STG is starting to think about this in some countries.
A: Only evidence in the core study in Cambodia (ASMQ and AS alone) indicates that is not an issue of the companion drug. Monotherapy could not be restricted to AS alone but also non-single use of any companion drug.
Q: What quality controls will be used? Need some data on resistance. It is important to combine resistance and adherence discussions.

Concerns were raised about:

- The kind of outlets are allowed to sell ACTs; the mechanism apart from training that lead to improvement in PV; the fact that Tanzania has tried training dispensers and distributors but did not see improvement. What else can be done?
- Whether the ACTs should be switched on product-by-product basis or by class, given that products are different (ASAQ and AL are the only two ACTs in Nigeria), whether the price of ACTs at the OTC level matches the situation in TZ or if it is different.
- The role of NAFDAC in assessing the quality of products such as double strength AL.

Getting the drugs through the supply chain: The Ugandan case	**Kinny Nayer** *Surgipharm (private sector)* Download presentation

In a pilot study, Uganda will provide a subsidized ACT in the private sector. What incentives to the trade will get the product on shelf? How will profiteering be disincentivised?

Very clear presentation on the proposed structure of the Consortium for ACT Private-Sector Subsidy (CAPSS) supply chain.

Discussion around the risk-benefit of OTC, need for follow up data via pharmacovigilance, and the importance of incentives in the supply chain

Q: What is the buffer stock amount (3.5 months) and where will it be held (district or national)?
A: Indication is that wholesalers and distributors have a few days of buffer stock, shared between surgipham and the distributor

Q: What are margins and how will this work?
A: MRRP (maximum recommended retail price) will be stamped on the pack. There will be agreement and contracts on the margins; it is easier to control at lower levels, but more difficult when national. Hopefully competition will sort that out.

Q: Where does surgipharm's responsibility end? What system have you put in place to make sure you have the data on what is being sold and to whom?
A: Surgipharm will be collecting data at distributor and retail level and will be monitoring stock, as this is a pilot. Normally, surgipharm's responsibility ends at sale to distributor.

Q: How will this low priced product impact the current model of high price, low volume? How will distributors react to a change in the business? (substitution of the high price product by lower priced product)
A: Currently, districts don't have pharmacies, there is only one in all 4 pilot districts, and ACTs only go to pharmacies, so this will expand distribution. With a different marketing strategy and offers of more opportunity for access – a comparison with current situation is not really possible.

Q:Do people pay more further from capital city?
A: No, people don't pay more further from the capital in the CAPSS pilot

Q: We know that different drugs have different costs; the subsidy will go further if you spend it on a drug cheaper to make. How does this impact the total profit?
A: This will be discussed with all manufacturers by product category….

Comments:

1) Need to think about how to dispose of the sharps for RDTs, and also when to set up new pilots - how do we work out how to include RDTs.

2) It will be a struggle for Surgipharm, as a medium size company, with the current forecasts to ensure that we will break even, especially with a falling dollar. Can't afford to work just for CSR or PR. This is an issue facing all companies.

3) Research is necessary for access. Is just as important as R&D and we should ensure that access research is given a similar position.

4) Communications for demand is critical; end user needs to know and understand that effectiveness of these drugs will help with access

5) Issue is all countries currently depend on GFATM. This is not sustainable and also it only covers one part of the population. Need to ensure sustainability.

6) What about stock outs? Need buffer stocks for a longer period.

Summary of the day's proceedings	**Alex Dodoo** **Catherine Hodgkin** Co-chairs

The presentations confirmed shared problems and need for exchange of information about possible approaches. In looking for common solutions a number of key issues were raised:

- Sustainability
- Malaria control is more than ACTs, but access to ACTs is important part of malaria control
- Important to consider malaria control, prevention and treatment in an integrated strategy
- Learn from past lessons (not just vaccines but also others)
- Consider different country contexts (socio-economic, cultural etc)
- Consider Access in all its dimensions – affordability, availability, accessibility, acceptability and adherence
- Adoption of ACT policies has been very wide, but country-wide scale up has been low, and impact on disease burden unacceptably low, especially for children under 5.
- Impact on people's daily lives and especially poorest must be assessed
- Some encouraging trends, but still more to do.

Next steps

- Balancing risks and benefits and factoring resistance into this equation
- Importance of forecasting and improving quantification of requirements
- Harmonise approach to evidence gathering ,where possible, so that knowledge can be better shared and compared
- Country leadership vital – but regional and international cooperation is also needed to bolster lack of capacity, support country strategies and provide inter-country info e.g., resistance monitoring, regulatory info etc.
- Robust M&E systems needed
- Continued evidence and operational research to learn about implementation strategies – and about private/public strategies, scaling up etc.