MMV Access Symposium

Getting Antimalarials to Patients

Kampala, Uganda, 9 May 2007

Summary Report

The Access Symposium in Kampala, Uganda, was well-attended and well-received. Apart from MMV stakeholders, it attracted well over 70 scientists, researchers, national malaria programme officers, and representatives of NGOs, from all over the world. Fourteen speakers gave presentations on topics ranging from the antimalarial landscape in Africa to current attempts to increase the reach of ACTs to the poor. **Francisco Songane** Director, Partnership for Maternal, Newborn and Child health, WHO, and **Catherine Hodgkin** Director Development Policy & Practice KIT, the Netherlands, chaired the meeting.

The objectives of the symposium were not only to assemble relevant players in Access and Delivery in east Africa, but also to look at the reality of antimalarial distribution in the private sector, highlight gaps in ACT provision especially to the rural poor, share innovative approaches to close this gap, and outline MMV's access initiatives.

Several critical issues were highlighted during the course of the presentations, including the need to maximise reach of ACTs without jeopardising safety or creating resistance, and to tailor the risk management approach to the needs of each country. Obstacles to roll-out of ACTs were identified, which included the need for harmonisation of regulatory approvals, readying the distribution infrastructure, sustained financing, behaviour change of all players (manufacturers, providers, users), and stemming the leakage of drugs from public to private sector and across national boundaries.

Consensus was achieved on the following important messages:

- Past experiences must inform present actions in access and delivery of ACTs
- A disconnect exists between scientific progress and policy change, and between policy/regulation and implementation
- The gap in access to ACTs for the poor is more of a chasm, as there is a scarcity of effective antimalarials in the public sector and chaotic, unaffordable excess in the private
- Countries need their capacity strengthened to conduct pharmacovigilance.

Next steps

- MMV will lead the move to share information amongst various constituencies and beyond, starting with a report of the Symposium proceedings including a synthesis of case studies.
- Access and Delivery issues will be raised whenever possible within RBM/WHO/Global Fund and other relevant stakeholders, access activities within countries will be encouraged, and another meeting with country decision-makers will be planned (an MMV information meeting is already planned for Francophone Africa in November 2007.

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Presentation Synopses

Introduction to MMV Access Symposium	**Chris Hentschel** President CEO **Penny Grewal** Director Global Access Download presentation

Session 1	**From CQ/SP to ACTs:** **The antimalarial landscape**

Purpose of the session:

- Making sense of the antimalarial market
- Looking at the reality of private sector distribution
- Ascertaining the ability of the rural poor to obtain antimalarials

A reality check in East Africa	**Nathan Mulure** Medical Director Novartis East Africa Download presentation

The grave burden of malaria in east Africa is not helped by the dismal situation regarding availability of ACTs.

Resistance to CQ and SP in this region is an acknowledged fact, and AQ cure rates are seen to be low in Kenya. For governments to change over to a new first-line treatment usually takes over a year due to financial issues, huge stocks of monotherapies and other antimalarials, inelasticity of demand to locally-produced antimalarials, and inadequate monitoring by health authorities.

In addition, when the drugs are delivered in the public sector (e.g. Coartem®) they are inadequately distributed, resulting in stock-outs. Although the situation is improving, significant levels of stock-outs exist in the public sector (as shown in Zambia and Kenya). The private sector paints a different picture – with an excess of antimalarials. The prices of these drugs, monotherapies, and other ACTs vary enormously – resulting in reduced access. Unfortunately, despite changes in policy to ACTs, other antimalarials and monotherapies continue to be registered.

To implement policy, efficacy studies of generics, the strict regulation of quality (to avoid development of resistance), and pharmacovigilance studies are essential.

Regulating antimalarials	**Hashim Yusufu** National Food and Drug Authority, Nigeria Download presentation

The burden of malaria in Nigeria is huge. The National Agency for Food and Drug Administration and Control (NAFDAC) controls the availability of food, drugs, and chemicals. However, a complex health care system, whose services are limited by poor financing, lack of infrastructure, corruption, and bureaucracy, limits smooth distribution of malaria treatment. Nigeria deploys preventive measures to control malaria and is committed to phasing out the use of artemisinin monotherapies. A significant challenge is the 628 brands of antimalarials sold in Nigerian markets with CQ and SP constituting 60%.

In 2005, Nigeria moved ACTs from prescription-only-medicine status (POM) to OTC status to improve access, and put training and community health programmes in place—this change saw a reduction of child mortality by more than 40%.

What do antimalarials sell for?	**Rosette Mutambi** **Executive Director HEPS Uganda** Download presentation

Medicine prices affect family income and thus access to and final choice of drugs. Prices vary between countries for different medicines for the same disease, by generic/originator, and by sectors/outlet type. To get a clearer picture of the situation Uganda began to gather data on medicine prices, affordability, and availability (PAA). The findings showed that in spite of low ex-factory prices, retail mark-ups double the price to the consumer. Depending on where they live and the drugs they need, families sometimes have to spend significant proportions of their income on treatment.

To understand where the new MMV drugs will fit into the Ugandan market, more information on antimalarial prices in the private sector must be gathered. This study will map the distribution channels for antimalarials, map all outlets, provide an inventory of all products and their market share, PAA, and explore how they are sold, stored and managed. To enable this study, new policies governing PAA of medicines, stronger NGO/MOH/WHO alliances, increased transparency and accountability, a more informed public, and continuous monitoring of medicines are needed.

Challenges of changing prescribing practices from CQ/SP to ACT in the private sector	**James Tibenderana** Drug Policy Change Specialist Malaria Consortium Download presentation

Good prescribing habits are essential if the private sector is to make the shift from CQ and SP to ACTs. Currently, prescriptions do not adhere to national guidelines in the Ugandan public sector – this has important implications on the prescription of ACTs.

Prescribers are influenced by markets forces (profitability and availability of a drug), awareness and preference, as well as previous experience. In the Ugandan context, a shift is needed from the current group that prescribes POMs (doctors, nurses, pharmacists etc.) to a group that can dispense OTC drugs (nursing assistants, drug shop owners etc.)

This involves training to change prescribing behaviour from CQ/SP to ACTs, supervision by professional bodies, and promotion of multiple brands on the market – each of which are challenging activities, as not only are CQ and SP cheaper and readily available than ACTs but also the calibre of private drug providers does not meet national standards and there is limited community awareness of ACTs.

Session 2 Increasing the reach of ACTs

Purpose:
- To highlight gaps in ACT provision
- To share innovative approaches to close this gap

What's being done for the rural poor?	**Naawa Sipilanyambe** Former NMCP Manager, Zambia Download presentation

Malaria results in households being trapped in poverty. The amount spent per household on malaria treatment varies enormously throughout Africa, with most of the family income being spent on home treatment and prevention. Although prompt access to treatment is vital, as the majority of children succumb to the disease within 48 hours of onset, the rural poor often delay treatment. Home is the first point of contact in malaria case management, where antimalarials are too often incorrectly used. If home management is conducted correctly there is a reduction in mortality of children under 5 by 40%.

In the Zambian public sector, implementation of policy changes in favour of ACTs has been slow and for a number of reasons these effective antimalarials have not been included in Rural Health Centre Kits. To have health impact at community level, ACTs must be made more affordable, the public made aware of the policy change and market price, free ACTs should be made available in private clinics, and the treatment of malaria be integrated with preventive measures.

Tanzania: Accredited Drug Distribution Outlets	**Setoke Ngedabanka** Director Business Support Tanzania Food and Drug Authority (TFDA) Download presentation

The Tanzanian pharmaceutical sector is relatively new. A 2001 assessment revealed that the OTC 'Poison shops' were poorly regulated, there was limited access to essential drugs in rural areas, and few skilled drug dispensers. A programme of 210 Accredited Drug Dispensing Outlets (ADDOs) was piloted in Ruvuma region between 2002 and 2005 and proved a success. Presence of unapproved antimalarials dropped from 26% to 2%, facilities dispensing effective antimalarials rose from 6% to 32%, overall availability of antimalarials increased from 74% to 90%, and there was improved regulatory functions and reporting.

Given the success of the pilot, Tanzania plans to roll-out the ADDO concept by 2012 to all regions of the country, although the cost is high. The concept is being refined as local authorities and Zonal Health Training Institutes get involved, cost sharing with ADDO owners and dispensers begins, and the TFDA coordinates quality assurance at the national level.

PRIMO: Subsidized ACT for Home Management of Malaria in Rwanda	**Corinne Karema** National Malaria Control Programme Manager, Rwanda Download presentation

In 2006, Rwanda launched a new malaria treatment policy, with ACTs (Coartem®) as the first-line drug. It ensured access to ACTs beyond the public sector, by integrating the private drug stores, clinics, and 7,700 community health workers into the launch. PRIMO Coartem® for children was specially blister packaged for easy use, with pictures and in the local language. This paediatric version of the ACT was registered for sale in the private market, training and accreditation given to private outlets and community health workers, and communications launched to improve treatment-seeking behaviour.

Monitoring and evaluation of its use is ongoing via pharmacovigilance studies, distribution monitoring, and health seeking behaviour monitoring. The launch of PRIMO is expected to double the access to ACTs, reduce time to first treatment, preserve artemisinin efficacy, reduce leakage of public sector ACTs into the private sector, and reduce the public cost per person treated. However, a few challenges remain around meeting private sector demand, funding private sector projects, producing packaging, OTC vs. POM and managing the supply chain.

Uganda: Home-based Management of Fever (HBMF) – the Kiboga Experience	**Dr. Allan Muruta** District Health Officer Kiboga, Uganda Download presentation

HBMF pilot was launched in Kiboga, Uganda in 2002 to address the heavy burden of malaria, lack of access to professional care, and high occurrence of incorrect treatment, so that children receive prompt and effective care within 24 hours of onset. Implementation completed 2006 – activities included sensitization of district health team, local council, community leaders, and training of Community Medicine Distributors (CMDs), advocacy in the community, monitoring and evaluation, as well as data collection.

The results showed a reduced number of deaths due to malaria in children under-5s and a fall in admissions of under-5s in Kiboga Hospital in 2006/07. However, to have lasting impact HBMF activities need more funding, increased access to ACTs, increased transport for home visits, and better data collection.

Session 3 MMV - Partnering for Access

Purpose:
- To share challenges facing MMV with downstream issues
- To present MMV's initiatives

Ensuring uptake of MMV products

Collaborating on Phase IV studies – Registration and Beyond	**David Ubben** Director Clinical Development MMV Download presentation

Between 2008 and 2012 as many as 4 new Acts will emerge from the MMV pipeline. ACTs are now becoming first-line options in many countries with increasing and widespread use. But a gap remains between sponsors and policy-makers.

MMV drugs in Phase III trials include Dispersible Coartem, DHA-PIP, CDA and PA. In Phase IV, sponsors want label extensions defining the profile of these 4 drugs to show usefulness as replacement first-line therapy, second line rescue therapy, treatment of malaria in pregnancy, use in emergencies, treatment for *P.vivax* malaria etc.

A number of consortia play a major role in special areas (e.g. malaria in pregnancy, preventive treatment for infants, pharmacovigilance etc.), but do not cover all the needs of the sponsors. MMV will interact with these consortia to identify and create tools where needed, and will add value in Phase IV activities as it has a unique relationship with regulators and industry and can advocate for the needs of its partners.

Safety and Effectiveness Studies of Antimalarial Drugs – the Phase IV Consortium	**Fred Binka** Executive Director INDEPTH Network Download presentation

Studies are needed via pharmacovigilance to provide decision-makers and NMCPs with independent and objective evidence on safety and efficacy of new malaria treatments, to guide their widespread use in real life within African health systems.

The objective of the Phase IV Consortium is to monitor safety and measure effectiveness of antimalarials at, and strengthen capacity of, 20 trial sites in Burkina Faso, Ghana, Guinea Bissau, Kenya, Malawi, Mozambique, Senegal, Tanzania, The Gambia, Uganda, DR Congo and Nigeria.

Total population in the study is over 1.5 million and the drugs used in the study are artemether lumefantrine, artesunate amodiaquine, CQ and SP.

Closing the ACT distribution gap in rural Uganda: a MoH MMV initiative	**Ambrose Talisuna** Asst. Commissioner of Health Ministry of Health Uganda Download presentation

Malaria is the leading cause of mortality and morbidity in Uganda – some estimates state that 49% of the population is infected by the disease. Although the country has made some progress in implementing control strategies by changing to ACTs, making them available at health facilities, launching an HBMF strategy, and scaling up preventive measures, gaps in access to ACTs remain. In the non-premium private sector where 60-80% of treatment is sought, ACTs are unaffordable and have prescription-only status (POM).

MoH Uganda and MMV are collaborating in an initiative to study the effect of providing a highly subsidized ACT through the private sector, test approaches to train the informal sector, and launch a social marketing campaign to inform users about malaria and ACTs. Although the methodology is still being refined, the study will target all age groups, align with NDA policies, and incorporate strong monitoring and evaluation.

Four study districts and one control district have been chosen. The first step will be to gather data that throws light on the supply and demand for antimalarials and the choice of health seeking behaviour of customers.

The impact of providing subsidised ACTs on hospital admissions, and on absenteeism at school and work will be studied. Results will determine scale-up of this initiative. Planning is ongoing and the study will be launched in January 2008.

Special session	**ACT subsidy design**	**Samantha Bolton** **Nicolas Theopold** Dalberg Global Development Advisors Download presentation

Purpose:
- To share thinking on the ACT subsidy
- To get input on the subsidy design

The Global ACT Subsidy has emerged from an idea proposed by the Institute of Medicine Report in 2005. The aim is to increase availability of ACTs in all market sectors and drive monotherapies out of the market thus ensuring a maximum lifespan for the ACTs. By significantly reducing the price paid by buyers to manufacturers and by cutting the retail price of ACTs the global subsidy aims to triple the reach of these life-saving drugs.

The subsidy foresees a fall in prices to current CQ and SP levels and only high-quality ACTs will be eligible for the subsidy. The subsidy is expected to be launched by November 2007, but before then extensive operational research will be conducted and a framework of monitoring and evaluation designed.

The subsidy will be managed by an existing organisation but a number of issues remain to be solved: funding, and the roles and responsibilities of partners.