Policy Brief:
ACT Demand Forecast, 2012-2013

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Prepared by the ACT Forecasting Consortium:

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MIT ZARAGOZA International Logistics Program

CLINTON HEALTH ACCESS INITIATIVE

This synopsis is intended to provide policymakers with a brief summary of the latest demand forecasts for antimalarial drugs and the implications for health and development policy. The demand estimates are produced by a consortium of forecasters including The Boston Consulting Group, the Clinton Health Access Initiative, and the Fundacion Zaragoza Logistics Center. The consortium is funded by UNITAID and operates under the leadership of a steering committee consisting of the Affordable Medicines Facility—malaria, The Global Fund to Fight AIDS, Tuberculosis and Malaria, the Medicines for Malaria Venture, the Roll Back Malaria Partnership, UNITAID and the World Health Organization.

Key Messages

- Public Sector ACT procurement is projected to increase substantially between 2011 and 2012, mainly due to transient international donor funding to individual endemic countries.
- While there is no indication that the "need" for ACTs will decrease, current donor funding commitments suggest a very sharp decrease in public sector procurement could occur in 2013.
- An additional risk to demand in 2013 is the decision regarding the future of the Affordable Medicines Facility – malaria (AMFm); the subsidized private sector represents about 30% of global demand for pre-qualified ACTs. If a decision is taken to terminate the AMFm after Phase 1 – which would further erode global ACT procurement levels – transitional funding will be critical to enable a responsible and orderly adjustment in the market.
- Additional funding across sectors, including the AMFm, international funding for public sector procurement, and domestic resources in endemic countries, will have a large impact on future demand.
- Communication of funding decisions in a timely manner is critical for accurate forecasting. It is also very important for those involved in producing ACTs and artemisinin (which has an especially long lead time).

Background

Growth in procurement of artemisinin-combination therapies (ACTs), the standard of care in malaria treatment, has been a key factor in the progress against the disease over the last decade. Sustained international donor funding for these relatively expensive drugs have led to a number of important outcomes:

- substantially increased access to effective and high-quality treatment for malaria in endemic regions *(1);*
- reduced use of oral artemisinin monotherapies, thereby helping to preserve this drug class against the development of resistance *(2,3);*
- revised clinical guidelines in a number of high-burden countries to make ACTs the recommended first-line therapy for uncomplicated malaria *(4);*
- encouraged pre-qualified ACT manufacturers and suppliers to add capacity to meet growing demand *(5,6);* and
- enticed new ACT manufacturers to enter and compete in the market, which has helped drive down prices *(7).*

World Health Organization

MMV Medicines for Malaria Venture

UNITAID

The Global Fund To Fight AIDS, Tuberculosis and Malaria

ROLL BACK MALARIA

There is still a significant challenge in targeting ACTs toward patients with malaria. While deaths from malaria have declined sharply, reported levels of mortality and morbidity indicate that many do not receive prompt and effective malaria treatment. At the same time, a significant number of incident fevers in endemic regions are incorrectly presumed to be caused by malaria, which can lead to inappropriate treatment with antimalarials. Recent WHO guidelines have called for the use of confirmatory diagnosis before treatment with ACTs, which may improve targeting over time.

Currently artemisinin is derived from agricultural sources. There is a >14-month production cycle from initial planting to conversion into an ACT. As a result, producers cannot react rapidly to sudden changes in demand[1]. Rapid growth in ACTs over the last decade has led to volatile artemisinin markets. Unpredictability in supply and demand has influenced pricing in an erratic manner, complicated planning by market players, and placed at risk the ability to ensure broad availability of ACTs. As a result, the forecasting consortium was established to provide global ACT procurement and artemisinin demand forecasts to inform policy makers and market participants.

Methods

The consortium forecast is based on the view that a combination of forecasting models, run in parallel and drawing from different sources of information, is more robust than a single model. It uses a variety of inputs and models to project global demand for ACTs across three channels: the public channel (which is largely paid for by international donor funds), the subsidized private channel (in 8 AMFm Phase 1 countries[2]), and the premium private market (which is paid for largely out-of-pocket in endemic countries). An array of sources – including incidence of malaria-like fevers, treatment seeking behavior, treatment penetration in private and public sectors, and country-level procurement trends, among others – are used to project demand.

Product demand can be assessed at multiple levels. The demand forecasted in the consortium's Q1 2012 report reflects demand at the level of projected orders to manufacturers.

This definition is different from potential demand estimates at the consumer level, or "need," and is linked closely to the funding available for procurement of ACTs.

Several caveats are important to keep in mind when assessing these forecasts. The forecasts are based on currently committed funding for ACT procurement; the emergence of new or expanded funding would change overall demand estimates. The forecasts also represent a snapshot in time, based on best-available information about the market for malaria drugs; as new and better quality inputs are developed, they will be incorporated into future forecasts.

Key Findings

The consortium forecasts significant volatility in the global ACT market over the next two years. The group projects global orders for pre-qualified ACTs to reach 319M treatments in 2012, an increase of 11% over 2011 estimates. This would mark a record year for pre-qualified ACT sales in 2012. The growth has been driven largely by increases in public donor funding for ACT procurement and the impact of the AMFm, which has yielded significant growth in ACTs in private channels through a subsidy model since its Phase 1 pilot was launched in eight countries in mid-2010 estimates. This would mark a **record year for pre-qualified ACT sales in 2012**. The growth has been driven largely by increases in public donor funding for ACT procurement and the impact of the AMFm, which has yielded significant growth in ACTs in private channels through a subsidy model since its Phase 1 pilot was launched in eight countries in mid-2010.

However, **orders are projected to fall sharply in 2013**, based on the amount of international funding that is currently committed to ACT procurement. In addition, a decision will be taken later this year by the Global Fund Board to continue, expand, modify, or terminate the AMFm after 2012. Therefore, two scenarios for global demand have been created for 2013. Scenario 1 assumes that funding comparable to 2012 levels is made available for the AMFm in 2013, either as a bridge to future expansion or to maintain the status quo. Scenario 2 assumes that a decision to terminate

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1. Later in 2012 Sanofi-Aventis is expected to launch a semi-synthetic form of artemisinin, which will have a much shorter lead-time and therefore should be more adaptable to changes in market demand. However, given capacity constraints, semi-synthetic artemisinin will be able to meet only a portion of market demand.

2. Cambodia, Ghana, Kenya, Madagascar, Niger, Nigeria, Tanzania (including Zanzibar), and Uganda

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or significantly scale back the AMFm is made by the Board and that an amount equivalent to roughly 6 months of funding is made available to enable and orderly and responsible transition in the market place. Both scenarios project public channel procurement based on currently committed funding. The results are shown in Figure 1[3] below.

If the decision is taken to continue the AMFm at comparable levels into 2013 (Scenario 1), orders for pre-qualified ACT treatments are forecasted to fall to 257M, a decline of nearly 20% from 2012 estimates. It is worth noting that this decline is independent of the recent Global Fund decision to terminate Round 11. Round 11 would have impacted ACT demand only starting in 2014; as a result, the level of future uncertainty around ACT procurement is even greater beyond 2013.

If the Global Fund Board decides to terminate or scale back the AMFm after Phase 1, global ACT orders would fall further. Even if 6-months funding is made available to continue some subsidies in 2013 in order to support an orderly market transition (Scenario 2), the consortium forecasts that the reduction would be as much as an additional ~40M treatments. This would reset global ACT demand back to roughly 2010 levels.

It is worth noting that **Scenario 2 is not the "worst case" for ACT procurement in 2013**. A decision to terminate the AMFm without any transition support (a "hard stop" scenario) would leave global ACT procurement at roughly 180M treatments for 2013, which would be less than global procurement in 2010. We should note, however, that all of these projections do not account for future increases in funding for ACTs from international or domestic resources for 2013 - from international or domestic resources for 2013 procurement above what is currently committed.

Policy Implications

There are several implications for policymakers from this forecast.

- The picture here reflects a **significant risk of unmet need for ACTs in 2013.** While committed funding levels suggest we are on track for a sharp decline in ACT procurement in 2013, there is no reason to believe underlying "need" for these products will decline at a similar rate. Despite ongoing success in malaria control efforts and the increasing use of Rapid Diagnostic Tests to confirm the presence of malaria before treatment, consumers' need for ACTs will likely remain high in 2013.
- There is **still time to fill this gap with new funding** for 2013. Additional funding from international or national resources could mitigate the projected decline in 2013. Given the efforts required to make such funding available and deploy it for procurement, however, steps need to be taken now to build awareness of the need and identify potential funding pools.
- Longer term, steps need to be taken by national and international stakeholders to **ensure sustained and predictable funding to meet the need for ACTs.** There is a tension between the volatility inherent in annual donor funding cycles and the production processes for ACTs. Given the long lead times associated with cultivation of artemisia, and the need for manufacturers to plan production capacity for ACTs, a more

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Figure 1 ACT demand forecast by sector, 2012-2013

	Prior estimates			Scenario 1	Scenario 2
ACTs (millions of treatments)	2010	2011	2012	2013	2013
Public sector	182	176	226	162	162
Private-Subsidized sector	12	88	83	85	43
Private-Premium sector	20-25 (est.)	23	10	10	14
Total	214–219	287	319	257	219

3. Due to a change in methodology, prior year estimates for the private sector segment are not directly comparable to the forecasts for 2012 and 2013. Premium private sector estimates for 2010-11 are overstated due to the inclusion of some non-pre-qualified ACTs in those forecasts.

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predictable longer-term model for funding could help stabilize the market. At the least, rapid communication of new funding decisions (and incorporation into future forecasts) will enable market participants to make appropriate decisions.

- Given the importance of the AMFm to global demand, the Global Fund Board's **decision on the AMFm's future should account for the market consequences.** If the decision is made to terminate or scale back the AMFm after Phase 1, additional support for an orderly and responsible transition of the market will be critical. The demand scenarios outlined above are not the "worst case" for ACT procurement in 2013; a decision to terminate the AMFm with no transition support for 2013 would leave global ACT procurement at pre-2010 levels (assuming no increase in donor funding above currently committed levels).
- In addition, the **decision on the AMFm's future needs to be made in a transparent manner** based on the results of the pilot. Given the investments made by Phase 1 countries and market players to participate in the pilot, it is important to ensure there is clarity around the decision process and criteria used by the Board; a situation where the pilot is deemed highly successful in its independent evaluation but terminated due to lack of donor interest or political pressure could have significant negative consequences. In the short term, such a decision could lead to market disruptions and stock-outs. In the longer term, it could dissuade countries from participating in other novel market interventions.
- Despite the growth in procurement of ACTs over the last several years, there are still frequent reports of stock-outs or shortages at the country level. In creating this global forecast, country level data confirmed the presence of localized supply challenges in many endemic countries. In the near-term, therefore, steps need to be taken to **ensure that ACTs are directed to areas where where they are most needed**. At the national and sub-national levels, ongoing support is needed for the WHO and RBM ACT Supply Task Force, which reviews inventory levels and prioritizes ACT deployment toward regions at risk of stock-outs.
- Longer term, at the level of case management, a **cost-effective roll-out of the WHO guidelines on confirmatory diagnosis** before treatment can facilitate more appropriate use of antimalarials. Improved targeting of ACTs toward patients with confirmed malaria can help ensure the most efficient use of this important treatment and improve overall utilization of scarce health resources.

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