

Demand Forecast for Artemisinin-based Combination Therapies (ACTs) in 2012-2013

Q3-2012 Update

Prepared by the ACT Forecasting Consortium:



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This report was prepared 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 the Affordable Medicines Facility – malaria (AMFM), the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Medicines for Malaria Venture (MMV), the Roll Back Malaria Partnership, UNITAID and the World Health Organization. All reasonable precautions have been taken by the authors to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall UNITAID or the World Health Organization be liable for damages arising from its use.

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KEY MESSAGES

- An estimated 251M treatments of pre-qualified Artemisinin Combination Therapies (ACTs) are expected to be procured in 2013. This is in line with historic trends but represents a decline from current estimates of 289M treatments for 2012.
 - The modest decline between 2012 and 2013 is driven mainly by changes within the public channel and currently available information suggests that this is due to reductions in donor commitment and country procurement plans. We will make updates to the 2013 estimates in our Q4-2012 forecast as more information becomes available.
- Since there is no indication that the “need” for ACTs will decrease, the potential exists for substantial shortfalls in ACT availability in endemic countries.
- Funding decisions across sectors will have a large impact on future procurement levels and, though some uncertainty exists, increased clarity is expected as several important decisions are being made:
 - The decision by the Global Fund Board to further support the AMFm beyond 2012 with modifications precludes some of the most pessimistic scenarios; however, funding for the transitional period (2013) has not been secured to date and the approach for 2014 and beyond still needs to be defined.
 - The Global Fund is expected to provide more information about its updated Procurement and Supply Management (PSM) plans and how the underlying mechanism will change going forward.
 - New Malaria Operating Plans (MOPs) are expected to be released by the President’s Malaria Initiative (PMI).
- Given the long lead times associated with ACT production, any additional funding for 2013 and beyond will need to be committed and communicated soon to influence the investment and production decisions of market players. For manufacturers involved in ACT production, it is too late to change artemisinin sourcing decisions for 2013; however, having greater clarity on funding for 2014 ACT procurement is crucial in influencing the upcoming planting, sourcing and production cycle.
- In the future, multi-year funding commitments by donors could significantly strengthen the accuracy of demand forecasts and improve the capacity and production decisions made by market players, and therefore contribute to stabilizing the market.

I. Context

This report updates the latest procurement forecasts for artemisinin-combination therapies (ACTs) and artemisinin in 2012-2013. It is produced by the ACT forecasting consortium which includes The Boston Consulting Group, the Clinton Health Access Initiative, and Fundacion Zaragoza Logistics Center (MIT-Zaragoza). Funded and coordinated by UNITAID, the project brings together forecasters originally working under the Roll Back Malaria (RBM) umbrella in an effort to produce a single ACT forecast for use by the malaria community. The consortium is overseen by a Steering Committee that includes representatives from the Affordable Medicines Facility-malaria (AMFm), the Global Fund, Medicines for Malaria Venture (MMV), Roll Back Malaria (RBM), UNITAID, and the World Health Organization (WHO).

This is the sixth in a series of consortium forecasts that will be produced through early 2013. Each quarter, the forecasts are revised based on new information about ACT funding and market dynamics. Since this Q3 forecast update is only modestly different from the Q1 and Q2 forecast, the new figures are summarized in this brief report, and we refer readers to our full Q1 report for a detailed description of the project context and methods. The Q1 and Q2 forecasts for 2012 are available on the UNITAID website at: <http://www.unitaid.eu/actforecasting>.

II. Summary of Findings

Pre-qualified ACT procurement is projected across three market channels – the public channel (including all sources of funding for public-channel purchases), the subsidized private channel (in AMFm Phase 1 countries), and the premium private channel. The forecasts reported here project demand at the manufacturer level, in the form of expected orders based on currently available and committed funding.

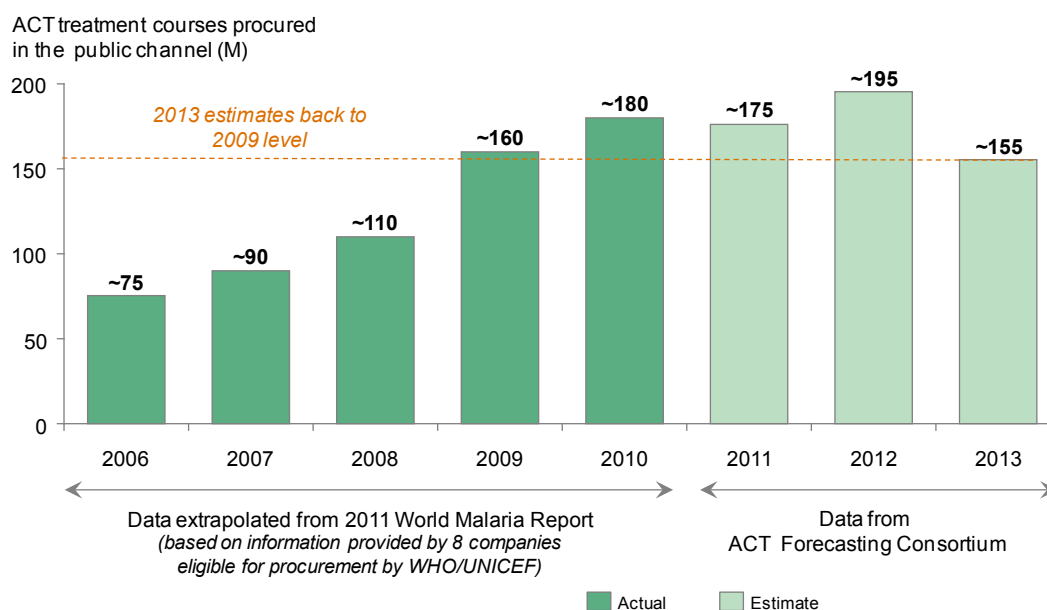
Overall, there have been only modest changes in our forecast between Q2 and Q3. These changes are largely due to the incorporation of new information about donor funding commitments and disbursement rates as well as country procurement plans within the public channel. Also, the decline in procurement estimates between 2012 and 2013 described in our Q2 forecast still remains in this update. This decline is driven mainly by changes within the public channel and represents a trend towards historic ACT procurement levels as shown in Figure 1. Information currently available within the public domain suggests that reduced donor commitment and country procurement plans are the underlying drivers of this decline. It is important, however, to note that funders and countries are expected to solidify their 2013 funding and procurement plans later this year and that the 2013 estimates in our Q4-2012 update will change accordingly. Our forecasting methods utilize regression models that incorporate historical international disbursement rates, reported funding allocations, and planned procurement data to project the rate of future ACT procurement in this channel.

WHO-pre-qualified ACT procurement in 2012 is now projected to be 289M treatments. This figure is ~14M treatments lower than our Q2 forecast but still marks a record year for pre-qualified ACTs, which reflects continued support from international funders who directly or indirectly pay for most of these treatments. **The public channel remains the largest driver of orders for pre-qualified ACTs**

with projected orders for 195M treatments in 2012 (down from 210 M in our Q2 report)¹. Despite the downward revision, this public-channel figure is higher than reported orders for 2010 and estimates for 2011 (182M and 176M, respectively), due to a relative increase in public funding available in several countries in 2012.

In the subsidized private channel, approved private-buyer orders are forecasted to be 83M treatments in 2012, roughly comparable to our final estimates for 2011 for that channel and identical to our Q2 forecast. Premium private sector orders are projected to be 11M treatments in 2012, which reflects a slight increase from the 10M treatments projected in our Q2 forecast.²

Figure 1: Trends in ACT procurement within the public channel³



Looking ahead to 2013, some uncertainty still remains around procurement levels for pre-qualified ACTs.

In our Q2 forecast, the uncertainty revolved mainly around what form the AMFm might take after the conclusion of the Phase 1 pilot at the end of 2012. The recent approval by the Global Fund Board to further support the AMFm, with a modified approach from 2014 and a transition in 2013,

¹ The public channel includes all ACTs procured for distribution in the public sector irrespective of funding source e.g. the Global Fund, PMI, World Bank, national governments, DFID, AMFm (excluding private buyers), etc.

² Due to changes in methodology and data sources, premium private channel estimates for 2012 and 2013 are not directly comparable with forecasts in earlier periods. Prior year estimates include some non-pre-qualified ACTs; as a result figures for earlier periods should be viewed as overstating demand for PQ ACTs in the premium market.

³ Data for 2006 to 2010 was extrapolated from Fig 6.10 in the 2011 World Malaria Report.

led us to deemphasize the fate of the AMFm as a significant driver of uncertainty in 2013⁴. It is important to note, however, that the funding for 2013 has not been secured to date.

In the Q3 forecast, a lack of information on ACT procurement in the public channel also added an element of uncertainty. Specifically, 2013 data is either missing or incomplete in a selection of countries. To reflect this lack of confidence with existing data, **we slightly adapted our methodology for 2013 in the public channel.**

In the public channel, as of the third quarter of 2012, committed international funding levels and country procurement plans for 2013 are lower than for 2012 as described earlier. In particular, currently available procurement plans from some countries suggest that they plan to buy fewer ACTs in 2013. However, it is also feasible that this situation reflects a delay in updating procurement plans, especially where there are steep declines from 2012 to 2013. To cope with information that we believe to be incomplete, we have assumed that currently available procurement plans are not accurate representations of what countries expect to happen in 2013 and that, in countries with Round 10 malaria grants or large Phase 2 renewals (e.g. Nigeria), significant drops in procurement plans are due to delays in publishing more recent procurement data. We therefore used the average procurement levels for the previous 2 years to predict actual procurement for 2013. **Based on these assumptions, our Q3 forecasts estimates public sector procurements at 155M ACTs.** These estimates are lower than our Q2 estimates by 7M.

In the subsidized private sector, as described above, we have assumed that sufficient funding will be available to support continued ACT co-pays throughout 2013, although AMFm 2013 funding is not secured to date. **Our 2013 procurement forecasts for the subsidized private channel comes to about 85M treatments** which is essentially unchanged from our relevant Q2 estimate and comparable to 83M in 2012. In the event that funding for co-pays is unavailable or reduced in 2013, ACTs procured via this channel will be lower than our current estimates.

The premium private market for ACTs is projected to remain at 11M treatments in 2013. Figure 2 summarizes our forecast of projected orders for ACTs across all three channels, along with the change (Δ) from our Q2 forecast. Under our new figures, global orders for ACTs are projected to fall to 251M treatments (a drop of 13% from 2012 level). Given that underlying consumer demand for effective antimalarial treatment is unlikely to drop in 2013, **this situation creates a risk of unmet need for ACTs.**

⁴ In our Q2 forecast released in July 2012, a first scenario assumed the AMFm would continue largely in its current form in the 8 Phase 1 countries – a situation which corresponds to the decision by the Global Fund Board in its 28th Board meeting to continue and modify the AMFm after Phase 1. The second scenario assumed a decision would be made to terminate or scale back the AMFm program, but that support equivalent to 6 months of funding would be provided to allow for a responsible and orderly adjustment in the ACT market.

Figure 2: Global demand for pre-qualified ACT procurement across channels⁵

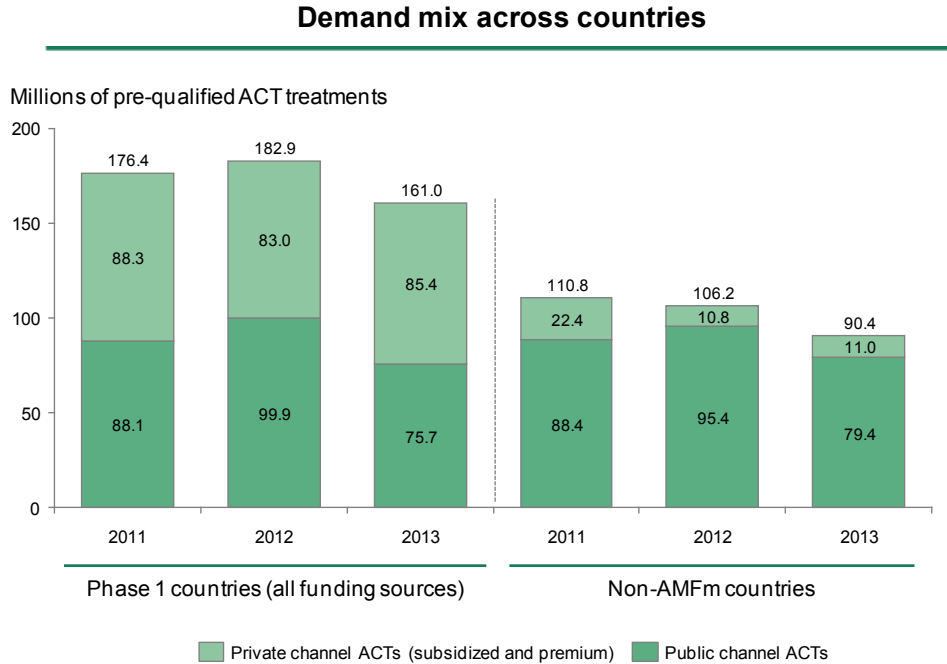
| ACTs (millions of pre-qualified treatments) | 2010 (Actual) | Estimates | | | | |
|---------------------------------------------------|------------------|-----------|------|------|------|-----|
| | | 2011 | 2012 | Δ | 2013 | Δ |
| Public sector | 182 | 176 | 195 | (15) | 155 | (7) |
| Private-Subsidized sector | 12 | 88 | 83 | | 85 | |
| Private-Premium sector¹ | 20-25 (est.) | 23 | 11 | 1 | 11 | 1 |
| Total | 214–219 | 287 | 289 | (14) | 251 | (6) |

(Δ = Q3 estimate – Q2 scenario 1 estimate)

The revised forecast also projects a slightly different distribution of demand across countries. Counting all sources of funding across all channels, the eight AMFm Phase 1 countries are still expected to comprise almost 2/3 of global orders for pre-qualified ACTs in 2012. However, based on the available funding and projected timing of their disbursements in the public channel, total orders in these countries are now projected to be lower than our Q2 forecast by 16M treatments in 2012. They are also higher by 16M treatments in 2013. In non-AMFm countries, our new forecast is slightly higher in 2012 and lower in 2013 than our Q2 projection. The breakdown across these country segments is summarized in Figure 3.

⁵ Numbers may not add up due to rounding

Figure 3: Global ACT procurement estimates in AMFm and non-AMFm countries (2011-13)



We have also converted these updated forecasts of pre-qualified ACT procurement estimates into requirements for artemisinin. To do this, we started with the milligrams of API needed to produce different dosages (e.g. by weight/age) of various ACT formulations (e.g. AL, ASAQ). We then allowed for a 5% loss in the conversion of API to tablets. Next, we calculated the percentage of treatments represented by each product and dosage form in our 2012 forecast and derived a weighted average of “number of treatments that may be obtained per unit of artemisinin”. This weighted average comes to approximately 2.16 million treatments per metric tonne of artemisinin in 2012. It is worth noting that there are differences in both product and dose mix across channels and countries. For 2013, under the different funding hypotheses, the market shares of different channels are very different, which alters the global product and dosing mix and slightly changes the conversion factor used to estimate artemisinin supply need. In addition, it is unclear whether countries and funders will allocate limited funds in different ways in 2013 (e.g., emphasizing child doses) in light of funding pressures. Given these uncertainties and in order to simplify comparisons, we have applied the 2012 artemisinin conversion ratio to 2013 ACT procurement projections to estimate demand for artemisinin in that year.

Figure 4 shows artemisinin requirements for pre-qualified ACTs in 2012 decline to 134 MTs, or 6 MTs less than our Q2 forecast. For 2013, artemisinin requirements for pre-qualified ACTs declines to 116MT.

Figure 4: Global demand for pre-qualified ACT procurement and Artemisinin

| | 2010 (Actual) | Estimates | | |
|-------------------------------------------------------|------------------|-----------|------|------|
| | | 2011 | 2012 | 2013 |
| ACTs (millions of pre-qualified treatments) | 214–219 | 287 | 289 | 251 |
| Artemisinin (metric tonnes) | ~100 | 133 | 134 | 116 |

Two caveats apply to the artemisinin need referenced above. First, the forecast for 2013 is based on information that is currently available within the public domain and may underestimate actual demand for 2013. We plan to have more complete estimates in our Q4-2012 update as funders and countries take firmer positions about their plans for 2013. Second, the numbers above are only for pre-qualified ACTs; additional artemisinin supply would be needed to produce non-pre-qualified ACTs, oral artemisinin monotherapies, IV artesunate for severe malaria, and to replenish manufacturer stocks that were depleted in 2011 and 2012. While these additional sources of demand for artemisinin are smaller than the demand for pre-qualified ACTs, they matter for farmers and extractors.

There are several implications in this update for policymakers and market participants. Though some uncertainty exists around future funding streams for ACT procurement, increased clarity is expected once several important decisions are made. The recent Global Fund decision to further support AMFm suggests transitional funding will be made available to help bridge procurement funding throughout 2013 in AMFm Phase I countries; however, donor funding decisions have yet to be confirmed. Also, more clarity is expected from the Global Fund about updated Procurement and Supply Management (PSM) plans and how its underlying mechanism will change. The President’s Malaria Initiative (PMI) is also expected to release new Malaria Operating Plans (MOPs) later this year. A resolution of funding uncertainty is critical to limiting the threat of product shortages. Importantly, the fluctuating patterns of funding and demand observed in the market place underscore the importance of effective policy and market coordination at the global and endemic country level. A rich understanding of market dynamics, patient need, and supply will become increasingly important to ensure these critical products are deployed most effectively, efficiently, and equitably. Longer-term commitments by donors and policies designed to improve the performance and predictability of public procurement processes at the international and national level can also increase efficiency, help stabilize the market and allow market participants to prepare effectively.