

Twenty First Board Meeting Geneva, 28-30 April 2010

> GF/B21/07 Attachment 1&2

REPORT OF THE AFFORDABLE MEDICINES FACILITY - MALARIA (AMFM) AD HOC **COMMITTEE (AHC)**

Attachment 1: Statement from Rwanda CCM

Attachment 2: TERG Position Paper to PSC on the Independent Evaluation of the AMFm















Statement from Rwanda CCM

General Statement from CCM.

Dear TRP members,

The CCM would like to confirm the commitment of Rwanda to the principles and philosophy of the AMFm. The Rwanda CCM would like to express its sincere gratitude for being selected for the pilot phase of AMFm.

The CCM reviewed the TRP's feedback and has provided responses and made major modifications on the proposal budget (see attached excel file). The revised budget for this proposal is \$ 6,659,387 and will cover the activities planned under this project in order to achieve targets in line with the AMFm and agreed by the TRP.

As The TRP has recommended OUSD additional funds having in mind available budget at the time of the proposal's submission with the budget of \$5 million from the round 5 Global Fund budget (\$3.4 million) and RCC phase 2 budget (\$2.4 million), Rwanda would have to mobilize extra funds to cover the gap in our request. However, it is important to inform you that the current balance in the Round 5 proposal is \$1.4 million as 1.9 million have been used to procure ACTs in order to avoid stock out, and the RCC phase 2 budget is not yet available in country because it is expected in 2011 given the request of non cost extension as the RCC has started with a delay of 1 year.

In addition, according to the current budget breakdown taking into account TRP recommendations (see attached excel file), Rwanda needs \$3,684,697million (year 1) and \$2,969,063 million (year 2). The current available budget in country (\$ 1.4 million) will only cover 39% of the year 1 budget. For year 2, the gap is currently 100%.

Therefore, the CCM would like postpone its participation to the pilot phase of AMFm until we resubmit Rwanda's application to be part of the phase 2 AMFm, as the current approved budget for phase 1 will not allow the sub-recipients to implement planned activities and achieve the agreed targets.

We look forward to the next opportunity to participate in the phase 2 AMFm.

TERG Position Paper to PSC on the Independent Evaluation of the AMFm

Background

At its meeting on 8-9 February 2010, the Technical Evaluation Reference Group (TERG) obtained a briefing on the objectives and status of the independent evaluation of the Affordable Medicines for Malaria (AMFm) initiative, and developed a set of views about that evaluation to convey to the Board through the Policy and Strategy Committee. This is consistent with the TERG's Board-mandated role in the AMFm initiative, namely to provide input to the Ad Hoc Committee on the Independent Evaluation about the technical features of the evaluation.

This paper highlights the views of the TERG with respect to whether and how the independent evaluation can inform future decision making about the AMFm facility, and suggests specific next steps that could be undertaken by the Ad Hoc Committee, with the consent of the Board. Throughout, the emphasis is on aligning the technical features of the evaluation with what is required for future decision making, while taking into consideration the realities of a short implementation period and challenges in making the type of valid comparisons that are required to draw inferences from evaluation results.

The TERG recognizes that the independent evaluation of the AMFm facility has already been the subject of considerable deliberation, and that extensive work has gone into the design, as well as the selection of the evaluation team. The comments and recommendations below are intended not to re-open debates that have been resolved, but to support a path forward given decisions that have already been taken regarding implementation period, resources for implementation and for the evaluation itself, and priority objectives.

Key Issues and Recommendations

Issue 1: Establish Realistic Success Metrics

The TERG observed that to be useful, the independent evaluation (in concert with the information and findings from the in-country monitoring and the implementation science activities) will need to provide valid and credible information that would permit stakeholders to conclude that the initiative is working effectively toward its objectives; is demonstrating some promise but falling short in ways that can likely be corrected through adjustments at the end of the first phase; or is failing to achieve progress toward its objectives and/or causing significant negative unintended consequences and should be stopped after Phase I. This implies:

- a) That the decision makers agree ex ante on what constitutes sufficient data in support of the conclusion that the initiative is working, falling short but can be improved, or failing and should be terminated in short, that they agree in advance on what success "means."
- b) That the evaluation is designed to obtain information on key outputs and outcomes of interest, in ways that are as scientifically sound as permitted by the prevailing non-experimental conditions; and
- c) That what decision makers need (or request) to be able to make an informed judgment about success must be reconciled with the methodological realities of the evaluation - for example, what outcomes are measurable with a high standard of evidence within the time and budgetary resources.

In the view of the TERG, if the criteria for success are not made explicit and/or the type of evidence they require are inconsistent with the technical realities of the evaluation, there is a very high risk that the independent evaluation will not advance evidence-based decision making about Phase II. Instead, it is foreseeable that there will remain a polarization of views about the appropriateness of the AMFm approach, with all sides using inconclusive evaluation results to support their perspectives.

The TERG therefore urges the Ad Hoc Committee to engage in an exercise to define success in terms of measures that are technically feasible, given a 12-month observation period and the likely variability and measurement error related to key outcomes. Doing this may require extensive engagement with the team designing and implementing the evaluation. It is essential that the criteria for judging success be developed during the detailed design process for the evaluation, subjected to independent peer review, and made available to the general public.

Issue 2: Apply Methods that Will Obtain Valid Evidence for Decision making

The TERG noted that AMFm could be usefully examined in two parts:

- a) The upstream part, with emphasis on the operational aspects, or "business model," of AMFm as a financing platform: The new element of the AMFm is the introduction of a factory-gate subsidy at the global level to reduce prices to the consumer. The process-related features of this approach can be studied with respect to how closely the actual implementation conforms to plans.
- b) The downstream part, with emphasis on service delivery to increase access to and use of ACTs, including by the poor. This part is expected to benefit from lower prices that result from the upstream part. The TERG noted that the downstream part is neither new nor unique to the AMFm.

In light of the short implementation period during which changes can be observed, the TERG agreed with earlier assessments on the value of examining and documenting the extent to which the operational aspects, or business models, are working within the duration of Phase 1. The independent evaluation would therefore concentrate on:

- a) Changes in the price of co-paid ACTs
- b) Changes in the availability of co-paid ACTs
- c) Changes in the <u>market share</u> of ACTs compared to undesirable monotherapies

An evaluation of the AMFm using these three parameters should form the core of the independent evaluation, and should be possible to execute in all countries participation in Phase I during the period of observation. The TERG noted that it is possible to examine the three parameters of price, availability and market share without household surveys, thus avoiding a major increase in the costs of data collection. Given the short implementation period, it is likely that conclusions regarding the success of the facility will depend on information about how rapidly these changes are occurring (as well as in what magnitude), and so threshold values (or range of values) for these parameters should be established during the aforementioned exercise to identify criteria for success.

The TERG further recognized that it would be useful for decision making to know about changes in uptake of co-paid ACTs at outlets and by people in remote locations. However, the TERG believes that this will be possible only in a subset of the implementing countries during the period of observation and within the available budget, and therefore is most fruitfully investigated by focusing on fast-moving countries, in which end-point outlet surveys will yield meaningful results. Arguably, those countries will not constitute a representative sample of

the pilot countries, or of all future countries, and so drawing inferences with external validity will be challenging. Again, this technical limitation makes it essential for the key parties to agree in advance on what evidence will support a conclusion of success or failure of the AMFm.

The TERG also observed that future decisions would be informed by a <u>comparison between the AMFm and other possible means of financing expanded access to affordable antimalarials</u>. In particular, there is value in comparing and contrasting how each financing model performs, not to compare AMFm (a financing model) with specific approaches to service delivery. For the reasons described above, it is likely that the focus will have to be on the speed and coverage of the comparator financing mechanisms, rather than on the access among the poor across all settings.

Given the observation that participating countries are likely to move at varying paces, and opportunities for learning are greatest in fast-moving countries, the TERG suggests that design of the evaluation prioritize in-depth country case studies, blending quantitative and qualitative methods, rather than primarily inter-country comparisons. This will provide opportunities to assess and learn, in addition to quantitative measures of what has changed, how and why the new model unfolds in a variety of contexts while drawing lessons that can help future operations. This will constitute a more limited independent evaluation of the downstream business model.

Issue 3: Use the Evaluation to Learn, Not to Identify "Red Flags"

The TERG is concerned about the conflation of the independent evaluation, which should be generating information that is useful for the decision about whether to move to Phase II, and the monitoring for severe problems that might warrant termination of the program. From a technical perspective, to use an evaluation in this way is not customary and it is highly unlikely that the evaluation will yield definitive enough information during its execution about ill effects to justify termination of the program. At the same time, the risk of attaching a "red flag" function to the evaluation is that this greatly elevates the stakes around obtaining any negative information, and may inadvertently lead to politicizing the evaluation itself. The TERG strongly recommends that the Ad Hoc Committee modify the guidance regarding the use of the independent evaluation so that it focuses exclusively on learning and obtaining information by the end of the evaluation that serves future decision making.

Accordingly the TERG strongly recommends that the Ad Hoc Committee adopt a multi-criteria approach for its recommendations on the meaning of the evaluation. Ad Hoc Committee may consider using the approach of a balanced scorecard with explicit criteria, and avoid an approach that uses a single indicator for decision making.

Issue 4: Logo and branding

The TERG notes the decision of the Board at its 20th meeting that all ACTs co-paid by the AMFm will have a universal logo. The TERG notes the Board's request to RBM partnership, to encourage other financiers of quality-assured ACTs to adopt the same logo. The TERG recommends that the independent evaluation include studies of how well AMFm Phase 1 achieves the intended effects of the logo, including: the use of the logo by countries for branding and communication campaigns; plausible effects of those communication campaigns on the sales of co-paid ACTs, even if such evidence is limited to qualitative data in view of the short duration of implementation; and the usefulness of the logo in facilitating recall by service providers and patients during outlet studies of ACT purchase and use. At the same time, the TERG recommends that the evaluation include studies of the effects of the logo on quality-assured ACTs that do not have the logo.

Issue 5: The contribution of TERG

The TERG notes the potential benefits to the Global Fund of learning from this evaluation. Accordingly, the TERG welcomes the opportunity for close collaboration with the Ad Hoc Committee, and recommends the preparation of updated guidelines for the TERG's work on the evaluation of AMFm Phase 1. Similarly, the TERG welcomes the opportunity to discuss with the Expert Advisory Group that has been convened by the Secretariat.

Conclusion

The TERG is convinced that the evaluation can yield important information about the potential value of the AMFm mechanism that will be useful for future policy decisions, including about the operational aspects and the effects on those who are intended to benefit from this use of scarce financial resources. That will occur if and only if all parties take into consideration from the outset the limitations on measurement that are imposed by real-world conditions. However, if there is scope for the Board to consider increasing the available financial resources and/or extending the duration of implementation significantly (with additional resources to support that implementation), then the TERG can work with the Ad Hoc Committee and the Secretariat to develop a different evaluation plan that will respond to a fuller set of evaluation needs. The TERG appreciates the opportunity to contribute to the independent evaluation of the AMFm, and looks forward to future interaction and collaboration with the Ad Hoc Committee.