



**UNITAID EXECUTIVE BOARD  
SPECIAL MEETING ON DIAGNOSTICS PROPOSALS  
26-27 MARCH 2012**

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## **1. ADOPTION OF THE AGENDA**

THE CHAIR opened the Special Session of the Board on Diagnostics Proposals, reminding that it is the first time the Board is evaluating and deciding funding proposals screened through the new selection process approved by the Board in June 2011. THE EXECUTIVE DIRECTOR announced the request of a McKinsey representative to be an observer. After discussion, considering that this was a restricted session, THE CHAIR told the McKinsey consultant that she was excused and would be welcomed to the next ordinary session.

### **DECISION**

**THE EXECUTIVE BOARD adopted the agenda.**

THE CHAIR congratulated the Secretariat for its excellent work during the last meeting in Paris, December 2011.

## **2. OVERVIEW OF PROPOSALS FOR FUNDING DECISIONS**

THE EXECUTIVE DIRECTOR presented an overview on the new proposal screening process started in 2011 and the time-line used to accept or refuse funding. He outlined the central role of the PRC in the final evaluation of the proposals. This call was posted in September, reviewed by the PRC in February 2012, and the selected proposals were being presented to the Board in this special Session. This "Call for Diagnostics" marked the first time the entire new process and all the tools had been used and it was a huge success. The Secretariat had noted a dramatic improvement in the quality of the proposals submitted. New partners had submitted a proposal and the landscapes provided proved to be a good basis for understanding context, issues and priorities. He reminded the Board about the overall approach to prioritization and updated the Board on how the diagnostic proposals would fit with market shortcomings and opportunities identified in diagnostics landscapes.

## **3. REPORT OF PROPOSAL REVIEW COMMITTEE**

THE PRC CHAIR reported to the Board. He began by thanking his predecessor as PRC Chair, Prof. McIntyre, for his hard work in establishing many of the tools that the PRC used in its assessment of the LOIs for diagnostics. The new Vice Chair of the PRC is Dr Stephanie Simmons; she was elected unanimously by the PRC. Prof. Ralph Edwards is now the PRC member for regulatory affairs. Dr Santha-Devi Thottikkamath (TB) and Dr Eric Donelli (malaria) have joined the PRC and Dr Susan Fiscus attended the last meeting of the PRC as an ad hoc member for HIV diagnostics.

The tools developed by the Secretariat for the LOI and proposal review processes were very useful. THE PRC CHAIR expressed concern about the size of the appendices

(some were hundreds of pages long) in a number of the proposals and about the clarity of the allocation of some budget items. Some of the proposals overlapped and two proponents were asked to submit a joint proposal. However, this did not result in a tightly integrated proposal. In some cases, it was difficult to work out the relationships between the various members of the consortia that were submitting proposals. Monitoring and Evaluation (M&E) plans were often minimal. A major challenge for all of the proposals was the issue of sustainability: details of how the projects would be continued after the ending of UNITAID funding were sparse.

The ethical relationship between increasing access to diagnostic tests and to subsequent treatment, if required, was debated by the PRC. Providing appropriate treatment was outside the scope of the proposals, but it was important to determine if diagnosed patients would be able to access treatment.

THE PRC CHAIR stressed that the overall scoring for each proposal should not be regarded as an arithmetical sum of the individual scores because this would not reflect the number and complexity of the issues that the PRC considered when reviewing proposals. Proposals were classed as: recommended for funding; recommended for funding if certain issues could be resolved to the Secretariat's satisfaction; recommended for funding if certain issues could be resolved to the PRC's satisfaction; and not recommended for funding.

THE PRC CHAIR concluded by saying that he was happy to answer questions from the Board. THE GATES FOUNDATION asked how new members of the PRC were appointed? He suggested that the PRC should ensure that proponents present more data on the public health impact of their projects so that it would be easier to check the underlying assumptions for each project. He suggested that the PRC assumption that UNITAID does not fund pilot studies because they do not have a public health or market impact should be discussed. THE GATES FOUNDATION called for more work to be done on defining the concept of 'value for money' and more consistency between the reviews of the various projects. THE PRC CHAIR responded that the replacement members had already undergone the appropriate screening process and were pre-approved by the Boards so there was no need to involve the PSC in their appointment. THE PRC CHAIR agreed that it was important to increase the numerical data supplied in the proposals and to define 'value for money' more precisely. He explained that a core group of reviewers reviewed each proposal and then their report was discussed by the PRC until a consensus decision was reached. He accepted that a greater degree of consistency between the various reports would assist the Board in its decision making process.

#### **4. FUNDING IMPLICATIONS**

THE SECRETARIAT provided an overview of UNITAID's finances and reassured the Board that, regardless of the funding decisions made during the current meeting, it is financially feasible to launch another call for proposals in 2012. THE REPRESENTATIVE OF FRANCE commented that it is very important that the Board has a very clear view of the decisions that they are taking in terms of complementarity and logic. THE

REPRESENTATIVE OF FRANCE believes that this will enable the Board to add value to the work of the PRC. THE REPRESENTATIVE OF THE UNITED KINGDOM described the Secretariat's presentation as very healthy and positive. She reminded the Board that several interesting opportunities will present themselves at the end of 2012 and that UNITAID must get as much value out of its projects as possible by ensuring the budgets for current proposals are appropriately managed down where possible by the Secretariat. THE REPRESENTATIVE OF NORWAY stressed that the Board should make its decisions on the basis of the projects fit with the landscape and UNITAID's vision. She called for the Board to trust the technical experts of the PRC in terms of their assessment of each project. THE REPRESENTATIVE OF COMMUNITIES LIVING WITH THE DISEASES agreed with the Representative of France and added that it was very important to ensure that the projects deliver at the country and beneficiary levels. It is very important that the diagnostic or therapeutic products are not stockpiled but used by the communities in need.

## **5. UPDATE ON THE 5-YEAR EVALUATION (5YE)**

THE CHAIR OF THE INDEPENDENT STEERING COMMITTEE (ISC) thanked the Board for its endorsement of the ISC recommendation to contract ITAD Ltd. to serve as the working-level evaluation team (EVT) for the first independent 5-Year Evaluation of UNITAID. This was the first time that an independent evaluation of UNITAID's overall programme would be conducted.

All three ISC members participated in the Selection Panel. The screening process led to a review of eight bids from large and small firms in Africa, Europe and North and South America. Proposals were assessed on the basis of their technical merit considering the following criteria:

- the quality of the overall proposal (including the degree of understanding of UNITAID's needs);
- the appropriateness of the proposed approach given UNITAID specificities;
- the experience of the team or firm in carrying out related assignments;
- the qualifications and competence of the consultants proposed for the assignment.

She introduced ITAD consultants Mr Sam Mc Pherson and Mr Soren Andreasen who will serve as EVT co-project managers. The ISC had vetted the experts for conflict of interest. ISC will oversee progress of the EVT's work in the coming months. The Evaluation Team will also prepare for the Board's endorsement in April, a 5YE Inception Report, which will provide details on the proposed methodologies, processes and workplan. Members were invited to provide comments to the EVT on their expectations of matters to be addressed in the Inception Report.

THE REPRESENTATIVE OF ITAD, reminded that the 5YE report will aim to be an instrument for strategic development. Going through the Terms of Reference (TOR) in detail, the team noticed that some goals were ambitious and listed key questions that would need to be asked.

THE SECRETARIAT reminded that members at the 2011 Board Retreat had acknowledged that the question of value for money (VFM) was widely embraced by the health community, but that VFM was defined differently by various organizations. They had engaged a taskforce to identify a common definition, but this had proven difficult. Settling on a common understanding continued to be a challenge. The EVT would be assessing how best to measure UNITAID's impact, but emphasized that gaps in market impact data, particularly at national and regional level require assessment at a very high level, and this would be difficult to quantify. Critical gaps in primary data would be addressed through triangulation of secondary sources and use of other proven methodologies.

THE ISC CHAIR noted that the proposed workstreams would look at components used by many institutions to assess VFM, and that although a specific VFM analysis might not be used, the aim would be to enable stakeholders to see VFM from their own perspectives through the answers to the evaluation questions asked.

The Board took note of the presentation of the Chair of the Independent Steering Committee and welcomes the ISC Chair's notation that regular updates will be provided to the Board and PSC.

## **6. PROPOSAL CHAI/UNICEF: "ACCELERATING ACCESS TO INNOVATIVE POINT-OF-CARE HIV DIAGNOSTICS"**

### **Overview (key points extracted from proposal)**

This project will address market shortcomings, in terms of barriers to entry and uptake of new diagnostic technologies, by accelerating access to high quality point of care (POC) HIV diagnostic products. Over a 4 year period, CHAI and UNICEF propose to undertake a set of activities that will simultaneously engage both the supply and demand sides of the market in 7 high volume, early adopter countries (Ethiopia, Malawi, Mozambique, Kenya, Tanzania, Uganda, and Zimbabwe). Together, these countries comprise ~30-35% of the global demand for CD4, early infant diagnosis (EID), and viral load (VL) testing (pages 5-6, of the Project submitted by CHAI and UNICEF). Funds requested from UNITAID: USD 95,960,738.

### **Proposal Review Committee (main points)**

This is a 4 year phased proposal, looking at 7 key outputs: (1) to reduce the cost of POC HIV test; (2) to increase national and international regulatory approvals of POC technologies; (3) to drive national and international guidance on POC testing; (4) to increase uptake of POC tests; (5) to establish operational processes and guidance; (6)

to increase the number of POC products and suppliers <sup>1</sup> ; and (7) to transition from UNITAID funding to other sources of funding in order to sustain this intervention over time. An initial one year approval was sought, with provision to extend it to a total of 4 years. Negotiations with the Secretariat will take place to finalise an appropriate contract.

The PRC recognizes that there are uncertainties about precisely which product(s) will be used, but the project appears to be well positioned to take up new tests as they enter the market.

72% of the budget will be spent purchasing commodities, so it is not, in itself, an innovative intervention.

The PRC stated that the 2 organizations have a strong record in price negotiation, and they also have in-country capacity.

The regulatory approval processes for diagnostics are very variable and this is a challenge, not just for this proposal but for all projects focused on diagnostic technologies.

The PRC considered that, given the scale of the commodity purchase, the number of patients and the number of countries involved, the reduced prices are feasible and can be attained. There is a chance of sustainable market impact and the ability to set prices so that other countries can benefit.

Value for money: the proponent anticipates price reductions. This project is aligned with CHAI's paediatric and second-line HIV treatment projects.

The PRC's recommendation is that this project can be funded, subject to the Secretariat obtaining a number of clarifications from CHAI.

### **Board discussion (main points)**

The proposal is complementary with the MSF, PATH/UNICEF and CHAI/PATH proposals. There is a significant overlap with the MSF proposal in terms of the countries. The potential to combine some aspects of these projects was queried. (REPRESENTATIVES OF THE UNITED KINGDOM AND THE GATES FOUNDATION).

UNITAID must avoid creating a monopoly in the market and deal with intellectual property (IP) issues in relation to diagnostic technologies. It was acknowledged that UNITAID support of a 'first to market' diagnostic product might reduce the incentives for other products to be developed/be launched into the market. Patent issues may have to be resolved. Cross licensing opportunities might encourage new suppliers to enter the market. (REPRESENTATIVES OF NGOS AND BRAZIL AND PRC CHAIR).

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<sup>1</sup> The PRC noted that that this indicator is an overlap with what it is proposed in the CHAI-PATH proposal.

The link between diagnostic testing and provision of treatment was highlighted: people who are diagnosed with a specific disease should receive the appropriate treatment. The proposal does not appear to explain how this will be achieved (REPRESENTATIVE OF COMMUNITIES LIVING WITH THE DISEASES)

UNITAID should consider involving more stakeholders in the financing of the project in order to avoid the risks that may arise if UNITAID finances 100% of this project. (REPRESENTATIVE OF BRAZIL) A first year commitment is reasonable (REPRESENTATIVE OF NGOS). The management costs are too high (the proponents are requesting 15%). (REPRESENTATIVE OF FRANCE).

Transition planning is required. A detailed and pragmatic transition plan should be provided. (THE GATES FOUNDATION).

The Board decided to fund up to USD20 million for the first year of the project.

### **DECISION**

**THE EXECUTIVE BOARD adopted by consensus Resolution no 5 (document UNITAID/EB15/SSDP/2012/R5), as amended by members during the meeting.**

## **7. PROPOSAL FRANCE EXPERTISE INTERNATIONAL (FEI) "OPEN POLYVALENT PLATFORMS (OPP) FOR A SUSTAINABLE ACCESS TO QUALITY AND AFFORDABLE VLT IN RESOURCE-LIMITED SETTINGS"**

### **Overview (key points extracted from proposal)**

The project attempts to create Open Polyvalent platforms and persuade a large number of suppliers from different areas, each of whom are making a piece of the platform, to contribute to one operating system. This project is based on the concept that different diagnostic technologies are needed at different administrative levels: POC testing takes place at a peripheral level (e.g. antenatal clinic, vaccination clinic) while high volume equipment is needed for the number of tests that are performed in a centralised reference Laboratory. Funds requested from UNITAID: USD 8,720,320.

### **Proposal Review Committee (main points)**

PRC recommended not funding this proposal because of its relatively small public health impact; the lack of sustainability of its market impact; and the difficulty of transitioning the intervention outside research settings.

The countries selected for the project only have a relatively modest number of patients with HIV infection and a fairly small number of patients on treatment. The public health impact would, therefore be modest.

The need for different technological interventions based on administrative levels alone is not clearly explained; for example:

- There is no clear definition of district level – this varies from country to country.
- Selecting the appropriate diagnostic technology depends on multiple factors and not just on the administrative level. The choice of diagnostic technology depends on the size of the population, transport availability, infrastructure, pathology/disease burden in the area, etc. For example, a centralised diagnostic technology may be suitable for a large and dispersed population with good access to transport, while POC tests might be appropriate for urban clinics that cater to a population with a low HIV disease burden.

Concerns were expressed about the guarantee of post-service delivery for OP systems:

- No one supplier takes responsibility for maintenance and repairs of the system. This is a common and inherent problem with OP systems. There is, therefore, a fundamental concern about the long term sustainability of OP systems in diagnostics.
- Experience with the OPP is predominantly in research laboratories, which are operated by the consortium's members.

There was insufficient information about the pathway towards commercialization of the OPP, and the roll out of the project to other regions/countries after the pilot phase has been completed.

Insufficient explanation on the leverage of this project and its interactions with other interventions were provided.

### **Board discussion (main points)**

A number of Board members supported the OPP proposal and believed that the project approach is in line with UNITAID's mandate. (REPRESENTATIVES OF FRANCE, THE NGOS, AND THE GATES FOUNDATION AND THE CHAIR) They considered that favourable aspects of the project include: it is a pilot project; it is innovative; and low cost. The PRC Chair noted that there is a difference of opinion about the innovative nature of the OP approach: some experts consider that it is already obsolete due to technological advances, while others consider it worthwhile.

THE BOARD accepted that there were certain risks associated with the innovative aspects of the project but did not consider that this should be the basis for rejecting the proposal.

THE BOARD proposed that the willingness of the proponents to rework certain aspects of the proposal should be assessed and instructs the Secretariat to engage in further



discussions with FEI and to report on the outcome of these discussions at the next Board meeting.

The following items should be addressed:

- Develop a business plan with a very clear pathway to commercialization.
- Address the issue of which supplier(s) is responsible for ongoing maintenance and trouble shooting, and how these activities will be funded.
- Address the intellectual property (IP) issues, which are significant for diagnostic machines and may impact on the capacity of this OP to be commercialised.
- Present a standardized package to simplify the scale up of the OP so that it can be launched in other countries where the method is not established and/or the staff are less skilled than those working on this project.
- Simplification of the project.
- Clarify the organization of the project and the respective responsibilities of the personnel working within the consortium.
- Justify the project's potential to meet certain needs in specific countries and situations.
- Discuss the potential of industrial upgrades to the system.

THE BOARD found the project extremely interesting, provided that the proponents provide the requested clarifications.

**Note:**

THE REPRESENTATIVE OF THE UNITED KINGDOM suggested that the programme raised questions on the criteria for UNITAID proposals e.g. it raised questions for the future strategy discussion regarding UNITAID involvement in demonstration projects. Additionally, repeatedly asking for proposal revisions and resubmissions, raised a question as to how we are managing proponent expectations. This needs to be considered carefully given the opportunity cost for all involved.

**DECISION**

**THE EXECUTIVE BOARD adopted by consensus Resolution no 7 (document UNITAID/EB15/SSDP/2012/R7), as amended by members during the meeting.**

**8. PROPOSAL CHAI/PATH: "ACCELERATING MARKET ENTRY OF LOW COST DIAGNOSTICS"**

**Overview (key points extracted from proposal)**

The goals of the proposal are to a) develop a competitive marketplace for HIV and TB point of care (POC) diagnostics by expanding the pipeline for new products and promoting market entry for new suppliers and b) to influence the demand side by promoting diagnostic uptake at country level and making the demand transparent to

suppliers. The aim is to accelerate the development and market entry of new high quality and lower cost HIV/TB POC products. It takes an innovative look at complex diagnostic markets and proposes to overcome market challenges by providing market intelligence to encourage development of needed low cost diagnostic tools. CHAI and PATH propose activities aimed at making the market more attractive for investment in the sector, as well as activities aimed at making the market more competitive overall. Funds requested from UNITAID: USD 8,410,573.

### **Proposal Review Committee (main points)**

There is considerable overlap between this project and the one proposed by CHAI/UNICEF.

The PRC questioned how the technical information and guidance provided by this project would differ from that obtained via the CHAI/UNICEF project.

The project will not have an immediate public health impact (within the 3 years of the project).

The PRC considered that it was very unlikely that the project's aim to bring four products to market in a 3 year period would be successful.

Reviewers had concerns about potential duplication with other donor funded-activities and the high budget for international staff.

The proposal is not supported due to the various drawbacks cited above.

### **Board discussion (main points)**

THE REPRESENTATIVE OF THE UNITED KINGDOM agreed with the PRC's assessment of the proposal.

THE GATES FOUNDATION noted that it was a common theme amongst the proposals that the proponents wanted to carry out a landscape analysis. It might be more efficient for the Secretariat to undertake landscape analyses and make them available to the community as a public good. The PRC Chair agreed with these statements.

THE GATES FOUNDATION suggested that this proposal should be merged with the one from CHAI/UNICEF. He acknowledged that an innovative aspect of this proposal was that low cost tests should be developed in countries such as Brazil and China. THE SECRETARIAT responded that the proponents were working at early stages of the development process and it was challenging to see how low cost manufacturers could be encouraged to enter the HIV or malaria diagnostic areas at this early stage. There might be the potential to attract new developers into TB diagnostics but there is considerable financial support for the GeneXpert technology and so this area might not be very attractive. THE PRC CHAIR agreed with these statements and commented that it might be possible to negotiate with the proponents.

## **DECISION**

**THE EXECUTIVE BOARD decided not to fund the proposal and adopted by consensus Resolution no 1 (document UNITAID/EB15/SSDP/2012/R1.**

### **9. PROPOSAL ANDI/PATH: "CAPACITY DEVELOPMENT INITIATIVE TO ACHIEVE SUSTAINED ACCESS TO QUALITY ASSURED POINT-OF-CARE DIAGNOSTICS IN AFRICA"**

#### **Overview (key points extracted from proposal)**

The aim of this proposal is to address the lack of access to critical diagnostic technologies for malaria, HIV and TB in Africa by building capacity for technology transfer and local manufacturing of these products. Phase 1 is the subject of this proposal, although three phases are envisaged:

1. Pan African market and gap analysis which expected to result in a landscape analysis;
  2. Pilot implementation of selected technology transfer opportunities and local production;
  3. Transition from UNITAID funding to a broader funding base.
- Funds requested from UNITAID: USD 3,247,333

#### **Proposal Review Committee (main points)**

The PRC reviewers noted overall weakness such as the links between the public health problem, lack of access of diagnostics and local production. There are data resources already existing in the public domain that have not been considered. The proposed market landscape should have been done prior to applying to UNITAID

It appears that the proponents are not the most appropriate actors to carry out the project, since they are a network of researchers and not of manufacturers.

The proposal does not specify which diagnostics would be explored.

The solution to the access of diagnostics tests in Africa is not convincing, i.e. how issues of affordability, accessibility and supply chain challenges would be addressed by technology transfer and local (African) manufacturing when existing diagnostic technology is already available and does not justify an intervention to try to encourage additional manufacturers to enter the market.

No concrete market changers are discussed with quantifiable data such as what is new in the market or what will be forthcoming in the next 3 years and what activities, technologies, policies or products may potentially influence the current shape, size or structure of the current market.

The PRC recommended that this proposal should not be funded.

### **Board discussion (main points)**

The consensus of the Board was that this proposal should not be funded.

### **DECISION**

**THE EXECUTIVE BOARD decided not to fund the proposal and adopted by consensus Resolution no 2 (document UNITAID/EB15/SSDP/2012/R2).**

## **10. PROPOSAL WHO/FIND/STTB: "SCALING UP ACCESS TO CONTEMPORARY DIAGNOSTICS FOR TUBERCULOSIS (TB) WITH A FOCUS ON HIV-ASSOCIATED TB, DRUG-RESISTANT TB AND EARLY TB CASE DETECTION : A 'TECHNOLOGY PUSH/DEMAND PULL' APPROACH BASED ON ECONOMIES OF SCALE AND INNOVATIVE INTERVENTIONS"**

### **Overview (key points extracted from proposal)**

This project aims to expand access to GeneXpert TB diagnostic technology in 33 high-burden countries in pursuit of the targets of the Global Plan to Stop TB 2011-2015. It would be coordinated by a consortium composed of the WHO Stop TB Department (WHO-STB), Stop TB Partnership (TBP) and the Foundation for Innovative New Diagnostics (FIND). Implementing Partners would include: Global Laboratory Initiative (GLI), EXPAND-TB, TB REACH, IRD (Interactive Research and Development) and the ASLM (African Society for Laboratory Medicine). Funds requested from UNITAID: USD 60,428,279.

### **Proposal Review Committee (main points)**

Detailed information is required about the recipient countries' readiness for the project, including the potential additional laboratory costs related to implementation of GeneXpert MTB/RIF, and the cost of providing appropriate treatment to diagnosed patients, especially those who are found to be infected with multi drug-resistant TB (MDR-TB).

The proponent should confirm that the formula used to calculate the estimated number of MDR-TB cases and, hence, the quantity of diagnostic tests required, does not dramatically inflate the estimated number. If it does, the main assumptions that support the proposal (i.e. country need for commodities, operational budget, etc.) would be altered considerably.

Public health impact: the statistical basis for the estimation of the number of 'TB cases detected' and of 'lives saved' needs to be further clarified. The proponents should state what proportion of those currently without access to diagnostic tests would have access to improved diagnostic capacity as a result of this project.

Clarification on the TB diagnostic market landscape is required. Even though GeneXpert MTB/RIF is highly recommended by WHO, UNITAID needs to be assured that the proposed request for funding is considered relative to other available products and/or other diagnostics that may enter the market during the period of requested funding.

Market impact: the link between the approval of this project and the lowering of the price of the cartridges used in the machine is not obvious. Would the price decrease occur even without UNITAID support?

### **Board discussion (main points)**

THE BOARD agreed that GeneXpert MTB/RIF represents a breakthrough diagnostic technology, especially for those living with TB/HIV and MDR-TB. GeneXpert scale-up, appropriately coordinated and managed, should therefore be encouraged and supported.

The market characteristics of this proposal are unprecedented from a UNITAID point of view: (i) the intervention involves direct negotiations on price with a manufacturer that holds (and will continue to hold) a market monopoly for the product, while the basis for price reductions in previous UNITAID projects has been to promote competition (usually among generic manufacturers); (ii) the countries that will dictate market impact for MDR-TB treatment and diagnosis are not low income countries (LICs) but BRICS (Brazil, Russia, India, China and South Africa) and middle income countries (MICs).

Price negotiations with Cepheid by the Bill and Melinda Gates Foundation (BMGF) and FIND have been extensive. The current prices agreed by Cepheid (volume dependent: US\$ 16.86, 14.00 or 10.72 depending on the volume threshold or volume independent: based on a US\$ 11.1 M 'buy-down') are quite competitive for a relatively small company (US\$ 277.6 M annual revenue and US\$ 2.6 M net income in 2011). Further price reductions may or may not be possible. In order to determine whether cartridge prices can be reduced further, the following considerations are relevant: a better understanding of the cost structure used by Cepheid for the cartridges; a collective approach and aggregation of demand (monopsony) vis a vis Cepheid by major buyers; and a negotiation approach couched in public health objectives rather than solely Cepheid's commercial outlook. In relation to aggregated demand, there appears to be a major gap in this proposal insofar as the country with the largest projected demand – South Africa – is not included as a key proponent.

UNITAID's value-add to this proposal has not been articulated sufficiently clearly. Without UNITAID financed volumes of GeneXpert cartridges, a volume associated price reduction of US\$ 14.00 can already be achieved based on the volumes procured by others (private and EME sales, TB REACH) plus South Africa. A further reduction to

US\$ 9.98 is based on a US\$ 11.1 M 'buy-down', which is requested from UNITAID without a clear indication of why this investment should come from UNITAID versus another donor and/or where the investment fits with all other major investments related to global GeneXpert scale-up/roll-out. The question of why UNITAID is uniquely placed to make the difference was posed. THE GATES FOUNDATION asked whether the Board had any objections to the 'buy-down' approach: none of the Board members voiced any concerns. THE GATES FOUNDATION requested that this lack of objection be minuted.

The cost effectiveness arguments of this proposal are quite strong, albeit without a full acknowledgement of the limitations of the studies upon which they are based. The cost-effectiveness question should be considered separately from that of affordability; moreover the affordability of GeneXpert should also be looked at alongside the relative affordability of other essential diagnostics e.g. CD4, VL and EID.

The link between scaled up diagnosis through GeneXpert and the related increase in treatment requirements is critical, but is not directly addressed in the proposal. More information is needed (from Stop TB, the Global Fund, Countries etc.) on the ability of the countries included in the proposal to be able to treat the additional TB patients (particularly MDR-TB cases) detected as a result of GeneXpert roll out (both from a medicines access and programmatic capacity perspective).

The absorptive capacity of the countries is this proposal needs to be validated and further information presented on how the numerous challenges of implementation (training, equipment calibration, policy changes to introduce new diagnostic algorithms, procurement and supply chain management etc.) will be addressed (by whom, with what funds, etc.)

### **Board conclusions**

The proponents should revise their proposal responding to the questions/requests for clarification from the PRC and the concerns of the Secretariat and the Board. The proposal should be resubmitted to the PRC core group, followed by a teleconference with the full PRC, after which the PRC will submit its recommendations to EB16.

In parallel, THE BOARD has authorized the Secretariat to directly explore with relevant parties mechanisms that may lead to an additional price reduction of the GeneXpert cartridges, including options involving stakeholders not yet included in the proposal and alternatives to the 'buy-down' approach proposed. THE SECRETARIAT will communicate the outcomes of its discussions to the PRC.

### **DECISION**

**THE EXECUTIVE BOARD adopted by consensus Resolution no 8 (document UNITAID/EB15/ SSDP/2012/R8), as amended by members during the meeting.**

It was agreed that the PRC will present a further report with recommendations at the next Executive Board meeting (EB 16).

## **11. PROPOSAL PSI: "CREATING A PRIVATE SECTOR MARKET FOR QUALITY-ASSURED RDTs IN MALARIA ENDEMIC COUNTRIES"**

### **Overview (key points extracted from proposal)**

The proposal was submitted by a consortium led by Population Services International (PSI), which includes FIND, the Malaria Consortium and WHO. The proposal seeks three years of project funding, with the aim of improving how malaria is diagnosed and treated in the private sector. The proponents requested USD 34 million from UNITAID; the balance of the project funding (USD 43 million) will come from other sources. The overall objective of the project is to create a private market for rapid diagnostic tests (RDTs) for malaria in five AMFm countries, namely, Madagascar, Nigeria, Kenya, Tanzania and Uganda. RDTs are a more practical option than microscopy for implementation of WHO recommendations in resource poor settings. As a result, RDT scale-up in the public sector is underway. However, 40-60% of the population in malaria endemic countries seek care and treatment for febrile illnesses from the private sector, where RDTs are nearly non-existent. Where RDTs do exist, they are usually more expensive than the subsidized ACTs made available by AMFm in the target countries. Ideally, all vulnerable populations should have easy access to providers that stock RDTs, provide ACTs when a client tests positive or offers the appropriate treatment or referral for other febrile illnesses. Funds requested from UNITAID: USD 34 million.

### **Proposal Review Committee (main points)**

The PRC acknowledged that this is a potentially important project and it is well recognised that the laboratory investigation and diagnosis of malaria in the target endemic countries is inadequate. However, the available epidemiology regarding the diagnosis of malaria and laboratory practice is not well described for the target countries. PSI has used its own data from ACTwatch and has documented that the availability of RDTs in the private sector ranges from 0.4% - 4% in the target countries. It is not stated what this metric actually represents regarding the denominator.

It is not clear how the expected project outcomes can be achieved, based on the current availability of RDTs: 40% of people seeking fever treatment through private sector outlets in the past two weeks received an RDT; 60% of people testing positive for malaria, using an RDT in the private sector in the past two weeks, received appropriate treatment according to national policy; 60% of people testing negative for malaria, using an RDT in registered private sector outlets in the past two weeks, did not receive ACT treatment.

The public health impact would be considerable if community behaviour is changed, and if prices were sustained, patients would have access to a product that would be useful.

The PRC's overall recommendation is 'approval, subject to clarifications', based upon the recommendation that all of the major project outcomes would require review and

that the proponent should be given the opportunity to respond within the timelines recommended for re-submission to the Executive Board.

### **Board discussion (main points)**

Several Board members expressed concerns that the timeline of the project is too short to achieve the ambitious programmatic targets; that the baseline data were not complete or accurate; and that the proposal was not very innovative nor good value for money. Other discussants expressed concern about the linkage with AMFm, as Phase 1 of AMFm will finish at the end of 2012 and the future of this project is very uncertain, regardless of the results of the Independent Evaluation.

It was suggested that the proponents should respond to specific questions and submit a new proposal with a phased implementation plan to the PRC and then to the Board for consideration at its June 2012 meeting. It was accepted that there is a very limited time frame for this suggestion to be implemented because the AMFm Phase 1 will finish at the end of 2012.

In conclusion, THE BOARD proposed that the UNITAID Secretariat should review a revised proposal that will be submitted by the proponents and manage the negotiations leading to the preparation of an agreement between the proponents and UNITAID within the limits of the Board project budget ceiling of USD 34.3 million.

### **DECISION**

**THE EXECUTIVE BOARD adopted Resolution No 6 (document UNITAID/EB15/SSDP/2012/R6), as amended by members during the meeting with the abstention of the Representative of NGOs.**

## **12. PROPOSAL FIND: "SUSTAINABLE GLOBAL AND NATIONAL QUALITY CONTROL FOR MALARIA RAPID DIAGNOSTICS TESTS"**

### **Overview (key points extracted from proposal)**

FIND (Foundation for Innovative New Diagnostics) submitted a proposal entitled "Sustainable global and national quality control for malaria rapid diagnostic tests". There are a large number of malaria rapid diagnostic tests (RDTs) on the market but there are weak or non-existent in-country regulatory and approval processes for those tests and little on-going assessment of adherence to quality standards. This proposal has three elements: (1) continue existing RDT product testing using the two central laboratories; (2) continue lot quality RDT testing, using the two existing central laboratories, and transition these two programmes to the use of recombinant malaria parasite antigen panels; and (3) transition to a manufacturer-funded process for RDT quality assurance within countries taking advantage of the new recombinant technology.

Funds requested from UNITAID: USD 9.5 million



## **Proposal Review Committee (main points)**

The PRC Chair pointed out the risks involved in the project design including the ability and the willingness of countries to engage in on-going lot quality testing; as well as the trust that country procurement programmes would have in manufacturer-driven testing and the acceptance of the results. Additional PRC concerns included the transition to the recombinant antigen system and moving to a system of payment for quality assurance testing that would be carried out by the RDT manufacturers. Considering all of these risks, the PRC considered that the proposal should include a better risk identification and mitigation plan.

The PRC expressed the opinion that the proposal would enable the RDT market to operate in a different way using innovative technology with a large potential public health impact. The PRC posed seven questions dealing with the viability of the technology, the feasibility of the project time lines, the intellectual property considerations and the solo supplier issues that need to be answered to the satisfaction of the Secretariat before a final agreement can be reached with the proponents.

The last issue identified by the PRC (point 8) concerned the role of WHO in establishing an essential equipment list or an essential diagnostics list; developing a good manufacturing practice risk-based approach to quality assurance in the diagnostics field; and establishing an appropriate global regulatory framework for diagnostics, including RDTs.

## **Board discussion (main points)**

Concerns were expressed about the risks involved in developing a single source of recombinant antigens for testing rather than having more than one source of the antigens.

The sustainability of the business proposal was questioned, especially in relation to every country being able to carry out lot quality testing rather than undertaking this testing at a central level.

There was support for the use of a recombinant antigen system, as opposed to wild type, because of improved quality control; increase cost effectiveness; and increased reliability in terms of field-based quality testing.

The Secretariat was asked to work with the proponent to produce an acceptable (to the Secretariat) revised proposal, work plan and budget, together with a revised business model that would increase the quality and sustainability of the project. THE BOARD agreed to commit a ceiling amount of USD 9,441,177 for this project contingent upon the fulfilment of the three conditions stated in the Board Resolution no. 4.

## **DECISION**

**THE EXECUTIVE BOARD adopted by consensus Resolution no 4 (document UNITAID/EB15/SSDP/2012/R4), as amended by members during the meeting.**

### **13. PROPOSAL MSF: "IMPLEMENTATION OF CD4 AND VL TESTING IN DECENTRALISED, REMOTE AND RESOURCE-LIMITED SETTINGS IN MSF HIV PROGRAMMES"**

#### **Overview (key points extracted from proposal)**

The purpose of the MSF project is to implement routine decentralised testing of viral load for treatment monitoring and point-of-care (POC) CD4 testing for ART initiation, and to investigate the feasibility of such testing in resource-limited settings. The project will benefit patients, and demonstrate the feasibility, programme acceptability in field conditions, sustainability, affordability and the potential market impact of decentralised screening and monitoring strategies. In addition to demonstrating medical benefits and improved operational outcomes, the activities will build a sustainable market for applicable technologies by collaborating with a large number of stakeholders including suppliers, Ministries of Health, large donors, healthcare organisations, etc. The project spans eight MSF-supported HIV/AIDS programmes across 7 African countries: Lesotho (Maseru), Malawi (Thyolo and Chiradzulu), Mozambique (Maputo and Tete), South Africa (uThungulu), Swaziland (Shishelweni), Uganda (Arua) and Zimbabwe (Buhera, Gutu and Chicomba). In parallel, MSF International will support evidence-based decision-making to improve access to the best-adapted tests through publications and interactions with civil society and manufacturers (from the Project Proposal, Page i). Funds requested from UNITAID: USD 28.7 million.

#### **Proposal Review Committee (main points)**

The overall objective of the project is to evaluate different POC testing strategies. It is an operational research project. The aim is to be a catalyst to shape the market, rather than a market intervention based on the volume of tests that are bought.

The PRC was convinced that this is a plausible intervention, and that MSF has a long history of working at a district level.

MSF has provided details of the entire cost of delivering care in the seven target countries and then indicated the amount that would be required for the

implementation of CD4 and viral load testing. Most of the tests, but not all, would be POC. There appears to be a considerable amount of co-finding for the programmes.

The project sites are at remote rural sites, where MSF is currently working and where it has an agreement with the MOH. MSF currently supports over 100,000 patients on ART in these areas. It would be useful to have data on the scale of the diagnostic need in these areas so that it is possible to assess how much of this need the project will address.

The reviewers were concerned that quality issues; in particular, involvement in external quality assessment programmes was not well described in the proposal.

The PRC considered that it is unlikely that this programme could have an impact on the prices of these products because the volumes are fairly small. POC is not appropriate for all settings. For example, it might be more economical for a district hospital that serves a very concentrated population nearby to use diagnostic technologies other than POC.

The PRC questioned an item that provided \$1.69 million dollars to fund a campaign for access to essential medicines. This should be clarified with the proponents.

The PRC considered that this project could be recommended for funding, conditional upon a number of clarifications that should be submitted to the Secretariat.

### **Board discussion (main points)**

This project is complementary to the CHAI/UNICEF proposal: the MSF proposal is a "bottom up" project, while the CHAI/UNICEF proposal is a 'top down' project. (REPRESENTATIVES OF THE UNITED KINGDOM AND NGOS AND THE PRC CHAIR). It was suggested by THE GATES FOUNDATION that the various proponents of the various proposals should explicitly be asked to collaborate.

The question was raised whether the proposal addresses an appropriate number of countries. (REPRESENTATIVE OF THE UNITED KINGDOM). THE PRC CHAIR acknowledged that the PRC had discussed this issue. He added that although the number of sites in each of these countries is relatively small, the number of individuals seeking diagnostic tests could be considerable in a high burden country.

THE BOARD accepted that this project would have a public health impact. The issue of whether a market impact could be achieved with this project, especially if the CHAI/UNICEF proposal were to be funded, was raised by THE GATES FOUNDATION AND PRC CHAIR. It was acknowledged that transparency of pricing of diagnostic technologies would be increased by the MSF project. THE REPRESENTATIVE OF THE NGOS suggested that MSF would need to use pool procurement in coordination with CHAI to obtain the best prices and described the proposal as a 'demand shaping project'.

MSF has good relationships with MOHs and other local authorities/donors, which should translate into resolution of sustainability and transition issues. More details on the programme relationships with governments in the seven countries and how the programmes will fit into national systems and not run as parallel systems are needed. (REPRESENTATIVE OF NGOS).

It was suggested that the MSF project would benefit from a UNITAID landscape analysis on IP for diagnostics, looking at royalty payments, etc. (REPRESENTATIVE OF NGOS). This is already in progress. (THE SECRETARIAT).

Gaining MSF as a UNITAID partner would help to broaden UNITAID's portfolio and provide additional information on the diagnostic market and local conditions, e.g. demand, number and quality of suppliers and products, support/maintenance issues, etc. (THE PRC CHAIR, THE CHAIR AND THE SECRETARIAT).

THE REPRESENTATIVE OF THE COMMUNITIES LIVING WITH THE DISEASES expressed concern about the number of patients covered by this project. During negotiations with MSF, the question should be asked as to whether the coverage of the project could be increased.

### **DECISION**

**THE EXECUTIVE BOARD adopted by consensus Resolution no 3 (document UNITAID/EB15/SSDP/2012/R3), as amended by members during the meeting.**

## **14. A2S2 PROJECT EXTENSION PROPOSAL**

### **Overview (key points extracted from proposal)**

The market of artemisinin has been highly unpredictable: previous over-production and loss of value in the production chain has impacted on the earnings of small scale farmers growing *Artemisia annua*. As a result, farmers and artemisinin extractors engaged in the business had withdrawn from the market and others would find it difficult to enter the market without some support.

The A2S2 proposal asked for upfront funding that would be used as a loan to extractors, who would repay the loan to A2S2 and this money would eventually be refunded to UNITAID. In addition to supporting the production of additional artemisinin, efforts to improve the artemisinin market intelligence and transparency were anticipated. Based on the merits of the project proposal, the UNITAID Board previously approved support for the A2S2 project for two years.

In order to continue the project, the implementing partner has submitted a proposal for the extension of project activities for two more years.

### **Proposal Review Committee (main points)**

The PRC review indicated that a) the project had only started slowly due to the protracted loan negotiations; b) to date, the loan facility has only contributed an estimated 15% of global artemisinin supply; and c) market intelligence sharing has not been helpful, due to the lack of an appropriate information sharing arrangement.

The PRC review indicated that the anticipated supply crisis has not occurred and is unlikely to recur in a way that requires the type of intervention envisaged by the A2S2 proponents. Large companies buying up supplies; there is a spot market; and the imminent introduction of semi-synthetic artemisinin is expected to increase supplies.

Based this assessment, the PRC recommended the extension of the A2S2 should not be funded, but a low cost extension of project activities should be allowed in order to ensure completion of the loan repayment process and refund of the money to UNITAID.

### **Board discussion (main points)**

Three members of the Board (REPRESENTATIVES OF NGOS, THE UNITED KINGDOM AND THE GATES FOUNDATION) expressed concern about the PRC's recommendation. THE REPRESENTATIVE OF NGOS voiced the opinion that support would still be needed for the Artemisinin project, as the market is still volatile. THE REPRESENTATIVE OF THE UNITED KINGDOM suggested that the market intelligence aspect of the project should be strengthened and that support for the Artemisinin conference would be beneficial. THE GATES FOUNDATION also expressed concern over the lack of communication between artemisinin extractors and the global community had a negative impact on farmers' plans to plant Artemisia. With the imminent advent of semi-synthetic artemisinin, farmers and extractors will need even more information on the predicted market shares for semi-synthetic and agricultural artemisinin. THE GATES FOUNDATION supported the idea of continuing to fund Artemisinin market intelligence activities.

After having considered the PRC review and its recommendations, as well as the concerns and opinions of some Board members, THE BOARD unanimously agreed a) not to approve the request for extension of the A2S2 projects, and b) to enable the UNITAID Secretariat to continue providing low cost support until the completion of the loan repayment and its refund to UNITAID.

### **DECISION**

**THE EXECUTIVE BOARD adopt by consensus Resolution no 9 (document UNITAID/EB15/SSDP/2012/R9), as amended by members during the meeting.**

## **15. PROPOSAL WHO: "FACILITATING ACCESS TO POINT-OF-CARE (POC) DIAGNOSTICS OF ASSURED QUALITY IN LOW- INCOME COUNTRIES"**

According to the PRC, no technical proposal was on the table. There was a need for a stronger regulatory device and pre-qualification of medicines. The Board encouraged the development of a stronger proposal.

## **16. SUMMARY OF FUNDING DECISIONS**

Proposal CHAI/PATH: Board decision not to fund.

Proposal ANDI/PATH: Board decision not to fund.

Proposal MSF: Board decision to commit funds up to 28.7 million USD, subject to conditions of the PRC and Board (including complementarity with other diagnostic proposals).

Proposal FIND: Board decision to commit funds up to 9.4 million USD, subject to the conditions of PRC and revised business model towards sustainability.

Proposal CHAI/UNICEF: Board decision to commit funds up to 20 million USD, for first year of project, subject to conditions.

Proposal PSI: Board decision to commit funds up to 34.3 million USD, subject to a revised proposal addressing issues raised by the PRC and the Board.

Proposal FEI: Board decision to instruct the Secretariat to hold further discussions with FEI on issues raised by the PRC and Board, and report at next Board.

Proposal WHO/FIND/StopTB: The Board invites WHO/FIND/StopTB to respond to issues raised by PRC and Board, in particular involving stakeholders in investigating best mechanisms to achieve price reduction.

Proposal A2S2: Board decision to not approve extension. No further loans approved, a revised proposal by i+solutions addressing the scope and the nature of market intelligence to be provided, to the satisfaction of the Secretariat.

THE EXECUTIVE DIRECTOR stated that the Secretariat would take note of all comments made and produce a more relevant document with better assessment of the projects.

## **17. NEXT CALL FOR LOI/PROPOSAL**

THE DEPUTY EXECUTIVE DIRECTOR requested that the Board consider issuing two calls for LOIs: an open call and a focused call on paediatric antiretroviral drugs. He provided support for this proposal. The consensus of the Board was that two calls should be issue as proposed by the Secretariat.

The proposed timeframe is that the calls for the LOIs (open and paediatric antiretroviral drugs) will commence at the beginning of April 2012. The Secretariat will screen the LOIs and invite qualified proponents to submit full proposals by September 2012. The PRC will review the proposals in October 2012 and submit their recommendations to the Board for a decision in December 2012.

### **DECISION**

**THE EXECUTIVE BOARD adopted by consensus Resolution no 10 (document UNITAID/EB15/SSDP/2012/R10), as amended by members during the meeting.**

## **18. OTHER BUSINESS (UPDATE ON THE ADVISORY GROUP ON FUNDING PRIORITIES - AGFP)**

Following a brief introduction in which he provided a summary of the constructive first AGFP meeting held, THE AGFP CHAIR began by remarking that the AGFP would submit a set of proposed prioritisation criteria for Board approval by the end of 2012, following PSC consideration. The priorities endorsed by the Board would inform the subject matter of any ensuing calls for Letters of Intent (LOIs, as well as critically feed into the work being conducted on developing UNITAID's strategy.

THE CHAIR outlined the strategic importance of the AGFP's work for UNITAID. He acknowledged that the global financial situation was having a significant effect on funding for international health projects, but that UNITAID's unique financing model made it uniquely well-placed to expand its funding base and, thereby, its contribution to improving global health. He also called for UNITAID to play a leadership role in sharing global health information and market intelligence.

Amongst the challenges discussed by the AGFP was that of defining value for money in a global health context, depending as it does on the perspective of the stakeholder (e.g. donor, government, patient), as well as the timescale over which value for money is considered. In response to the Secretariat's request that the AGFP indicate areas of particular interest to UNITAID on which the upcoming call for LOIs might focus, the Chair explained that the group had come up with a preliminary list . He

underlined that the AGFP was a small group, limited in terms of managing and organizational capacity and as such would rely on the support of the Secretariat in commissioning studies, such as the remaining landscapes, that would facilitate informed consideration of various areas. The AGFP noted the usefulness of the diagnostics landscapes for the work of the group and that they will not duplicate this. With regard to optimally leveraging synergies within UNITAID, the complementarities between the AGFP and PRC should be more effectively explored going forward so as to capitalize on the potential for capacity building for both groups.

## **18. OTHER BUSINESS (DISCUSSION ON THE DEVELOPMENT OF THE UNITAID STRATEGY 2013-2015)**

The UNITAID Strategy is being updated for the period 2013-15. The following discussion points were made about this issue:

THE CHAIR announced that the Gates Foundation had offered to contribute \$700,000 towards the proposed review of the UNITAID Strategy. He indicated that \$50,000 was available for this work in the current version of the UNITAID budget but that the actual costs are likely to be much higher. He acknowledged that some Members of the Board were concerned that UNITAID would seem over dependent on the Gates Foundation if they provided the funding. THE CHAIR suggested that Board Members and the PSC could choose the consultants who would then be paid by the Foundation. He also mentioned that the WHO process for selecting consultants could be burdensome. THE REPRESENTATIVE OF FRANCE said that transparency throughout the process was critical and asked about the selection process that would be used to retain consultants.

THE REPRESENTATIVE OF FRANCE stated that they wanted to ensure that the Secretariat would lead the strategy review. THE REPRESENTATIVE OF NGOS agreed with this stance.

THE REPRESENTATIVE OF ASIAN COUNTRIES noted that the timing of the strategy review was critical as 2015 coincides with the target date for achieving the Millennium Development Goals (MDGs). Support was expressed for the workplan but concern was expressed that it may be too ambitious. (REPRESENTATIVE OF ASIAN COUNTRIES).

THE REPRESENTATIVE OF NORWAY suggested that a brainstorm session among Board members might be a good way to discuss the ideas put forward in the document. THE REPRESENTATIVE OF NGOS agreed with this idea and proposed that the strategy should focus on how UNITAID could work better with its partners and how UNITAID can ensure impact at country level, including within marginalized populations. THE REPRESENTATIVE OF THE COMMUNITIES LIVING WITH THE DISEASES wished to include 'value for money' in the strategy update.

THE REPRESENTATIVE OF NORWAY emphasised that the landscape analysis of the place of UNITAID in the global health landscape is particularly important. THE CHAIR supported the comment about the landscape analysis.



THE REPRESENTATIVE OF NGOS specified that elements such as how UNITAID could work better with its partners and how UNITAID can ensure impact at country level , including on marginalized populations, should be considered in this process.

THE REPRESENTATIVES OF THE COMMUNITIES LIVING WITH THE DISEASES supported the position of the NGOs and mentioned that value for money and effectiveness at country level as two areas of special interest for them.

THE REPRESENTATIVES OF NGOS AND THE COMMUNITIES LIVING WITH THE DISEASES agreed with France that the financing of the work should be neutral. THE REPRESENTATIVE OF NGOS expressed concern about the Secretariat's work load. THE REPRESENTATIVE OF BRAZIL expressed the view that UNITAID should fund the Strategy update.

THE REPRESENTATIVE OF CHILE emphasised the importance of the Strategy update and its role in refocusing UNITAID's work. THE REPRESENTATIVE OF CHILE called on the Board to discuss how the financial offer from the Gates Foundation would be managed so that transparency, neutrality and the absence of a conflict of interest were maintained.

THE EXECUTIVE DIRECTOR explained that external perceptions of the Gates Foundation's support could be dealt with if the Board agreed upon the funding of the activities. The Secretariat will be in charge of the project. He noted the issues that Board Members had mentioned as being areas of special interest during the Strategy review process. The process will be long and complex; the 5-Year evaluation and the work of the AGFP will support the Strategy review. The WHO procurement process for consultants for budgets above USD200,000 can be cumbersome. He therefore suggested that the selection process could be organized by the Secretariat but the contracting and payments could be supplied by another source, thereby enabling consultants to start work immediately.

THE DEPUTY EXECUTIVE DIRECTOR provided an overview of the Strategy review work that is already ongoing, such as priority setting by the AGFP, the 5-Year evaluation, the landscape analyses, and the development of tools to measure public health impact or value for money. All of these activities are taking place in addition to the Secretariat's normal work, including the upcoming calls for proposals. THE GATES FOUNDATION mentioned that the list of AGFP priorities should undergo further clarification. The strategy update should be the result of a dialogue between the Board, the AGFP and the Secretariat about UNITAID's role and future work.

THE GATES FOUNDATION said that spending a million dollars every three to five years to develop a good strategy for an organization that spends USD300m a year is a good use of money. The offer was made in order to provide funds and flexibility to UNITAID in managing this process. The Secretariat would define the terms of reference for the consultants and select them, while the Foundation would fund and issue contracts their work However, if the Board was not comfortable with this offer, the Gates Foundation would withdraw it.

THE REPRESENTATIVE OF WHO explained that putting a contract in place at WHO is not difficult with proper planning. Any contracts initiated by UNITAID, even with funds from the Gates Foundation, have to go through the usual system. The UNITAID Chair

asked the WHO if the contracting process could be completed within a month, if the Gates Foundation transfers funds to UNITAID for that purpose. THE REPRESENTATIVE OF WHO explained that the Secretariat needed to do preparatory work prior to the launch of a request for proposals (RfP), which could take time. THE EXECUTIVE DIRECTOR stated that the Representative for the WHO had been instrumental in shortening the contracting time for the 5-Year evaluation work and UNITAID would welcome similar support in the future. THE REPRESENTATIVE OF NORWAY cautioned the Board that any decision should not appear as a shortcut to avoid WHO regulations.

THE REPRESENTATIVE OF NORWAY reminded the Board that the budget presented by the Secretariat in December 2011 had been cut by the Board. THE EXECUTIVE DIRECTOR stated that the Board had made a \$2m cut in the budget presented by the Secretariat and that the only way to fund the strategy update from the budget was to increase the ceiling.

THE REPRESENTATIVE OF BRAZIL stated that they would prefer UNITAID to pay for the work. They continued that while additional contributions were welcome, they did not want any difficulties linked to conflicts of interest. Brazil asked if the Board could make a decision with the information already available to Board members.

THE REPRESENTATIVE OF NGOS expressed concern over the timeline presented by the Secretariat and stated that they would support an extension of the timeline and that they thought that the end of year deadline was somewhat artificial.

THE GATES FOUNDATION clarified that the funds that they provide for grants are handled differently from the funds they provide for contracting and that the former takes much longer than the latter. The Gates Foundation would favour an increase in the Secretariat budget to support the Strategy update work.

THE REPRESENTATIVE OF FRANCE said that funding for this increase should first come from a revision of the overall budget.

THE CHAIR reaffirmed the need for UNITAID to follow all applicable rules and regulations. The Secretariat and the Board must be able to select contractors independently. He sought clarification from WHO as to whether the Gates Foundation would be able to pay contractors who have been selected by UNITAID. THE REPRESENTATIVE OF WHO explained that the procurement and selection process cannot be separated from the contracting process.

Given the discussions, THE BOARD authorized the Secretariat to use up to USD 700,000 of its budget for the Strategy.

## **DECISION**

**THE EXECUTIVE BOARD adopted by consensus Resolution no 11 (document UNITAID/EB15/SSDP/2012/R11), as amended by members during the meeting.**

THE CHAIR reminded that the next Board was scheduled for 12 and 13 June 2012.

As there was no other business, THE CHAIR closed the meeting on Tuesday 27 March 2012.

## **ANNEX - LIST OF PARTICIPANTS**

### **BOARD MEMBERS / REPRESENTATIVES**

CHAIR

Dr Philippe Douste-Blazy

VICE-CHAIR CHILE

Alt: Dr Guy Fones

AFRICAN COUNTRIES

Ms Tanja Praya-Gujadhur

Alt: Ms Fernande Mvila

ASIAN COUNTRIES - REPUBLIC OF KOREA

Alt: Dr Dukhyoung Lee

BRAZIL

Ms Maria Louisa Escorel de Moraes

COMMUNITIES LIVING WITH THE DISEASES

Dr Esther Tallah  
(CCAM, Cameroon Coalition Against  
Malaria)

Alt.: Mr Nelson Otwoma  
(NEPHAK)

FRANCE

Alt.: Mr Philippe Meunier

FOUNDATIONS

Mr Girindre Beeharry  
(The Bill & Melinda Gates Foundation)

Alt: Ms Susan Nazzaro  
(The Bill & Melinda Gates Foundation)

NGOS

Ms Kim Nichols  
(African Services Committee)

Alt: Dr Tido von Schoen-Angerer  
(Médecins Sans Frontière)

NORWAY

Ms Sidsel Bleken

Alt: Ms Beate Stirø

SPAIN

Mr Miguel Casado Gómez

Dr Estíbaliz García

UNITED KINGDOM

Alt.: Ms Samrita Sidhu

WHO

Dr Hiroki Nakatani

## **OTHER MEMBERS OF DELEGATIONS**

ASIAN COUNTRIES

Dr Ganglip Kim

BRAZIL

Mr José Roberto de Andrade Filho  
Ms Stephanie Dauch

FRANCE

Mr Stéphane Renaudin  
Ms Geneviève Chedeville-Murray  
Ms Pauline Pannier

FOUNDATIONS

Mr Gene Walther  
(The Bill & Melinda Gates Foundation)

NORWAY

Ms Kirsten Myhr  
Mr Christian Eliassen

NGOS AND COMMUNITIES LIVING WITH THE DISEASES

Ms Jessica Hamer  
Dr Mogha Kamal-Yanni

WHO

Mr Issa Matta

## **PROPOSAL REVIEW COMMITTEE**

CHAIR

Mr Andy Gray

VICE-CHAIR

Dr Stephanie Simmonds

## **ADVISOR GROUP ON FUNDING PRIORITIES**

CHAIR

Prof James McIntyre

## **INDEPENDENT STEERING COMMITTEE – 5YE**

CHAIR

Mrs Johannah-Joy Phumaphi

## **CONSULTANTS – 5YE**

ITAD

Mr Sam McPherson

Mr Soren Peter Andreasen

## **OBSERVERS**

Mr Khalil Elouardighi  
(Coalitions Plus)

Ms Billie-Jean Niewenhuys  
(Stop AIDS Alliance)

## **UNITAID SECRETARIAT**

Dr Denis Broun  
(Executive Director)

Dr Philippe Duneton  
(Deputy Executive Director)

Dr Raquel Child  
(Director, Market Dynamics and  
Operations)

Ms Brigitte Laude  
(Director, Administration and Finance)

Ms Brenda Waning  
(Coordinator Market Dynamics)

Mr Edward Vela  
(Senior Adviser to Executive Secretary)

Mr Frederic Martel  
(Strategy & Planning Officer)

Ms Sophie Genay-Diliautas  
(Board Relations Officer)

Ms Louise Kleberg  
(Technical Officer, PRC & Advisory  
Committees)

Ms Gelise McCullough  
(Technical Officer)

Ms Vibhu Garg  
(Executive Officer)

Ms Susanna Volk  
(Executive Board Assistant)