Minutes of UNITAID's

19th Executive Board Special Session on Proposals

5 May 2014

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Executive Summary

- The UNITAID Executive Board Meeting Special Session on Proposals was held on 5 May 2014 at WHO headquarters in Geneva, Switzerland. The CHAIR OF THE EXECUTIVE BOARD welcomed the participants to the restricted session.
- The agenda was adopted and proceedings commenced at 09.00.
- Prior to the meeting, Declaration of Interest disclosures had been received from France (on France Expertise Internationale), Communities (on NEPHAK / International Federation of the Red Cross), the NGOs (on Coalition Plus, on Remed, on Médecins sans Frontières and on International Treatment Preparedness Coalition), WHO (on Population Services International and on International Federation of the Red Cross) and the Gates Foundation (on Malaria Consortium and on Population Services International).
- The objective of the meeting was to review eleven proposals for funding decisions. The proposals included six grants for point-of-care diagnostics for malaria and HIV corresponding to Strategic Objective 1 (SO1); two for Hepatitis C (HCV) to improve treatment access (SO3); two for Multi-Drug Resistant Tuberculosis (MDR-TB) to streamline regimens and shape the market (MDR-TB) (SO5); and one for malaria prevention (SO6).
- The EXECUTIVE BOARD agreed that UNITAID's strategic focus was to help poor people in low-income countries. However, it was acceptable to fund projects that included some middle-income countries where there was a significant burden of disease, for example multi-drug resistant tuberculosis (MDR-TB) and hepatitis C (HCV).
- A project funding ceiling of US$317 million was available for investment in new grants. Having considered the proposal assessment reports from the Secretariat, and the recommendations from the PRC, the EXECUTIVE BOARD passed resolutions supporting six of the eleven grant applications for a total funding amount of US$157.7 million. Four proposals were rejected. Clarification was requested on certain aspects of the PSI project on HIV self-testing: this proposal will be reviewed at the next meeting of the Executive Board in June 2014 (EB20).

- A summary of the funding decisions is given in the table below:

Res. No.	Area	SO	Proponent	Title	Amount awarded
1	TB	SO5	Partners in Health	Expand New Drug Market for TB	$60,369,772
3	HCV	SO3	Coalition Plus	HIV/HCV Drug Affordability Project	$5,230,000
4	HCV	SO3	MSF	Access to the HCV treatment revolution	$14,981,330
			Tides Centre	Access to treatment for PLHIV in MIC	$6,000,000

8	Malaria	SO6	Malaria Consortium / Catholic Relief Services	Achieving Catalytic Expansion of SMC Services in the Sahel	$67,434,637
			NWGHF	Lynx p 24 EID POC	$3,704,500
			PSI	HIV self testing in Africa	NA For review at EB20

- The VICE-CHAIR OF THE EXECUTIVE BOARD closed the meeting and thanked the Board Members for their constructive contributions to the discussions. He also thanked the Secretariat for its hard work in preparing the proposals and the PRC for the excellent quality of the proposal evaluations. The EB19 Special Session on Proposals closed at 18.20 on Monday 5 May 2014.

1. Welcome and opening of the session

Opening remarks of the Chair

The CHAIR OF THE EXECUTIVE BOARD of UNITAID welcomed participants to the 19th Executive Board Special Session on Proposals. He extended a warm welcome to Gonzalo Vega Molina, the new Board Member for Spain, and thanked his predecessor for his commitment to UNITAID.

The GATES FOUNDATION was unable to attend the meeting in person. However, an audio link was established enabling the GATES FOUNDATION to participate in the discussions. Written responses on all the proposals from the GATES FOUNDATION had been provided to the Chair prior to the meeting.

The CHAIR explained that the objective of the Special Session was to review eleven proposals in the areas of HIV/AIDS (HIV), Tuberculosis (TB), Malaria, and Hepatitis C (HCV). This was the first time that the Executive Board had considered proposals for hepatitis C (HCV), an important co-infection of HIV.

Due to the confidential nature of the discussions, this was a restricted session. Pending the adoption of Declaration of Interest (DoI) principles, all Board Members and Alternates had completed DoI forms prior to the meeting. Disclosures had been received from FRANCE (on France Expertise Internationale), COMMUNITIES LIVING WITH THE DISEASES (COMMUNITIES) (on NEPHAK / International Federation of the Red Cross), the NGOs (on Coalition Plus, on Remed, on Médecins sans Frontières and on International Treatment Preparedness Coalition), the WHO (on Population Services International and on International Federation of the Red Cross) and the GATES FOUNDATION (on Malaria Consortium and on Population Services International).

Discussion

- The NGOs informed the Executive Board that the members of their delegation, for Coalition Plus and Remed projects were not present at the Executive Board meeting. Neither had they been involved in the internal, preparatory meetings that had been held by the NGO delegation prior to the Special Session on Proposals.

2. Adoption of the agenda

The agenda for the 19th Executive Board Special Session was adopted.

During the meeting, the order of the items was modified so that the proposal on Intellectual Property Issues was discussed in the afternoon after the section on HCV.

DECISION

The EXECUTIVE BOARD *adopted by consensus* the agenda for the EB19 Special Session on Proposals.

3. Overview of proposals received

Overview of proposals for funding decisions

The EXECUTIVE DIRECTOR A.I. informed the Executive Board that the Secretariat had received and screened 69 Letters of Intent (LOIs). The most relevant and promising LOIs had been developed into the eleven proposals that would be presented for funding decision. A further proposal was on hold pending the provision of information concerning suppliers.

The eleven proposals covered the disease areas as follows: two for malaria; two for TB; two for HCV; four for HIV and one for Intellectual Property (IP) related to HIV (Figure 1). A project funding ceiling of US$317 million was available to fund new projects

Figure 1 Summary of proposals for funding decisions

Area		Proponent	Title	Amount in Proposal
Malaria	SO1	FEI	Increasing access to affordable RDTs and ACT	$54,835,515
Malaria	SO6	Malaria Consortium / Catholic Relief Services	Achieving Catalytic Expansion of SMC Services in the Sahel	$67,434,637
TB	SO5	Partners in Health	Expand New Drug Market for TB	$57,500,000
TB	SO5	CePAT	Secure the Supply of quality assured API for MDR TB	$5,000,000
HCV	SO3	Coalition Plus	HIV/HCV Drug Affordability Project	$15,200,000
HCV	SO3	MSF	Access to the HCV treatment revolution	$14,981,330
HIV	SO1	IFRC	HIV Oral Fluid tests	$39,603,932
HIV	SO1	PSI	HIV self testing in Africa	$47,601,855
HIV	SO1	NWGHF	Lynx p 24 EID POC	$3,704,500
HIV	SO1	ASLM	New HIV diagnostics in Africa	$8,528,180
HIV IP	SO3	Tides Centre	Access to treatment for PLHIV in MIC	$6,000,000

Market dynamics dashboards were presented for each disease area to give an overview of current market shortcomings and opportunities for intervention. For HCV, several areas for intervention had been identified in the landscape report:

- To increase the affordability of medicines and diagnostics in resource-limited settings
- To facilitate the uptake of new medicines and diagnostics
- To accelerate and improve the efficiency of the approval process for new medicines and diagnostics in low and middle-income countries
- To develop new diagnostic and treatment approaches tailored for resource-limited settings and to demonstrate their feasibility

Discussion

- NORWAY and the GATES FOUNDATION thanked the Secretariat for compiling the Market Dynamics dashboards, which they considered to be extremely useful for guiding Executive Board decisions on future projects. NORWAY requested that an overview of all proposed projects showing the link between individual projects and identified priority interventions under each strategic objective as outlined in the dashboard be part of the written documentation submitted ahead of the Board meetings.
- NORWAY and the UNITED KINGDOM expressed concern about the focus on middle-income countries in the proposals under consideration, as this did not align with UNITAID's Strategy to help poor, low-income countries. The UNITED KINGDOM asked the Secretariat to identify priority areas that were not fully addressed by the proposals under consideration.

  The CHAIR agreed that UNITAID should help the poorest countries first. He said that UNICEF had demonstrated that the most effective way of using aid money was by targeting the poorest people.
- NORWAY requested assurance that there would be sufficient funds available for grant awards in December 2014 if all of the projects under consideration in May were funded. The Secretariat confirmed that, if all of the funds pledged to UNITAID were received in 2014, there would be sufficient resources to award grants in December.
- BRAZIL proposed that burden of disease, particularly prevalence of Multi-Drug Resistant Tuberculosis (MDR-TB), should be taken into account when considering requests for funding. He said that decisions should not be solely based on the country's classification as low- or middle-income. He pointed out that Haiti was the only low-income country in Latin America and the Caribbean where many people are living in poverty.
- THE COMMUNITIES agreed with BRAZIL saying that some of the people living in middle-income countries are too poor to afford medicines. For this reason, they stressed the importance of considering both macro and micro economic indicators and urged UNITAID to consider how to address health issues related to poverty in middle-income countries, rather than simply using the World Bank's classification of countries as a categorization method.
- FRANCE indicated that it is important to have good quality projects and for them to be balanced between the three diseases. He acknowledged that even good proposals might have elements that need to be fine-tuned during the grant development phase and suggested that UNITAID needs a mechanism to achieve this. FRANCE called for clarity in the terms that are used in the review: terms such as 'Phase I', a 'phased approach' and 'evidence of progress' are not clearly defined. There may be a need to request further work on, or more details about, a proposal. FRANCE suggested the Secretariat be given the option of awarding small (micro) grants, as outlined in the UNITAID strategy. This approach could lead to a dialogue between proponents and, ultimately, assist the review process.
- The CHAIR agreed that presentations should begin with a summary of a list of priorities for each disease and identify the gaps in each field.
- The CHAIR said that the Board should discuss how much the Secretariat should work on a project proposal, particularly in view of the amount of time required

to develop immature or poor quality proposals. He added that national governments of middle-income countries have a responsibility to prioritise healthcare for their poorest citizens.

PRC's overview of proposals

The CHAIR OF THE PROPOSAL REVIEW COMMITTEE (PRC) told the Executive Board that the work of the reconstituted Committee had been very successful. The new Committee included six former PRC members and six newly recruited members, all of whom have experience across a wide range of issues that were relevant to the proposals under review. The PRC CHAIR complimented the Market Dynamics team for its valuable input and positive collaboration: nevertheless, he emphasised that the opinions of the PRC are independent of those of the Secretariat. The PRC had not needed to seek additional expertise for this round of proposals, but the PRC CHAIR expressed some concern about the skill set of the PRC for future reviews and said that *ad hoc* input might be needed. He warned that if the PRC were obliged to consult external experts in the future, it would be difficult to complete the review procedure within the allotted timescales.

Referring to a previous request from the UNITED KINGDOM for a clear 'yes or no recommendation', the PRC CHAIR said that the Committee had endeavoured to make its recommendations as clear as possible. However, he explained that, although the PRC can evaluate technical details and offer conditional recommendations, it is not in their remit to advise on funding priorities. He suggested that the Secretariat could offer guidance to the Executive Board regarding priorities based on the landscape analyses.

The CHAIR OF THE EXECUTIVE BOARD thanked the PRC for their dedication in reviewing the proposals.

Discussion

- The COMMUNITIES expressed their appreciation of the hard work undertaken by the PRC for the in-depth technical reviews of the proposals and for the support offered by the Secretariat. They said that there should be early evaluation of each proposal by the Secretariat to ensure that there was a good fit with UNITAID's strategy.
- The UNITED KINGDOM observed that some of the proposals were lacking in innovation and others were country-based, which meant that they did not comply with the principles of country ownership and aid-effectiveness.
- The PRC CHAIR said that the PRC was also cautious about recommending single country proposals unless they offered the possibility of shaping or changing markets or if the information gleaned from a project could be used elsewhere. He added that the PRC is reluctant to support conditional approvals because of the pressure that this places on the Secretariat. He noted that Letters of Intent (LOIs) are an important part of the screening process and if proposals are considered inadequate by the PRC, the applicant should be encouraged to submit a new LOI.
- FRANCE agreed that LOIs were useful to define a proposal but questioned their relevance in setting up feasibility projects.

Strategic context and perspective for the Board

The EXECUTIVE DIRECTOR A.I. assured the Executive Board that all of the proposals were linked to UNITAID's Strategic Objectives as described in the Secretariat's assessments. He said that, thanks to the efforts of the Market Dynamics team, the quality of the proposals was constantly improving.

In response to the earlier question regarding UNITAID's focus between low- and middle-income countries, the EXECUTIVE DIRECTOR A.I. explained that the Secretariat was aware of this issue and had raised it as a topic for discussion during the market forums. The Global Fund was also considering how to address this question. The EXECUTIVE DIRECTOR A.I emphasised that UNITAID's strategic focus remains on low-income countries but said that the high burden of MDR-TB disease in middle-income countries was also recognised. Of the eleven projects under review, four included both low- and middle-income countries: MSF, Coalition Plus and the MDR-TB proposal from Partners in Health. In addition, the Intellectual Property (IP) proposal from the Tides Center concerned improved treatment access for people living with HIV specifically in middle-income countries.

The EXECUTIVE DIRECTOR A.I pointed out that understanding the market dynamics in developing countries is increasingly important in term of access to healthcare products. The size of the market in low income countries may be too small to develop new adapted medicines, and the technologies (such as point of care [POC] diagnostics) that are needed by the poorest people in low income countries. This is particularly the case for MDR-TB diagnosis and management. He cited the example of GeneXpert use in South Africa, where government funding has been provided after the price negotiations concluded by UNITAID, the Gates Foundation and USG. He added that one of the main challenges facing the Secretariat is to help partners to build sufficient capacity at county level to manage the projects.

Before beginning the proposal review, the CHAIR OF THE EXECUTIVE BOARD thanked the Head of Market Dynamics and her team for their excellent work in preparing the proposals.

4. Malaria

Proposal – France Expertise International (FEI)

Proposal title	**Increasing access to affordable RDTs and ACT in Central and Western Africa**
Fit with Strategic Objectives	Addresses SO4: malaria medicines
UNITAID funding request	US$ 54.8 million in eight countries over five years
PRC recommendation	Rejection

The SECRETARIAT provided a short overview of the project and how its objectives fitted with UNITAID's Strategic Objectives (SOs). The aim of the proposal is to increase access to rapid diagnostic tests (RDTs) and ACTs in Central and Western Africa. Although the intervention aimed to increase the geographical coverage of UNITAID's malaria portfolio and that there is a need for access to RDTs and ACTs in these areas, the proposal did not provide a clear theoretical framework or rationale for market shaping activities, according to the SECRETARIAT.

The PRC CHAIR presented the PRC's assessment of the proposal. Demand for quality assured RDTs and ACTs must be created before private suppliers will invest in supply chains to rural/hard to reach areas. Even if the prices of these commodities are significantly reduced, it is not certain that patients will be able to afford them. The PRC unanimously advised the Executive Board to reject the proposal because it is not clear that it is feasible or will achieve its objectives.

Discussion

- FRANCE observed that the proposal is compatible with UNITAID's remit and suggested that it should not be rejected without further consideration. He agreed that there is a problem with the disposition of pharmacies in many African countries and solutions to this problem need to be found. He proposed funding the applicants for 1-2 years so that they could fine-tune the proposal.
- The NGOs agreed with the PRC and Secretariat that the proposal should not be funded in its entirety. However, they suggested that UNITAID should develop a mechanism to assist with the development of promising new ideas.
- BRAZIL echoed the views of the PRC CHAIR and the NGOs. The proposal lacks structural details and the market impact should be better defined. The ability of the proponents to manage and distribute large amounts of funds was questioned. Nevertheless, BRAZIL pointed out that important partners are willing to support the initiative. In addition, the eight selected countries would benefit from changing their regulatory framework if the project went ahead. BRAZIL wondered whether a phased approach, with a pilot phase that could demonstrate the feasibility of this intervention was possible because the proposal is aligned with SO2 and SO4 of the UNITAID strategy. The UNITED KINGDOM supported BRAZIL, indicating that either a resubmission or a phased approach might be appropriate.

- The COMMUNITIES noted that only 11 of the 69 proposals (LOIs) had been presented to the Board. They considered that there are some merits to the FEI proposal and suggested that developing a phased approach may be appropriate.
- NORWAY agreed that the area covered by this proposal is important but requested clarification on the proposed 'seed money' grants. No mechanism for reviewing and distributing these has been agreed. It may not be good governance to award small grants on a non-competitive basis. FRANCE and the GATES FOUNDATION supported NORWAY's concerns about governance issues in relation to awarding small grants in a non-competitive manner.
- CHILE had concurred with the original recommendation to reject the application. On listening to other Board Members' opinions, however, CHILE agreed that the proposal should be revisited, especially because of its focus on local regulatory strengthening and regional harmonization. CHILE would appreciate receiving more information on these issues if a resubmission were to be made.
- FRANCE and the GATES FOUNDATION agreed that the target of the intervention was important but expressed concern about whether this was the best method of achieving market-shaping changes.
- The CHAIR OF THE EXECUTIVE BOARD supported rejection of the proposal and suggested that the applicants should be encouraged to submit a new LOI that would be reviewed on a competitive basis.

DECISION

The EXECUTIVE BOARD *adopted by consensus* resolution n°7 as amended by members during the meeting.

Proposal – Malaria Consortium

Proposal title	**Achieving catalytic expansion of SMC services in the Sahel to save lives (ACCESS-SMC)**
Fit with Strategic Objectives	Addresses SO6: malaria prevention
UNITAID funding request	US$ 67.4 million in seven countries over three years
PRC recommendation	Approval

The SECRETARIAT provided a short overview of the proposal and how its objectives were compatible with UNITAID's SO6. The SECRETARIAT described the proposal as a robust set of activities addressing supply- and demand-side issues that limit access to SMC; and considered that it has a high potential for market and public health effects. They cautioned that the timeframe is challenging for a three year project, and that strategies are needed to address certain feasibility issues.

The PRC CHAIR presented the PRC's assessment of the proposal. The PRC considered that the proposal is ambitious and that community uptake may require an educational campaign. The cost per patient is high as compared to other benchmarked projects. The vertical nature of the proposal, i.e. its lack of integration with other healthcare initiatives, may present a risk. The PRC scored the proposal very highly, as it is innovative and builds on other SMC initiatives. The PRC unanimously advised the Executive Board to accept the proposal, subject to clarification of the core review team's concerns.

Discussion

- The UNITED KINGDOM questioned whether UNITAID should be funding large, 'top down' service delivery projects since they may not have a market shaping effect. He suggested that this could form part of a strategic discussion during the mid-term review of the UNITAID strategy. The UNITED KINGDOM suggested that there was no evidence of national ownership in the proposal, even though national malaria control programs were mentioned. The UNITED KINGDOM questioned the involvement of Roll Back Malaria (RBM) and the Global Fund in the proposal. He raised concerns about the accuracy of some parts of the proposal, because funding from DFID was mentioned in the document but the UNITED KINGDOM said that this would not be possible. The UNITED KINGDOM indicated they would accept a phased approach, whereby full approval of the project was obtained from each country during the first year. Information should also be provided as to how the programme could be sustained in the future, and how the drugs will be supplied. Collaboration with the RBM and the Global Fund is essential to ensure that the project is sustainable.
- SPAIN considered that the creation of a sustainable market for SMC would be positive. Concerns about links with government institutions, as well as data accrual and analysis, were expressed. Further information on these topics would be very useful.
- BRAZIL described the consortium as 'very strong with unparalleled experience in the field'. The development of child-friendly formulations is urgently needed and will benefit other implementers. BRAZIL supported the program, subject to the conditions suggested by the PRC and a careful cost review. BRAZIL agreed with the UNITED KINGDOM that funding for one year to demonstrate the feasibility of the project might be appropriate.
- The COMMUNITIES and the NGOs supported the PRC's recommendation. The COMMUNITIES noted that in-country consultation should move beyond the national malaria control programs. UNITAID grantees need to engage with in-country civil society and communities as this will lead to sustainable projects. Active community involvement may help to create demand for SMC. The NGOs were sympathetic to the suggestion of identifying clear funding milestones. They would like to understand how a funding request to the Global Fund, if it were to be made, would link to this proposal. The NGOs supported UNITAID to work with communities to improve treatment literacy and create demand for appropriate interventions. The NGOs expressed concern about the issue of the development of drug resistance, and considered that it is not sufficiently addressed in the proposal. The NGOs suggested that a significant part of the proposal be directed to the development of a new drug regimen to

overcome resistance. They considered that direct contracting with suppliers might not be appropriate.

- The SECRETARIAT explained that WHO identified SMC as a priority area in 2012. UNITAID contacted the Global Fund to enquire whether they intended to support work in this area and were told that there were no plans to do so. UNITAID discovered that several countries were keen to introduce this intervention but did not have the funding to do so. The approach in this proposal mirrors that used in Global Fund grants and UNITAID is working to ensure national ownership of the proposal. All of the national malaria programs in the target countries have provided letters of support and the consortium has been very active in developing the proposal.
- The CHAIR OF THE EXECUTIVE BOARD stated that, if UNITAID were to fund this proposal, it would be a revolutionary change of approach for the organisation. He noted that the proposal is innovative but agreed with the UNITED KINGDOM that its success is dependent on national governments' commitment to the project. The CHAIR OF THE EXECUTIVE BOARD suggested that a meeting of Ministers of Health could be organized through the Global Fund in order to discuss the expansion of SMC services in countries at risk of malaria.
- The GATES FOUNDATION supported the proposal, despite acknowledging that there are challenges related to its size and complexity. She questioned whether the proposal had been submitted to the Global Fund. The GATES FOUNDATION is funding a pilot program in SMC in Northern Nigeria and the lessons learnt from this project could be built upon.

DECISION

The EXECUTIVE BOARD *adopted by consensus* resolution n° 8 as amended by members during the meeting

5. Tuberculosis (TB)

Proposal – Partners in Health (PIH)

Proposal title	Expand new drug markets for TB (END-TB)
Fit with Strategic Objectives	Addresses SO5: TB medicines
UNITAID funding request	US$ 57.3 million for 17 countries
PRC recommendation	Approval

The SECRETARIAT provided a short overview of the proposal and how its objectives fitted with UNITAID's SO5. END-TB aims to alter the MDR-TB market by identifying simpler, shorter and more effective regimens to treat MDR TB by accelerating uptake of the newly approved MDR-TB drugs (bedaquiline and delamanid) in 17 countries. The intervention will have long-term market effects by consolidating the market; and expanding access to new, effective, and user-friendly treatment regimens for patients with MDR-TB. The SECRETARIAT described the proposal as a 'strong, well articulated, and timely market-based intervention from a new lead partner with considerable implementing strength and recognized thought leadership in TB'. The adaptive trial design is complex but should help with the approval and use of these drugs in target countries.

The PRC CHAIR presented the PRC's assessment of the proposal. The PRC recommended funding of the proposal, subject to a number of clarifications. It was suggested that an expert panel on trial design should review the adaptive trial design, which is innovative in TB studies. The PRC chair commented that approval of bedaquiline is only based upon Phase IIB data. The intervention involves approximately 3,200 patients with 2,600 in the managed cohort. The PRC considered that the intervention is feasible within the timeframe and scored the proposal very highly. The PRC CHAIR indicated that there were concerns over whether 1.0% of the budget for resistance screening was sufficient. The consortium was very impressive, in the PRC's opinion.

Discussion

- BRAZIL fully supported the proposal and noted that it fulfils BRAZIL's request at EB18 to link the expansion of access to diagnostics with increased access to therapy. The proposal will develop new markets in a range of countries. It was suggested that intellectual property (IP) issues should be further discussed to reduce barriers in middle-income countries. This topic should be addressed in conjunction with the Medicines Patent Pool to accelerate the development of appropriate fixed dose combinations (FDCs). A meeting with the Medicines Patent Pool and the Global TB Alliance was proposed to review new drug regimens for MDR-TB.
- The COMMUNITIES, the UNITED KINGDOM, FRANCE, CHILE and the NGOs all expressed their support for the proposal. The COMMUNITIES requested that the allocation of 40% of the budget to staff be questioned. The COMMUNITIES, CHILE and the NGOs asked why high-income countries were excluded from the proposal and suggested that this issue be addressed. The COMMUNITIES

commented that the proponent would need to work with generic manufacturers to ensure that the market for new MDR-TB drugs is sustainable. The Phase III trials of bedaquiline have not yet been completed and there are concerns about the drug's liver and cardiac toxicity. The UNITED KINGDOM noted that the proposal has been endorsed by the WHO. The NGOs suggested that the project would put UNITAID in a position of leadership by supporting this innovative strategy. They noted that although the cost per patient is high, it is warranted by the trial design and the analytical component of the proposal.

- The NGOs indicated that there have been supply problems with certain TB drugs, and drug access is a risk to the proposal. Intellectual property issues are critical and a FDC regimen for MDR-TB should be developed. Several owners of intellectual property need to collaborate, on either a voluntary or compulsory basis, to ensure that this occurs.
- NORWAY said that there had been concerns initially about the complexity of the programme. She added that, after listening to the discussion, NORWAY supports the proposal.
- CHILE questioned whether a cohort of 3,200 patients was sufficient to meet the goals of the study. CHILE did not want the intervention delayed due to the obligation to answer many questions on the proposal.
- The GATES FOUNDATION agreed with all of the comments made by the Board members. It was stressed that the design of the trial is complex and a review of the design by an expert committee should be made a condition of the grant agreement. The PRC CHAIR assured the GATES FOUNDATION that the PRC had already requested an expert review as a condition of the grant.
- The SECRETARIAT noted that, given the complexity and ambitious goals of the project, the Secretariat and PRC both recommended that PIH ensure that adequate resources are in place for project management and oversight. As a result of this review, the Secretariat recommended, in the draft resolution, that the Executive Board approve limited additional funds for this purpose.

DECISION

The EXECUTIVE BOARD adopted by consensus resolution n° 1.

Proposal – Center for Pharmaceutical Advancement and Training (CePAT)

Proposal title	**Secure the supply of quality-assured active pharmaceutical ingredients for MDR-TB medicines and increase the pool of quality assured finished pharmaceutical products**
Fit with Strategic Objectives	Addresses SO4: malaria medicines
UNITAID funding request	US$ 5.3 million
PRC recommendation	Rejection

The SECRETARIAT provided a short overview of the proposal and how its objectives were in line with UNITAID's SO4. Although the proposal addresses fairly new territory and addresses a key theme of the 2013 TB Market Forum, it was not framed as a market-based approach. The strategic design of the proposal is inadequate to achieve market or public health effects; and there is a risk of over-fragmenting the market (especially the API market).

The PRC CHAIR presented the PRC's assessment of the proposal. The PRC assessed it as being weak in a number of areas, and considered that the proponents were not equipped to manage the intervention. There was no rational basis or explanation for the expected price reductions in the proposal. Market effects were projected only in relation to a number of assumptions. The PRC recommended not funding the proposal.

Discussion

- The NGOs, BRAZIL and the GATES FOUNDATION all supported the PRC's recommendation. The NGOs supported the concept of having quality assured drug manufacturing facilities in Africa and suggested that this idea should be explored further. It is clear that the older TB drugs will need to be replaced in the near future and it would be advisable for UNITAID to take a lead in this. However, the best implementing partners to achieve this have not yet been identified. BRAZIL and the GATES FOUNDATION agreed that this proposal addresses an important area for UNITAID but stated that it has shortcomings. They speculated that a new strategic approach might achieve UNITAID's goals in this area.

DECISION

The EXECUTIVE BOARD *adopted by consensus* resolution n°2.

6. HCV

Stefan Wiktor, Team Lead, Global Hepatitis Programme Unit, Department of HIV/AIDS, WHO, presented an update on HCV epidemiology and treatment. The recent introduction of direct acting antiviral drugs has transformed the treatment of HCV and enabled many patients to be cured. However, the very high price of these drugs is a significant barrier to access. WHO welcomed UNITAID's involvement in HCV projects as there is limited knowledge on how to roll out HCV treatment programmes outside of a clinical trial setting and these issues must be addressed.

Proposal – Coalition Plus

Proposal title	**HIV/HCV drug affordability project**
Fit with Strategic Objectives	Addresses SO3: medicines for HIV co-infections
UNITAID funding request	US$ 15.2 million
PRC recommendation	Approval for phase 1 only

The proposed intervention promotes the negotiation of voluntary licences and lower prices for HCV treatments. The SECRETARIAT'S assessment was that the proposal is innovative, and, if successful, could have a significant impact on the market. However, there was concern about the proponent's limited experience in managing large grants. It was felt that Coalition Plus might not have sufficient infrastructure to undertake such an ambitious intervention; a phased approach was therefore suggested to mitigate risk.

The PRC CHAIR said that the proposal is a 'good fit' for UNTAID as it builds upon the expertise of the Medicine's Patent Pool. If successful, the intervention would achieve rapid market entry of new generic products resulting in increased access and excellent value for money. The use of the new HCV drugs requires a certain level of infrastructure to support their delivery; and the choice of countries may also reflect the generic drug production capabilities. Like the Secretariat, the PRC had identified some significant risks as to whether governments would be prepared to use compulsory licensing and whether the proponent is sufficiently equipped to handle the organisation across all the proposed countries. The Committee recommended a phased approach to funding.

Discussion

- The NGOs said that 'the time to intervene on HCV is now' and this proposal could have a dramatic impact on HCV treatment. The innovative part of the proposal is to address IP problems upfront instead of afterwards. The focus on middle-income countries was correct because it corresponds to the burden of disease, and improved access to HCV drugs in these countries will eventually result in better access in low-income countries. A large number of countries should be involved: it is important to achieve a critical mass of countries that could co-operate. The NGOs agreed with a phased funding approach but cautioned that progress should be reviewed with care.

- BRAZIL welcomed the innovative approach proposed by Coalition Plus and said that the results would have an influence in many other countries. BRAZIL supports improved treatment of HIV/HCV co-infected patients. BRAZIL closely follows the treatment guidelines outlined in the USA and the United Kingdom. BRAZIL supports interventions on IP issues upfront. It believes that it is important that UNITAID signals to the world that they are prepared to invest in HIV and HCV co-infection.
- The UNITED KINGDOM fully supported the proposal. He asked the Secretariat for more information concerning the overall strategy for HCV and whether it would be possible to endorse negotiations regarding the supply side, in line with the PRC recommendations. The CHAIR OF THE EXECUTIVE BOARD requested that the Secretariat should identify future proposals to support the supply side.
- The COMMUNITIES welcomed the potential public health impact of this proposal and the important role that would be played by the patients themselves. They supported the PRC's recommendation of a phased approach and urged the Secretariat to act as quickly as possible.
- FRANCE described the proposal as 'ambitious and innovative'. He agreed with the NGOs' view that it would be better to seek to involve a wide range of countries, especially as some would probably not take part for various reasons. He suggested that Vietnam and Cameroon be included. The NGOs said that UNITAID should check with Coalition Plus in these countries before including the additional countries. FRANCE agreed with this suggestion.
- FRANCE proposed that UNITAID should seek the support of WHO as this would confer increased importance on the intervention, especially when communicating with governments and ministers. He pointed out that there will be a meeting of all ASEAN Health Ministers in September or October 2014, which would be an opportunity for the Secretariat to discuss the intervention with them.
- CHILE and NORWAY agreed with the principle of a broad based alliance and the phased approach to funding. CHILE warned against loss of momentum and urged the Secretariat to ensure that the first phase starts as quickly as possible with a rapid follow up to the second phase. It was proposed that preparatory work on the second phase of the proposal could take place while the first phase is ongoing.
- The NGOs were concerned that too much oversight from UNITAID could prevent proponents from working effectively. The PRC CHAIR reiterated this when the Executive Board reviewed the proposed wording on the resolution. He suggested replacing the end of year operational review by the establishment of clear milestones and deliverables.

  The EXECUTIVE DIRECTOR A.I. explained that, although he understood that it could have an impact on timing, there were risks associated with the proposal so it was essential to carry out the independent review before proceeding to phase two.
- The GATES FOUNDATION considered that, although it was important to improve access to HIV and HCV treatments, there were too many open questions in the proposal. She added that the link between the activities and the public health

impact was weak. For these reasons, the GATES FOUNDATION could not approve the proposal even if a phased approach were adopted.

- Summarising the discussions, the EXECUTIVE CHAIR said that the Coalition Plus intervention would be 'an extraordinary opportunity for UNITAID to bring HCV drug prices down'. He stressed that the Secretariat would have to work closely with the proponents and maintain high level of visibility for UNITAID with the countries involved. He said that the EXECUTIVE BOARD supported the proposal from FRANCE to include Vietnam and Cameroon if this was acceptable to Coalition Plus.

DECISION

The EXECUTIVE BOARD *adopted* resolution n°3 as amended by members during the meeting

(The GATES FOUNDATION voted against the resolution).

Proposal – Médecins sans Frontières (MSF)

Proposal title	**Ensuring access to the HCV treatment revolution for HCV/HIV co-infected patients in low and middle-income countries**
Fit with Strategic Objectives	Addresses SO3: medicines for HIV co-infections
UNITAID Funding request	US$ 15 million (for a total requirement of US$ 48 million)
PRC recommendation	Approval

The SECRETARIAT presented a favourable assessment of this proposal. It is a complex but comprehensive intervention, which included demonstrating the feasibility of treating HCV/HIV co-infection in low- and middle-income countries; gathering data to determine the most effective drug combinations; facilitating price reductions; accelerating registration and validating tests. MSF has the capacity to implement this proposal successfully, especially as it can build on existing HIV treatment projects. The infrastructure is already in place, and so the intervention could start quickly and it would offer good value for money. Letters of support have been received from target countries.

The PRC CHAIR agreed that the consortium was strong and would have the necessary skills for the proposal. However, there were some reservations and weaknesses on the supply side (reservations were also expressed by the UNITED KINGDOM and the GATES FOUNDATION). The PRC had also commented that MSF had recently had problems with the government in Myanmar although they appeared to have been resolved; and there were operational risks associated with working in the Ukraine. Nevertheless, the PRC were positive about the proposal in terms of public health impact, innovation, value for money and transition plans. The PRC CHAIR also noted

that two-thirds of the budget had already been funded; UNITAID will only be responsible for the final third.

Discussion

- BRAZIL commended MSF and the other members of the Consortium, saying that they would add value and change the HCV landscape by introducing the most effective treatments that are currently available. BRAZIL strongly supported approval of the proposal.
- The NGOs said that this high quality intervention would help to 'kick-start' the market, and create awareness and demand from patients by providing access to treatment. They advocated that MSF should work with Civil Society and patient groups, including those for injecting drug users, on demand creation for new treatment options.
- The GATES FOUNDATION said that the proposal showed what could be done in this market place. However, she urged the Secretariat to pursue complementary solutions on the supply side. The UNITED KINGDOM and FRANCE agreed with the GATES FOUNDATION'S proposal.

DECISION

The EXECUTIVE BOARD *adopted by consensus* resolution n° 4.

7. Intellectual Property (IP) Issues

Proposal – Tides Centre (ITPC)

Proposal title	**Access to Treatment for People Living with HIV in Middle-income Countries**
Fit with Strategic Objectives	UNITAID's constitutional mandate recognises that middle-income countries face patent barriers for new antiretroviral drugs (ARVs).
Funding request	US$ 6 million
PRC recommendation	Approval

The SECRETARIAT gave a positive assessment of this proposal that would result in expansion of the market for generic ARVs and encourage more efficient production. The SECRETARIAT pointed out the complementarity between this proposal and the work by the Medicines Patent Pool (MPP) and the Lawyers' Collective. The SECRETARIAT considered that the consortium of partners would be capable of implementing this proposal and the strong support from the target countries was noted.

The PRC review was favourable across all parameters. The PRC CHAIR warned that the timelines might be tight because of potentially lengthy legal processes. He also mentioned the need for vigilance concerning the current unstable political situation in Ukraine, which is one of the targeted countries. Overall, the PRC had concluded that the public health impact would be considerable and that the intervention would offer good value for money.

Discussion

- The NGOs, BRAZIL, SPAIN and CHILE expressed their support for the proposal. The NGOs confirmed that ITPC had good technical capabilities, and noted that the proposed interventions are firmly engrained within UNITAID's mandate and strategy.
- The NGOs agreed with the PRC that the timeframe was ambitious and suggested that expert consultation should be sought in the early stages. They also noted that a time extension should be anticipated from the outset.
- BRAZIL commented that the intervention would build on the WHO guidelines and that the intervention would implement TRIPS flexibilities and help to avoid TRIPS-plus measures.
- CHILE said that the project would be well aligned with UNITAID's strategy and emphasised that it was 'great value for money'.
- FRANCE was uncomfortable with the proposal. Although he recognised the potential benefits of the intervention, FRANCE considered it inappropriate for UNITAID to intervene in Argentina, Brazil, and Thailand, which are all countries with significant capacity to fund their own healthcare budgets.
- The COMMUNITIES and the GATES FOUNDATION enquired about the country selection. The NGOs pointed out that details for each choice of country were

given in the proposal; although they would have liked to see more countries included in the intervention.

- The SECRETARIAT confirmed that justification for country selection had been supplied. She added that the ITCP had undertaken to share experience and lessons with other countries.

DECISION

The EXECUTIVE BOARD *adopted* resolution n° 5

(FRANCE abstained; the GATES FOUNDATION voted against the resolution).

8. HIV

Proposal – International Federation of the Red Cross (IFRC)

Proposal title	**Transforming the market for HIV oral fluid tests through the scale-up of community-based voluntary testing and counselling: Proof of Concept in Kenya and Malawi**
Fit with Strategic Objectives	Addresses SO1: Point-of-care diagnostics
UNITAID Funding request	US$ 39.6 million
PRC recommendation	Rejection

The SECRETARIAT gave its assessment of this proposal. There is a considerable need to expand diagnostic testing for HIV as less than half of people living with HIV know their serostatus. Most tests are done via facilities and community campaigns, managed by health staff and using blood-based rapid diagnostic tests (RDTs). This model limits access to testing by key populations including those living in rural areas and those at repeated risk of HIV infection (e.g. sex workers). The proponent suggested that oral fluid tests could be used to change this status quo. The oral fluid test is approximately eight times more costly (~US$4) than the blood-based tests at present and can only be obtained from one manufacturer. The proposal suggests this price could be reduced by ~60% in 4 years,. The SECRETARIAT considered that this proposal will have a limited public health impact; has a low potential to increase HIV testing overall; but could eventually displace current testing. The data obtained on self-testing, in one district only, will not be sufficient to develop new testing guidelines. Clarification would be needed as to how people undergoing oral fluid testing would be able to access treatment.

The PRC review considered that there is a degree of conflict between this proposal and the one from the Population Services International (PSI) (see next section for details). Although having a range of HIV testing options would be beneficial, it is not clear the potential impact why this proposal will expand and shape the market for oral fluid testing. The link between the test and accessing treatment or prevention is not clear in the proposal. Questions were raised about the costs of the intervention;; its timeframe; and the number of diagnostic manufacturers that would be prepared to enter the market for oral tests. Despite a small amount of co-funding being available and an assessment that the consortium partners have the appropriate experience and structures in place, the PRC's conclusion was that the proposal should not be funded.

Discussion

- The NGOs commented that this proposal and the one from PSI were high risk. They questioned whether oral tests are more acceptable than blood-based tests in communities. A move towards self-testing would increase the number of first and repeated tests that must be carried out to obtain a definitive diagnosis. The NGOs suggested that the IFRC and PSI proposals should be discussed together.

- The GATES FOUNDATION indicated she would not support funding this proposal, based upon the feedback that the Foundation had received.

DECISION

The EXECUTIVE BOARD *adopted by consensus* resolution n°6.

Proposal – Population Services International (PSI)

Proposal title	**Stimulating and shaping the market for HIV self-testing in Africa: two tier demonstration and evaluation of accuracy and linkage in four countries**
Fit with Strategic Objectives	Addresses SO1: Point-of-care diagnostics
UNITAID Funding request	US$ 47.6 million
PRC recommendation	Approval based on technical quality but serious question about need

The SECRETARIAT provided a short overview of the proposal and how its objectives fitted with UNITAID's SO1. The aim of the intervention is to distribute oral fluid tests using various models of self-testing in four African countries in order to generate data for policy guidance; and to demonstrate demand and facilitate market entry of quality-assured oral fluid tests. The SECRETARIAT considered that a robust case had been made for UNITAID funding before general scale-up of the product can take place,. They considered that the project has a high potential for public health impact *if* overall HIV testing rates are increased (and displacement does not occur) and links are made to care and prevention. However, there was concern that market effects (price reduction) are ambitious, given the volume of tests that would be distributed.

The PRC CHAIR presented the PRC's assessment of the proposal. Some members of the PRC were concerned about the feasibility and need for this intervention. It was not clear why rural communities would be more likely to take an HIV test with an oral fluid test rather than a blood-based test. The link between testing and care was not well articulated. The PRC considered the proposal to be technically sound and the consortium members to be well equipped to carry out the proposal. However, the PRC suggested that the UNITAID Board should decide whether, in the wider framework of priorities for funding, this proposal should be funded. They suggested that if the Board agreed that funding for this area is justified at present, a number of modifications/clarifications/inclusions to the proposal should be requested.

Discussion

- The NGOs said that they would only support funding for this proposal if rural populations could be excluded from it. There seems to be a better public health and equity reason for focusing the proposal on sex workers. Civil Society groups can work with sex workers and build awareness of the need to test for

HIV. Sex workers require repeated HIV tests, and so self-testing could be a rational approach. The NGOs perceived value in repeated self-testing in populations who may be excluded from routine testing due to prejudice. The proposal addresses an interesting research question about the value of self-testing, in their opinion. Originally, the NGOs had considered suggesting that the PSI proposal and the one from IFRC be merged, but now considered this was inappropriate, given the lack of enthusiasm for the IFRC project.

- NORWAY indicated that HIV testing is a difficult issue and it is not easy to develop new methods of testing for hard to reach populations. She supported removing rural populations from the proposal but suggested that ways to reach people who have limited access to medical care should be addressed.
- The UNITED KINGDOM expressed caution about supporting a proposal that is technically strong but where there is doubt about the need for this intervention. He commented that the proposal would only be sustainable if there is national government support for it.
- The GATES FOUNDATION was supportive of the proposal. She suggested that an increased choice of HIV tests would encourage more people to be tested because there would be a greater likelihood that a specific test would be acceptable. The price of the oral fluid test should be addressed – at present, there is only one approved supplier and so pricing negotiations could be challenging. The GATES FOUNDATION recommended that the final project agreement includes pricing and global access agreements from OraSure, as their product is the only approved oral fluid self-test on the market and the pricing needs to be clear and agreed upon before the intervention commences.
- The COMMUNITIES agreed with the PRC's assessment of the proposal. They expressed concern about the risk of stigma and discrimination if self-testing is promoted in rural communities. Concerns were also expressed about the lack of linkage between diagnosis and existing HIV care services.
- The SECRETARIAT reminded the Board that WHO does not have a strong statement on self-testing. Most experts think that self-testing would be most effective with an oral fluid test rather than a finger prick to obtain a blood sample. An evaluation of the feasibility of self-testing using but the test may not be included in guidelines if the price is too high. Substantive price reductions for the oral fluid test are needed to improve access to the test;. Studies have shown that use of oral fluid self-tests does increase the number of people taking a test and entering HIV care.
- The PRC CHAIR observed that the feasibility and success of self-testing is not dependent on the test alone. In addition to linkage to care, an infrastructure must be put in place to help people interpret the assay result. In the USA, people can read the package insert, or access help via the telephone or a Web site. Taking a similar approach in developing countries is not simple, because of the large number of languages spoken and the lack of universal access to the Internet. An adequate model to support people who are self-testing in low-income countries needs to be designed.
- The NGOs asked if the Secretariat has information on oral fluid self-testing in rural communities. The SECRETARIAT responded that data on this topic are lacking but it is clear that high numbers of people are not taking HIV tests in these regions.

- The CHAIR OF THE EXECUTIVE BOARD suggested that a vote could be taken on the proposal if rural communities were excluded from the project. The GATES FOUNDATION and NORWAY indicated this would change the study numbers and the impact of this on the proposal needs to be determined. The PRC CHAIR suggested that the decision be deferred until EB20 and, in the meanwhile, the Secretariat could discuss the PRC's and the Board's concerns with the applicants. The UNITED KINGDOM stated that either the proposal should be discussed at EB20 or a phased approach to funding should be considered. The NGOs supported the proposal to discuss the project at EB20 if a phased approach to funding could not be agreed upon. The SECRETARIAT commented that a phased approach to show proof of concept could be adopted. Scale up could be approved after the first milestone was achieved. However, this strategy would have a negative impact on negotiating initial price reductions.
- The CHAIR OF THE EXECUTIVE BOARD proposed an amendment to the Resolution, inviting the PSI to submit a small grants request for funds (similar to the text added to Resolution 1). The CHAIR OF THE EXECUTIVE BOARD asked if anyone objected to the new text. The GATES FOUNDATION stated that she would object. The COMMUNITIES proposed that if the PRC does not support a proposal, it should be returned to the LOI stage for revision and re-submission. Using a small grant to enable applicants to receive funding for their proposal is not fair or transparent. The COMMUNITIES agreed that UNITAID does need a small grants strategy but this should be fully developed so that the process is fair and transparent before it is implemented. NORWAY concurred with the COMMUNITIES that a small grant should be open to all applicants and not used to solicit specific applications. NORWAY requested rejecting Resolution 12 and removing the last paragraph from Resolution 1. The NGOs suggested that FEI could be invited to submit a small exploratory proposal. NORWAY considered that Resolution 12 was unnecessary. It had been decided that small grants were appropriate in the UNITAID strategy. This policy should be implemented. The EXECUTIVE DIRECTOR, A.I indicated that small grants had not been considered to be a priority in the past by the Board. The Secretariat can now work on a proposal since it is now considered a priority. WHO suggested that a request be included in the minutes for a small grant policy to be developed for consideration at the next Board meeting. The SECRETARIAT indicated that developing a policy for the next Board meeting was not possible because there was insufficient time. The CHAIR OF THE EXECUTIVE BOARD replied that he wanted the Secretariat to work on a proposal and to submit it at the next Board meeting. The last paragraph of Resolution 1 would not be needed if a small grants policy were in place. The GATES FOUNDATION agreed that the development of a small grant policy had been de-prioritized but developing one in a few weeks would not be feasible. She noted that small grants are permitted in the UNITAID Constitution. The GATES FOUNDATION expressed its concern about transparency, fairness and due process regarding small grants mechanism and said that the Foundation requires submission of a new proposal. WHO proposed a compromise: to prepare a concept paper on how a small grant concept could be developed and then refer this to the Executive Committee. The COMMUNITIES suggested that ideas about the small grants policy could be discussed at the June meeting and then the topic could be discussed fully in November. The policy should be set up so that anybody can apply for a small grant in a fair and transparent manner. The GATES FOUNDATION commented that this could not be a

resolution because it was not prepared in advance of the meeting. The NGOs suggested that it be minuted that the Secretariat develop a policy on small grants, including the financial implications of providing such funding, and provide a document for review by the Board. This should be presented as soon as possible, but no later than the December Board meeting. Electronic voting on this topic could be considered if the documentation was ready for review. NORWAY agreed that the small grants policy should be discussed at the December Board meeting. The COMMUNITIES considered that this policy falls under the purview of the Policy and Strategy Committee (PSC). The CHAIR OF THE EXECUTIVE BOARD agreed that the small grant policy development should be minuted and the last paragraph of resolution 1 be removed.

DECISION

The EXECUTIVE BOARD decided to defer the decision on the PSI proposal until EB20 (June 2014), after clarifications by PSI

Proposals – Northwestern Global Health Foundation

Proposal title	**LYNX p24: Establishing and sustaining a market-based intervention for early infant diagnosis of HIV at the Point of Care**
Fit with Strategic Objectives	Addresses SO1: Point-of-care diagnostics Facilitates SO2: paediatric HIV medicines
UNITAID Funding request	US$3.7 million
PRC recommendation	Approval

The SECRETARIAT presented a summary of the proposal and explained how it was compatible with SO1 and SO2. A simple, point-of-care HIV diagnostics test for babies born to HIV-infected women could enable scale-up of paediatric diagnosis and, if linkage to care occurred in a timely manner, could facilitate increased access to paediatric HIV treatment. The SECRETARIAT considered the proposal to be sound and expects it to have a profound impact on infant mortality for a modest budget.

The PRC CHAIR summarized the PRC's evaluation of the proposal. The PRC had agreed with most of the Secretariat's comments but was concerned about the proposed number of countries in the project. The diagnostic product has advantages over others in development, and the amount of money requested is relatively modest. The proposal builds on UNITAID's current interventions in this area. Eventual uptake of the test will depend upon a number of factors that may differ from country to country. The risks related to the proposal are minimally explained in the proposal, although a feasibility project is underway in Mozambique that should supply information about these risks. The PRC questioned whether the budget is sufficient to support work in 29 countries and suggested that it may be appropriate to limit the proposal to African countries. With these caveats, the PRC recommended approval of the proposal.

Discussion

- The NGOs expressed support for the technology but were also concerned about the small budget in relation to the large number of target countries. The affordability of the programme should be proven as an output and not necessarily assumed. The point-of-care instrument is cheaper than a laboratory based machine but more of them are required to run the same number of tests. Therefore, the full cost for each test should be established for comparative purposes. The sponsor claims a $10 saving if the test could be reduced to $7; CHAI has negotiated a price of $12.5 with Abbott and Roche for developing countries and the NGOs suggest that this price should be used for comparative purposes. The NGOs have concerns about whether this small organization has the capacity to distribute the test. The proposed IP and access policies can be detailed when negotiating the grant. The UNITED KINGDOM agreed with the NGOs' suggestions and sought assurances that if India were excluded from the proposal, only Tier One countries would be included in the intervention. The resolution was amended appropriately.
- SPAIN had questioned the public health impact of the project with respect to linkage to care, but was reassured by the PRC's comments. It would have been preferable if the data from the Mozambique project were available before a decision was made but SPAIN accepted that this was not possible.
- The SECRETARIAT indicated that the proponents had based their budget on previous submissions to UNITAID.

DECISION

The EXECUTIVE BOARD *adopted by consensus* resolution n°9 as amended by members during the meeting.

Proposal – African Society for Laboratory Medicine (ASLM)

Proposal title	**Enabling the market for new HIV diagnostics in Africa: Building a comprehensive market intelligence and post-market surveillance framework in high burden countries**
Fit with Strategic Objectives	Addresses SO1: point-of-care diagnostics Facilitates SO3: HIV medicines
UNITAID Funding request	US$ 8.5 million
PRC recommendation	Rejection

The SECRETARIAT explained that the objectives of the proposed intervention were to map HIV testing in target high-burden African countries and establish a connectivity-enabled market intelligence and post-marketing surveillance mechanism. Although the proposal would address urgent market needs, the Secretariat was concerned

about the lack of clarity concerning the standardisation of connectivity and consequently a proof-of-concept phase was suggested to establish feasibility.

The PRC judged the proposal to be weak in many areas. Insufficient consideration had been given to the way in which the data were currently gathered and shared. The PRC believed that the public health benefit of improved diagnostics was clear, but they questioned the likelihood of achieving the anticipated gains, and so the value for money is questionable. It is not clear how information gathering can be undertaken, when this has not already started at the national level. Details of a transition plan were not provided. The PRC recommended that the proposal should be rejected

Discussion

- The NGOs supported the recommendation of the PRC to reject the proposal. They specified that they did not think it appropriate to invite the ASLM to resubmit their proposal. They highlighted the need to understand the scope of Secretariat's investments in market intelligence.
- The other EXECUTIVE BOARD MEMBERS agreed with the views expressed by the NGO delegation.

DECISION

The EXECUTIVE BOARD *adopted by consensus* resolution n° 10.

Closure of the meeting

The VICE-CHAIR OF THE EXECUTIVE BOARD thanked the Board Members for their valuable input in reviewing the proposals for funding decisions. On behalf of the CHAIR OF THE EXECUTIVE BOARD, the VICE-CHAIR also thanked the Secretariat for organising the meeting.

The Special Session of the Executive Board was closed at 18.20 on Monday, 5 May 2014.

Annex 1 - List of Participants

BOARD MEMBERS/ REPRESENTATIVES

CHAIR	– Philippe Douste-Blazy
VICE-CHAIR (CHILE)	– Alt.: Guy Fones
AFRICAN COUNTRIES	– Tilana Grobbelaar
BRAZIL	– Alt.: Jorge Bermudez
COMMUNITIES LIVING WITH THE DISEASES	– Nelson Otwoma – Alt.: Violeta Gracia Ross Quiroga
FRANCE	– Philippe Meunier
GATES FOUNDATIONS	– Susan Nazzaro (by teleconference)
NGO'S	– Tido von Schoen-Angerer – Alt.: Brook Baker
NORWAY	– Kari Marjatta Hoel – Alt.: Kjetil Aasland
SPAIN	– Gonzalo Vega Molina
UNITED KINGDOM	– Jason Lane

OTHER MEMBERS OF DELEGATIONS

BRAZIL	– José Roberto de Andrade Filho
COMMUNITIES DELEGATION	– Mercy Annapoorani – Louis da Gama – Blessi Kumar – Kenly Sikwese
FRANCE	– Stéphane Renaudin – Margot Nauleau

LIAISON OFFICER, CIVIL SOCIETY	– Jessica Hamer
UNITED KINGDOM	– Lloyd Cameron
WHO	– Issa Matta – Stefan Wiktor

PROPOSAL REVIEW COMMITTEE

CHAIR	– Andy Gray
VICE-CHAIR	– Stephanie Simmonds

OTHERS

– Laurence Thurion (office of the Chair)

UNITAID SECRETARIAT

– Philippe Duneton (Executive Director, a.i.)

– Mauricio Cysne (Head of External Relations)

– Sophie Genay-Diliautas
(Board Relations Officer)

– Brigitte Laude
(Head of Finance and Administration)

– Sonia Lees Hilton (Senior Legal Officer)

– Taufiqur Rahman (Head of Operations)

– Brenda Waning (Head of Market Dynamics)

– Catherine Kirorei Corsini
(Executive Board Assistant)

– Gelise McCullough
(Technical Officer, Executive Office)

– Susanna Volk
(Executive Assistant, Executive Office)

On Specific Agenda Items:

– Alexandra Cameron
(Technical Officer, Market Dynamics)

– Clare Courtney (Communications Officer)

– John Cutler
(HIV Portfolio Manager, Operations)

– Janet Ginnard
(Technical Officer, Market Dynamics)

– Robert Matiru
(Portfolio Manager TB, Operations)

– Gulmira McHale
(Resource Mobilization Officer)

– Yamuna Mundade
(Technical Officer, Operations)

– Carmen Perez-Casas
(Technical Officer, Market Dynamics)

– Kate Strong
(Programme Monitoring Officer, Operations)

– Karin Timmermans
(Technical Officer, Market Dynamics)