



UNITAID Executive Board Meeting

22nd Session

3 - 4 June 2015

Fiocruz Headquarters

Rio de Janeiro, Brazil

**Minutes of the
21st Executive Board meeting
(11-12 December 2015)**

For Information ☐ **For Review & Advice** ☐ **For Approval** ☒

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Executive Summary

- ❖ The 21st meeting of the UNITAID Executive Board (EB21) took place in Geneva on Thursday 11 December and Friday 12 December 2014.
- ❖ After an Executive Session, proceedings commenced at 14.00 on Thursday 11 December 2014. The agenda was adopted.
- ❖ The minutes of EB20 were approved.
- ❖ The EXECUTIVE DIRECTOR provided an update on recent activities by the UNITAID Secretariat, including the 2015 priorities.
- ❖ The VICE-CHAIR OF THE FINANCE AND ACCOUNTABILITY COMMITTEE (FAC) reported on the 13th session of the FAC. The EXECUTIVE BOARD adopted by consensus Resolution N°1: 2015 budget.
- ❖ The CHAIR OF THE POLICY AND STRATEGY COMMITTEE (PSC) reported on the 12th session of the PSC. Implementation of the UNITAID Strategy, the Market Intelligence System, Market Fora, Operations, and the impact of the Ebola crisis had been discussed.
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°2: CIFF-UNITAID Paediatric HIV Partnership.
- ❖ The SECRETARIAT presented an overview of the Market Intelligence System. It will offer open access to global data thereby facilitating evidence-based assessments of market interventions for UNITAID and any other external organisations.
- ❖ The Civil Society Engagement Plan will ensure systemic involvement of Civil Society with grantees at country level and within projects. The EXECUTIVE BOARD adopted by consensus Resolution N°3: UNITAID Civil Society Engagement.
- ❖ The EXECUTIVE BOARD congratulated the Medicine's Patent Pool for its success in negotiating voluntary licences for eleven priority HIV medicines, including World Health Organisation (WHO) approved first-line antiretroviral treatments for both adults and children.
- ❖ The DEPUTY EXECUTIVE DIRECTOR provided an update on the EndTB project and Operations. The EXECUTIVE BOARD instructed the Executive Director to contact the EndTB proponents to clarify the grant negotiation process.
- ❖ UNITAID's income for 2014 was 12% lower than projected because of reduced contributions from France, the United Kingdom and Norway. Resource Mobilization plans for 2015 were discussed.
- ❖ Twenty-seven Letters of Intent (LoIs) are being reviewed by the Secretariat for response in January 2015. Tuberculosis (TB) is the priority disease area for the next round of proposals.
- ❖ An update on the partnership with the Global Fund was presented. Detailed workplans are under joint development.

- ❖ Declarations of Interest (DOIs) relevant disclosures had been received from France, the Gates foundation and NGOs and summarised by the WHO LEGAL.
- ❖ The EXECUTIVE BOARD took note of the reports on the projects submitted for funding decisions by the PRC Chair and the Secretariat.
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°4: Market entry of a novel HIV viral load monitoring platform for near point-of-care testing (Cavidi AB).
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°5: Creating Access to Low Cost EOSCAPE-HIV Viral Load Testing in Low and Middle Income Countries (Wave 80 Biosciences, Inc.).
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°6: Rapid, point-of-care urine test to monitor adherence to antiretroviral therapy (Massachusetts General Hospital).
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°8: Introduction of point-of-care Early Infant Diagnosis in decentralized settings: creating a market for affordable, effective, and equitable HIV testing of exposed infants (Elizabeth Glaser Pediatric AIDS Foundation).
- ❖ The EXECUTIVE BOARD adopted Resolution N°7 (Norway abstained): Open Polyvalent Platforms for a sustainable access to quality and affordable Viral Load Testing in resource-limited settings (France Expertise Internationale).
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°9: Grant Management Process.
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°10: Secretariat Functional Organization Structure.
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°11: UNITAID Office Relocation.
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°12: Market Intervention to Accelerate Uptake of New Vector Control Tools (IVCC).
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°13: Medicines Patent Pool Foundation.
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°14: Governance issues.
- ❖ The EXECUTIVE BOARD adopted by consensus Resolution N°15: Calendar of UNITAID Board meetings for 2015
- ❖ The CHAIR of the EXECUTIVE BOARD recognised the important contributions made to UNITAID by Tido von Schoen-Angerer from the NGO delegation and Brigitte Laude, Head of Finance and Administration, both of whom are leaving their current positions.
- ❖ The CHAIR thanked the Board Members for valuable contributions to the meeting. The 21st session of UNITAID Executive Board closed at 16.10 on Friday, 12 December 2014.

1. Opening remarks of the Chair

After an Executive Session, the open session of 21st meeting of the EXECUTIVE BOARD OF UNITAID (EB21) began at 14.00 on Thursday 11 December 2014. The CHAIR OF THE EXECUTIVE BOARD welcomed the new Executive Director, Mr Lelio Marmora and assured him of the full support of the Executive Board in his position. The CHAIR said that the arrival of Mr Marmora marked the beginning of a new era for UNITAID.

The agenda topics for EB21 included reports from the Finance and Accountability Committee (FAC) and the Policy and Strategy Committee (PSC), updates on the Medicines Patent Pool (MPP), Operations, Resource Mobilization, Partnerships and Letters of Intent (LOIs), and a review of seven proposals for funding decisions.

2. Adoption of the Agenda

The agenda for the 21st meeting of the Executive Board was adopted.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted the agenda for EB21.

3. Minutes from EB20

The minutes from EB20 were accepted without any modifications.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted the minutes of EB20.

4. Report of the Finance and Accountability Committee (FAC)

The VICE-CHAIR OF THE FAC presented a brief overview of the FAC's recent meeting (FAC13). The meeting had focused on the proposed budget for 2015 but had also covered revised financial policies and guidelines, treasury management, the financial performance framework, a new internal audit plan, the grant financial performance dashboard, risk management, fraud awareness and prevention, FAC governance and the project funding ceiling. The FAC requested Executive Board approval for the proposed 2015 budget

4.1 2015 budget

Assuming that donor contributions remain stable, expected revenue for 2015 is US\$283.7 million. However, there is uncertainty about some contributions, especially from existing major donors. Multi-year commitments have not been renewed by either France or the United Kingdom.

Operating expenses for 2015 are estimated at US\$183.6 million:

- Secretariat: US\$20 million.
- Governing bodies: US\$1.2 million.
- Projects, Special Projects and Secretariat Initiatives: US\$161 million.
- Strategy Design and Implementation Support (SDIS): US\$1.4 million. This will include impact and value for money assessments; information system development; functional review; and UNIPRO grant management systems.

Budgets were also presented for the following: US\$250,000 to cover travel and office costs for the Office of the Chair; US\$220,568 for increased outreach by Civil Society; and US\$1,184,000 to support joint HIV and hepatitis C (HCV) initiatives in conjunction with the World Health Organisation (WHO).

Discussion

- ❖ The COMMUNITIES LIVING WITH THE DISEASES (COMMUNITIES) explained that the increased Civil Society budget would enable them to create better awareness and understanding of UNITAID within the countries, and to stimulate demand for treatment resulting in scale up of existing projects.
- ❖ The NGOs agreed with the request from the COMMUNITIES for a liaison officer to work on the Civil Society Engagement Plan. They observed that successful implementation of the Engagement Plan would expand the geographic reach of the NGOs.
- ❖ The GATES FOUNDATION requested more detail on budget for HIV/HCV initiatives and enquired whether they were covered by the existing Memorandum of Understanding with the WHO.

The DEPUTY DIRECTOR explained that the HIV/HCV budget would support the Diagnostics Access Initiative and also contribute to analytical work performed by the WHO's HIV department on diagnostics and HCV. The analysis would be based on data from UNITAID funded projects and supplied by CHAI, UNICEF, MSF and the London School of Hygiene and Tropical Medicine. The conclusions would contribute to UNITAID's Value for Money assessments, and guide future investments.

The VICE-CHAIR OF THE FAC noted that the WHO had insufficient funds to carry out the work on its own and that the FAC had been satisfied with the proposal.

Follow-up actions and decisions

The EXECUTIVE Board adopted by consensus Resolution N°1.

4.2 Report of the Office of the Chair of the UNITAID Board

The CHAIR OF THE EXECUTIVE BOARD reported on his activities in 2014. He had held several meetings with UNITAID's partners including the Gates Foundation, the Clinton Foundation, the Global Fund, UNICEF, and the Medicines Patent Pool. A visit had been made to the Clinton Foundation and the CHAIR had spoken with

President Clinton. The Chair had also held discussions with both Bill and Melinda Gates on separate occasions.

Regular meetings had taken place with the Executive Director of the Medicines Patent Pool (MPP), and the Chair had met with Gilead, Pfizer and Glaxo to discuss licensing issues relating to their products.

A key part of the Chair's role is to raise awareness for UNITAID's work. In 2014, he participated in the World Economic Forum in Davos, the United Nations General Assembly and several other international events to talk about UNITAID's aims and achievements.

Ongoing efforts are being made in relation to resource mobilisation. The Chair's visit to Morocco, in October 2014, resulted in a pledge from the Moroccan Government to introduce an air ticket levy to collect funds for UNITAID. Significant progress had also been made with the Japanese government concerning an air ticket levy; however, no decision can be made until after the forthcoming elections.

The CHAIR recognised that the Secretariat had undergone a difficult period of transition in 2014, with many staff changes and the arrival of a new Executive Director. He thanked the Senior Legal Officer of the WHO and the Vice-Chair of the Executive Board for their advice and support throughout this time.

Looking ahead to 2015, the CHAIR said that UNITAID's focus would be on achieving better 'Value for Money' and exploring ways to maximise the complementarity of UNITAID and the Global Fund in their new partnership agreement.

5. Report of the Policy and Strategy Committee (PSC)

The CHAIR OF THE POLICY AND STRATEGY COMMITTEE (PSC) presented his report on the recent meeting of the PSC (PSC12). The following items had been discussed:

- Implementation of the UNITAID Strategy.
- Market Dynamics – the Market Intelligence System, new grant proposals and the Market Fora organised with the Global Fund.
- Operations – active projects, grant performance criteria and linkage to Strategic Objectives.
- Partnerships – The Global Fund, PEPFAR, the Paediatric HIV treatment Initiative (PHTI), Children's Investment Fund Foundation (CIFF), and the Civil Society Engagement Plan.

There had been divergent points of view within the PCS about the Small Grants Initiative and so a recommendation on this initiative has been postponed until after the functional review has been completed.

The PSC had also considered UNITAID's role in the Ebola crisis. There is the potential to misdiagnose Ebola and malaria because the initial symptoms of Ebola are similar to those of malaria. The number of severe malaria cases has increased because of late diagnosis in countries affected by Ebola, and this may have an impact on some UNITAID-funded projects.

5.1.CIFF UNITAID partnership

The Children's Investment Fund Foundation (CIFF) is a major investor in paediatric HIV diagnostics in low income countries. CIFF shares common objectives with UNITAID in relation to paediatric diagnosis and treatment, which makes it an interesting potential partner.

The shortcomings of the current Point-of-Care (POC) diagnostics market were reviewed and plans for accelerating Early Infant Diagnosis (EID) and viral load (VL) POC access were described. The proposed partnership would build on existing investments and support the commercialisation and scale up of EID diagnostics wherever possible. It would also offer the possibility of innovative approaches, such as volume commitments, and opportunities for co-financing of projects.

The Executive Board was asked to approve finalisation of the partnership.

Discussion

- ❖ The UNITED KINGDOM strongly supported the proposed cooperation, but requested more detail concerning the framing of the partnership and its likely impact on UNITAID's activities in other disease areas.

The PORTFOLIO MANAGER, OPERATIONS replied that the partnership framework was under development. An update would be provided at the next meeting of the Executive Board in June 2015 (EB22).

- ❖ The GATES FOUNDATION welcomed the proposal and informed the Executive Board that the Gates Foundation already has several successful partnerships with CIFF. The COMMUNITIES said that Civil Society should be more closely involved in this area and could help to improve treatment compliance within the countries.
- ❖ The NGOS described children with HIV as a 'neglected population' and recognised that UNITAID has a tremendous potential to leverage existing capacities. They agreed with the COMMUNITIES that intervention from Civil Society would help parents to understand the need to test their children on a regular basis, and would improve knowledge about treatment resulting in better long term adherence.

The SECRETARIAT agreed that Civil Society engagement was vital and this would be discussed at a forthcoming consultation meeting in Dar-es-Salaam.

- ❖ UNAIDS praised UNITAID for helping to 'move the agenda on the global AIDS response'. It said that UNITAID's partnership with CIFF would help to fill the treatment gap in paediatric HIV.
- ❖ FRANCE suggested that a similar approach could be adopted for tuberculosis (TB).

The DEPUTY EXECUTIVE DIRECTOR described the partnership with CIFF as a 'push and pull' initiative to leverage infant diagnostics. He assured the Board that the Secretariat was exploring possibilities of similar interactions with other partners in different disease areas. The PORTFOLIO MANAGER, OPERATIONS added that extensive consultation was ongoing with stakeholders, implementers, and other investors including the Global Fund and the Gates Foundation, to identify comparative advantages and to explore different funding vehicles.

➤ **Follow-up actions and decisions**

- **The EXECUTIVE BOARD requested the Secretariat to provide an update on the partnership framework between UNITAID and CIFF at the next EB meeting (EB22).**
- **The EXECUTIVE BOARD adopted by consensus Resolution N°2.**

5.2. Market Intelligence System

The HEAD OF MARKET DYNAMICS presented the history of the Market Intelligence System (MIS), which had begun in 2002 when the Global Fund asked its recipients to supply information on all transactions for diagnostics and medicines. In 2014, UNITAID had signed an agreement with IMS Health to develop and manage the system. Details of the design and a proof of concept will be available by May 2015.

The objective of the MIS is to provide a global health data resource with ‘real-time market information across the entire value chain to improve efficiency, timeliness and landscape analyses’. Timelines and costs were discussed, as well as risks and strategies for mitigation. The type of information that will be collected is shown in Figure 1.

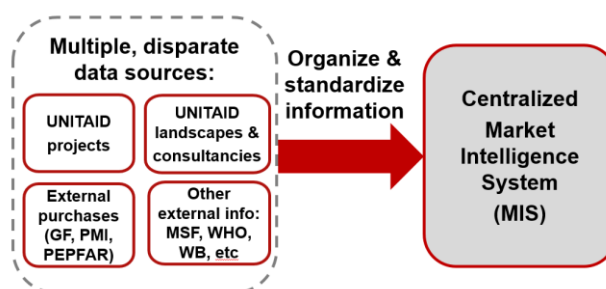


Figure 1. MIS data sources

The SECRETARIAT emphasized the importance of this project. For the first time, there will be open access to global market data, thereby facilitating evidence-based assessments of market interventions by UNITAID and other interested organisations.

Discussion

- ❖ FRANCE expressed surprise that the Board had not been consulted at an earlier stage during the lengthy development process of the MIS. He asked for an opportunity to review the quality of the project in greater detail and questioned whether it should be part of UNITAID’s core business. He stated that the involvement of the Global Fund would be a pre-requisite for the system’s success.
- ❖ The UNITED KINGDOM also commented on the length of time it had taken to develop the MIS and expressed concern about the long term commitment necessary to maintain the system. She agreed with FRANCE that the cooperation of the Global Fund was essential for the success of the project.
- ❖ The NGOs and UNAIDS (as observers) were very enthusiastic about the MIS. They said that it would have a significant and positive impact on market

intelligence, and would influence future investment strategies. UNAIDS considered that the project was well aligned with UNITAID's objectives. He offered UNAIDS' support in ensuring that the MIS would be correctly maintained.

The CHAIR suggested that the Board should look at the MIS prototype in May 2015 before deciding on next steps. He agreed that although UNITAID is driving the project, it does not have the critical mass to carry it alone in the long term and would therefore need to work with other partners.

The HEAD OF MARKET DYNAMICS said that the MIS would supply the data needed for market interventions and to provide evidence for public accountability. The DEPUTY DIRECTOR agreed saying that the MIS would enable impact measurement and facilitate assessments of Value for Money. Offers of collaboration from the Global Fund and UNAIDS would be very welcome.

Follow-up actions and decisions

The EXECUTIVE BOARD took note of the report on the Market Intelligence System and requested the Secretariat to present an update of MIS prototype at EB22.

5.3. Civil Society Engagement Plan

The aim of the Civil Society Engagement plan is to ensure systemic involvement of Civil Society with grantees at country level and within projects. The PSC had requested that the Secretariat identify existing networks and suggest opportunities for information sharing, demand creation and feedback. The revised Engagement Plan was currently under review by the Civil Society delegations.

Discussion

- ❖ The NGOs and the COMMUNITIES both thanked the Secretariat for moving forward with the Engagement Plan. The NGOs emphasised the need for country buy-in and the role of Civil Society for raising awareness. They pointed out that 'Products will not be used if people don't know why they need them and how they should be used'. The NGOs said more information was required about the networks before decisions could be taken concerning Track 1. However, progress could be already made in relation to Track 2 in terms of demand creation.
- ❖ The COMMUNITIES suggested adapting Global Fund mechanisms and networks to the UNITAID model. They stressed that Civil Society players needed a clear understanding of how UNITAID operates in order to be effective within countries.

The EXECUTIVE DIRECTOR agreed that UNITAID's role is poorly understood at country level and said that efforts would be made to rectify this. He recognised the ability of Civil Society to reach places that UNITAID, implementers or governments could not reach.

- ❖ NORWAY, the GATES FOUNDATION and UNAIDS (observers) advised UNITAID to work with existing networks rather than setting up new ones that could cause fragmentation within the countries. UNAIDS briefly described its long standing relationship with Civil Society and offered to help with the implementation of the Engagement Plan.
- ❖ CHILE agreed with the previous comments and said that the plan should be more 'specific' as to how it would fulfil its objectives. He also requested more clarity in the wording of the proposed resolution and questioned the necessity of producing a report to evaluate existing networks.

The EXECUTIVE DIRECTOR explained that it was important to adopt a systematic approach to ensure that processes were in place and so that UNITAID did not have to rely on specific people.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted by consensus Resolution n° 3 as amended by the members during the meeting.

6. Update on Medicines Patent Pool (MPP)

The EXECUTIVE DIRECTOR OF THE MEDICINES PATENT POOL (MPP) presented an update on its achievements to date. The MPP has succeeded in negotiating voluntary licences for eleven priority HIV medicines including WHO-recommended first-line antiretroviral treatments for both adults and children. Ten sub-licence manufacturers are working with the MPP on a total of 53 product development projects. The Access to Medicines (ATM) Index praised the MPP for 'offering pro-public health access and transparent terms, and having the highest level of flexibility and broadest geographical scope.'

Recently the MPP has reached agreements with Gilead for tenofovir alafenamide (TAF) and with AbbVie for paediatric lopinavir/ritonavir (LPV/r). It has also expanded the geographic availability of the paediatric form of abacavir from ViiV; increased the number of partnerships with generic companies; and made significant progress with the Paediatric HIV Treatment Initiative. A database listing the status of patents is under development and should eventually be integrated into the UNITAID market intelligence system.

From the first quarter of 2012 to the second quarter of 2014, total public health savings of US\$41.7 million have been achieved. By 2028, it is estimated that the MPP will have generated US\$1.4 billion in direct savings, benefiting approximately 24 million patients.

On behalf of the Executive Board, the CHAIR congratulated the MPP on its 'extraordinary achievement'. He also recognised the major contribution of the former Executive Director of UNITAID, Mr Jorge Bermudez, for his vision and his commitment to the project.

Discussion

- ❖ FRANCE thanked the Board Members who had been involved in setting up the MPP and observed that commendation by the ATM Index confirmed the great success of the project.
- ❖ BRAZIL urged the MPP to seek ways of improving universal access to treatment for TB, particularly multi-drug resistant (MDR) strains, and hepatitis C (HCV). He informed the Board of the communiqué issued by Ministers from the five BRICS countries regarding a cooperation plan to improve access to treatment for TB in middle income as well as low income countries.

The MPP assured the Executive Board that feasibility studies were ongoing for TB and other disease areas.

- ❖ The GATES FOUNDATION pointed out that the total direct savings of over US\$40 million by 2015 would mainly be due to royalty savings. SHE urged the Executive Director of the MPP to share the challenges faced by the MPP, as well as the results it has achieved.

The MPP BUSINESS DEVELOPMENT DIRECTOR observed that the MPP's impact could be measured by royalty savings and price reductions. He said that the availability of more licenses was creating a greater level of competition within the countries resulting in lower prices. The MPP will try to demonstrate both of these elements in future reviews.

The EXECUTIVE DIRECTOR replied that the MPP mainly encounters problems related to regulatory authorisation for drugs in developing countries.

Follow-up actions and decisions

The EXECUTIVE BOARD took note of the report from the Medicines Patent Pool.

7. Update on Operations

The HEAD OF OPERATIONS provided a brief overview of UNITAID's operations in 2014. The number of active projects in 2014 was 27 and the number of grantees has increased from five in 2007 to 22 in 2014. UNITAID projects now provide antiretroviral therapy (ART) to 122,854 children. Two new POC products are being tested in countries. Negotiations have resulted in the price of injectable artesunate falling to US\$1.45 per vial. More than 24,000 cases of TB were detected in 21 countries. Pre-qualification of nine ARVs, five ACTs and one TB medicine has been achieved. A number of lessons have been learned from the EndTB project; the market entry projects; the Coalition Plus project; and the injectable artesunate project. An integrated risk assessment approach, including a fraud prevention system, must be managed by Operations.

The DEPUTY EXECUTIVE DIRECTOR summarised the status of the EndTB project. In May 2014, the EXECUTIVE BOARD approved a grant of US\$60 million over four years to accelerate uptake of new medicines for the treatment of Multi-Drug Resistant TB (MDR-TB). Between June and August 2014, the Secretariat undertook grant development activities with the proponents. In September 2014, additional due

diligence was initiated to review indicators of effectiveness, risks and compliance with WHO guidelines. The draft report of the due diligence was presented to the Proposal Review Committee (PRC) in November 2014. The PRC made a series of recommendations that were shared with the proponents and the WHO. In particular, the PRC considered that steps should be taken to ensure that safety and efficacy of the data collected during the project can be used to update the WHO MDR-TB guidelines.

A revised grant development timeline and deliverables were agreed upon for the EndTB project. A fiduciary assessment was completed in December 2014. The aim is to complete the capacity evaluation and clinical trial assessment in January 2015 and sign the grant by the end of February 2015.

The EXECUTIVE DIRECTOR said that the PRC had suggested that the amended proposal might need Board approval after the WHO MDR-TB experts had provided technical input, especially about the clinical trial design. The EXECUTIVE DIRECTOR explained that misunderstandings had developed during the grant negotiation process and that everyone is working hard to resolve the issues. In the future, press releases about Board decisions on funding will be more carefully worded in order to manage expectations.

The CHAIR added that he has received letters from the proponents asking why the grant money has not been released. He urged everyone to show a united front in order to protect UNITAID's reputation.

Discussion

- ❖ The NGOs agreed that this issue was of great interest to the TB community. He pointed out that applicants work for several months on proposals and do not always appreciate that further work has to be done during the grant development process. The NGOs wondered whether it would be better to undertake due diligence before Board approval was granted rather than afterwards. They also suggested that the observational cohort component of the project (using approved TB drugs) could proceed while further work was carried out on the design of the clinical trial (using new combinations of novel and approved TB drugs). The NGOs accepted that the clinical trial design uses a novel methodology but said that the results could revolutionise the treatment of MDR-TB.
- ❖ The CHAIR proposed that the Executive Director and the Deputy Executive Director should contact the proponents within the next few days and find a solution to the situation.
- ❖ The UNITED KINGDOM acknowledged that the project is very complex and expressed the hope that a compromise can be reached speedily. The UNITED KINGDOM commented that considerable pre-grant expenses had already been provided to the proponents and asked for more details about this expenditure. The DEPUTY EXECUTIVE DIRECTOR described the expenditure as necessary to ensure that the implementers have the capability to put the project team in place. HE considered that the funds were a clear signal that UNITAID wants the project to succeed. Both the PRC and the Board would like the proponents to conduct the cohort and clinical studies with all of the necessary pharmacovigilance and laboratory monitoring already in place at the study sites. HE added that UNITAID is very happy to work with the proponents to

ensure that the studies are run to international standards so that the WHO can use the results when constructing new MDR-TB guidelines.

- ❖ The CHAIR confirmed that the Executive Director will contact the proponents and explain the need to meet the WHO's requirements.

Follow-up actions and decisions

The EXECUTIVE BOARD instructed the Executive Director to contact the EndTB proponents to clarify the grant negotiation process.

8. External Relations Update

The HEAD OF EXTERNAL RELATIONS reviewed the status of donor contributions and informed the Board of Resource Mobilization activities. Expected contributions for 2014 total US\$252 million: this includes the contribution from Chile that has not yet been received. There has been an overall reduction of 12% in UNITAID's income despite receipt of the outstanding payment of US\$43 million from Brazil. This is due to a reduction in contributions from France, the United Kingdom and Norway, UNITAID's major donors. Only a small proportion of funds are now raised through multi-year commitments and this creates difficulties for long term planning. The SECRETARIAT said that efforts were being made to engage with existing and past donors, and to build relationships with new contributing partners. Future potential partners include Japan, the European Commission, India and Sri Lanka.

As part of the UNITAID external relations strategy, the Secretariat is seeking support from global leaders for the innovative financing model. An independent study on the economic impact on the transport of an air ticket levy will be performed in France, Chile, Korea and Mauritius: results will be presented at EB22. The financial transaction tax also remains an important part of the strategy for 2015. The Secretariat will leverage the opportunity provided by Chile's presidency of the Leading Group on Innovative Financing for Development that will meet in spring 2015. Also under consideration is the possibility of appointing a well-known figure as International Goodwill Ambassador for UNITAID.

The CHAIR agreed that communication must be a priority to raise UNITAID's profile with potential donors.

➤ Follow-up actions and decisions

- **The EXECUTIVE BOARD took note of the report on Resource Mobilization.**
- **Results of an independent study on the economic impact on the transport of an air ticket levy in France, Chile, Korea and Mauritius will be presented at EB22.**

9. Update on Letters of Intent (LOIs)

The Secretariat received twenty-seven Letters of Intent (LoIs) in response to the call for proposals that was launched in September 2014 and closed in December 2014. The DEPUTY EXECUTIVE DIRECTOR presented an overview of the LoIs by disease area and by proponent. He noted that the majority of LoIs had been received from NGOs (42%). The breakdown by disease area is given in Figure 2.

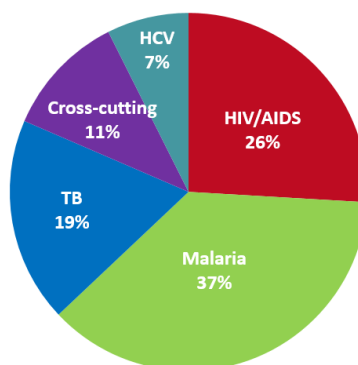


Figure 2. LoIs by disease area

The DEPUTY EXECUTIVE DIRECTOR informed the Board that tuberculosis was UNITAID's priority for this call. The Secretariat will complete its review by mid-January and inform the proponents whether or not they will be invited to submit a proposal.

Discussion

- ❖ The NGOs thanked the Secretariat for providing the information on LoIs in response to a previous Board request for insight into this stage of the grant process.

Follow-up actions and decisions

The EXECUTIVE BOARD took note of the update on LoIs.

10. Partnerships (The Global Fund)

The SECRETARIAT updated the Executive Board on the status of the collaboration between UNITAID and the Global Fund. They have agreed to work together in the following areas:

1. Market shaping and interventions for access in:
 - HIV diagnostics and paediatric formulations;
 - MDR-TB; and
 - Indoor residual spraying (IRS) for malaria.
2. Market intelligence activities for ACT market stabilization.
3. Data sharing to support the Market Intelligence System and the joint dashboard on interventions.

An operational plan has been developed by UNITAID in consultation with the Global Fund. Detailed work plans are now under joint development by portfolio managers from both organisations. These plans will include systems for monitoring and reporting to both Boards.

Discussion

- ❖ The UNITED KINGDOM and the GATES FOUNDATION requested more information about the objectives of the partnership and its strategic framework. The GATES FOUNDATION observed that UNITAID would be able to offer valuable market dynamics support to the Global Fund that would help to guide engagement and procurement strategies.

The EXECUTIVE DIRECTOR said that the Secretariat would work on the development of more concrete steps over the next semester and report back to the Board.

Follow-up actions and decisions

The EXECUTIVE BOARD took note of the update on UNITAID's partnership with the Global Fund and requested the Secretariat to present more concrete steps of the partnership at EB22.

11. Overview of Proposals for Funding Decisions

Declarations of Interest (DOIs) were summarised by the WHO LEGAL:

- ❖ FRANCE declared that France Expertise Internationale, FEI, is a French public industrial and commercial organisation (EPIC).
- ❖ The GATES FOUNDATION declared that they fund IVCC's product development work.
- ❖ NGOs declared that it was initially planned that a representative from the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) would be part of the NGO delegation, but she was recused from all participation about the proposal from her organisation.

The DEPUTY EXECUTIVE DIRECTOR provided an **overview of the seven proposals** (three market entry projects; an HIV early infant diagnosis [EID] project; a malaria prevention project; and two current projects: the OPP-ERA FEI HIV point of care [POC] viral load [VL] project and the Medicines Patent Pool [MPP]) under consideration for funding and the timeline for this round of grants (Table 1). The total value of the projects under consideration was US\$107.477 million, which was substantially less than the funding ceiling (US\$279.90 million). A total of 94 letters of intent (LOIs) were received and six were selected for proposal development. One proponent decided that it was premature to submit an application in late 2014. The other proposals were developed and submitted to the PRC for review. The value for money provided by each of the projects under review by the Board for funding decisions has been evaluated by the Secretariat (Table 1).

The DEPUTY EXECUTIVE DIRECTOR observed that several lessons have been learned from the ongoing market entry projects. HE compared these projects to ‘start up’ companies that are at risk of failure due to lack of funding. The companies face many barriers to entering the market, such as obtaining product registration, establishing appropriate manufacturing capacity and performing outreach activities. The Secretariat must carry out appropriate due diligence to identify critical issues, and guidance for this process is in development. External resources may be needed to provide technical support to develop and monitor market entry grants. It may be necessary to work on market entry projects with partners, e.g. CIFF for EID projects, in order to obtain sufficient finance for commercialisation of these products. Flexibility in financial programming may be required.

The HEAD OF MARKET DYNAMICS reported that the grant review process had worked well and expressed her appreciation of the PRC’s independent review of the applications. All proposals submitted for funding decisions were linked to UNITAID’s Strategic Objectives (SOs).

The HEAD OF MARKET DYNAMICS noted that UNITAID has been at the forefront of increasing access to HIV diagnostic and monitoring tools. UNITAID is supporting the Global HIV Diagnostics Access Initiative and sits on its steering committee. Meetings of this group take place two or three times per year, and are focused on improving coordination between stakeholders. Cost effective ways of improving access to HIV diagnostics and checking that each product is used in the optimal part of the healthcare system (e.g. POC, near POC or centralized laboratories) are essential to ensure that these new technologies are used in the most efficient manner. The HEAD OF MARKET DYNAMICS expressed her confidence that the proposals match the opportunities identified in the market landscapes. The main SO that they address is SO1 – improving access to POC diagnostics.

Follow-up actions and decisions

The Executive Board took note of the Secretariat’s report.

Table 1: Overview of proposals for funding decisions and value for money

Area		Proponent	Title	Value For Money	Proposal amount (\$)	Draft resolution amount (\$)
HIV - ME	SO1	Cavidi AB	Market entry of a novel HIV viral load monitoring platform for near point-of-care testing	VL tests averts death and saves money for treatment Ex Botswana between USD 880k and USD 2.2 million a year saved through drug preservation of first line	3,513,228	3,513,228
	SO1	Massachusetts General Hospital (MGH)	Rapid, point-of-care urine test to monitor adherence to antiretroviral therapy	Save on human resource cost Price reduction of tests expected	3,872,184	3,872,184
	SO1	Wave 80 Biosciences	Creating Access to Low Cost EOSCAPE-HIV Viral Load Testing in Low and Middle Income Countries	VL monitoring allows better treatment and saves money	4,393 605	4,393,605
HIV	SO1 & 2	Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)	Introduction of point-of-care Early Infant Diagnosis in decentralized settings: creating a market for affordable, effective, and equitable HIV testing of exposed infants	Reduction in loss to follow up and lives saved - Cost saving to donors and countries of \$56 million an year	63,082,069	63,082,069
HIV	SO1	France Expertise Internationale (FEI)	Open Polyvalent Platforms (OPP) for a sustainable access to quality and affordable Viral Load Testing in resource-limited settings (Phase 2)	Cost per reduction per test – from \$40 to \$36	12,796,101	3,400,000
MAL	SO6	Innovative Vector Control Consortium (IVCC)	Market intervention to accelerate uptake of new vector control tools	Direct overall saving of \$12-18 million pa once new price has been achieved of \$6 a unit. Without insecticide, further 55 million cases of malaria and cost \$550 m per annum	49,000,000	0
IP		Medicines Patent Pool Foundation (MPPF)	Medicines Patent Pool Foundation	For every million spent up to \$20 million saved - \$60 million investment in three years potential of \$1.2 billion saved	29,215,571	29,215,571
TOTAL					165,872,758	107,476,657

12. Report of the Proposal Review Committee (PRC)

The PRC CHAIR reported that the PRC core review team for each proposal had presented their evaluations to the PRC meeting, held 11-12 November 2014. All of the PRC members had then discussed the projects, and developed funding recommendations by consensus. An additional document – the draft report of the independent evaluation of the FEI OPP-ERA project – was received after the PRC meeting and it was circulated to the committee.

The PRC CHAIR noted that one of the PRC members has recently married an employee of the Medicines Patent Pool (MPP). She recused herself from discussions about the MPP to avoid a conflict of interest.

Discussion

- ❖ The CHAIR asked the PRC Chair and the Head of Market Dynamics to consider the implications of UNITAID granting money to companies and small scale developers. The CHAIR said that he supports increased competition in order to reduce the prices of healthcare products. However, funding market entry activities by start-up companies has inherent risks, especially if it is unclear whether they have the money to roll out their products on a large scale in resource limited settings (RLS).

The HEAD OF MARKET DYNAMICS responded that it is never 100% certain that innovative products will reach the market, irrespective whether they are developed by large or small companies. She described the process as ‘risky’ but pointed out that some large manufacturers have responded to the imminent introduction of POC tests by reducing their prices for centralised HIV diagnostic tests. The HEAD OF MARKET DYNAMICS acknowledged that small developers may tailor their products for use in RLS but are then unable or unwilling to sell them to larger companies for commercialisation. Equally, large companies tend to only be interested in purchasing innovative technologies once they have reached the very late stages of development and the risk of failure is minimal.

The PRC CHAIR outlined two different problems: 1. the need to bridge the gap between the proof of concept and the commercialisation of the product (early market entry); and 2. obtaining data from operational research so that international donors are willing to purchase the product(s) after they have been pre-qualified or approved by international organisations. In the first situation, it is unrealistic to expect developers to have funding to scale up production at that point in the product development process. In the second situation, it may be useful to conduct product agnostic operational research projects to demonstrate that the products can be used at scale, thus making it easier for national programmes to integrate them into their healthcare systems.

The UNITED KINGDOM agreed with the Chair that UNITAID should fund private companies that are developing appropriate and innovative products. However, she stressed that the funding conditions should be carefully considered.

- ❖ The GATES FOUNDATION suggested that a pre-grant assessment of the specifications and performance of the tests being developed in the three market entry proposals under consideration should be performed. The capacity of the three applicants to complete the projects should also be evaluated. The GATES FOUNDATION noted that the Cavid and Wave 80 proposals had previously been rejected by the Executive Board.

The HEAD OF MARKET DYNAMICS replied that the previous Cavid and Wave 80 proposals were premature but said that the technologies are now at the 'proof of concept' stage and so can be considered for UNITAID funding.

- ❖ The UNITED KINGDOM expressed concerns about the three market entry proposals: she noted that, if UNITAID encourages governments in RLS to adopt these technologies, it must be confident that both the technology and the price are optimal. In addition, there must be a commitment to provide maintenance and product support in the future. It could be challenging for start-up companies to provide such commitments.
- ❖ The NGOs commented that UNITAID is a leader in the HIV diagnostics field and suggested that a document should be written to publicise UNITAID's role in this area. The NGOs and the COMMUNITIES welcomed the HIV VL proposals but called for thorough due diligence on both the products and the developers in order to assess the risks to UNITAID. The NGOs suggested that the management of these projects might have to be out sourced if the Secretariat does not have sufficient resources or the appropriate skills to manage them. The NGOs called for clarity on the pricing and access conditions for RLS. Attention should also be paid to demand creation and patient literacy.

THE HEAD OF MARKET DYNAMICS responded that it might be necessary to outsource management of market entry projects.

- ❖ The UNITED KINGDOM proposed that UNITAID should consider a number of different ways of funding market entry projects; for example: grants, loans, and/or equity options. A strategic approach is needed to obtain the best value for money for each project. FRANCE agreed that funding commercial projects was challenging. SOUTH AFRICA supported the United Kingdom's comments and called for thorough due diligence of market entry projects. SOUTH AFRICA was particularly concerned about the capacity of small companies to scale up manufacturing if their product(s) were adopted by countries such as South Africa that care for large numbers of HIV-infected patients. Pricing is a key issue for such countries as the cost of the technologies could become unaffordable if large scale implementation is achieved.
- ❖ The WHO LEGAL stated that the WHO has strict rules about their hosted partners engaging with commercial companies. All due diligence must be carried out using the existing WHO systems since it is the WHO that signs the grant agreement on behalf of UNITAID.
- ❖ CHILE agreed with the concerns of the other Executive Board members about the capacity and sustainability of some start-up companies. He called for UNITAID to be proactive in supporting novel technologies for HIV diagnosis and monitoring. He suggested that due diligence could be carried out at an earlier stage in the grant approval process than is done currently.

The HEAD OF MARKET DYNAMICS and the DEPUTY EXECUTIVE DIRECTOR responded that the Board had previously decided that due diligence should take place after a positive Board funding decision had been taken, because of the resource implications of carrying out due diligence on several proposals before they had been reviewed by the Board. They acknowledged that the Board could revise this approach; in this case, additional resources (staff, funds, external consultants) would be needed to implement the due diligence of a number of projects. Prior to the PRC review of the proposal, the applicant must provide a considerable amount of confidential and commercial information.

The HEAD OF MARKET DYNAMICS suggested that applicants could be asked to supply some information that is currently obtained during the due diligence process. However, she stressed that the applicants only have eleven weeks to provide information at present and some companies find this challenging. She doubted that they would be able to provide information on commercialisation within the time allowed.

- ❖ The NGOs agreed with the requirement for due diligence but stressed the urgent need to support new methods of HIV testing, even if this is associated with certain risks. UNITAID has adopted a policy of investing in market entry projects and so this should be implemented in the NGOs' opinion.
- ❖ NORWAY and the UNITED KINGDOM expressed concern about the Secretariat's capacity to manage the grant making process for seven proposals, given that there are a number of staff vacancies at present. The question was raised as to whether projects should be prioritised if resources are limited.

The EXECUTIVE DIRECTOR thanked the Board for their trust in the Secretariat's ability to deliver and their concern. He said that the Secretariat would strike a careful balance when communicating about the progress of the grant making process.

Follow-up actions and decisions

The EXECUTIVE BOARD took note of the overview of the proposals submitted for funding decisions.

13. Proposal: Cavid AB - Market entry of a novel HIV viral load monitoring platform for near point of care testing

The PRC CHAIR summarised the aims and design of the Cavid AB market entry project. The applicant is developing a novel near POC VL test that can detect HIV-1, HIV-2 and circulating recombinant HIV strains. Cavid AB has requested US\$3.5 million for market entry activities in seven countries.

The PRC identified a number of areas within the proposal that require careful negotiation. The business plan should be updated, especially in relation to the competitive environment for HIV VL tests; the number of staff required; the costs of senior staff; and the management of post launch scale up. The protocol for the

proposed utility study should be consistent with the protocols designed by the London School of Hygiene and Tropical Medicine (LSHTM).

The PRC suggested that funding for the project should be provided on a milestone basis.

Discussion

- ❖ The NGOs, the COMMUNITIES and the UNITED KINGDOM expressed disappointment with the projected pricing of the Cavid device and consumables. The COMMUNITIES called for reductions in the price of HIV VL testing in order to encourage countries to move away from CD4 cell monitoring to VL monitoring. They noted that Roche has already reduced the price of its HIV VL test and questioned whether a price of US\$20/test would be competitive or attractive to governments in RLS. The COMMUNITIES suggested that part of the due diligence should be to determine if lower prices could be achieved sooner than anticipated if rapid scale up is achieved.

The HEAD OF MARKET DYNAMICS and the DEPUTY EXECUTIVE DIRECTOR replied that the prices for the Cavid and Wave 80 projects are conservative estimates and the actual prices will depend on the market volume at the time of launch; the cost of goods; and the market share achieved. The HEAD OF MARKET DYNAMICS reassured the Board that the Secretariat would push for the lowest possible prices. She pointed out that the loss to follow up after centralised HIV testing is approximately 50% and so she considered that the price of each centralised test was effectively double that quoted by the manufacturer.

The DEPUTY EXECUTIVE DIRECTOR observed that centralised testing is not available to patients living in rural areas, whereas POC and near POC testing will enable these patients to be tested and monitored.

- ❖ The UNITED KINGDOM suggested that UNITAID should wait until Cavid has entered the market in four countries; gather information about this experience; and then re-evaluate the grant application to enter another seven markets in a year's time. She asked whether the funding discussed in the application (US\$4 million equity and a US\$10 million loan) was already in place. FRANCE agreed that delaying a decision about the Cavid project, while looking at alternative methods of funding this project, could be considered, especially if it meant that the UNITAID funding could be leveraged in an optimal way.

- **Follow-up actions and decisions**
- **The EXECUTIVE BOARD tasked the Secretariat to conduct due diligence on the Cavid project and further develop the operational plan necessary for the implementation of the proposal.**
- **The EXECUTIVE BOARD adopted by consensus Resolution N° 4 as amended by the members during the meeting.**

14. Proposal: Wave 80 Biosciences, Inc. - Creating Access to Low Cost EOSCAPE-HIV Viral Load Testing in Low and Middle Income Countries

The PRC CHAIR summarised the aims and design of the Wave 80 market entry project. Wave 80 is developing a high performance, easy to use, POC HIV VL technology (the EOSCAPE HIV test). The PRC recommended that the Board should fund the proposal, although they acknowledged that it was a fairly high risk project.

Discussion

- ❖ The UNITED KINGDOM expressed concerns about the viability of the Wave 80 Biosciences Inc. company. She observed that the senior staff were paid high salaries and described the enterprise as ‘very risky’.
- ❖ The NGOs expressed their support for the Wave 80 technology.

➤ Follow-up actions and decisions

- **The EXECUTIVE BOARD tasked the Secretariat to conduct due diligence on the Wave 80 project and further develop the operational plan necessary for the implementation of the proposal.**
- **The EXECUTIVE BOARD adopted by consensus Resolution N°5 as amended by the members during the meeting.**

15. Proposal: Massachusetts General Hospital - Rapid, Point-of-Care Urine Test to Monitor Adherence to Antiretroviral Therapy

The PRC CHAIR summarised the aims and design of the Massachusetts General Hospital (MGH) market entry project. The intention is to develop a POC test to detect tenofovir levels in the urine as a surrogate marker of adherence to tenofovir-based antiretroviral therapy (ART). The PRC CHAIR acknowledged that the PRC had initially been excited by the proposal but doubts had emerged as the project was scrutinised in greater depth. Although the applicants have demonstrated a proof of concept, the PRC considered that more work needs to be done on the sensitivity and specificity of the test in a Phase 1 study involving healthy volunteers who take tenofovir in a simulation of various patterns of adherence and non-adherence. The proponent had been asked to supply additional information after the November PRC meeting, but the replies had been unsatisfactory and had not addressed the PRC’s major concerns.

Discussion

- ❖ CHILE and NORWAY agreed that the proposal was very interesting and said that there is an unmet need for adherence monitoring. CHILE suggested that the test should be focused on the majority of patients, rather than being concerned about false positives and false negatives. CHILE questioned whether the PRC had been asking too much of the test.

The PRC CHAIR responded that an adherence test that measures isoniazid levels has been available for several years. Since adherence is a major factor in the development of MDR-TB, an adherence test would appear to be helpful. However, it has not proved to be very useful in the field.

- ❖ The GATES FOUNDATION said that her organisation had created a target product profile for a similar product two years ago and had evaluated a project to develop an adherence test. The Foundation had rejected the proposal on similar grounds to the PRC's concerns about the practicality of this test and whether a non-adherent patient would take his/her tablets just prior to clinic visits, thus giving a false positive result. Operational research on the use of an adherence test in the field is required before the test is rolled out on a wide scale; the NGOs and NORWAY concurred with this statement.

The PRC CHAIR agreed that there are considerable challenges with the use of this test, especially to prevent inappropriate switching to second line regimens. The majority of people who have elevated VLs are able to re-suppress their VLs when given adherence counselling and support.

- ❖ The NGOs commented that their delegation was excited about the test but had expressed concern on how it would be used and its impact on clinical practice. Their first priority is to roll out VL testing to all HIV infected patients. During the first year of ART, VL testing is an effective adherence test, they noted. There is limited information about current adherence levels; most of the existing data is out of date by several years. The NGOs called for patient literacy to form part of the project. They were supportive of the proposal, provided that there was an operational research component in the project; NORWAY concurred with this suggestion.

The PRC CHAIR commented that the NGOs' reaction was similar to that of the PRC, who were convinced that a modelling Phase 1 study would provide useful data about the sensitivity and specificity of the test before it was used in the field.

The DEPUTY EXECUTIVE DIRECTOR commented that the Secretariat agreed with the PRC's recommendations and suggested that they should seek further clarification from the proponent about the Phase 1 study.

➤ **Follow-up actions and decisions**

- **The EXECUTIVE BOARD tasked the Secretariat to conduct due diligence on the Massachusetts General Hospital project and further develop the operational plan necessary for the implementation of the proposal.**
- **The EXECUTIVE BOARD adopted by consensus Resolution N°6 as amended by the members during the meeting.**

16. Proposal: Elizabeth Glaser Pediatric AIDS Foundation - Introduction of Point-Of-Care Early Infant Diagnosis in Decentralized Settings: Creating a Market for Affordable, Effective and Equitable HIV Testing of Exposed Infants

The HEAD OF MARKET DYNAMICS provided an overview of the proposal: early testing of infants at risk of HIV infection is essential to ensure that they can be treated immediately they have been diagnosed as HIV infected. A pipeline of POC early infant diagnostic (EID) products for use in decentralised settings exists, but creating a market for these products is challenging. The EGPAF has identified a number of strategic areas in order to improve access to EID products. Demonstration projects will create demand and identify the most cost effective EID technologies. The project addresses SO1 [Simple, point-of care (POC) diagnostics] and SO2 [Affordable, adapted paediatric medicines], and leverages UNITAID supported interventions on the selection, procurement and evaluation of EID technologies. There is a commitment to fund paediatric treatment as part of the project: the aim is to treat 41,000 infants and save over 37,000 lives. The intention is to reduce the cost of EID tests by 40% and create a POC market for EID.

The PRC CHAIR explained that the project will be to scale and will be product agnostic. He acknowledged that the budget is very large, but said that this was necessary to enable EGPAF to work across nine countries and to identify the best technologies for use in the field. The PRC CHAIR commented that POC testing has a major impact on the parent's ability to have their child tested e.g. reduced travel costs/times, minimal loss of earnings, etc. The public health impact of the project is expected to be considerable. The PRC CHAIR said the opinion of the PRC was that it was an innovative and important project. As the number of HIV infected children falls (thanks to effective prevention of mother to child transmission [PMTCT] programmes), there is a diminishing incentive for manufacturers to invest in the diagnosis and treatment of HIV infected children.

The PRC considered that the transition plans for the project were not comprehensive and the budget, especially for staff and office costs, should be carefully negotiated. Despite these caveats, they recommended that the Executive Board should fund the proposal.

The EXECUTIVE DIRECTOR described the project plan as 'good' but added that a number of major issues must be addressed including: developing a detailed operational plan; a performance framework; a strategic and procurement plan; identification of overlap with other projects; a detailed budget to ensure that UNITAID funds are only spent on the UNITAID project; capacity assessment; fiduciary assessment; and validation of operational research plans. The Secretariat has estimated that it will take 4-6 months to complete these tasks. The EXECUTIVE DIRECTOR suggested that the applicant should work with the Secretariat to develop a full proposal that could be submitted to the Board for a funding decision. The project would be ready to commence immediately after the funding decision in this scenario.

Discussion

- ❖ The NGOs asked whether the Executive Director was trying to introduce a 'green light' approach to funding decisions. He added that a change of this magnitude required further discussion before being adopted. The NGOs

described EGPAF as a mature organisation that understands the need for negotiation and fulfilment of UNITAID's requirements before funds are released. The NGOs acknowledged the political implications of this funding decision but was certain that EGPAF could resolve the outstanding issues with the Secretariat. The NGOs added that they had a number of suggestions to improve the project that they would like to share with the proponent e.g. improving parental literacy so that parents understand the need for early HIV testing. The UNITED KINGDOM acknowledged that there are communication issues surrounding the outcomes of UNITAID Board meetings. The UNITED KINGDOM supported funding of the EGPAF proposal but agreed that a number of steps have to be taken before funds can be released to the applicant. The UNITED KINGDOM was reluctant to delay a funding decision until June 2015.

- ❖ BRAZIL shared the NGOs' concerns but said that it is necessary to move quickly to improve access to EID. BRAZIL suggested that the funding decision could be conditional on resolving the major issues identified by the Executive Director. FRANCE agreed with Brazil that funding should be approved, provided that appropriate financial controls were in place.
- ❖ FRANCE suggested that the applicant be offered less money than that requested in the application.
- ❖ CHILE noted that all funding decisions are conditional on the applicant meeting certain conditions. He considered that this safeguarded UNITAID.

The EXECUTIVE DIRECTOR replied that people tend not to read the conditions of the grant.

- ❖ The CHAIR concurred with the other Board members that the funding decision should not be delayed until the next Board meeting. He suggested that a stepped approach could be taken to providing funds to the EGPAF or that further negotiations could take place and then the Board could take an e-vote. The UNITED KINGDOM was supportive of holding an e-vote or a telephone conference to make a final decision after the applicant had resolved the issues identified by the Executive Director.

The EXECUTIVE DIRECTOR agreed that the project is necessary and it is in UNITAID's interests to fund the proposal. He promised that the applicant's and the community's expectations would be managed appropriately. Communication about this Board decision would ensure that the funding pathway was clear to all interested parties. The EXECUTIVE DIRECTOR pointed out that the timing of the resolution of all of the issues was not in the Secretariat's control because the applicant will have to provide much of the information. He considered it normal to spend 4-6 months negotiating a multi-million dollar grant. The EXECUTIVE DIRECTOR drew a distinction between the United Kingdom method of working, where a grant is only signed after all of the issues have been resolved, and the continental system, where an agreement is signed as a signal to work together to create a project. He asked for support from Civil Society to deal with any political pressure that the Board's decision might create.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted by consensus Resolution N° 8 as amended by the members during the meeting.

17. Proposal: FEI - OPP-ERA (Phase 2)

The DEPUTY EXECUTIVE DIRECTOR described the OPP-ERA project, which aims to increase access to HIV VL testing and EID for adults and children living with HIV by scaling up the FEI activities in four countries and introducing the approach to three new countries. At present, most HIV testing is carried out using ‘closed’ systems, such as those marketed by Abbott and Roche. FEI set up open polyvalent testing systems in four countries in Phase 1 of this project. An evaluation of Phase 1 of the project has been carried out: the technology was introduced into seven sites within four countries but obtaining pre-qualified reagents has proved to be difficult, mainly due to the lack of a regulatory pathway. The final version of the evaluation report was not available at the time of the PRC meeting but it was subsequently shared with the PRC and the Board.

The PRC CHAIR noted that using an open system challenged the monopoly or duopoly of closed systems and prevented countries from being ‘locked in’ to a specific technology. The various components of the system are procured from a range of manufacturers and then combined at the testing site. Although an open system has the potential to detect multiple HIV strains and other infectious organisms e.g. hepatitis C, demonstrating this advantage has been hard to achieve. The PRC CHAIR acknowledged that Phase 1 of the project had only been operating for a few months before the Phase 2 application was submitted. FEI has found that appropriate quality reagents can only be sourced from one manufacturer; there is, therefore, a risk that the applicant is ‘captured’ by the manufacturer. The PRC noted that the prevalence of HIV in West Africa is relatively low and so it is not an attractive market for manufacturers/suppliers to enter. The PRC speculated that it might be more appropriate for FEI to negotiate better contracts with Abbott and/or Roche in order to improve access to VL testing. Open systems require considerable expertise and infrastructure; as a result, they can only be used in large hospital laboratories or reference laboratories and not at POC or near POC. The PRC CHAIR observed that, although the theory of open systems is good, the potential for success in the field is low. The PRC recommended rejection of funding for the Phase 2 application, but provision of funds to enable FEI to complete Phase 1.

Discussion

- ❖ The NGOs described the PRC’s comments as very convincing but said that they disagreed with their conclusions. They believed that the open system was working well at the Level 3 test sites and said that it was putting pressure at Abbott and Roche to negotiate better commercial deals with countries. The NGOs acknowledged that the potential to buy reagents from multiple suppliers has not yet materialised and that BioCentric had become the ‘one stop shop’ for the OPP-ERA supplies, thus reducing some of the complexities of the open system. The NGOs considered that scaling up the project was appropriate.

They suggested that the target countries for expansion should be consulted to see if they were interested in adopting the open system.

- ❖ The CHAIR acknowledged that he was unable to vote on this resolution but supported funding this proposal on several grounds. These included the need to scale up access to VL testing, as recommended by the WHO; a desire to increase competition in the diagnostics market; the fact that there is a limited HIV market in West Africa, due to the low HIV prevalence in that region, means that it is unattractive to large manufacturers; the need to develop hepatitis C testing in West Africa; and a political desire to reverse the historical neglect of West African public health development.

The EXECUTIVE DIRECTOR accepted that it is difficult to develop a HIV diagnostics market in West Africa, mainly because of the lack of healthcare infrastructure in that region. He described HIV/AIDS as a major problem in this area and described the market potential as 'considerable'. He noted that the Global Fund is devoting significant resources to healthcare in West Africa. Between 40% and 60% of this money is allocated to HIV. The EXECUTIVE DIRECTOR suggested that this project could access some of these funds.

- ❖ The COMMUNITIES supported the stance of the NGOs and the Executive Director. They were concerned about the potential for the existing relatively small pockets of HIV infection in West Africa to explode into a generalised epidemic. The COMMUNITIES also expressed concern about the impact of hepatitis C on the health of West Africans. They supported the proposals, subject to a number of clarifications.
- ❖ The GATES FOUNDATION accepted the value of HIV testing but asked whether the Phase 1 evaluation has demonstrated that the open system has resulted in a more cost effective way to increase access to VL testing than closed systems. The GATES FOUNDATION noted that their technical experts have a number of questions about the FEI approach.

The DEPUTY EXECUTIVE DIRECTOR explained that relatively little data have been obtained from Phase 1 of the project so far. He supported enabling the applicants to complete Phase 1 so that the case for using an open system can be fully evaluated.

- ❖ SOUTH AFRICA expressed support for improving healthcare in West Africa and said that it was important to work with organisations in the region. Even though the HIV prevalence is relatively low at present, it is critical to understand the size of the epidemic and to look at its potential impact on the health of West Africans.
- ❖ NORWAY commented that they have struggled with this proposal. Although they support increased access to HIV testing, they questioned whether the open system was the best technological solution. Norwegian technical experts have identified a number of issues that should be addressed and further information is required about its feasibility and suitability.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted Resolution N°7 as amended by the members during the meeting (Norway abstained).

18. Proposal: IVCC – Market Interventions to Accelerate Uptake of New Vector Control Tools

The HEAD OF MARKET DYNAMICS provided a summary of the IVCC proposal: there is a need to develop non-pyrethroid insecticides for indoor residual spraying (IRS) because resistance to pyrethroids is emerging in the majority of African malarial areas. The IVCC proposal addresses SO6 [Preventatives for HIV/AIDS, TB and malaria] by accelerating access to a new type of insecticide (3GIRS), which is very effective but also approximately ten times more expensive than pyrethroids. The IVCC proposal described a range of market-based interventions to accelerate adoption of 3GIRS for IRS.

The PRC CHAIR summarised the PRC's review of the proposal. They acknowledged the urgent need to use new insecticides for IRS. The IVCC consortium is extensive and built around the Liverpool University School of Health. The PRC noted that the WHO has recommended a rotation of three different 3GIRS products, but only one is currently available. The PRC considered that achieving a 25% decrease in the price of the 3GIRS product during the project was unlikely to make the insecticide sufficiently attractive to national malaria programmes or international donors so that they would use their own funds to purchase the product. The ability of this project to transition is dependent on achieving the projected price reduction because the subsidy would be withdrawn after four years. The PRC acknowledged that the proposal leverages funds from the President's Malaria Initiative and the Global Fund, but was not certain that the most vulnerable people living in very rural, endemic regions would benefit from the project because their housing might not be suitable for IRS. The PRC was also concerned that the University of Liverpool might not be the most efficient way to distribute funds for IRS, given the time sensitive nature of the disbursements in order to carry out IRS at the correct time. The PRC's recommendation was that the consortium should re-work their proposal and resubmit it for PRC review and a funding decision.

Discussion

- ❖ The UNITED KINGDOM described the issue of pyrethroid resistance as 'incredibly important' and supported the PRC's suggestion that the applicants should work on the proposal so that it is appropriate for UNITAID funding. The GATES FOUNDATION, NORWAY, FRANCE and the NGOs agreed with the PRC and the United Kingdom that the proposal should be refined and re-submitted.
- ❖ The CHAIR commented that the proposal is a perfect example of how UNITAID can work in partnership with the Global Fund.
- ❖ The GATES FOUNDATION proposed that the manufacturer should offer a discount in return for a volume guarantee or an underwriting arrangement. At present, nothing is being offered. The GATES FOUNDATION considered that the project timeframe is ambitious. More clarity on the structure of the consortium is needed. The GATES FOUNDATION shared the PRC's concern that a 25% price reduction might not achieve the desired market changes. She accepted that the price will not reach that of pyrethroids but advised that a more thorough price analysis was needed.

- ❖ NORWAY suggested that the environmental impact of using 3GIRS should be evaluated.
- ❖ The NGOs called for a cost of goods analysis to be undertaken and all possible market interventions to be explored.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted by consensus Resolution N°12 as amended by the members during the meeting.

19. Proposal Medicines Patent Pool – Multi-year funding proposal

The SECRETARIAT highlighted the importance of improving access to generic ARVs, especially in fixed dose combinations (FDCs), for the fifteen million people living with HIV who currently have no access to treatment. The number of new product patents is increasing, resulting in a lack of affordable FDCs and appropriate paediatric formulations. UNITAID seeks to increase access to affordable paediatric medicines (SO2) and to emerging medicines and new formulations (SO3). The Medicines Patent Pool (MPP) addresses these objectives through voluntary licensing of HIV medicines, especially those ARVs that have been identified as priorities by the WHO and expert advisors.

The MPP requested a continuation of funding to enable it to:

- Work with the pharmaceutical industry to remove market entry barriers and negotiate pro-public health voluntary licenses in as many countries as possible.
- Accelerate market entry for FDCs and paediatric formulations.

Over the next five years, the MPP is expected to bring about price reductions of 80%; accelerate the availability of generics, especially FDCs and paediatric formulations; and to bring about significant public health benefits.

The PRC's assessment of the MPP was overwhelmingly positive. The MPP makes a significant difference to public health: generic licensees are expected to provide 21.7 million patient years of medicines by 2028. The MPP offers a high level of innovation, excellent value for money and sustainable market impact that is expected to generate total direct savings of US\$1.18 billion by 2028. Access to ARVs is improving, especially in low income countries and for children. The MPP is also leveraging 2nd and 3rd line regimens.

Discussion

- ❖ The EXECUTIVE BOARD was unanimous in supporting the continuation of funding for the MPP. The COMMUNITIES praised its achievements and said that they had no reservation in supporting the proposal.
- ❖ BRAZIL repeated its earlier call for more interventions in Middle Income Countries (MICs) and for the scope of the MPP to be expanded to include HCV and MDR-TB.

- ❖ The NGOs emphasised the importance of intervening ‘further upstream’ to obtain licenses for newer drugs. They pointed out that access to 2nd and 3rd line therapies is essential, particularly in MICs where prices are very high. The NGOs urged the Secretariat to develop an IP strategy for MICs that would include complementary actions, such as those undertaken by the Lawyers Collective, to put additional pressure on pharmaceutical companies. Although they were pleased to see growing numbers of generic products, the NGOs stressed that UNITAID must ensure that these products are also available in smaller markets.
- ❖ The GATES FOUNDATION noted that the CEPA report had raised questions regarding the quality of the milestones defined by the MPP. She requested that the resolution should specify that future milestones should be based on ‘measurable results’. She reiterated the Foundation’s earlier request to include the challenges faced by the MPP in their report. She also questioned whether greater diversification of financing could enhance the MPP’s credibility.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted by consensus Resolution N° 13.

20. Outcome of the Functional Review

The outcome of the functional review of the Secretariat was discussed during the Executive Board Closed Session held in the morning of 11 December 2014. (This session was not minuted). The EXECUTIVE DIRECTOR presented three resolutions resulting from the functional review concerning the grant management process, the functional organizational structure of the Secretariat and the relocation of UNITAID’s offices.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted by consensus Resolutions N°9, 10 and 11.

21. Governance issues

The EXECUTIVE BOARD reviewed the proposed recommendations of the Steering Committee on Governance. The revised version of the Steering Committee report includes the clarifications that had been requested at EB20.

Discussion

- ❖ The UNITED KINGDOM welcomed the open and frank discussions that had taken place during the governance review. She noted that, although there were no formal consequences regarding the implications of non-payment of contributions by a Board member, there had been an informal agreement that the delegation would not seek appointment as **Chair** or **Vice-Chair** of any committees.

- ❖ KOREA expressed concern about the qualifications for Board membership outlined in the report. He pointed out that if membership were based solely on the amount of the annual contribution, this would affect Korea and Spain's membership of UNITAID. He therefore requested that the size of the total contribution, including previous contributions, should be taken into account. FRANCE supported this view.

The VICE-CHAIR reassured the Board that existing membership would not be affected by the recommendations, and that there would be a case by case evaluation for new donors.

The CHAIR requested that wording of the resolution should be modified to specify 'total' contribution. He congratulated the Vice-Chair and the NGOs for their work in defining the governance principles for the Executive Board and asked the Secretariat to update the governance documents to reflect these amendments.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted by consensus Resolution N° 14 as amended by the members during the meeting.

22. Any Other Business: calendar of Board meetings for 2015

The following dates were agreed for the Board meetings in 2014:

EB Special session:	27 April 2015
14 th Finance and Accountability Committee:	28 April 2015
13 th Policy and Strategy Committee:	29 April 2015
22 nd Session of the Executive Board:	3-4 June 2015
15 th Finance and Accountability Committee:	4 November 2015
14 th Policy and Strategy Committee:	5 November 2015
23 rd Session of the Executive Board:	14-15 December 2015

Discussion

- ❖ BRAZIL observed that the Board meetings are always held in Geneva. He proposed that Brazil should host the June meeting (EB22) in Rio de Janeiro. CHILE supported the suggestion of holding future meetings in Latin America as this would offer an opportunity for other events to be organised at the same time e.g. donor outreach, discussions on patent issues etc. FRANCE also agreed that the location of Board meetings could vary: he suggested that, like the

Global Fund, UNITAID should consider holding meetings in the countries with which it works.

The CHAIR thanked Brazil for the invitation to host EB22. However, he explained that the decision to hold Board meetings in Geneva was based on cost. He requested that the Secretariat evaluate the cost of organising EB22 in Rio de Janeiro for discussion by the Board. The CHAIR also suggested that Government Ministers from donor, or potential donor, countries could be invited to attend Board meetings to raise UNITAID's profile and achieve ministerial recognition.

Follow-up actions and decisions

The EXECUTIVE BOARD adopted by consensus Resolution N°15 as amended by the members during the meeting.

NB: after the meeting, the Board endorsed by e-vote on January 16 the new dates for the EB special session, FAC 14 and PSC 13 as follows:

EB Special session:	21 April 2015
14 th Finance and Accountability Committee:	22 April 2015
13 th Policy and Strategy Committee:	23 April 2015

23. Closure of the meeting

Before closing the meeting, the CHAIR announced that **Tido von Schoen-Angerer** would no longer be representing the NGOs delegation. THE BOARD MEMBERS expressed their appreciation of Dr von Schoen-Angerer's skills, innovative ideas and positive approach and wished him luck in his future work. On behalf of the Board, the CHAIR also thanked **Brigitte Laude, Head of Finance and Administration**, who will leave the Secretariat in early 2015. He expressed the Board's great admiration for her management of UNITAID's financial affairs and said that she had made a tremendous contribution to the organisation.

The CHAIR OF THE EXECUTIVE BOARD thanked the Board Members for their contributions to the meeting.

The 21st session of UNITAID EXECUTIVE BOARD closed at 16.10 on Friday, 12 December 2014.

24. Appendix - List of Participants

BOARD MEMBERS

CHAIR	– Philippe Douste-Blazy
VICE-CHAIR – CHILE	– Marta Maurás
	– Alt.: Guy Fones
AFRICAN COUNTRIES	– Lindiwe Makubalo
ASIAN COUNTRIES – Republic of Korea	– Eun Kyeong Jeong
	– Alt.: Kyu Cheol Kang
BRAZIL	– Regina Maria Cordeiro Dunlop
	– Alt.: Jorge Bermudez
COMMUNITIES LIVING WITH THE DISEASES	– Kenly Sikwese
	– Alt.: Mercy Annapoorani
FRANCE	– Philippe Meunier
	– Alt.: Marianne Barkan-Cowdy
FOUNDATIONS (GATES)	– Alt.: Susan Nazzaro
NGOs	– Tido von Schoen-Angerer
	– Alt.: Brook Baker
NORWAY	– Bjørg Sandkjær
	– Alt.: Kjetil Aasland
SPAIN	Gonzalo Vega Molina
	Alt.: Miguel Casado Gomez
UNITED KINGDOM	– Sarah Boulton
	– Alt.: Charlotte Howman
WHO	– Hiroki Nakatani

ADDITIONAL MEMBERS OF DELEGATIONS

BRAZIL	– José Roberto de Andrade Filho
FRANCE	– Catherine Dauphin Llorens
NORWAY	– Jens Plahte
WHO	– Issa Matta

CIVIL SOCIETY

LIAISON OFFICER, CIVIL SOCIETY
NGOs

- Rebecca Shadwick
- Catherine Connor
- David Deakin
- Khalil Elouardighi
- Mogha Kamal Yanni
- Cecilia Lodonu-Senoo
- Liudmyla Maistat
- Anna Miller
- Bruno Rivalan

COMMUNITIES LIVING WITH THE
DISEASES

- Endalkachew Fekadu Demmisse
- Hope Mafaranga
- Rondinho Calavete Vileguelia

PROPOSAL REVIEW COMMITTEE

CHAIR
VICE-CHAIR

- Andy Gray
- Stephanie Simmonds

PARTNERS (OBSERVERS)

MEDICINES PATENT POOL

- Greg Perry
- Chan Park
- Sandeep Juneja

STOP TB PARTNERSHIP
UNAIDS

- Joel Keravec
- Carlos Passarelli

OTHER

OFFICE OF THE CHAIR

- Laurence Thurion

UNITAID SECRETARIAT

Executive Director	– Lelio Marmora
Deputy Executive Director	– Philippe Duneton
Advisor to Executive Director	– Sanne Fournier-Wendes
Head of External Relations	– Mauricio Cysne
Board Relations Officer	– Sophie Genay-Diliautas
Head of Finance and Administration	– Brigitte Laude
Senior Legal Officer	– Sonia Lees-Hilton
Head of Operations	– Taufiqur Rahman
Head of Market Dynamics	– Brenda Waning
Executive Board Assistant	– Catherine Kirorei-Corsini
Technical Officer, Executive Office	– Gelise McCullough

On Specific Agenda Items

Technical Officer, Finance & Administration	– Irina Avchyan
Technical Officer, Market Dynamics	– Alexandra Cameron
Technical Officer HIV/AIDS, Operations	– Smiljka de Lussigny
HIV Portfolio Manager, Operations	– John Cutler
Technical Officer, Operations	– Danielle Ferries
Portfolio Manager-TB, Operations	– Robert Matiru
Technical Officer, Market Dynamics	– Carmen Perez-Casas
Technical Officer, Market Dynamics	– Karin Timmermans
Executive Assistant, Executive Office	– Susanna Volk