



Minutes

19th Executive Board Meeting

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1. Executive Summary

- The UNITAID Executive Board Meeting (EB19) was held on 12-13 December 2013 at the CCV in Geneva, Switzerland. The meeting commenced at 14.00 on 12 December 2013, after a closed session was held in the morning of 12 December 2013.
- The CHAIR OF THE EXECUTIVE BOARD thanked UNITAID's Board members and the Secretariat for their hard work in preparing for the Executive Board Meeting.
- The EXECUTIVE BOARD adopted the agenda and approved the minutes of EB18, without any amendments.
- The EXECUTIVE DIRECTOR reported on the activities of the Secretariat. Following the recent appointments of Head of Operations, and Head of External Relations, a full senior management team is in place. A Management Organisation Review is planned to address certain structural issues and ensure that UNITAID can adapt to changes in the global health landscape.
- UNAIDS offered UNITAID the opportunity of collaborating in a meeting on making use of flexibilities in Trade Related Aspects of Intellectual Property Rights (TRIPS). This approach was welcomed by the members of the Executive Board.
- The CHAIR OF THE POLICY AND STRATEGY COMMITTEE (PSC) gave a report on the recent PSC meeting (PSC10). Agenda items had included the status of grant performance and proposals, the composition and terms of reference for the new Proposal Review Committee (PRC), a report on Market Dynamics activities and models for measuring Public Health Impact.
- The EXECUTIVE BOARD passed a Resolution approving the Terms of Reference for the new Proposal Review Committee (PRC). **(Resolution N°1).**
- The RUSSIAN DELEGATION thanked UNITAID for the invitation to participate as observers at the meeting of the Executive Board. A decision will be made shortly concerning Russia's potential participation in UNITAID.
- Funding approval was sought from the Executive Board for proposals focused on access to paediatric antiretrovirals (ARVs); the World Health Organisation (WHO) pre-qualification (PQ) programme for medicines and diagnostics; point of care (POC) HIV diagnostics; and the Strategic Rotating Stockpile (SRS) for drugs for multi-drug resistant TB (MDR-TB). All of the proposals were funded with conditions. **(Resolutions N°2-7).**
- 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 the WHO (on WHO pre-qualification programme) and the GATES FOUNDATION (on Zyomyx, on GDF (SRS) and on WHO pre-qualification programme).
- The EXECUTIVE DIRECTOR OF THE MEDICINES PATENT POOL (MPP) announced a new contract with Bristol-Myers Squibb (BMS) in relation to atazanavir (ATV), a 2nd line HIV treatment. Agreements have also been made recently with ViiV for the paediatric formulation of abacavir (ABC), and Roche for valacyclovir in the treatment of HIV-related cytomegalovirus retinitis. The MPP achieved a total saving of US\$14.2 million from Q1 2012 to Q2 2013.
- A Strategy implementation framework has been developed by the Secretariat: it focuses on the six Strategic Objectives and the five Core Action Areas.

- The Civil Society report outlined areas where further support was available at country level to help UNITAID fulfil its mandate. The EXECUTIVE BOARD discussed the request from Civil Society for UNITAID to terminate its involvement in the Global fund's tiered pricing task force.
- The report from the Finance and Accountability Committee (FAC) focused on the proposed budget for 2014. The Board agreed to cap the travel budget at US\$2.5 million. Three Resolutions were passed to approve the budgets for UNITAID and more specifically for Civil Society delegations to the Board and for the Office of the Chair Of The Executive Board. **(Resolutions N°8, 9 & 10).**
- The CHAIR OF THE EXECUTIVE BOARD praised Operations on its progress in quality management. The department has recently introduced a Grant Management Dashboard, an online reporting module for implementers, and interactive data visualisation. The SECRETARIAT presented the Board Key Performance Indicators (KPIs), which had been revised after feedback provided during the Board Retreat in November 2013. The KPIs will be used to track changes over time and to monitor UNITAID's progress towards Strategy implementation.
- The EXECUTIVE DIRECTOR OF THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA, Mark Dybul, addressed EB19. He described UNITAID as one of the most important partners for the Global Fund and said that its innovative approach was essential for the Global Fund to function well.
- Michael Johnson (GLOBAL FUND ATTACHÉ, UNITED STATES MISSION TO THE UN) attended EB19. He praised the increased collaboration between UNITAID and PEPFAR at both Board and Secretariat level, which has been formalised by a letter of co-operation.
- The Executive Board meetings for 2014 will be held on the following dates:
 - Special session: Monday 5th May
 - EB20: Thursday 12th - Friday 13th June
 - EB21: Thursday 11th – Friday 12th December **(Resolutions N°11).**
- THE CHAIR OF THE EXECUTIVE BOARD thanked the meeting participants for their active participation and constructive contributions. The 19th Session of the Executive Board closed at 17.25 on Friday 13th December 2013.

2. Opening remarks of the Chair

The CHAIR OF THE UNITAID EXECUTIVE BOARD, Dr Philippe Douste-Blazy, welcomed the participants to the 19th Executive Board meeting (EB19). He outlined the important topics that would be discussed during the meeting that would include decisions on funding, the strategy implementation framework, the new Proposal Review Committee (PRC), governance issues and revised key performance indicators.

2.1 Adoption of the agenda

The agenda for the Executive Board meeting was adopted.

DECISION

The EXECUTIVE BOARD adopted the agenda for EB19.

2.2 Minutes of EB18

THE EXECUTIVE BOARD approved the minutes of EB18 without any amendments.

DECISION

The EXECUTIVE BOARD approved the minutes of the EB18.

2.3 Report from the Executive Director of UNITAID

The EXECUTIVE DIRECTOR of UNITAID presented a report on the vision and performance of the Secretariat. He described UNITAID funding for HIV/AIDS services in the community; successes in reducing morbidity in children and improvements in treatment regimens for tuberculosis (TB).

Following the appointments of Taufiqur Rahman as Head of Operations, and Mauricio Cysne, as Head of External Relations, the Secretariat now has a full senior management team. Weekly management meetings are held to discuss activities and issues.

The EXECUTIVE DIRECTOR gave a brief summary of the performance of Operations, Market Dynamics, and Finance teams, as well as an update on resource mobilisation.

He highlighted the need for a Management Organisation Review to address certain structural issues and prepare for ‘the next chapter of UNITAID’. He stressed that UNITAID’s business model has to evolve to respond to changes in the global health landscape. This evolution will require rapid, well organized coordination with the Global Fund to ensure sustainability; continued strategic partnerships with major organisations; and a closer relationship with the private sector. The EXECUTIVE DIRECTOR observed that the Secretariat needs effective mechanisms to vet products, manufacturers and implementers, and a streamlined grant management process to deal with the increasing number of implementers.

The Executive Board received the assurance that all the resolutions from the previous meeting had either been implemented or were being implemented.

Discussion

The COMMUNITIES LIVING WITH THE DISEASES (the COMMUNITIES) welcomed the proposal for increased collaboration between UNITAID and the Global Fund.

BRAZIL commended the Secretariat on its achievements to date.

UNAIDS informed the Executive Board that a consultation on access to HIV/AIDS medication in middle income countries had been held with the participation of UNAIDS, WHO, UNITAID and other partners. Access to second and third line regimens had been extensively discussed.

BRAZIL and the NGOs welcomed the opportunity for UNITAID and UNAIDS to work together. They observed that this approach is in line the UNITAID Strategy, which seeks to improve prices of key healthcare products in middle income countries.

UNAIDS also highlighted the essential role of Civil Society in promoting flexibilities arising from the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). UNAIDS invited UNITAID to help with the organisation of a meeting on TRIPS that will take place around the time of the World Health Assembly in May 2014.

The CHAIR OF THE EXECUTIVE BOARD noted that UNITAID was planning a meeting with the Medicines Patent Pool (MPP) and suggested that UNAIDS should contact the Secretariat to discuss possible collaborations.

DECISION

The EXECUTIVE BOARD *took note of the report from the Secretariat.*

3. Report of the Policy and Strategy Committee

The CHAIR OF THE POLICY AND STRATEGY COMMITTEE (PSC) summarised the discussions and decisions from the PSC meeting that had taken place in November 2013 (PSC10). Agenda items included the status of grant performance and proposals; the composition and terms of reference of the new Proposal Review Committee (PRC): a report on Market Dynamics activities; and the development of models to measure the Public Health Impact of UNITAID's projects.

3.1 Grants and Proposals

The majority of the grants are performing well. Efforts are ongoing to further improve the grant management processes.

Eleven new proposals are currently in development. These proposals will be reviewed during the Special Session of the Executive Board in May 2014.

The deadline for the 2014 submission of Letters of Intent is in June.

3.2 The Proposal Review Committee (PRC)

The new PRC will be composed of twelve members plus the PRC Chair. The list of nominees was previously approved by the Executive Board. All nominees have accepted and the PRC induction will take place in February by teleconference.

When additional expertise is required for a specific proposal evaluation, the PRC can seek the assistance from external specialists.

The PRC Terms of Reference (TOR) have been revised to reflect the evolution of the PRC.

DECISION

The EXECUTIVE BOARD approved by consensus resolution n°1.

3.3 Market Dynamics

The PSC has reviewed the activities of the Market Dynamics team (Market Landscapes, Market Fora and the development of the Market Dynamics dashboard). The PSC has asked the Secretariat to focus on TB, and suggested that UNITAID's stance in relation to low and middle income countries should be reconsidered. In relation to HIV/AIDS, the PSC has recommended further investigation of how intellectual property (IP) rights can be used to increase the availability of antiretroviral drugs (ARVs).

The DEPUTY EXECUTIVE DIRECTOR discussed the opportunities for intervention that had been identified in the Market Landscapes and during the Market Fora. Many opportunities exist in the three disease areas, and also in relation to the treatment of hepatitis C (HCV).

3.4 Public Health Impact

The ANALYST, MARKET DYNAMICS, explained how the measurement of Public Health Impact has been incorporated into the UNITAID Strategy for 2013-16. Modelling is used to estimate the long-term impact of interventions across multiple countries. These models are important for project planning and evaluations. However, it was

emphasised that the Excel tools must be constantly updated to ensure that any new information or environmental changes are taken into account.

Discussion

- ❖ THE NGOS praised the Market Dynamics team for its excellent work on Market Landscapes, Fora and impact modelling. They observed that the Malaria Market Forum had underlined the need for urgent intervention to stabilise the Artemisinin market and asked how this could be included within the UNITAID project cycle.

The DEPUTY EXECUTIVE DIRECTOR agreed that market stabilisation was vital and progress was already being made through some UNITAID projects. However he pointed out that it was a complex problem: manufacturers have no long term visibility of the market and it has not been possible to reach an agreement with partners to set up an Artemisinin bank. The situation is being closely monitored by the Secretariat.

- ❖ The NGOs suggested developing a model to measure the impact of new HCV medication at different price points.
- ❖ The UNITED KINGDOM congratulated the Secretariat for its work on cost-effectiveness and Public Health impact. He thanked UNITAID for its support of the Affordable Medicines Facility - malaria (AMFm) and confirmed that the UK government would offer financial assistance to the AMFm until 2014. After this, the AMFm will be supported through the Global Fund funding model.

The UNITED KINGDOM requested that the Secretariat provide the Executive Board with a clear indication of the actions that would be taken to follow up on the recommendations made during the Market Fora. He asked how the work on Public Health impact would be shared and used by other organisations; and whether the Market Dynamics Action Group (MDAG) would have a role to play in this process.

The CHAIR OF THE EXECUTIVE BOARD agreed that it was important to integrate UNITAID into the overall Public Health architecture.

The DEPUTY EXECUTIVE DIRECTOR pointed out that UNITAID collaborates with a wide range of partners. All of UNITAID's major partners had taken part in the Market Fora and, in general, they adopt an 'outward looking approach'. He observed that UNITAID disseminates the market information that it produces, and this is often referenced during international meetings.

- ❖ BRAZIL and the COMMUNITIES urged the Secretariat to examine the patent status and attempt to overcome regulatory barriers to enable access to new ARVs.
- ❖ BRAZIL suggested that the area of diagnostics should be expanded and UNITAID's geographic scope revised to include middle income countries.
- ❖ BRAZIL and FRANCE proposed that the possibilities to encourage new fixed dose combinations to treat MDR-TB should be discussed with the Medicines Patent Pool (MPP). FRANCE highlighted the fact that there is increasing political momentum to tackle TB and that the French Ministry of Health is keen to support initiatives in this area.

The COMMUNITIES expressed their support for efforts to improve testing for TB and to simplify TB treatment. Efforts are in progress to expand activities at country level.

DECISION

The EXECUTIVE BOARD took note of the report from the PSC.

4. Discussion with the Russian delegation

The RUSSIAN DELEGATION thanked UNITAID for the invitation to participate as observers at the meeting of the Executive Board. The delegation was made up of representatives from the Ministries of Health, Finance and Foreign Affairs.

Russia is currently considering whether it would be interested in becoming a UNITAID donor and to what extent it would wish to become involved. The representative of the delegation observed that during a period of crisis in the global economy, any additional financial obligation had to be carefully considered. However, she added that Russia was impressed by the mechanisms for resource mobilisation used by UNITAID and the impact achieved in facilitating greater patient access to medication. She concluded that the delegation would report back to the relevant departments so that a decision could be made concerning Russia's potential participation.

On behalf of the Executive Board, the CHAIR OF THE EXECUTIVE BOARD thanked the members of the Russian delegation for their interest in UNITAID.

DECISION

The EXECUTIVE BOARD was grateful for the interest in UNITAID expressed by Russia.

5. Proposals for funding decisions

Overview of proposals for funding decisions

The EXECUTIVE DIRECTOR of UNITAID presented a summary of the proposals that were submitted to the Executive Board for funding decisions. The proposals focused on access to paediatric antiretrovirals (ARVs); the World Health Organisation (WHO) pre-qualification (PQ) programme for medicines and diagnostics; point of care (POC) HIV diagnostics; and the Strategic Rotating Stockpile (SRS) for drugs for multi-drug resistant TB (MDR-TB).

The EXECUTIVE DIRECTOR of UNITAID stressed the need to ensure that all children who had accessed paediatric ARVs via UNITAID-funded projects are able to continue their treatment. Further support for the paediatric ARV market is needed because of its fragile and fragmented nature.

The request for funding of the WHO PQ programme was a revised version of a proposal that had been submitted previously. It is likely that increased access to TB diagnostics will increase the detection rate of patients with MDR-TB: there is a pressing need to ensure continued access to the appropriate drugs via the SRS until the Global Fund's new Rapid Supply Mechanism is put in place (~18 months' time).

Report from the PRC Chair

The PRC CHAIR explained that the proposals were complex and the PRC's recommendations were constrained by the need to protect access to medicines for paediatric HIV and MDR-TB or to meet an unmet need (WHO PQ proposal). He outlined the severe time constraints that the PRC had worked within in order to present recommendations to EB19. The core groups reviewed the proposals initially, and then a teleconference of the whole PRC was held on 14 November. The PRC CHAIR commented that a teleconference was not an ideal way of coming to consensus decisions about the proposals: face to face meetings are more efficient in the PRC's opinion.

5.1 CHAI/UNICEF: Point of Care Diagnostics Phase 2

The PRC CHAIR noted that the proposed Resolution did not reflect the PRC's recommendations. The PRC was concerned that pace at which new diagnostic technologies are becoming available might not match the timeline outlined in the proposal. The PRC also expressed reservations about the proposed budget: the sums allocated to staff travel and telecommunications seemed very high. They had requested more information on the findings from Phase 1 of the project but this was not available at the time of the PRC teleconference. The PRC CHAIR commented that there was a risk that Phase 1 of the project would create a monopoly for a specific diagnostic technology (PIMA): the PRC therefore felt obliged to create space in the market for alternative technologies. The PRC CHAIR pointed out that switching from one POC assay to another was more complex than switching from one supplier of a generic drug to another, because of the need to train staff to use the new test. Initially, the PRC had recommended rejection of the proposal for Phase 2 of this project, but had then agreed to support a more nuanced, phased approach linked to the market entry of new diagnostics and to the achievement of specific milestones.

The DEPUTY EXECUTIVE DIRECTOR explained that many of the PRC's concerns had been shared by the Secretariat. However, feedback from Phase 1 of the project and clarifications from the applicants have provided the justification for supporting

Phase 2. There is a need to prevent one CD4 point-of-care from gaining a monopoly in the market; the field is moving away from CD4 testing to viral load measurement for diagnosis and monitoring of HIV infection; and countries must be prepared for the introduction of POC tests. The timeline of the original proposal was too ambitious and so it has been extended to four years instead of three. Milestones will have to be met in order to release tranches of the grant. Signals will be sent to the market that the focus has shifted to viral load assays.

The PSC CHAIR agreed with the PRC CHAIR and the DEPUTY EXECUTIVE DIRECTOR that a phased approach was preferable and the risk of creating a monopoly must be avoided.

The SECRETARIAT explained that they had worked with the applicants to address the concerns of the Board, the PRC and the PSC. Phase 2 of the project will address the market shortcomings for HIV POC diagnostics and support the market entry of several POC devices. Phase 1 of the project achieved substantial gains but the country preparedness for POC diagnostics is limited. A number of lessons learned in Phase 1 have been incorporated into the design of Phase 2. The SECRETARIAT has carefully scrutinised the budget and will maintain close oversight of spending during Phase 2. The eventual aim is to collaborate with other partners, such as the Global Fund and PEPFAR, in order to increase the purchasing power of the project and increase market penetration of the devices.

Positive but conditional approval of Phase 2 of the POC HIV diagnostics project was sought from the Executive Board.

Discussion

- ❖ The NGOs described this proposal as a key project for UNITAID. They supported the suggestion that funding be dependent on meeting milestones.
- ❖ The NGOs stressed the need to maintain flexibility in order to take advantage of new POC assays becoming available in the future and to meet the countries' diverse needs. They had been informed by the Secretariat that delaying the project risked creating a monopoly in the market and sending negative signals to developers about the demand for POC assays.
- ❖ The NGOs and NORWAY agreed that they would have preferred a higher quality proposal. The NGOs commented that information on the pricing, ease of use and performance of the tests was lacking from the proposal. The CHAIR OF THE EXECUTIVE BOARD praised the PRC and the Secretariat for their hard work in improving the quality of the proposal.
- ❖ The NGOs and NORWAY would have appreciated more information on the lessons learned during Phase 1 of the project. NORWAY requested that this important information be placed in the public domain as soon as possible.
- ❖ NORWAY commented that the presentation from the Secretariat was more positive than the papers that had been sent to the Board prior to EB19. She expressed the hope that UNITAID funding will act as a catalyst to encourage more commercial investment in HIV POC assays.
- ❖ NORWAY emphasised that the aim is to offer countries a range of POC options so that a monopoly is not created and countries are not 'locked in' to a specific technology. She praised the staged approach as a 'workable compromise' that will not compromise the achievements of Phase 1, but will support the market entry of multiple POC assays.

- ❖ The GATES FOUNDATION called for caution in investing in a very volatile and unpredictable market and said that it is very difficult to identify the optimal POC assay(s). She agreed with the need to send a signal to the market and to national governments about the need to scale up CD4 and viral load testing. She supported the idea of setting milestones, which have to be met before further disbursements are made to the implementers. Ongoing consultations with the WHO and the Global Fund are necessary to monitor the market and identify new trends in diagnosis and monitoring of HIV infection, the GATES FOUNDATION counselled.
- ❖ The NGOs suggested that an analysis of the diagnostic market would provide useful information to the Executive Board. They agreed with the COMMUNITIES about the need to educate communities about the importance of HIV diagnosis and regular viral load monitoring. They suggested that community organisations could be sub-contracted to carry out this role.
- ❖ The PRC CHAIR commented that the PRC would have preferred to have received the applicants' responses to their comments and to have evaluated a revised proposal. However, they understood that delaying a funding decision until May 2014 could have been seen as a negative signal by the diagnostic market. The PRC CHAIR said that it is important to inform both the market and national governments that viral load testing is replacing CD4 testing as programmes move towards the 'Test and Treat' approach. CD4 testing will become almost irrelevant over the next few years. In some situations, laboratory based viral load testing might be more appropriate than POC viral load tests. Preparing the countries for adoption of appropriate POC tests is a crucial part of the project.

DECISION

The EXECUTIVE BOARD approved resolution n°2 after it had been amended.

5.2 CHAI: Innovation in ARV paediatric market access (IPMA)

The SECRETARIAT described the challenges in the paediatric ARV market. The revised proposals were scaled into three areas: (i) The need for in-country support with the adoption of treatment guidelines, and IATT list, but also by strengthen forecasting, and procurement planning; (ii) the market intelligence and analytics support of all members in PeadARV Procurement Working Group (PAPWG). It thus creates a link between country-demand and global-supply; (iii) warehouse of high supply-risk products with stopgap until Global Fund RSM launched.

The original proposal has been extensively revised and scaled down to US\$12 million over three years compared to US\$29.8 million in the 2012 application. A clear plan to transition to the Global Fund Rapid Supply Mechanism has been included in the proposal.

The PRC CHAIR explained that the CHAI proposals were put to the Executive Board as two resolutions, even though the operating costs for CHAI to assist three countries (Malawi, Mozambique and Uganda) to maintain access to paediatric ARVs while they transition to Global Fund support were included in the IPMA proposal. The PRC CHAIR focused on the PRC's concerns about the original IPMA proposal. The PRC was concerned about the project's timelines: it is not yet known when the Global Fund Rapid Supply Mechanism will be operational and this will impact on the timing

of the warehouse (both its initiation and duration of operation). The PRC was not convinced that CHAI could make a short term impact on the market by improving demand forecasting. The PRC considered that organisations other than CHAI might be better placed to carry out market analysis. The timing of transition to Global Fund disbursements for Malawi, Mozambique and Uganda is uncertain at present: conflicting information was presented to the PRC.

The PRC were aware of the moral imperative to maintain and support the paediatric ARV market until it can be transitioned to other funding bodies and/or is no longer needed due to effective Prevention of Mother to Child Transmission (PMTCT) programmes. They therefore recommended approval subject to a number of conditions.

Discussion

- ❖ FRANCE suggested that it might be more efficient for UNITAID to work directly with the Global Fund on the paediatric ARV market rather than fund a CHAI project. He added that the project timelines are very tight and asked whether there was a possibility that the Global Fund Rapid Supply Mechanism could be set up before the CHAI warehouse. The DEPUTY EXECUTIVE DIRECTOR explained that UNITAID is in constant contact with the Global Fund and they anticipate that the Rapid Supply Mechanism will be operational in 2015.
- ❖ The NGOs and the COMMUNITIES acknowledged the importance of this proposal in ensuring that HIV infected children receive ARVs. They requested that UNITAID closely monitors the Global Fund's work in this area. The NGOs suggested that conditions be placed on the IPMA grant so that the funding can be adjusted depending on the speed of progress in the country transition plans and the setting up of the Global Fund Rapid Supply Mechanism. The PRC CHAIR replied to FRANCE and the NGOs that the Secretariat had provided information about how they work with the Global Fund but there was a difference of opinion about how quickly the Global Fund Rapid Supply Mechanism would be operational. The PRC did not consider it likely that the Global Fund Rapid Supply Mechanism would be set up before the CHAI warehouse but has suggested funding conditions that will ensure that the project is only supported for as long as it is needed. The DEPUTY EXECUTIVE DIRECTOR agreed that tight conditions should be imposed on the grant to ensure that the money was spent in an appropriate and timely manner. The Secretariat will monitor the project very closely and take action when necessary.
- ❖ The NGOs shared the PRC's concerns about the ability of CHAI to build procurement capacity in-country over the next three years, since they have not achieved this during the past seven years of working in this area. They suggested that UNITAID impose strict conditions on the funding for this aspect of the project. The PRC CHAIR responded that there is a global need for intelligence on the paediatric ARV market and it is likely that the Global Fund will take on responsibility for this when it provides funding for all purchases of paediatric ARVs by qualifying countries. The DEPUTY EXECUTIVE DIRECTOR agreed that in-country capacity to manage the paediatric ARV market must be strengthened. At present, the Global Fund does not support this type of activity but this might change in the future.
- ❖ The NGOs requested that CHAI works closely with Civil Society to educate parents about the treatment of paediatric HIV disease. Implementing the 2013 WHO guidelines for paediatric HIV infection should increase demand for

paediatric ARVs and thus improve the market. The PRC CHAIR expressed doubt that the paediatric ARV market will increase in size in the future, because PMTCT programmes in high burden countries should reduce the number of HIV positive babies born. Rapid diagnosis of HIV infection in newborns is needed to identify those in need of therapy, but there are considerable challenges in ensuring that all children are tested, he added. The DEPUTY EXECUTIVE DIRECTOR expressed the hope that increased access to POC early infant diagnosis (EID) tests will improve the diagnosis of paediatric HIV infection. Pooled procurement is necessary, in the opinion of the PRC CHAIR, in order to protect the market and to encourage the development of new ARVs and more appropriate formulations.

- ❖ The PRC CHAIR said that funding for the transition part of the project (for Malawi, Mozambique and Uganda) would only be provided until the Global Fund disbursements become available.
- ❖ KOREA proposed that conditions be added to the Resolution that funding is only available for the second part of the grant period if the midterm review (at 1.5 years) is deemed satisfactory by the PRC and the Secretariat. The CHAIR OF THE EXECUTIVE BOARD agreed with KOREA's suggestion.

DECISION

The EXECUTIVE BOARD approved resolution n°3.

5.3 CHAI: ARV Paediatrics Cost extension

The DEPUTY EXECUTIVE DIRECTOR explained the background to the request from CHAI for a cost extension to the ARV paediatrics project. By the end of 2013, all of the countries that had participated in the CHAI paediatric ARV had transitioned to alternative funding sources, apart from Malawi, Mozambique and Uganda. These three countries applied to the Global Fund for support of their paediatric ARV and diagnostic programmes. The Global Fund's disbursements will not translate into commodity deliveries until Q2/3 2015. CHAI therefore applied to UNITAID for a cost extension to provide these essential items until the Global Fund deliveries start. The Secretariat will work with CHAI and the Global Fund to ensure a smooth transition of support in the three countries.

Discussion

- ❖ The COMMUNITIES expressed their support for this proposal but warned about the risk of cost extensions. They would prefer UNITAID not to become a core funder and asked why the national governments were not taking responsibility for managing paediatric HIV in their own countries. The COMMUNITIES called for Civil Society Organisations to lobby their governments to budget for healthcare spending rather than depending on donor funding. The CHAIR OF THE EXECUTIVE BOARD agreed with the COMMUNITIES and suggested that the cost extension be described a 'final cost extension'. However, he cautioned that UNITAID has a responsibility to continue supporting the provision of paediatric ARVs.

- ❖ FRANCE asked whether this proposal duplicated work described in the IPMA proposal. The CHAIR OF THE EXECUTIVE BOARD replied that the financing of the two projects is complementary. He committed the Secretariat to ensuring that no duplication of funding occurs and to implement rigorous financial controls.

DECISION

The EXECUTIVE BOARD approved resolution n°4 after it was amended.

5.4 WHO: Pre-qualification of Medicines and Diagnostics

The DEPUTY EXECUTIVE DIRECTOR outlined the rationale for, and the scope of, the WHO Pre-qualification (PQ) of Medicines and Diagnostics proposal. This represented an update of two proposals that were submitted previously (diagnostics PQ 2011 and medicines PQ in 2012). The WHO has reorganised its PQ operations into one department. The Secretariat is supportive of continued support to WHO medicines PQ activities, on the condition that they are aligned closely with UNITAID's strategic priorities and operational efficiency is maximised. It also recommended funding of the WHO diagnostic PQ activities, provided that an Expert Review Panel (ERP) is established; the programme's outputs are aligned with UNITAID's strategic objectives; and operational efficiency is maximised.

The PRC CHAIR presented the PRC's view on the proposal: although they considered that it was an improvement on the previous applications, they were concerned about the large sums of money requested and the risk of the project straying beyond UNITAID's requirements ('mission creep') especially in relation to diagnostics and some medicines. The PRC identified several aspects of the project that appear to duplicate the efforts of other organisations, e.g. PQ of biosimilars. The PRC acknowledged that the WHO's PQ work is essential for the activities of both UNITAID and other international donors but has provided the Secretariat with a list of its concerns. The PRC CHAIR suggested that the Board approved funding of the project with stringent conditions to ensure that the project is compatible with UNITAID's requirements.

Discussion

- ❖ The NGOs had identified some weaknesses in the diagnostics part of the proposal, especially in relation to the management of the project. Although they acknowledged that a business case for PQ activities would be useful, they considered that this did not represent one of the WHO's strengths. They suggested that the WHO PQ department should focus on providing technical assistance since this is within the WHO's remit. The NGOs requested that the Secretariat should evaluate the potential impact of the WHO charging user fees for PQ activities, because they are concerned that this might deter manufacturers from undergoing the PQ process.
- ❖ The CHAIR OF THE EXECUTIVE BOARD commented that PQ of medicines is at the core of UNITAID's work. As the number of PQ'd medicines increases, competition increases between the generic manufacturers and this reduces prices for both governments and donors, thus improving access to much needed drugs.
- ❖ The GATES FOUNDATION commented that her organisation had been discussing providing funding to the WHO for their PQ activities. She acknowledged that PQ of diagnostics is a challenging area because there are no internationally accepted protocols to carry out quality assurance (QA) on diagnostics. She

called for an optimal long term QA vision as well as short term plans to achieve QA of medicines and diagnostics. The GATES FOUNDATION agreed that PQ is essential so that governments and donors purchase QA products. She pointed out that delays in access to new products are not just due to scrutiny by stringent regulatory authorities but also by barriers at the country level (e.g. registration, policy/guidelines). The GATES FOUNDATION speculated that it might be possible to charge for PQ of products that can be sold at high volumes (e.g. adult ARVs) but charging for PQ of low volume and/or low profit products (e.g. TB drugs) might not be feasible.

DECISION

The EXECUTIVE BOARD approved resolution n°5.

5.5 GDF and Stop TB Partnership: MDR-TB Accelerating Access Initiative: Strategic Rotating Stockpile (SRS) Cost Extension

The SECRETARIAT explained that the MDR-TB Accelerating Access Initiative was due to close on 31st December 2013. The proposal requests a cost extension from 1st January 2014 until 30th June 2015 as well as a limited expansion of the project by 4,000 regimens to 9,800 regimens. The expansion is required because of a rapid increase in the number of patients initiating treatment during the past two years. This is due to enhanced access to TB diagnostics and a change in the treatment guidelines, which increased the duration of the intensive phase of treatment from six to eight months. The SRS project will transition to the Global Fund Rapid Supply Mechanism in mid-2015. The additional budget requested was USD 14.89 million. The SRS has a proven track record of being able to address drug shortages quickly. The SECRETARIAT recommended funding of the proposal, subject to the conditions that had been agreed upon by the PRC and the Secretariat. These include submission of a detailed budget that will be verified by the Secretariat and preparation of a Joint Operational Plan between GDF and the Global Fund.

The PRC CHAIR agreed with the SECRETARIAT's conclusions and sought a decision from the Executive Board about whether the value of the drugs in the stockpile should be returned to UNITAID at the end of the project or transferred to the Global Fund.

Discussion

- ❖ The NGOs agreed with the Secretariat's and the PRC's recommendations. They called for the SRS to be substantially increased in size so that it can shape the market for TB drugs, i.e. stimulate price reductions. Expanded access to TB diagnostics and the growing number of Eastern European patients with MDR-TB will result in an increased need for TB drugs.
- ❖ FRANCE supported the proposal and asked for clarification about the geographic area served by the SRS. He enquired whether the SRS covers the same countries as those served by the Global Fund.
- ❖ The HEAD OF MARKET DYNAMICS explained that UNITAID is in close communication with the Global Fund about the Rapid Supply Mechanism. The Global Fund Market Dynamics Advisory Group (MDAG) has advised the

Global Fund to expand the SRS in order to prevent stock outs during a period of increased demand but also to shape the market for MDR-TB drugs.

DECISION

The EXECUTIVE BOARD approved resolution n°7 after it had been amended.

6. Governance issues:

Declaration of Interest

The WHO SENIOR LEGAL OFFICER stated that, pending adoption of Declaration of Interest (DOI) principles by the Board, the Secretariat had developed a short DOI form and requested all Board Members and Alternates to complete it. It was stressed that this exercise was primarily focused on ensuring transparency in the context of interests that Executive Board Members and Alternates may have with respect to proposals being considered for funding. This approach was well received by the Executive Board.

The WHO Senior Legal Officer subsequently summarized the disclosures made by the WHO and the GATES FOUNDATION:

Disclosures

The WHO disclosed that WHO PQ, medicines and diagnostics, had submitted a proposal that was being considered for funding by the Board.

The GATES FOUNDATION disclosed that:

- It has made a programme-related investment in Zyomyx for the purpose of assuring access to a CD4 technology under development, at a price affordable (if approved) to the developing world. The Foundation has provided the Secretariat with details regarding this investment.
- It is one of the funders of a grant to the WHO in support of optimizing its pre-qualification programme and the Foundation has worked in partnership with UNITAID to align on a vision for improving this pre-qualification programme.
- It provides grant funding to the Clinton Health Access Initiative to improve global access to MDR-TB medicines, which is cited in the Global Drug Facility (GDF) proposal as a critical partner to the SRS initiative. The Foundation does not directly support the SRS.

DECISION

The EXECUTIVE BOARD took note of the Declarations of Interest made by WHO and the Gates Foundation.

7. Medicines Patent Pool

Update on progress report 2013

The EXECUTIVE DIRECTOR OF THE MEDICINES PATENT POOL (MPP) was delighted to announce that a new contract had been signed with Bristol-Myers Squibb (BMS) for their product Atazanavir (ATV). Atazanavir is used as a 2nd line treatment for HIV infection in adult patients. Two other agreements had been signed in 2013: ViiV for the paediatric formulation of abacavir (ABC), and Roche for valacyclovir in the treatment of HIV-related cytomegalovirus retinitis.

The MPP EXECUTIVE DIRECTOR and the GENERAL COUNSEL presented the status of the MPP portfolio and out licensing agreements. The MPP EXECUTIVE DIRECTOR described the positive impact that had been achieved in terms of patient years gained and reductions in treatment costs. A total saving of US\$14.2 million had been achieved from Q1 2012 to Q2 2013 inclusive.

The focus for 2014 will be on obtaining licensing agreements for tenofovir alafenamide fumerate (TAF), dolutegravir (DTG) and lopinavir/ritonavir (LPV/r) for paediatrics; persuading Johnson & Johnson and Merck to enter into negotiations; and seeking opportunities for patent sharing to develop paediatric formulations.

Operational review

The Managing Consultant from the Cambridge Economic Policy Associates (CEPA), presented an update of the ongoing operational review to assess the strategic direction, positioning and operations of the MPP. An initial draft report had been submitted to UNITAID and the MPP in early December. An updated report would be available in January 2014.

Discussion

BRAZIL, the COMMUNITIES, the NGOs, the AFRICAN COUNTRIES and NORWAY all congratulated the MPP on its success to date.

The NGOs pointed out that a significant number of countries were still without access to the most effective treatments at affordable prices; access in some low and middle income, high burden countries is still limited. They urged UNITAID to be more pro-active in seeking agreements for the countries currently excluded from licensing agreements. Attention should be focused on fixed dose combinations. The NGOs urged UNITAID to focus more on IP issues.

The AFRICAN COUNTRIES expressed their strong support for the MPP and recognised its efforts in helping many African countries where there is a high burden of HIV.

NORWAY asked how the MPP assessed the possibility of expanding the scope of the MPP to include TB and of getting other donors to co-fund the MPP.

The Chair of the Executive Board referred to the work of the MPP as a 'revolutionary approach' and emphasised the importance of its close collaboration with the Secretariat. He observed that, because of the HIV/AIDS epidemic, IP has become an important political subject. He stressed that it is essential not to jeopardise the considerable progress achieved in increasing access to HIV/AIDS treatment. However, the CHAIR OF THE EXECUTIVE BOARD agreed that there was also a need to look closely at licensing opportunities for TB treatments and suggested that UNITAID should take the lead in this work. The CHAIR OF THE EXECUTIVE BOARD

suggested that the MPP, the Global Fund and UNITAID should work together in order to achieve universal access to ARVs.

DECISION

The EXECUTIVE BOARD took note of the update on progress report and the operational review.

8. Strategy implementation framework

The Executive Board endorsed the UNITAID Strategy 2013-16 in April 2013 and passed resolution n°5 in June 2013. This resolution requested the Secretariat to commission organisational management support to evaluate the state of the Secretariat's organizational capacity, design and systems to effectively execute the Strategy and implementation plan; and to support the Secretariat, as needed, in developing an implementation plan to execute the Strategy. A Strategy implementation framework has been developed by the Secretariat: it focuses on the six Strategic Objectives and the five Core Action Areas. This framework was used to guide the workplans, and to outline the activities and milestones that must be implemented over the next four years in order to achieve the Strategy. A framework tool has been developed to track the implementation of the Strategy. The DEPUTY EXECUTIVE DIRECTOR stressed that the framework was not intended to be a costing exercise for the Strategy. He added that the framework was based on the assumption that revenue will be USD 250 million/year and the size of the Secretariat will remain stable.

UNITAID projects are now classified by Strategic Objectives so that progress towards achievement of the Strategy can be monitored. The DEPUTY EXECUTIVE DIRECTOR explained that the framework tool would be used to track progress within the Secretariat and to report on activities. Interventions will be balanced between down stream and up stream activities; innovation and market entry; as well as market introduction versus procurement.

Discussion

- ❖ The NGOs and the COMMUNITIES thanked the Secretariat for their work on the Strategy Implementation. The NGOs believed that it would be useful to have some outside help to set targets for each year and identify potential implementing partners.
- ❖ The NGOs and the COMMUNITIES stressed the need to work on increased engagement with Civil Society. They expressed caution about obtaining private sector funding because of the potential for conflicts of interest.
- ❖ The NGOs and the COMMUNITIES supported the concept of innovative small grants. They promised to send their detailed input to the Secretariat.
- ❖ The COMMUNITIES offered to assist with a range of Strategy implementation activities, including resource mobilisation, IP issues, and monitoring of service delivery.
- ❖ The GATES FOUNDATION enquired whether the Secretariat has the capacity and finances to implement the Strategy in its entirety. She suggested that it might be necessary to prioritise various activities/interventions.
- ❖ The DEPUTY EXECUTIVE DIRECTOR acknowledged the need to set priorities and to work with the resources available since it is unlikely that UNITAID's revenues will increase substantially over the Strategy period. The DEPUTY EXECUTIVE DIRECTOR considered that is feasible to implement the Strategy. He thanked the NGOs and the COMMUNITIES for their offers of help in implementing the Strategy.

DECISION

The EXECUTIVE BOARD approved resolution n°6.

9. Update on the Civil Society Meeting

The COMMUNITIES and the NGOs presented their respective reports on a one day consultation meeting with the Secretariat that had taken place on 9th December 2013. The objective of the meeting was to examine further opportunities for Civil Society to help UNITAID in fulfilling its mandate.

Report from the Communities

The report from the COMMUNITIES focused on areas where Civil Society could offer greater support to UNITAID, namely:

- Country monitoring of UNITAID investments.
- Demand creation for UNITAID funded commodities.
- Intellectual Property issues, although more clarification is required to define how Civil Society can help at country level (government lobbying, working to overcome patent barriers etc.).

The COMMUNITIES called for a landscape report on the IP issues related to medicines and commodities.

Concluding their presentation, the COMMUNITIES said, *“Only empowered communities and patients adhere to treatments, change laws and policies, and create the demand for the most up to date technologies and commodities.”*

Report from the NGOs

The NGOs thanked the Secretariat from organising the consultation meeting. They described that the cooperation between Civil Society and UNITAID as excellent. UNITAID was encouraged to make fuller use of Civil Society’s knowledge and experience in identifying opportunities for engagement. Echoing the COMMUNITIES, the NGOs called for a new Civil Society Engagement Strategy that would encompass:

- Policy formation and project design to increase contextual and end-user perspectives.
- In-country performance monitoring for project recalibration and evaluation and as a grounded, qualitative addition to mid-term and final project evaluations.
- Catalytic demand creation, so that expedited and expanded demand accelerates the impact of novel, improved product introduction.

The NGOs stressed the need for cross-cutting IP work, in collaboration with Civil Society, in order to address IP barriers and develop policies on competitive markets for new and improved technologies.

There was a request from Civil Society that UNITAID should terminate its involvement in the Global Fund’s tiered pricing task force because this approach had not worked in the past and was in conflict with UNITAID’s pro-competition policy. Instead, the NGOs urged UNITAID to concentrate on working with middle income countries to resolve IP and access issues.

Discussion

- ❖ The UNITED KINGDOM observed that, as tiered pricing means low prices for poor people, it was appropriate for UNITAID to participate in the debate. He stressed that UNITAID should have the opportunity to shape the discussion.

The EXECUTIVE DIRECTOR agreed with this point of view and said that if UNITAID did not participate in the discussion, it could not influence the outcome.

- ❖ The NGOs responded that there had been a unanimous resolution from Civil Society to ask UNITAID to withdraw from the task force because tiered pricing would result in exclusivity for pharmaceutical companies, whereas UNITAID's policy and particularly its IP strategy are based on the promotion of robust competition within the market place. They pointed out that tiered pricing had already proved ineffective in the HIV space.
- ❖ The COMMUNITIES expressed reluctance to engage in this area stating that there was no indication that tiered pricing would improve access to HIV treatment. They emphasized the need to focus on low and middle income countries.
- ❖ The CHAIR OF THE EXECUTIVE BOARD asked the Executive Board whether it considered tiered pricing to be compatible with the work of the Medicines Patent Pool.
- ❖ BRAZIL stated that it was essential to work with patent opposition to eliminate IP barriers. However, he urged UNITAID to look beyond the MPP and continue to work with the Communities and NGOs to reform policies and laws especially in middle income countries.
- ❖ The HEAD OF MARKET DYNAMICS warned that tiered pricing had become a 'politicised issue' and recommended that the Secretariat and the Executive Board should speak with 'one voice'. She remarked that the Global Fund's plans were not yet clearly defined and advocated finding out more about the process so that a proper analysis could be made by the Secretariat.

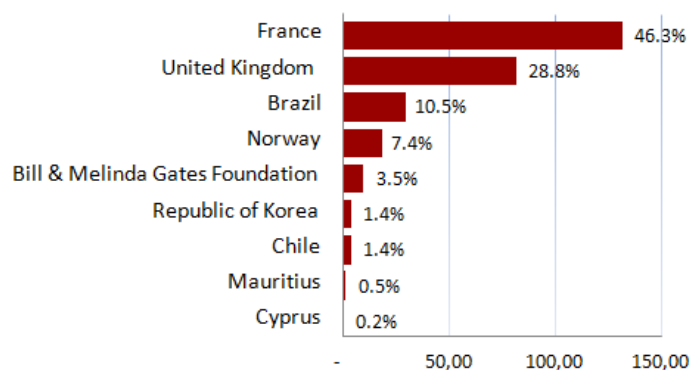
10. Report of the Finance and Accountability Committee

The CHAIR OF THE FINANCE AND ACCOUNTABILITY COMMITTEE (FAC) presented its report to the Executive Board. The FAC CHAIR gave an overview of the annual FAC workplan consisting of fixed items, such as the proposed budget, and regular review items that include budget performance, grant financial performance and audit status. Additional items discussed at FAC11 were updates on frameworks for financial performance and quality management; guideline approvals; fraud risk and whistleblowing. The FAC CHAIR also informed the Board of the workplan for 2014.

10.1 Budget for 2014

The CHAIR of the FAC presented the proposed budget for 2014 for Board approval. The total **revenue budget** of US\$282.8 million represents an increase of US\$10 million compared to the 2013 budget projection. Estimated arrears of US\$30 million from Brazil will be paid in 2014. However France announced that it will decrease its contribution in 2014 by €10 million to US\$132 million. Norway stated that the level of Norwegian contribution for 2014 had not yet been fixed, but it would be less than in previous years.

Figure 1. Proposed Budget for 2014 (US\$)



The FAC CHAIR warned that short-term donor commitments resulted in an unpredictable revenue budget leading to a lack of visibility over the long term and difficulties for planning and risk management. He concluded that multi-year commitments from donors should be encouraged.

The proposed minimum expenses budget to cover the Governing Bodies, the Secretariat, Projects, Special Projects, Secretariat Initiatives and Strategy implementation had been modified following the FAC review. Questions had been raised about the costs for Strategy implementation, travel, support for the Civil Society Delegation and the budget of the Office of the Chair of the Executive Board.

In response to the FAC's request for more information, the CHAIR OF THE EXECUTIVE BOARD presented a brief summary of his role. He explained that, as international ambassador for UNITAID, he meets regularly with partner organisations and has established good working relationships with them. Many of his activities are related to Resource Mobilisation and include high level meetings with Ministers and Heads of States. The CHAIR OF THE EXECUTIVE BOARD took the opportunity to announce that the Prime Minister of Morocco had just confirmed that his country would implement an air ticket levy and that a proportion of the monies raised would be donated to UNITAID.

Discussion

- ❖ The UNITED KINGDOM requested that the travel budget be removed from the overall budget and capped at US\$2.5 million (equivalent to 2012 budget). He suggested that the Secretariat rework the budget based on the model used by the UK and French governments, i.e. any travel that is not considered essential for business needs is removed. Essential travel should include travel related to monitoring of projects.
- ❖ FRANCE, the NGOs and NORWAY all supported the UNITED KINGDOM's request regarding travel. FRANCE advocated that the rigorous cost control applied by the French administration should also be applied within UNITAID. However, he recognised that the Secretariat had already met the requests made by the French delegation in relation to the budget.
- ❖ NORWAY reminded the Secretariat of the FAC's request that the travel budget should be reviewed again.

The HEAD OF FINANCE AND ADMINISTRATION pointed out that 60% of the UNITAID travel budget was allocated to travel costs of external parties (such as consultants) and only 40% was reserved for staff travel. The travel budget had been increased to respond to the requirements of the Resource Mobilisation Plan and to enhance the engagement of partners at country level. She noted that the use of the travel budget by external parties in 2013 had been lower than expected, which may imply that a smaller travel budget for external parties would be required for 2014.

- ❖ FRANCE requested that the cost control for expenditure related to Secretariat Initiatives should be as rigorous as possible.
- ❖ The GATES FOUNDATION was concerned about the overlap between costs for advancing the Strategy and the administrative costs for the Secretariat. She wondered whether these costs could be organised by Strategic Objective.

The HEAD OF FINANCE AND ADMINISTRATION explained that 90% of the total budget is allocated to projects and this is broken down by Strategic Objective. It is not possible to present the rest of the budget in this way. The budget for the Secretariat is structured according to core action areas, which support the achievement of the overall Strategic Objectives.

DECISION

The EXECUTIVE BOARD passed the following resolutions:

Resolution n°8: Approval of the UNITAID 2014 Budget.

Resolution n°9: Approval of the Office of the CHAIR of the Executive Board - Budget 2014

Resolution n°10: Approval of Support to the Civil Society Delegations for 2014.

10.2 2013 projected budget performance

Projected revenue for 2013 was US\$273 million, representing 86% of the total budgeted. The shortfall was due to the delayed contribution of US\$50 million from Brazil, a reduction of US\$3 million in Korea's contribution and exchange rates fluctuations. For the expense budget, US\$149 million had been implemented (95% of budget).

10.3 Grant financial performance

Overall, grants were performing well, with recent grantees showing strong financial management. The FAC congratulated the Secretariat on the newly developed financial performance dashboard.

10.4 Guidelines

The FAC approved the new audit guideline (n°8) and the revised guideline on financial considerations in grant management (n°5).

10.5 Fraud management and whistleblowing

Recommendations for limiting the risk of fraud for UNITAID and its partners have been discussed. The FAC recommended that the Fraud Prevention and Awareness Task force should be revived and had asked the Secretariat to present the risk management tools that were at its disposal at the next meeting of the FAC.

The FAC took note of the results of a benchmarking exercise on whistleblowing and requested that the Secretariat prepare an action plan for review.

The FAC called for access to the full report on risk of fraud and whistleblowing.

10.6 FAC terms of reference (TORs)

No significant changes were made to the FAC TORs.

DECISION

The EXECUTIVE BOARD took note of the FAC report.

11.Operations

The PROGRAM MONITORING OFFICER, OPERATIONS presented a rapid update on Operations. UNITAID has active grants in 55 countries. Based on the semi-annual reports supplied by implementers, 90% of these grants are judged to be performing well. (Figure 2).

Figure 2. Overview of grant performance

	On track	Minor delays	Delayed	May not meet all objectives	Poor Performance	Total
HIV	1	4		1		6
TB	6					6
Malaria	4					4
Cross cutting		1	1			2
Special	1					1
Total	12	5	1	1		19

The status of the four new market entry grants was also discussed.

Grants and investments are now grouped according to Strategic Objectives. A new strategic investment analysis tool has been developed to help in planning activities.

The Secretariat has been working to improve its efficiency in grant management. Recent quality management initiatives include a Grant Management Dashboard, an online reporting module for implementers, and the availability of interactive data visualisations on the Impact Page of the UNITAID website.

All grants undergo mid-term and final evaluations. These independent evaluations are carried out by reputable international firms and the results are shared with the implementers. A list of the evaluations conducted in 2013, and those planned for 2014, was shared with the Executive Board. The guidelines for performing evaluations are currently under review and will be presented to the PSC for endorsement in May 2014.

Discussion

- ❖ The NGOs suggested that, based on lessons learned, UNITAID's future involvement in market entry projects should be discussed at the next meeting of the Executive Board.
- ❖ The NGOs proposed that Civil Society could play a role in the evaluation of projects.
- ❖ KOREA welcomed the introduction of the Grant Management Dashboard and praised the robust process for project collaboration.
- ❖ The GATES FOUNDATION stated that it would be prepared to collaborate with the Secretariat over access agreements. The GATES FOUNDATION suggested that future updates on partnerships should provide a global picture, rather than by specific UNITAID department.
- ❖ The CHAIR OF THE EXECUTIVE BOARD praised Operations for the great progress it had achieved.

DECISION

The EXECUTIVE BOARD took note of the update on Operations.

12. KPI revision

The SECRETARIAT presented the Board Key Performance Indicators (KPIs), which had been revised after feedback provided during the Board Retreat in November 2013. The KPIs will be used to track changes over time and to monitor UNITAID's progress towards Strategy implementation. Seven Board KPIs have been developed: KPI 1 and KPI 2 monitor performance in relation to market and public health outcomes; KPI 3 monitors market intelligence gathering and analysis; KPI 4 monitors portfolio and grant management; KPI 5 addresses resource mobilisation; KPI 6 monitors relationships with global partners, countries and civil societies; and KPI 7 monitors Secretariat management and governance. Measures and targets have been developed for each KPI and these were presented to the Executive Board (see PowerPoint presentation for details).

Discussion

- ❖ The NGOs, the UNITED KINGDOM, BRAZIL, NORWAY, the COMMUNITIES and the GATES FOUNDATION praised the Secretariat's work on the revised KPIs. They agreed that the KPIs should be finalised by email and then subjected to electronic approval.
- ❖ The NGOs, the UNITED KINGDOM, NORWAY and the COMMUNITIES requested that the investment targets in KPI 1 be aligned with the UNITAID constitution. The NGOs would prefer the term 'low income' to be removed from KPI 1 and replaced with 'high burden'. On one hand, BRAZIL and the COMMUNITIES agreed with this suggestion and proposed that the focus of UNITAID's work should be in high burden countries, regardless of whether they were low income or middle income countries. Brazil cited the example of MDR-TB, which is a substantial problem in several middle income countries. The Communities pointed out that there are large numbers of disadvantaged people in middle income countries who need access to quality healthcare commodities. On the other hand, the United Kingdom and Norway were opposed to this suggestion and recalled UNITAID's constitution that stipulates that 85 % of the funding should go to low income countries, this poverty focus was very important to Norway and the United Kingdom.
- ❖ The GATES FOUNDATION speculated that KPI 1 might deter innovation because 90% of grants must achieve their public health outcomes by grant closure. This could encourage implementers to adopt a conservative approach in order to meet the target.
- ❖ The GATES FOUNDATION enquired whether KPI 3 was feasible (>90% of countries and donors have their price information on the Market Intelligence System by 2016). The SECRETARIAT agreed that this was not feasible at present because the system is not fully functional. It might be more realistic to focus only on tracking the prices of key commodities over time.
- ❖ NORWAY asked how the proportion of investment in the different diseases, as stated in KPI 4, had been decided upon. She requested that this issue be discussed and decided upon by the Executive Board. The SECRETARIAT explained that this division of resources was based on the Global Fund's distribution of resources. She agreed that it should be discussed and refined by the Executive Board so that it is specific for UNITAID.
- ❖ The NGOs and the COMMUNITIES suggested that a more meaningful measurement of involvement with Civil Society be developed (KPI 6). The

COMMUNITIES considered that having Civil Society involved in 30% of the grants should be the starting point rather than the ultimate target.

- ❖ NORWAY had suggested ‘staff satisfaction’ as the measure of Secretariat management and believed that this captured the important KPI, rather than resource management (KPI 7).
- ❖ COMMUNITIES supported the use of the term ‘gender balance’ rather than setting targets for each gender (KPI 7) and called for a gender policy to be developed for both UNITAID staff and projects. NORWAY was against a target merely for women’s representation, she would prefer one that promoted gender balance and proposed that the aim should be to have 40% of each gender represented in the senior staff..
- ❖ The COMMUNITIES commented that transition of projects is not included in the KPIs. The COMMUNITIES called for UNITAID to send a message to national governments that they must take responsibility for their own people’s healthcare rather than depending on donors. The SECRETARIAT explained that transition is captured in the management KPIs.
- ❖ The GATES FOUNDATION proposed that KPIs on cost savings and/or project evaluation should be developed. She noted that there must always be a balance between reducing prices and the risk of decreased competition because manufacturers are deterred from entering a market or leave due to poor profitability. The SECRETARIAT agreed that this was an important issue: both prices and competition within key markets should be monitored and visualised in a dashboard.
- ❖ The GATES FOUNDATION asked why the Board KPI on Board satisfaction had been removed from this draft. The SECRETARIAT explained that Board satisfaction is captured in the management KPIs.
- ❖ The SECRETARIAT thanked the Board for their feedback and agreed to refine the KPIs.

DECISION

The EXECUTIVE BOARD decided to finalise and approve the Board KPIs by electronic vote.

13. Global Fund Partnership

The EXECUTIVE DIRECTOR OF THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA, Mark Dybul, addressed EB19. The EXECUTIVE DIRECTOR OF THE GLOBAL FUND described UNITAID as one of the most important partners for the Global Fund and said that its innovative approach was essential for the Global Fund to function well. He praised the close relationship between the two organisations and said that they were working towards a seamless partnership. The EXECUTIVE DIRECTOR OF THE GLOBAL FUND said that the Global Fund industrialises and leverages UNITAID's innovative achievements. The ultimate aim of both UNITAID and the Global Fund is to improve public health.

The CHAIR OF THE EXECUTIVE BOARD thanked the EXECUTIVE DIRECTOR OF THE GLOBAL FUND for his comments and willingness to work with UNITAID. He commented that UNITAID is keen to work more closely with the Global Fund and requested that the roadmap of the UNITAID/Global Fund collaboration should be updated. He emphasised UNITAID's innovative approach and flexibility. The CHAIR OF THE EXECUTIVE BOARD stressed UNITAID's involvement in the Medicines Patent Pool and asked how the Global Fund can assist in its work. He said that working with pharmaceutical companies, especially those in middle income countries, can be challenging, but the Medicines Patent Pool's achievements contribute to the Global Fund's mission. Increased collaboration between UNITAID, the Medicines Patent Pool and the Global Fund is essential, in his opinion. The CHAIR OF THE EXECUTIVE BOARD cited the example of access to paediatric ARVs, which has been a key project for UNITAID. Although successful PMTCT programmes have reduced the number of babies born with HIV infection, there is still a substantial need for novel and well adapted paediatric ARV formulations. Improving access to these life saving drugs can be achieved if UNITAID and the Global Fund work closely together.

The EXECUTIVE DIRECTOR OF THE GLOBAL FUND agreed that updating the roadmap between the two organisations would be very useful. He agreed that the Medicines Patent Pool's work is essential and suggested that meetings between the three organisations would facilitate communication and collaboration. The EXECUTIVE DIRECTOR OF THE GLOBAL FUND said that young children with HIV infection are some of the most disadvantaged individuals and he was personally committed to increasing access to treatment for these patients.

Discussion

- ❖ The NGOs and the COMMUNITIES praised the Global Fund for their work on market shaping and for their collaboration with UNITAID. They called for the two organisations to be aligned at the strategic level. The COMMUNITIES expressed the hope that UNITAID and the Global Fund will work closely together on transition issues so that patients continue to access the healthcare commodities that they need. The UNITED KINGDOM commented that his country provide funds to both the Global Fund and UNITAID, and was delighted that the two organisations are collaborating.
- ❖ FRANCE agreed with the CHAIR OF THE EXECUTIVE BOARD's statements and said that France is keen to work closely with the Global Fund, especially on TB. Recent developments in the TB arena mean that a turning point has been reached in the management of this disease, in FRANCE's opinion. The EXECUTIVE DIRECTOR OF THE GLOBAL FUND agreed that TB is an important area for the Global Fund and said that he looked forward to collaborating with UNITAID on TB initiatives.

- ❖ The NGOs expressed concern that the Market Dynamics Advisory Group (MDAG) does not appear to collaborate very well with the Global Fund. They would like this relationship to improve. They hope that the Global Fund will use its procurement capacity and other tools to obtain better value for money and to shape markets. The UNITED KINGDOM agreed that this was an important issue and asked for feedback from the EXECUTIVE DIRECTOR OF THE GLOBAL FUND. He replied that, although there had been challenges in the past, a working relationship between MDAG and the Global Fund had now been established. MDAG will no longer be involved in procurement decisions since this is outside its area of expertise. Instead, MDAG will be involved in market shaping activities and become a link between UNITAID and the Global Fund.
- ❖ The NGOs, the UNITED KINGDOM, BRAZIL and the COMMUNITIES sought further information on the Global Fund's tiered pricing initiative. The NGOs said that there is evidence that tiered pricing can provide short term gains, but can result in 'locked in' prices in the long term. They suggested that a competitive market is the best, long term method of achieving sustainable, low prices. The NGOs and BRAZIL pointed out that UNITAID is already working on pricing issues in middle income countries (e.g. the recent pricing conference in Brazil) and encouraged the Global Fund to become involved in these efforts. BRAZIL called for UNITAID and the Global Fund to build upon the results of the Brazilian pricing conference. The EXECUTIVE DIRECTOR OF THE GLOBAL FUND said that he understood the BOARD MEMBERS' concerns and said that one of the Global Fund's goals is to ensure the best access to healthcare commodities in the three diseases. Increasing access in middle income countries is a critical part of this mission but it is a major challenge. He suggested that tiered pricing might be part of the answer to this problem in the future: different strategies might be needed in different situations/countries as appropriate. He stressed that the Global Fund does not set prices itself but encourages maximal competition amongst suppliers. He apologised for the miscommunication and misunderstanding about the Global Fund's tiered pricing initiative.

The CHAIR OF THE EXECUTIVE BOARD suggested that the Board should send a letter to the Global Fund asking for clarification of the tiered pricing initiative: a draft will be circulated to the Board for comments. The NGOs agreed with this suggestion.

- ❖ FRANCE suggested that increasing the visibility of joint UNITAID and Global Fund activities would be beneficial for both organisations. Improved external communications to explain how the two organisations co-operate and benefit from each other's activities should be a priority in FRANCE's opinion. The CHAIR OF THE EXECUTIVE BOARD agreed with FRANCE's suggestion and committed himself to increased communications about collaborations.

BRAZIL said that building a roadmap between UNITAID and the Global Fund was a useful exercise. Collaboration between the two organisations provides benefits for everyone, in his opinion.

The EXECUTIVE DIRECTOR OF THE GLOBAL FUND agreed with this approach and expressed his appreciation for the increasing co-operation between UNITAID and the Global Fund.

DECISION

The EXECUTIVE BOARD took note of the comments by the EXECUTIVE DIRECTOR OF THE GLOBAL FUND.

14. PEPFAR

PEPFAR was represented by Michael Johnson (Global Fund Attaché, United States Mission to the UN). He praised the increased collaboration between UNITAID and PEPFAR at both Board and Secretariat level, which has been formalised by a letter of co-operation. PEPFAR stressed the need for multilateral engagements between global health organisations. He called for creative solutions and the use of technical knowledge to solve priority global health problems. PEPFAR's Scientific Advisory Board has, on the basis of scientific evidence, called for an AIDS-free generation. PEPFAR and UNITAID can collaborate on harmonisation of procurement policies and market shaping activities, as well as at a scientific level. PEPFAR cited key areas such as paediatric ARVs, access to new ARVs, the introduction of novel laboratory diagnostics and POC tests. Management of hepatitis C is a fast moving area and PEPFAR expressed the hope that access to the new oral therapies will be achieved in low and middle income countries in the future.

The CHAIR OF THE EXECUTIVE BOARD thanked PEPFAR for attending EB19 and said that PEPFAR plays an important role in global healthcare. UNITAID will be delighted to work more closely with PEPFAR in the future.

DECISION

The EXECUTIVE BOARD took note of collaboration between PEPFAR and UNITAID.

15. Calendar of Board meetings for 2014

The Executive Board agreed the meeting dates for 2014.

The Board Relations Officer noted that the December meeting had been scheduled to allow sufficient time for Civil Society activities related to World AIDS day that takes place at the beginning of month.

DECISION

The Executive Board approved resolution n°11.

16. Any other business

Election of the Vice Chair of the Board

The CHAIR OF THE EXECUTIVE BOARD thanked CHILE for having carried out the responsibilities of Vice Chair with discretion and efficiency over the two year term of office. Discussions were to be prolonged on the election of a new vice chair.

Discussion

- ❖ BRAZIL reminded the Executive Board that geographic and gender balance should be observed.

DECISION

The EXECUTIVE BOARD took note of the election process for the VICE CHAIR of the EXECUTIVE BOARD

17. Closure of the meeting

On behalf of the EXECUTIVE BOARD, the CHAIR OF THE EXECUTIVE BOARD expressed his thanks to the Russian Delegation, the Medicines Patent Pool, the Global Fund, PEPFAR and the Secretariat for participating in the meeting. He also thanked the Committee Chairs and the other Board Members for their constructive contributions.

The EXECUTIVE DIRECTOR thanked the members of the Executive Board for the support and guidance provided to the Secretariat.

The 19th Session of the Executive Board closed at 17.25 on Friday 13 December 2013.

Annex 1 - List of Participants

BOARD MEMBERS / REPRESENTATIVES

CHAIR	– Philippe Douste-Blazy
<u>VICE-CHAIR</u> CHILE	– <u>Alt.</u> : Guy Fones
AFRICAN COUNTRIES	– Lindiwe Makubalo – <u>Alt.</u> : Najoua El Berrak
ASIAN COUNTRIES	– Unyeong Go
BRAZIL	– Jorge Bermudez
COMMUNITIES	– Nelson Otwoma – <u>Alt.</u> : Gracia Violeta Ross Quiroga
FRANCE	– Philippe Meunier – <u>Alt.</u> : Marianne Barkan-Cowdy
FOUNDATIONS	– Blair Hanewall
NGOs	– Tido von Schoen-Angerer – <u>Alt.</u> : Brook Baker
NORWAY	– Kari Marjatta Kolstrøm Hoel – <u>Alt.</u> : Kjetil Aasland
SPAIN	– <u>Alt.</u> : Gonzalo Vega Molina
UNITED KINGDOM	– Carlton Evans – <u>Alt.</u> : Jason Lane
WORLD HEALTH ORGANIZATION	– Hiroki Nakatani

ADDITIONAL MEMBERS OF DELEGATIONS

ASIAN COUNTRIES	– Ganglip Kim
BRAZIL	– Maria Luisa Escorel de Moraes – José Roberto de Andrade Filho – Flavia Castellano
FRANCE	– Stéphane Renaudin – Margot Nauleau
NORWAY	– Karoline Barkvoll Hostad – Christine Årdal
UNITED KINGDOM	– Donal Brown

WORLD HEALTH ORGANIZATION

– Issa Matta

COMMUNITIES DELEGATION

– Louis da Gama
– Kenly Sikwese
– Mercy Annapoorani
– Endalkachew Demmisse

NGOs DELEGATION

– Mohga Kamal Yanni
– Khalil Elouardighi
– David Deakin
– Evaline Kibuchi
– Pavel Aksenov
– Austin Obiefuna
– Annemarie Meyer
– Mandy Slutsker

LIAISON OFFICER, CIVIL SOCIETY

– Jessica Hammer

PROPOSAL REVIEW COMMITTEE

– Andy Gray (Chair, PRC)

OBSERVERS

- PARTNERS

MEDICINES PATENT POOL

– Greg Perry
– Chan Park

ROLL BACK MALARIA PARTNERSHIP

– Jan Van Erps

STOP TB PARTNERSHIP

– Lucica Ditiu

PEPFAR

– Michael Johnson

UNAIDS

– Carlos Passarelli

THE GLOBAL FUND

– Mark Dybul

- RUSSIAN DELEGATION

– Svetlana Valeievna Akselrod
– Elena Vladimirovna Talanova
– Anastasiya Viktorovna Smirnova
– Dilyara Salihzianonva Ravilova-Borovik
– Elena Vladimirovna Slobodina
– Olga Vladimirovna Galagan
– Alexey Kulikov

- CONSULTANTS

- Prashant Yadav
- Kaveri Kumar (CEPA Consultant)

WHO

- Colin Boyle (by teleconference)

OTHERS

- Laurence Thurion (office of the Chair)
- Sharon Shaacks (FIND)

UNITAID SECRETARIAT

- Denis Broun (Executive Director)
- Philippe Duneton (Deputy Executive Director)
- Mauricio Cysne (Head, External relations)
- Sophie Genay-Diliautas (Board Relations Officer)
- Catherine Kirorei Corsini (Board Relations Assistant)
- Brigitte Laude (Head, Finance and Administration)
- Sonia Lees-Hilton (Senior Legal Officer)
- Frédéric Martel (Strategy & Planning Officer)
- Gelise McCullough (Technical Officer, Executive Office)
- Gulmira Mc Hale (Resource Mobilization Officer)
- Taufiqur Rahman (Head, Operations)
- Robin Thompson (Manager, Market Dynamics)
- Brenda Waning (Head, Market Dynamics)

And on specific agenda items:

- Irina Avchyan (Finance Officer, Finance & Admin.)
- Raegan Boler (Technical Officer, Finance and Admin.)
- Lynn Hye Choi (Consultant, Operations)

- Clare Courtney (Communications Officer)
- Philippa Crompton
(Analyst, Market Dynamics)
- John Cutler
(Portfolio Manager, Operations)
- Smiljka De Lussigny
(Technical Officer, HIV, Operations)
- Jason Maddix
(Technical Officer, Market Dynamics)
- Sarah Mascheroni
(Events Officer, External Relations)
- Robert Matiru (Portfolio Manager,
Operations)
- Yamuna Mundade
(Technical Officer, Operations)
- Carmen Perez Casas
(Technical Officer, Market Dynamics)
- Kate Strong (Technical Officer, Operations)
- Romane Theoleyre
(Technical Officer, Operations)
- Karin Timmermans
(Technical Officer, Market Dynamics)
- Monique Van Vliet (Finance Officer,
Finance and Administration)
- Susanna Volk
(Executive Assistant, Executive Office)