



**Minutes of UNITAID's
20th Executive Board meeting
12 - 13 June 2014**

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Executive Summary

- The 20th meeting of the UNITAID Executive Board started at 08.45 on Thursday 12 June 2014.
- The agenda was adopted and proceedings commenced at 09.00.
- Prior to the meeting, Declaration of Interest disclosures had been received from Norway, the World Health Organization (WHO) and the Gates Foundation.
- The minutes of 19th Executive Board (EB19) and 19th Executive Board Special Session on Proposals (EB19 SSP) were approved, after changes requested by Norway and the Gates Foundation had been implemented.
- The EXECUTIVE DIRECTOR A.I. provided an update on recent activities by the UNITAID Secretariat, including the 2014 priorities.
- The CHAIR OF THE POLICY AND STRATEGY COMMITTEE (PSC) reported on the recent meeting of the PSC, which was held in May 2014. The PSC wishes to adopt a forward looking vision for the UNITAID portfolio.
- The VICE-CHAIR OF THE FINANCE AND ACCOUNTABILITY COMMITTEE (FAC) reported on the 12th session of the FAC that was held in May 2014. The 2013 Audited Financial Statements were approved by the Executive Board (Resolution n°1).
- The strategic framework for the partnership between UNITAID and the Global Fund was discussed. The EXECUTIVE DIRECTOR and CHIEF PROCUREMENT OFFICER OF THE GLOBAL FUND highlighted the complementary way in which the two organisations could collaborate across the disease areas in the future.
- The External Relations strategy was presented. The objective is to secure predictable and sustainable funding from existing donors and new donor targets with the support of an effective communications plan.
- WHO HIV DEPARTMENT provided an overview of HIV self-testing. The PRC CHAIR presented a summary of the PRC's review of the proposal by a consortium led by Population Services International (PSI) to evaluate HIV self-testing at scale. An electronic vote on this project will take place in the summer 2014.
- The EXECUTIVE BOARD approved a no cost extension request for the EXPAND-TB project, which is being undertaken by the Global Laboratory Initiative (GLI) and the TB Department of WHO. (Resolution n°2)
- The Operations report covered grant performance and the implementation of guidelines for effective grant management.
- The EXECUTIVE BOARD congratulated the Secretariat for its work on the development and reporting of Key Performance Indicators (KPIs). The 2013 KPI report will be published on 30 June 2014.
- The EXECUTIVE BOARD took note of the report from the Steering Group on Governance.
- The EXECUTIVE BOARD approved the Terms of Reference for the Functional Review. (Resolution n°3)

- The EXECUTIVE DIRECTOR OF THE MEDICINES PATENT POOL (MPP) and Cambridge Economic Policy Associates (CEPA), the consultancy company that conducted the Operational Review, respectively, provided an update on the activities of the MPP and the findings of the Operational Review. (Resolution n°4)
- The CHAIR OF THE EXECUTIVE BOARD concluded the meeting and thanked all the attendees for their input. The open session of EB20 closed at 14.45 on Friday 13 June 2014.

1. Welcome and opening of the session

1.1. Opening remarks of the Chair

The 20th meeting of the UNITAID Executive Board started at 08.45 on Thursday 12 June 2014. The CHAIR OF THE EXECUTIVE BOARD of UNITAID welcomed the participants. He extended a particular welcome to:

- Dr Eun Kyeong Jeong, the Alternate Board member for the Asian countries;
- Ms Marianne Barkan-Cowdy, the Alternate Board member for France;
- Ms Sarah Boulton, the alternate Board member for the United Kingdom; and
- Mr Kenly Sikwese, the alternate Board member for the Communities Living with the Diseases (Communities).

The Chair of the Executive Board thanked Mr Nelson Juma Otswana the outgoing Communities Board member for all of his hard work on behalf of UNITAID.

1.2. Declarations of interest

Declarations of interest were received and the following interests were declared:

- NORWAY declared that Population Services International (PSI) is a recipient of Norwegian Aid Money.
- WHO declared that it is a member of the consortium led by PSI and has submitted a request for a no cost extension for the UNITAID-funded EXPAND-TB project.
- The GATES FOUNDATION declared that it is funding the International Initiative for Impact Evaluation (3IE) to explore the use of HIV self tests in sub Saharan Africa. PSI is a sub-grantee of 3IE for the HIV self test work. The proposal under review by UNITAID would likely complement this effort.

2. Adoption of the agenda

The agenda for the 20th Executive Board was adopted without changes.

DECISION

The EXECUTIVE BOARD *adopted* the agenda for the EB20 meeting.

3. Minutes from EB19

The minutes from EB19 were accepted after the implementation of two changes that NORWAY had requested.

DECISION

The EXECUTIVE BOARD *adopted* the minutes of the EB19 meeting subject to the amendments requested by Norway.

4. Minutes from EB19 Special Session (EB19 SS)

The minutes from EB19 SSP were approved after the implementation of two changes that NORWAY and THE GATES FOUNDATION had requested.

DECISION

The EXECUTIVE BOARD adopted the minutes of the EB19 SSP meeting subject to the amendments requested by Norway and the Gates Foundation.

5. Report from the Executive Director a.i.

The EXECUTIVE DIRECTOR A.I. provided an update on recent activities by the UNITAID Secretariat, including the 2014 priorities:

- Senior Management Team (SMT) operation;
- Strategy Implementation Framework;
- The UNITAID and Global Fund Partnership agreement;
- Call for Letters of Intent (LOI) – held in May 2014;
- Investment opportunities based on the 2013-2016 Strategy.

Nine key issues are being tracked:

SMT <ul style="list-style-type: none"> • Organization of Secretariat • Human Resources • Quality Management • Planning & Budget • Crosscutting Initiatives • Functional Review (Q3/Q4) 	Grants <ul style="list-style-type: none"> • Management of 25 active grants • EB19SS – 6 new grants approved (kick off meetings on track) 	Reports <ul style="list-style-type: none"> • KPIs • Project Evaluation Framework PSC • Evaluations of projects • Reviews (France/UK) • MPP Review • Audits • Market and PH impact • HIV Market Forum
Strategy 2013-2016 <ul style="list-style-type: none"> • Letters of Intent • Strategy Implementation and mid term review (2015) • Investment Analysis (work in progress) 	Risk Management <ul style="list-style-type: none"> • Identification of risks(11) • Action Plan under development • Fraud risk Analysis (FAC May) 	Resources <ul style="list-style-type: none"> • Multi year agreements • Current donors • New donors
Board <ul style="list-style-type: none"> • Executive Committee • Board/Committee Meetings 	Partnerships <ul style="list-style-type: none"> • GFATM (Agreement) • PEPFAR (to review) • WHO • Civil Society (PSC Nov) 	Communication <ul style="list-style-type: none"> • Annual Report • Draft Strategy (May 2014) • Website

In particular:

- The **SMT** has set priorities to ensure that the organisation and functioning of the Secretariat are optimal. Attracting and retaining key staff with the right skills is essential. Planning for the 2015 budget has started. A number of crosscutting initiatives have been identified and the Strategy Implementation Framework has been updated. The Terms of Reference (TOR) for the Functional Review, which will take place in Q3/4 2014, have been reviewed by the Executive Committee and submitted to the Executive Board for approval. A mid term review will take place in 2015.
- 25 active **grants** are being managed by the Secretariat and six new grants are about to commence, following funding approval at EB19 SSP in May 2014. Meetings with the implementers of the new grants have taken place, and work plans are being developed.
- Work on **risk management** is in progress and 11 potential risks to UNITAID have been identified. An Action Plan to mitigate these risks is being developed. The Finance and Accountability Committee (FAC) discussed the Fraud Risk Analysis at its meeting in May 2014. Potential risks and risk mitigation strategies will be discussed with implementers before new projects start.
- **On partnerships**, an agreement between UNITAID and the Global Fund for AIDS, TB and Malaria (GFATM) was signed on 6 June 2014. The agreement with PEPFAR is currently under review. Discussions are ongoing with WHO about its partnership with UNITAID. The Civil Society Engagement Plan will be submitted to the PSC in November 2014.
- A number of documents and **reports**, such as the KPI report and the feedback from the HIV Market Forum, are in preparation or are being finalised.
- In terms of **resource mobilisation**, the priorities are to secure multi-year funding agreements with key donors and to work with current and potential donors on funding opportunities. The Annual Report for 2013 has been finalised and an interactive version is now online. A draft strategy on External Relations has been submitted to the Executive Board for review and advice.

The EXECUTIVE DIRECTOR A.I. expressed his thanks to the Proposal Review Committee (PRC) for their hard work reviewing the proposals that were discussed at the EB19 SSP. An Open Call for proposals was held in May 2014 and 94 LOIs were received in response. After the screening process had been implemented, six proposals were selected as having a high potential for success and as meeting UNITAID's criteria for funding. The proponents were notified of the decision in the week of 9 June 2014 and the Secretariat will assist with proposal development until the submission date of 29 September 2014. The majority of rejected proposals were not compatible with UNITAID's business model and Strategy, e.g. they were single country projects or focused on health systems strengthening. The EXECUTIVE DIRECTOR A.I. outlined the six LOIs that will be developed into proposals.

The Secretariat is developing a process to identify potential strategic investment opportunities. The EXECUTIVE DIRECTOR A.I. shared the key assumptions in this process with the Executive Board and said that a draft of the paper is being developed with assistance from the United Kingdom. One option would be to have more directed Calls for Proposals in order to fill gaps in the UNITAID portfolio and ensure that funding is appropriate for priorities set, and Strategic Objectives.

Discussion

- ❖ The NGOs, the GATES FOUNDATION, NORWAY, the UNITED KINGDOM, the COMMUNITIES and the CHAIR OF THE EXECUTIVE BOARD expressed their pleasure at receiving an excellent overview of the Secretariat's work. The GATES FOUNDATION commented that substantial progress had been made in six months.
- ❖ The NGOs expressed disappointment that only one proposal was being developed for the area of malaria, given that a number of investment opportunities had been highlighted at the Malaria Market Forum.
- ❖ The GATES FOUNDATION requested an opportunity to look at the detail behind the Resource Mobilisation and External Relations strategies, and offered to work with the Secretariat on these issues.
- ❖ The GATES FOUNDATION suggested that it would be necessary to look beyond intellectual property (IP) and quality assurance (QA) projects for new crosscutting interventions.
- ❖ NORWAY asked why the Secretariat had used 'stable revenue' as one of its key assumptions. She wondered if this could affect fund raising. NORWAY enquired whether the Secretariat was assuming that existing donors would maintain their current level of funding or if new donors would be needed to achieve a stable funding level.

The EXECUTIVE DIRECTOR A.I. replied that 'stable revenue' was used as a key assumption because agreements with new donors have not yet been signed. The FAC has instructed the Secretariat to focus initially on current donors and then to work on attracting new donors. The EXECUTIVE DIRECTOR A.I. agreed that if UNITAID were able to attract increased funding, it would be able to adjust UNITAID's funding capacity such as prevention areas.

- ❖ The NGOs suggested that calculating the funding envelope needed to fund the new investment opportunities identified by UNITAID (via its landscapes and Market Fora) would be a useful approach. Resource mobilisation efforts would be assisted if UNITAID could demonstrate that it sequences its interventions.
- ❖ The UNITED KINGDOM commented that there is a gap between the LOIs received and the UNITAID portfolio. He said that a range of proposals in new areas is needed and suggested that more directed calls for proposals might achieve this.

The EXECUTIVE DIRECTOR A.I. replied that UNITAID now has twice as many implementers as in previous years (16 vs. 8). When an unmet need is highlighted in a landscape analysis or a Market Forum, the Secretariat attempts to identify appropriate organisations and invites them to design appropriate interventions. LOIs are submitted in response to Calls for Proposals and the normal, competitive proposal review process then takes place.

- ❖ The COMMUNITIES expressed their hope that new drug formulations, with fewer toxicities and better efficacies, would become available in the next few years.

DECISION

The EXECUTIVE BOARD *took note* of the report from the EXECUTIVE DIRECTOR A.I.

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

The CHAIR OF THE POLICY AND STRATEGY COMMITTEE (PSC) reported on the recent meeting of the PSC, which was held on 6 May 2014. The PSC wishes to adopt a forward looking vision for the UNITAID portfolio.

The inaugural **HIV Market Forum** was co-hosted by UNITAID and WHO. It covered four main areas:

- Shaping markets for timely access to new WHO-recommended treatments;
- Market approaches to scale up hepatitis C (HCV) treatment innovations;
- Optimizing markets for robust, affordable HIV and HCV diagnostics;
- ‘Hot topics’ (including pooled procurement, tiered pricing & price transparency).

UNITAID was urged to be innovative in its approach to improving access to HCV diagnostics and drugs, especially for HIV/HCV co-infected patients. The report on the meeting will be published in June 2014.

Operations have increased their focus on results-based management, value for money and country ownership. Effective partnerships are being created with the Global Fund and other donors in order to transition and scale up UNITAID investments. In-country verification of projects is being undertaken and civil society is participating in this work. The first synergy meeting on HIV diagnostics has taken place. The Secretariat is constantly improving its internal systems, especially in relation to efficient grant management and risk assessment. Cumulatively, 49% of UNITAID’s funds have been invested in HIV; 15% in TB; 24% in malaria; and 8% in crosscutting activities.

The PSC has recently endorsed the **Grant Evaluation Framework**, which was revised in response to a decision taken at EB19. Key revisions include a focus on country level verification; increase consultations with country stakeholders; corroboration of grant achievements by partners; focus on value for money, impact and country ownership; and transparent communication with grantees and stakeholders.

Access and IP Guidelines have been developed to assist grantees working on market entry projects that facilitate the development of products and new formulations. Grantees must make upfront commitments regarding price, registration, marketing, and supply; and must provide access to information without limitations. The PSC commented on the document at the 11th PSC meeting and the document has been revised on the basis of all the inputs received.

Evaluating the **impact of UNITAID projects on public health** is crucial for strategic decision making. A set of user friendly tools have been developed to assess the value of POC diagnostics for HIV, TB and Malaria, which:

- Estimate DALYs/lives saved per intervention;

- Explore direct and indirect public health impact;
- Estimate cost effectiveness (HIV POC diagnostics).

Two new studies are planned for 2014: assessing the public health impact of UNITAID investments in HIV/HCV co-infection and multi-drug resistant TB (MDR TB).

UNITAID is consolidating its **partnership agreements**. An agreement has been signed with the Global Fund and the PSC stressed that the road map of the co-operation must be finalised and approved rapidly. A Memorandum of Understanding has been signed with PEPFAR and a high level meeting is planned for Q3 2014. The Paediatric Treatment Initiative was launched on 18 May 2014, during the World Health Assembly. A plan to improve UNITAID's engagement with Civil Society will be presented to the next PSC meeting.

The results of the **PSC self-assessment** were shared with all PSC members. Areas of improvement included:

- Improve understanding of the Secretariat work;
- Strategy implementation oversight;
- Partnership follow-up;
- PSC members engagement and expertise;
- Portfolio performance.

A **PSC work plan** has been developed and it reflects all of the key decisions made by the PSC. A discussion on the Small Grants policy will take place at the November 2014 PSC meeting. The aim of the policy will be to provide flexibility to start working on innovative projects, which can then be developed into large interventions if successful.

Discussion

- ❖ NORWAY requested that the minutes of the HIV Market Forum include the discussions about the need to reach marginalised, vulnerable and criminalised groups of patients. The COMMUNITIES, FRANCE and the CHAIR OF THE EXECUTIVE BOARD supported this request and stressed its importance in UNITAID's work. The CHAIR OF THE EXECUTIVE BOARD called for the same drugs to be made available in both rich and poor countries, and for under privileged patients to be able to access healthcare products regardless of where they live.

UNAIDS commented that they are working very hard on discrimination issues. He called for UNAIDS and UNITAID to work together on indicators of lack of access to healthcare and an equity strategy

- ❖ SPAIN considered that one of the important points from the HIV Market Forum was that the World Bank classification of countries might not be the most appropriate way to classify countries when considering access to healthcare resources. He cited the example of disadvantaged populations living in middle-income countries that are unable to access appropriate drugs, diagnostics or disease prevention items.

UNAIDS supported this point and described the current World Bank classification as 'insufficient' to convey the complexities of healthcare access. UNAIDS would like to work with UNITAID on this issue.

- ❖ NORWAY suggested that the Decision Points in the PSC minutes should be renamed 'Discussion Points' since they summarise the opinions of the PSC.
- ❖ The NGOs and the COMMUNITIES commented on the section on Partnerships and the role of civil society. They said that the main role of civil society is to create demand for better healthcare products. In addition, civil society can help to increase the visibility of UNITAID projects and provide feedback on project performance. The COMMUNITIES said that this had been conveyed to the Secretariat during the Consultation with civil society that was held in December 2013.

The CHAIR OF THE PSC agreed that the role of civil society goes beyond increasing the visibility of UNITAID projects and that further discussion is needed during the November 2014 PSC meeting on how UNITAID can engage better with civil society.

- ❖ In relation to UNITAID partnerships, SPAIN stressed the need to bear in mind the principles of aid effectiveness when establishing partnerships.
- ❖ The COMMUNITIES gave their support to establishing the Small Grants Policy.

DECISION

The EXECUTIVE BOARD *took note* of the report from the CHAIR OF THE PSC

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

The VICE-CHAIR OF THE FINANCE AND ACCOUNTABILITY COMMITTEE (FAC) gave an overview of the items discussed during the 12th session of the FAC that was held on 7 May 2014. Topics included a summary of the 2013 Audited Financial Statements; the FAC Work plan; UNITAID's funding ceiling and cash levels; the grant performance dashboard; the organisational risk analysis and updates on internal and external audits, fraud awareness and prevention.

The VICE-CHAIR OF THE FAC informed the Executive Board that since the EB19 SSP in May 2014, UNITAID has received the 2014 contribution from Norway of US\$19.2 million and funding commitments from donors of US\$157.7 million. The funding ceiling prior to the new grant approvals at EB20 was US\$178 million.

Discussion

- ❖ THE GATES FOUNDATION and NGOs expressed concern about the methodology used for calculating the funding ceiling and the high cash levels held by UNITAID. They believe that current situation could discourage donors and place UNITAID in a risky position for future resource mobilisation. The GATES FOUNDATION requested that time is allocated to discuss this topic in depth at the next FAC meeting in November 2014.

2013 Audited Financial Statements

Highlights of the 2013 Audited Financial Statements were presented

- **Donor contributions** in 2013 totalled US\$279 million. FRANCE and the United Kingdom were the major donors with respective contributions of US\$149 and US\$87 million. Operating expenses were US\$147 million with project-related expenses accounting for US\$127.7 million, staff costs US\$12.3 million and Governing bodies, Secretariat activities and Strategy implementation accounted for US\$6.7 million.
- **Project expenses** were presented according to Strategic Objective (SO). Simple, point-of-care (POC) diagnostics represented 43% of expenditure. Total disbursements for 2013 were US\$121.7 million, which was 99% of the budgeted amount. 35% of disbursements were for HIV grants, 34% for malaria, 26% for tuberculosis and 5% for crosscutting projects. The ratio of disbursements by disease area will change in 2014 when many large malaria projects come to an end.
- UNITAID had US\$707 million of **net assets** at the end of 2013 of which US\$372 million was available for commitment.

The External Auditor certified the UNITAID 2013 accounts that were in accordance with WHO financial regulations. Two minor comments in the Management Letter were already being addressed by the Secretariat.

The Vice-CHAIR OF THE FAC requested approval from the Executive Board for the 2013 Audited Financial Statements.

DECISION

The EXECUTIVE BOARD adopted by consensus

Resolution n°1

8. Partnerships

The Global Fund

The EXECUTIVE DIRECTOR OF THE GLOBAL FUND thanked the Secretariat of UNITAID, particularly the Executive Director a.i., for the efforts that have been made to develop a strong strategic framework as a basis for the partnership between their two organisations. He described UNITAID as a 'market shaper' and an 'innovator' that acts in a complementary way to the Global Fund because UNITAID intervenes at a more upstream level than the Global Fund. The EXECUTIVE DIRECTOR OF THE GLOBAL FUND highlighted the successful collaboration enjoyed by their organisations for paediatric HIV and said that they should now consider what actions could be taken in other commodity and disease areas. He explained that, under the new partnership agreement, the Global Fund and UNITAID would have collective Key Performance Indicators and would report jointly to their respective Boards. He emphasised that the focus of the Global Fund would continue to be on transition and equitable growth.

The EXECUTIVE DIRECTOR OF UNITAID A.I. presented the strategic framework for the partnership. A letter of agreement had been signed on 6 June 2014 outlining the basis for their joint collaboration that aimed to ensure rapid development and uptake of high quality medicines and diagnostics; to promote simpler treatment regimens and point of care (POC) diagnostics; and to improve value for money by achieving greater market and public health impact. He emphasised the potential complementarity of their activities and said that a cooperation plan would be developed for 2015: UNITAID would concentrate its activities at global level to bring about market impact, while the Global Fund would focus on transition and scale up at country level. Respective roles will be clearly defined to avoid any duplication of effort and implementation will be tracked through the development of specific KPIs and Board reporting.

Paediatric antiretrovirals (ARV) will continue to be a key area of collaboration between UNITAID and the Global Fund. The organisations will work together on the following projects: Innovation in Paediatric Market Access (IPMA), DNDi, CHAI-UNICEF HIV Point-of-Care Diagnostics (POC Dx), and the Paediatric HIV Treatment Initiative (PHTI). The EXECUTIVE DIRECTOR OF UNITAID A.I. concluded that this partnership could bring about substantial improvement in terms of access to treatment.

The CHIEF PROCUREMENT OFFICER (CPO) OF THE GLOBAL FUND said that the Global Fund was the 'customer of choice' for manufacturers that 'opens upstream doors'. There were no longer any issues with cash flow and the Global Fund was in a position to commit to longer term contracts than it had been previously.

Discussion

- ❖ The NGOs and the UNITED KINGDOM expressed their appreciation of the efforts made by the Global Fund and UNITAID to reach this agreement so rapidly. The UNITED KINGDOM described it as a 'hugely important step towards greater collaboration between the organisations' that would provide a constructive way forward towards an equitable access initiative.

The EXECUTIVE DIRECTOR A.I. said that the paediatric initiatives were examples of what could be achieved through market shaping interventions to provide simple, more accessible treatment to vulnerable people across the three disease areas. The overall result of the partnership would be improved value for money.

- ❖ FRANCE underlined that as the partnership between the Global Fund and UNITAID develops, cooperation involving countries should be sought.
- ❖ The NGOs were pleased to see the success to date. They asked how the problem of access to more affordable products in middle income countries would be handled and requested more detail on strategic engagement particularly with regard to equitable transition mechanisms. They asked whether Intellectual Property (IP) issues had been discussed and whether this was an area where UNITAID and the Global Fund could work together.

The CPO OF THE GLOBAL FUND replied that equitable transition would be considered in the future. He confirmed that the IP was an important area for potential collaboration even though it had not been detailed in the background documentation. The Global Fund was interested in exploring how IP

flexibilities can be exploited earlier in the lifecycle of drugs than is presently the case.

- ❖ The CHAIR OF THE PROPOSAL REVIEW COMMITTEE (PRC) requested that the decisions of the Global Fund's Technical Review Panel (TRP) should be communicated to the PRC. He pointed out that TRP decisions could affect the PRC reviews.
- ❖ FRANCE praised the rapidity of the partnership development. He stressed that external communications should focus on concrete examples of the benefits of collaboration. These examples should be linked to the UNITAID's Strategic Objectives. He suggested that it would be timely to talk about tuberculosis. Communication should be a joint process and should use fora, such as the World Health Assembly.

The CHAIR OF THE EXECUTIVE BOARD responded that both UNITAID and the Global Fund would be present at the UN general assembly where a meeting has been scheduled. This could be a useful opportunity to demonstrate how innovative funding could complement Official Development Assistance (ODA).

The EXECUTIVE DIRECTOR OF UNITAID A.I. assured the Board that communicating about the new partnership was a priority: a joint press release about the agreement had been issued. The Secretariat was currently drafting a summary of what the organisations were planning to achieve together. This summary would include concrete examples of ongoing or planned collaboration.

- ❖ The GATES FOUNDATION urged the Secretariat to identify areas where UNITAID can complement Global Fund activities. She asked how portfolio managers from each organisation planned to work together to make operational decisions. She suggested that Strategic Product Reviews carried by the former Market Dynamics Advisory Group of the Global Fund (MDAG) would be a good opportunity for UNITAID and the Global Fund to interact.

The CPO OF THE GLOBAL FUND said that the portfolio groups at the Global Fund were adopting a more integrated and coordinated approach that would take into account both internal and external overlap between the respective Secretariats. The Strategic Product Review will become one of the delivery platforms for the new Market Dynamics Advisory Group (MDAG) at the Global Fund. This review will identify areas where UNITAID can provide support.

DECISION

The Executive Board *took note* of the information on the Partnership with the Global Fund

9. External Relations

The CHAIR OF THE EXECUTIVE BOARD emphasised the need for UNITAID to make greater progress in terms of external relations. He welcomed the appointment of the new Head of UNITAID External Relations to the Secretariat.

External Relations Strategy

The HEAD OF EXTERNAL RELATIONS introduced the members of his team to the Executive Board and then presented an overview of the External Relations strategy. The strategy is based on the UNITAID 2013-2016 Strategy and the outcomes of the 5-Year Evaluation. Its main objective is to 'secure and raise predictable and sustainable resources for UNITAID's activities'. Having highlighted the problems of fluctuating funding levels and uncertainty concerning future pledges, the HEAD OF EXTERNAL RELATIONS presented the following classification of existing members of UNITAID:

- **List A:** Includes donors who have previously made significant contributions to UNITAID and, consequently, expectations are high for future contributions.
- **List B:** Includes countries that have contributed to UNITAID in the past but no longer do so and so the expectations for future payments are not high.
- **List C:** Includes countries that joined UNITAID as members but have never made contributions.

He then presented a prioritisation of new contributors according to regional hubs: there would be a focus on Asia and the Middle East where new investment opportunities existed for HCV co-infection with HIV. UNITAID would seek high level support by using former Heads of State and global leaders as advocates and to work together with the Leading Group on Innovative Financing for Development.

The HEAD OF EXTERNAL RELATIONS raised the possibility of organising a pledging conference to present UNITAID's business model and successes, and to bring together UNITAID supporters to confirm their future pledges to UNITAID. He pointed out that this type of event had worked well for other institutions such as the Global Fund.

Communications are of vital importance to establish and promote UNITAID's brand and to consolidate relationships with existing global stakeholders. The new Communications plan will reflect the changing media environment using new opportunities such as Twitter and blogs. Third party endorsement from influential sources will be sought. Plans are also in place to improve internal communication: these plans include a media training programme for UNITAID spokespeople.

The External Relations strategy takes into account the need to develop strong relationships with key partners in global health, civil society, contributing countries, foundations, academia and the private sector.

The next steps in the External Relations Strategy are to prioritise the planned interventions and to develop a clear workplan for the Secretariat. A monitoring tool to track progress against the stated objectives will also be developed. The HEAD OF EXTERNAL RELATIONS concluded his presentation by describing what had already been achieved in terms of press coverage, events and publications.

Discussion

- ❖ THE NGOs called for a structured approach to resource mobilisation that should include the financial transaction tax; this should be specified in the documentation. The NGOs asked about the brand development process, particularly for information on the desired brand image for UNITAID and the

key messages that would be communicated at country level. They stressed that ‘impact on the ground is what we’re looking for’.

The HEAD OF EXTERNAL RELATIONS agreed with the NGOs saying that more analytical data were available and could be added to the documentation.

- ❖ NORWAY congratulated the Secretariat on its strategic approach to External Relations. She requested that a single fundraising strategy be adopted that would include the activities of the Chair of the Executive Board. Caution was expressed concerning a pledging conference: there was a need to clarify its aims and the proposed targeting of donors. She recommended that a risk analysis should be carried out and other options evaluated before proceeding. BRAZIL agreed with Norway and pointed out the notion of ‘pledging’ could discourage participation from some stakeholders. He emphasized that it would require careful planning and offered Brazil’s support in developing a model for such an event. These views were echoed by the AFRICAN COUNTRIES: the possibility of additional support for UNITAID will be discussed with the South African government.
- ❖ FRANCE emphasised that UNITAID’s image was linked with innovative funding and agreed with the NGOs that the financial transaction tax should be mentioned as it makes an important contribution to funds for global health. Like Norway and Brazil, FRANCE was concerned that a pledging conference could send out mixed messages to donors and weaken the clear differentiation that currently exists between UNITAID and other institutions. He suggested that the Secretariat could further explore resource mobilisation possibilities in North America and particularly Canada, which is already engaged with the Global Fund.
- ❖ CHILE praised the ambitious approach of the External Relations department, which he described as ‘timely and opportune’. He highlighted the unique role played by UNITAID in advancing innovative financing initiatives and expressed Chile’s commitment to this approach.
- ❖ The HEAD OF EXTERNAL RELATIONS assured the Executive Board that a risk analysis and extensive planning would be performed for the pledging session. An action plan would be presented at EB21 in December 2014.

The CHAIR summarised the session by saying that UNITAID holds a unique position in the Global Health arena, however it needs to demonstrate its complementarity with other health organisations. Predictable and sustainable funding is essential and so he suggested that the Executive Board could consider holding a pledging conference on a four yearly basis. He recommended that a Retreat for the Executive board should be organised to offer an opportunity for the Executive Board to discuss new methods of innovative funding and to ensure that UNITAID continues to lead the debate on a political level. During the Retreat, the Executive Board should discuss how UNITAID could maintain its place as a global health player in HIV, malaria and TB, as well as considering other options.

DECISION

The EXECUTIVE BOARD *took note* of the External Relations Strategy review

10. Proposals

10.1. Proposal – Population Services International (PSI)

WHO HIV DEPARTMENT provided an overview of the rationale for HIV self-testing and research evidence in this area. More than 50% of people living with HIV (PLHIV) do not know their status. Self-testing would allow people to test at their own convenience in the privacy of their own homes without the need to go to healthcare facilities. This has the potential to dramatically increase the number of people who know their HIV status, and provide them with the autonomy to test when and how often they want to. People who test HIV positive with a self-test will have to have a second, confirmatory test and then be linked to HIV care. Most of the data on self-testing have been derived from pilot studies: acceptability rates have ranged from 74% to 96% in a wide range of populations. At present, unregulated HIV self-tests are available from pharmacies and via the Internet. One of the aims of the PSI project is to support the development of a regulatory framework and ensure the availability of quality assured tests. WHO guidelines on self-testing could be developed using data from this project.

Although concerns have been raised about the ethical implications of self-testing (e.g. risk of coercion and/or partner violence; lack of counselling and support), there have been no reports of these problems from the pilot studies. A risk mitigation strategy has been developed by the applicants and an Advisory Board will be set up to monitor the project.

Discussion with WHO HIV Department

- ❖ CHILE described the proposal as very promising and asked for more details about the scale up of the intervention.

WHO HIV DEPARTMENT replied that scale up has not yet happened but the applicants have no concern about this aspect of the project. HIV self-testing is a relatively new concept. It is available in the USA and only one country (Kenya) has included self-testing in its National HIV Programme. HIV self-testing has worldwide potential and could improve equity of access to testing.

- ❖ The NGOs asked about the size of the intervention: how many tests are needed to prove the concept and for WHO to develop guidelines.

WHO HIV DEPARTMENT acknowledged that this was a difficult question. WHO has not set a target for the number of tests needed to develop guidelines. However, the intervention must be carried out at scale to show that self-testing is acceptable in a wide range of populations in several high burden countries, including the key at risk populations. In areas where there are legal constraints, e.g. in relation to targeting men who have sex with men (MSM), a general population approach might be the most effective way of reaching at risk populations.

- ❖ FRANCE asked about the impact of self-testing in low burden countries, such as certain Francophone African countries. He said that it would be interesting to gather data in this setting.

WHO HIV DEPARTMENT replied that, even within countries with generalised epidemics, there is a wide range of rates of HIV infection in different

populations. It is anticipated that this project will yield information on self-testing in both high and low burden settings. Evidence from the USA suggests that people from a range of high and low risk groups self-test because they consider that they are at risk of HIV infection.

- ❖ The AFRICAN COUNTRIES commented that counselling is an important part of HIV testing in Africa and asked how people who self-test are linked to counselling and care.

WHO HIV DEPARTMENT acknowledged that this is a key aspect of the project. She added that the role of pre-test counselling has diminished in recent years but post-test counselling is very important. A wide range of post-self-test counselling options are needed: community and peer support groups will be essential; and telephone help lines may be useful. Information about support options will be distributed with the test kits.

- ❖ The NGOs commented that there is very little information on the general population's testing literacy. At present, a healthcare worker performs the test but self-testing will require a person to perform the test and interpret the results. Social marketing and community mobilisation will be needed to enhance testing literacy.

WHO HIV DEPARTMENT commented that a range of options will be used to educate users e.g. pictorial instructions, videos, cell phone Apps, demonstrations of the test within the community, etc.

WHO then left the meeting due to a potential conflict of interest with both projects that were discussed. The meeting went into a restricted session.

The PRC CHAIR presented a summary of the PRC's review of the proposal on HIV self-testing by a consortium led by Population Services International (PSI). During the PRC meeting, the proposal was scored highly in terms of technical elements. A request for clarifications was sent to the consortium; these included questions about the project's public health impact; information on the estimated number of HIV self-tests for each target population; and ethical issues about unsupervised self-testing and linkage to counselling and support services, as well as the potential for coercion. After the responses had been received, the PRC concluded that:

- The proponents are well recognized in the field;
- There is a need to evaluate this new approach among key populations;
- An important objective is to evaluate self-testing as a complement to current models;
- The proposal has shown due regard for the human rights questions that arise from this effort.

The majority of the PRC recommended that lessons could be learned in a shorter timeframe from a smaller, more focused project in specific populations, e.g. MSM, female sex workers and peri-urban populations. This would help to define the role of self-testing as a complement to provider-initiated testing and early involvement of public health authorities would make it possible to establish guidelines (regulatory and clinical) and define the transition process. The PRC considered that a number of

issues that they had raised in their initial assessment still need to be addressed, e.g. the involvement of public health authorities and institutions; a discussion on IP and technology transfer aspects of the test; and a comparison of self-testing with other established rapid HIV tests. A minority of the PRC was convinced of the need to explore the impact of self-testing at scale, including in rural areas, and supported the original proposal's request for funding of a planned phased approach.

Discussion

- ❖ The NGOs asked about the SECRETARIAT's opinion of the proposal.

The EXECUTIVE DIRECTOR A.I. replied that self-testing is a complex issue and the SECRETARIAT understood the PRC's initial reservations about the proposal. Discussions have been held with PSI and a phased approach could be feasible. Data from phase 1 could be assessed before a commitment is made to WHO project.

- ❖ The CHAIR OF THE EXECUTIVE BOARD commented that a review of the budget should be conducted.
- ❖ The NGOs asked for clarity about the target populations that would be included in the project.

The EXECUTIVE DIRECTOR A.I. responded that this topic would be discussed further with PSI. The SECRETARIAT and the PRC would prefer several population groups to be included, rather than just vulnerable groups, in order to gain information about the acceptability of self-testing in the widest range of people possible. WHO will provide support during the implementation phase.

- ❖ NORWAY said that she had been convinced by PSI's responses to the PRC's questions. In her opinion, it appeared that PSI believed that market shaping would be less effective if a phased approach is employed than if the intervention was at scale.

The PRC CHAIR agreed that it is challenging to determine how large an intervention of this type should be in order to shape the market for HIV self-tests. The test is available in the USA. There is only one manufacturer (Orasure) and the price is substantially higher than blood-based tests. The PRC CHAIR was not certain that 2.8 million tests would change the market but said that the aim of the project was to collect information in a variety of settings and populations. In time, it is hoped that this project will result in an increased number of manufacturers, and better quality assurance and regulatory procedures for HIV self-tests.

- ❖ FRANCE reiterated its request to investigate the impact of self-testing in low burden countries.

The PRC CHAIR responded that information that can be generalised to low burden countries would be collected during this project.

- ❖ NORWAY and the UNITED KINGDOM asked for more information about the content of the resolution that will be submitted for an e-vote.

The CHAIR OF THE EXECUTIVE BOARD replied that Phase 1 of the project was already budgeted for and so this could be approved in a resolution.

The EXECUTIVE DIRECTOR A.I. said that a phased approach with a relevant budget would be proposed in the resolution. The CHAIR OF THE EXECUTIVE BOARD agreed with this suggestion.

- ❖ The UNITED KINGDOM asked for clarity about the grant review process. He expressed doubt about the wisdom of allowing applicants to lobby the Executive Board when their applications have already been processed in a transparent manner and considered in the appropriate committees. He questioned whether a resolution was needed since an electronic vote (e-vote) is planned for July 2014.

The CHAIR OF THE EXECUTIVE BOARD agreed that it was not clear whether a resolution was required.

The EXECUTIVE DIRECTOR A.I. replied that a resolution was not needed. The aim of the discussion was to seek guidance from the Executive Board. An e-vote of an amended resolution will take place during the summer 2014.

The CHAIR OF THE EXECUTIVE BOARD suggested that the Executive Board give its approval to the Secretariat's plan.

**The EXECUTIVE BOARD *agreed to hold an e-vote on*
the PSI proposal during the summer 2014.**

11. Proposal – No Cost Extension Request for EXPAND-TB Project – WHO/GLI

The SECRETARIAT presented the no cost extension request for the EXPAND-TB project that is being undertaken by the Global Laboratory Initiative (GLI) and the TB department of WHO. The majority of the project's targets have been met: 72,000 cases of MDR-TB cases have been detected cumulatively up until 2013 (the target was 74,949). The majority of project laboratories (92/100) are functioning and three new technologies have been adopted. Price reductions for the line probe assay (LPA), rapid speciation and liquid drug susceptibility testing (DST) have been achieved. The increased rate of case detection has resulted in a greater number of patients accessing treatment for MDR TB and manufacturers are now more interested in the MDR TB drugs market.

Thirteen countries have already identified alternative funding sources and are in the process of transition. A no cost extension request has been submitted to cover the 14 countries that have not yet achieved transition. Of the cost savings to the Project, a majority has accrued due to lower than expected utilisation of consumables and a lower requirement for equipment than anticipated. This sum could be used to fund the extension and enable the 14 countries to transition to alternative funding sources during 2015. Continuation of the grant will facilitate discussion with the Global Fund under the New Funding Model for transition and scaling up. The SECRETARIAT recommended that this request be approved.

The EXECUTIVE BOARD unanimously approved the no cost extension without discussion.

DECISION

The EXECUTIVE BOARD *adopted by consensus* Resolution n°2

12. Operations Update

The evolution of UNITAID's grants since 2007, current grant performance and key results as of 2013 were presented. The HEAD OF OPERATIONS also updated the Executive Board on the status of grants that had been approved at EB19 and the operational guidelines.

In 2014, UNITAD has 28 active projects, managed by 27 grantees. These grants include the six projects approved at EB19 SSP and IPMA, which was approved at EB19. Internal planning and meetings are in progress to kick off the new grants.

At the end of 2013, all of the grants were considered to be 'on track' because they had met or exceeded the minimum requirements that had been laid out by UNITAID in their grant agreement. New evaluation criteria included the following:

- Submission of semi-annual and annual reports
- Quality of information contained in the annual report
- Responsiveness to Secretariat questions
- Meeting grant targets and milestones
- Proactive risk assessment and management
- Responsiveness to audit and other performance assessments
- Financial performance.

Guidelines for Effective Grant Management have been developed to help the portfolio team and the grantees to ensure that they obtain maximum value for money across all domains. Specific guidelines are available to support grantee capacity assessment; procurement and quality assurance; programme oversight and transition/scale-up frameworks.

UNITAID is working closely with other organisations such as the Global Fund and PEPFAR on transition and scale-up. Joint workplans have been developed and inter-agency meetings are held on a quarterly basis. The grant oversight framework enables UNITAID to assess the success of grant implementation and to learn how to improve future grant performance.

13. Update on Key Performance Indicators (KPIs)

The KPIs enable the Executive Board to monitor UNITAID's performance and its success in implementing the 2013-2016 Strategy. A focused set of KPIs for the

Executive board was approved in January 2014. The PROGRAM MONITORING OFFICER, OPERATIONS, presented highlights from the 2013 KPI report in the form of 'dashboards': these included the top 10 achievements according to Strategic Objectives. She pointed out that by 2014 the grants would cover the full range of Strategic Objectives set out for 2013-2016. The time from Board approval to grant signature is decreasing and should reach the 100 day target by 2016.

The KPI report provides insight into market and public health outcomes, portfolio and grant performance, and UNITAID's overall grant management. The report shows how the Secretariat is able to track the indicators over time in a reliable and consistent manner.

The 2013 KPI report will be available on 30 June 2014 and interactive programme data will be available on the Impact page of the website.

Discussion (Operations and KPIs)

- ❖ The UNITED KINGDOM congratulated the Operations team on the quality and timeliness of its work on the KPIs and the detail of its presentation. He observed that a substantial amount of information could be used for the United Kingdom's annual review that would take place shortly. The review will be publically available when finalised. There is consistency between the United Kingdom's log frame and UNITAID's KPIs, which facilitates comparison. The UNITED KINGDOM enquired about the timing of discussions on the KPI report and whether this would be possible prior to its publication.

The HEAD OF OPERATIONS recognised the value of discussing the report prior to publication in the future but recognised that the timing would be very tight because of its publication at the end of June. The PROGRAM MONITORING OFFICER, OPERATIONS said that as this was the first experience with this set of KPIs, it would be useful to review the KPIs, the report and the dashboard presentation at the Policy and Strategy Committee (PSC) meeting in November. Recommendations from the PSC would be presented at the Executive Board meeting in December (EB21).

- ❖ The NGOs congratulated the Secretariat on the Operations review and the KPI report, both of which provided valuable data for the Executive Board (e.g. achievements against project indicators). They suggested that it would be useful to look at reporting on lessons learned and steps that will be taken to address operational challenges. The GATES FOUNDATION supported this point: she requested that more detail on the findings of the project evaluations be supplied.
- ❖ The GATES FOUNDATION was impressed by the updates on Operations and the KPIs. She said that she had some specific comments which would be shared electronically. She asked why some grantees that had not met their targets (e.g. WHO pre-qualification of diagnostics) were still considered to be performing adequately, as indicated by a yellow or green score for average or above average performance.

The PROGRAM MONITORING OFFICER, OPERATIONS explained that grants were evaluated according to whether or not they were progressing in relation to the

KPIs. Sometimes, for example when there had been temporary problems leading to delays in reporting on a grant, the Secretariat had accepted that there were acceptable reasons for this delay and the grants were still categorised as meeting minimum requirements (yellow colour). She mentioned that the reporting of the pre-qualification programme was improving although there were still problems with timeliness.

- ❖ The ASIAN COUNTRIES (KOREA) proposed that Secretariat Costs (item 7.1) should be benchmarked against other similar international organisations. It was suggested that this would be useful to monitor the efficiency of the UNITAID Secretariat.

The PROGRAM MONITORING OFFICER, OPERATIONS agreed that this was an excellent suggestion and said that the Secretariat would look at the feasibility of a carrying out a benchmarking exercise. She pointed out that the Secretariat budget for grant management accounted for only 1.7% of expenses, which was very low in comparison to other organisations.

The EXECUTIVE DIRECTOR A.I. thanked the members of the Executive Board for their feedback. He noted that good progress had been made over the previous year, which had been facilitated by the clear guidance received from the Board. The United Kingdom's review had proved a useful experience for testing the model for KPI reporting.

The EXECUTIVE DIRECTOR A.I observed that the PSC and FAC meetings in November 2014 would provide opportunities to discuss outcomes and performance. He suggested that if the Board wished to review the KPI report sooner, this could be done either face-to-face or via teleconference. He thanked the Board for their support in this area.

DECISION

The EXECUTIVE BOARD *took note* of the updates on Operations and KPIs

14. Governance issues

14.1. *Report from the Steering Group on Governance*

The VICE-CHAIR OF THE EXECUTIVE BOARD reported on the recent activities of the Steering Group on Governance. The Steering Group on Governance was set up in June 2013, after the 18th Executive Board (EB18). It has met twice; once by phone and once in person. A first version of its report was presented at the Executive Board Retreat on 13 November 2013. Governance issues have now been discussed within the newly created Executive Committee. The amended report was shared with the Executive Board and the document has been revised in the light of Board members' comments.

WHO LEGAL provided input on the legal aspects of penalties for non-payment of promised funds to UNITAID. There is no commitment in UNITAID's Constitution or Memorandum of Understanding for countries or organisations that occupy Board seats to contribute a specific amount to UNITAID. There is an expectation that contributions will be made but it is not mandatory. As such, it is difficult to apply

punitive sanctions to non-payers in the opinion of WHO Legal Department. A more detailed analysis of the situation, and probably an amendment to the Constitution, would be required if the Executive Board wished to introduce penalties for non-payers. Many legal and practical decisions would have to be taken before this approach could be implemented. Further work by the Executive Committee would be required as well as an Executive Board decision.

Discussion

- ❖ The GATES FOUNDATION and the UNITED KINGDOM thanked WHO LEGAL for his input. The GATES FOUNDATION added that the Boards of other organisations have rules about non-contributing members, and suggested that their policies be studied in order to determine best practice in this area. BRAZIL and NORWAY supported this suggestion.
- ❖ The VICE-CHAIR OF THE EXECUTIVE BOARD noted that the Executive Board had accepted the text of the report by the Steering Group on Governance but the input from WHO Legal Department has resulted in a need to reconsider the situation.
- ❖ The UNITED KINGDOM asked whether UNITAID could impose a progressive loss of privileges if whole of the Executive Board agreed with this policy.

WHO LEGAL advised that this would be possible if the Constitution required a mandatory contribution from all Board members. The governing documents for UNITAID would have to be amended to permit this.

- ❖ The VICE-CHAIR OF THE EXECUTIVE BOARD noted that it might be necessary to add UNITAID Partners as Permanent Observers (point 9 of the report). This point was raised for advice only; a decision was not needed.

WHO LEGAL suggested that the text could be amended to read: *Permanent Observers: UNITAID donors who are not Board members and other entities that the Board has granted the status of Permanent Observers to.*

NORWAY suggested that the text could be simplified: *Permanent Observers: All entities that the Board has granted the status of Permanent Observers to.* WHO LEGAL agreed that this was feasible.

- ❖ The NGOs stressed the need to keep the Executive Board as compact as possible. They suggested that usage of existing Board seats should be maximised (e.g. rotation and/or sharing of seats) before new seats are created: “Before the creation of new Board seats, existing seats should be maximized, for example through sharing or rotating of seats.”

The VICE-CHAIR OF THE EXECUTIVE BOARD and BRAZIL agreed that the Executive Board should remain as small as possible. The VICE-CHAIR OF THE EXECUTIVE BOARD proposed that the NGOs’ text be added to the document.

NORWAY asked how the maximum usage of a seat could be defined: this would be a very subjective judgement in her opinion and it would be difficult to agree if a seat had been used to the maximum. She would prefer the option of shared seats for existing and new donors, and suggested that more details of this option should be included in the document.

- ❖ FRANCE described the report as a living document that stimulates the Executive Board to think about sensitive issues. NORWAY agreed that it is essential that the Executive Committee or another body should continue to work on the document. She suggested that the final document should be concise and include a summary of the legal implications of any proposed policy changes. SPAIN suggested that a document on governance will continue to evolve and may need further revision in the future.
- ❖ BRAZIL and SPAIN called for time to think about the implications of changing the Constitution.
- ❖ The VICE-CHAIR OF THE EXECUTIVE BOARD proposed that new Executive Board members should be considered on a case by case basis and that the aim should be to keep the Executive Board as small as possible, while following the principles outlined in the Governance document.
- ❖ The ASIAN COUNTRIES (KOREA) acknowledged that restructuring the Executive Board is an important issue. It is important to attract potential donors to join the Executive Board, but it is also necessary to maintain Executive Board seats for traditional donors. The ASIAN COUNTRIES (KOREA), the NGOs and SPAIN called for a careful discussion of this topic so that an appropriate balance can be maintained within the Executive Board.
- ❖ The NGOs suggested that the section on Executive Board seats could be moved to later in the document. In their opinion, the number of seats should only be increased if there is a good reason to expand the Executive Board.
- ❖ NORWAY commented on the gender balance issue, which she described as being very important. However, she considered that it is old fashioned to only focus on women and pointed out that this statement could, in theory, lead to an all female Executive Board. In Norway, the goal is usually to achieve a 40% representation of each gender but this is not imposed for small delegations (e.g. two members). NORWAY suggested that the gender balance should apply to whole of the Executive Board rather than each delegation. The UNITED KINGDOM agreed with NORWAY's suggestion.
- ❖ The UNITED KINGDOM welcomed the work being done on governance issues and called for it to be completed as soon as possible, while also looking at best practice in similar organisations and taking into account the legal implications of any changes to the UNITAID Constitution. The UNITED KINGDOM suggested that the work should be performed by the Executive Committee, the Steering Group on Governance or a new Governance committee.
- ❖ The VICE-CHAIR OF THE EXECUTIVE BOARD thanked the Executive Board for their insightful comments and acknowledged the urgency of completing this work. The document will be finalised by the Executive Committee and will then be submitted to the next Executive Board meeting (December 2014).

DECISION

The EXECUTIVE BOARD *took note* of the report from the Steering Group on Governance

14.2. Functional Review - Terms of Reference

The VICE-CHAIR OF THE EXECUTIVE BOARD noted that the Terms of Reference for the Functional Review have been reviewed and refocused by the Executive Committee with input from the Executive Board Members. Advice has also been received from the Senior Management Team of the Secretariat.

DECISION

The EXECUTIVE BOARD adopted by consensus Resolution n°3

15. Update on the Medicines Patent Pool Operational Review

15.1. Update from the Medicines Patent Pool

The EXECUTIVE DIRECTOR OF THE MEDICINES PATENT POOL (MPP) provided an update on the activities of the MPP. The objectives of the MPP are to increase access and innovation of HIV treatments for people living with HIV (PLHIV) in developing countries by negotiating voluntary public health-oriented licences. In April 2014, the MPP and ViiV announced that they had negotiated a licence for dolutegravir (DTG). An innovative licensing approach was used: tiered royalties (three tiers depending on the Gross Domestic Product [GDP] of the country) and segmentation to maximise access to DTG by adults in 73 countries (effectively >93% of HIV infected adults). In 6/73 countries, a segmentation approach will be utilised. ViiV will retain the royalties for sales in the private sector. Children in 121 countries (>99% of children infected with HIV) will be able to access DTG under the MPP licence. Sub-licences for DTG are being negotiated and it is hoped that an announcement will be made in summer 2014.

In December 2013, the MPP entered into negotiations with AbbVie for the paediatric formulation of lopinavir/r (LPV/r). Merck (MSD) started negotiating the terms of a license for paediatric raltegravir (RAL) in May 2014. Negotiations are at an advanced stage with Gilead in relation to tenofovir alafenamide (TAF) and are ongoing with Boehringer Ingelheim. Sub-licences are being negotiated for atazanavir (ATZ) and DTG: seven applications have been submitted for each drug by generic manufacturers, including one non-Indian company.

UNITAID, the MPP and the Drugs for Neglected Diseases Initiative (DNDi) have launched the Paediatric HIV Treatment Initiative (PHTI) to enable patent sharing and technology transfer from intellectual property (IP) holders; to develop urgently needed paediatric antiretroviral (ARV) formulations; and to effectively shape the paediatric market.

The impact of the MPP to date was summarised by the EXECUTIVE DIRECTOR OF THE MPP. Almost three million patient-years of tenofovir-based treatments have been supplied by MPP sub-licensees (January 2012-December 2013). MPP sub-licensees have been selling tenofovir in 106 countries, and 24 new countries have benefited from generic competition for tenofovir-containing formulations by purchasing drug from MPP sub-licensees. The prices of tenofovir-containing formulations have dropped by between 45% and 87% compared to Q1 2012. The EXECUTIVE DIRECTOR OF

THE MPP described this as a good return on investment: US\$ 22 million of total savings for the global public health community through MPP licences from July 2010 until December 2013. UNITAID has invested Swiss francs 13.2 million over the same period. The estimated projected savings were approximately US\$ 690 million; this figure was calculated prior to the agreements with Bristol Myers Squibb and with ViiV being signed, and was described as a 'conservative estimate'. The aim is to create licences that go beyond the norms of a generic licence in order to create opportunities for middle-income countries to benefit from the agreements with the MPP.

Key priorities for the MPP from mid-2014 onwards include: concluding sub-licensing agreements for DTG; implementing the PHTI; finalising agreements with Gilead (TAF), AbbVie (paediatric LPV/r) and MSD (paediatric RAL); and strengthening the MPP's relationship with civil society. An Operational Review of the MPP has been conducted and the organisation is already working on some of its recommendations such as building on MPP's partnership approach with pharmaceutical companies; engaging more with 'beneficiary' governments; developing novel approaches to licensing such as tiered royalties and segmentation; paediatric initiatives; and engaging with the Expert Advisory Group (EAG) at earlier stages of negotiations than has been the case. The MPP will continue to work with UNITAID to implement other recommendations, especially those focused on monitoring and evaluation (M&E).

15.2. Medicines Patent Pool Strategic Review

A Strategic Review of the MPP has been carried out by Cambridge Economic Policy Associates (CEPA) of the United Kingdom. A representative of CEPA presented the results of the review by teleconference. The review covers the period from the MPP's inception in July 2010 until April 2014. It assessed the relevance and effectiveness of the MPP's strategy and business model, as well as its performance. CEPA provided strategic and operational recommendations to strengthen the MPP model.

New approaches to licensing, such as tiered royalties and segmentation, have made the MPP's approach more attractive to originator companies. Momentum is building in terms of licensing new ARVs with a greater number of pharmaceutical companies. The MPP's sub-licensing approach is viewed as being credible and gives value to generic companies. Strategic assessments will have to be conducted to determine how the MPP can provide sub-licence management over a prolonged period of time and across a growing number of countries. Mixed feedback was received on the added value of the MPP in sub-licence management. Issues such as non-payment of licence fees have to be managed in an equitable manner.

Stakeholder engagement and advocacy by the MPP have both improved recently. A partnership approach to pharmaceutical companies has been well received. Engagement with civil society has improved e.g. PLHIV are now on the MPP Board and involved in the EAG. CEPA recommended that the MPP increase its engagement with beneficiary governments, especially those in middle-income countries, and work more closely with other partners, such as UNITAID and other HIV-focused organisations.

The MPP business model is aligned with its goals, but it is a major challenge for the MPP to achieve all of its goals within a five year period, in CEPA's opinion. It is a costly and lengthy process to bring WHO-recommended ARV combinations and formulations to the marketplace.

CEPA made a number of recommendations in its report:

- Evaluate the need for potential fixed dose combinations (FDC) and support qualified generics, especially for paediatric patients.
- Improve awareness of the MPP's work.
- Primarily focus on ARVs in the immediate term, but perform a landscaping analysis of potential diseases (e.g. TB, hepatitis C [HCV]) where the MPP could play a useful role (subject to agreement by the Boards of UNITAID and the MPP).
- Investigate alternative commercial approaches to negotiations.
- Explore alternative models to support licensing e.g. pricing agreements, technology pools.
- Develop a tailored approach to sub-licence management.
- Assess resource requirements as the MPP portfolio expands.
- Continue to engage constructively with industry, civil society, and governments, as well as global health and IP organisations.
- Develop a comprehensive proposal to seek future funding from UNITAID.
- Diversify and mobilise funding from other donors.
- Develop a logical results framework, and invest in tracking transaction costs and value add of MPP.
- Utilise EAG expertise more extensively.
- Develop a standard pro forma for the review of licences and reporting purposes.

CEPA concluded that the MPP is fit for purpose.

Discussion

- ❖ The CHAIR OF THE EXECUTIVE BOARD commented that the progress made by the MPP in 2-3 years was unimaginable. He described the MPP as 'revolutionary' and expressed satisfaction that pharmaceutical companies are now willing to engage with the MPP. He commented that attitudes towards IP are becoming more nuanced than in the past. He added that innovation is very important, but it is also vital to save millions of lives by improving access to much needed drugs, especially those adapted for children.

BRAZIL, CHILE, FRANCE, the GATES FOUNDATION, the AFRICAN COUNTRIES, SPAIN and NORWAY agreed with the comments made by the CHAIR OF THE EXECUTIVE BOARD. They praised the work carried out by the MPP within a short period of time. FRANCE urged the MPP to maintain the momentum of its recent progress and said that UNITAID should continue to support the MPP.

- ❖ BRAZIL stressed the need for improved access to affordable drugs in high burden, middle-income countries.
- ❖ BRAZIL and FRANCE supported the proposal that the MPP should work in other diseases than HIV, such as TB and HCV. BRAZIL highlighted the need for FDCs

to treat multi drug resistant TB (MDR TB) and suggested that the MPP could be a 'game changer' in TB and HCV. SPAIN called for a careful assessment of the impact of expanding the MPP's remit to additional diseases. NORWAY said that she would like to know the MPP's opinion on extending its mandate.

- ❖ BRAZIL commended the MPP's involvement in the PHTI and welcomed its increased engagement with civil society.
- ❖ The GATES FOUNDATION sought more information on how the projected saving of US\$ 22 million had been calculated. The GATES FOUNDATION also requested information about the MPP's impact on the market for generic drugs other than tenofovir.

The MPP replied that this was a very conservative estimate and excludes the global price reduction for tenofovir. Royalties for tenofovir were previously 5% but are now 0% or 3%. Generic tenofovir is now available in countries where it was not previously possible to sell this drug.

- ❖ The GATES FOUNDATION suggested that it might be beneficial if the MPP could secure funding from sources other than UNITAID. The UNITED KINGDOM agreed with the GATES FOUNDATION's suggestion and said that it was important to ensure the sustainability of funding for the MPP.
- ❖ The UNITED KINGDOM proposed that UNITAID should test the market by seeking competitive bids for the work carried out by the MPP (an open call for letters of intent). This would ensure good governance and transparency of UNITAID's funding decisions, as well as value for money.

The NGOs pointed out that the MPP was created because the previous system for ARV licencing was not functional. The MPP has transformed this situation. The NGOs urged the MPP to continue its good work. They added that if an appropriate organisation applies for UNITAID funding to carry out voluntary licensing activities, its application should be considered. However, the NGOs considered it unlikely that such an organisation exists and expressed support for funding the MPP for a few more years. BRAZIL stated that the MPP provides significant value for money for UNITAID and agreed with the NGOs' proposal that funding for the MPP should be continued.

NORWAY agreed with the need to continue funding the MPP. She considered that the United Kingdom's proposal of an open call has some merits but was not convinced that it was the best approach. NORWAY expressed concern that seeking competitive bids would send a negative signal to pharmaceutical companies and increase their reluctance to negotiate licences with the MPP. She called for careful consideration of the consequences of holding an open call for proposals.

FRANCE said that it would be a mistake to slow down the MPP's work and called for the organisation to be supported by UNITAID.

- ❖ The NGOs pointed out that fundraising from non-UNITAID sources would require a significant investment by MPP and could divert resources (both human and financial) away from its mandate. NORWAY agreed with this statement and speculated whether there are, indeed, organisations that would fund the MPP, apart from UNITAID.

- ❖ THE CHILEAN AMBASSADOR to the UN in Geneva presented herself as she had just taken her position and expressed her full commitment to UNITAID, personally and through the mission. CHILE suggested a compromise that would not delay the MPP's work but would enable the organisation to evaluate alternative funding options and moving into new disease areas. She proposed that the MPP should submit a proposal to UNITAID for funding of its core work in HIV, while also evaluating the costs of obtaining resources from alternative sources and of diversifying into non-HIV diseases.

The EXECUTIVE DIRECTOR A.I. stressed the need to protect the MPP's core business by ensuring predictable funding and ensuring that pharmaceutical companies have confidence in the MPP. He acknowledged that investigating resource mobilisation options and the needs in non-HIV diseases would require both time and resources.

The GATES FOUNDATION, the UNITED KINGDOM, the NGOs and FRANCE endorsed CHILE's proposal. The GATES FOUNDATION offered her organisation's assistance in landscaping drug options in TB. She added that the cost implications of diversifying the MPP's mandate should be considered: working in TB might attract support from middle income, high burden countries, for example. The GATES FOUNDATION did not wish to send a negative signal about the MPP's work but they also wanted to make a responsible decision about funding. The CHAIR OF THE EXECUTIVE BOARD agreed with the GATES FOUNDATION's position.

The UNITED KINGDOM called for evidence of the value for money provided by the MPP. He agreed that it is likely that the MPP is the only body that can carry out its mandate but said that this must be checked by an open call for proposals. By doing this, UNITAID will adhere to the principles of good governance. The UNITED KINGDOM stressed the need for the MPP to consider its future funding strategy since UNITAID funding cannot be relied on forever. He agreed with the GATES FOUNDATION that middle-income countries might be interested in investing in the MPP in the future. The UNITED KINGDOM reiterated his support for the MPP and said that the Executive Board has a responsibility to ensure that it grows and fulfils its mandate.

The CHAIR OF THE EXECUTIVE BOARD stated that the Executive Board has two responsibilities: to ensure that UNITAID funds are put to good use; and to safeguard past investments in the MPP, e.g. by not sending out negative signals about its future.

The NGOs commented that the MPP was set up by UNITAID because there were legal constraints that prevented UNITAID from doing the work in-house. He expressed the opinion that if an open call were held, it is likely that only the MPP will apply for funding.

FRANCE agreed with the UNITED KINGDOM that UNITAID has a responsibility to prepare the MPP for its future. However, he expressed concern about the potential consequences of UNITAID appearing reluctant to fund the MPP, when it has developed internal expertise and has had several successes.

The CHAIR OF THE EXECUTIVE BOARD said that there is no reason to halt the MPP's work and pointed out that no other organisations have been able to negotiate voluntary licences on this scale.

The MPP commented that losing UNITAID funding would send a negative signal and would risk losing the confidence in the MPP that has been built up within the pharmaceutical industry (both innovator and generic companies). The GATES FOUNDATION suggested that the MPP could consult some of its industry contacts about the potential implications of losing UNITAID funding. She added that when the Foundation has invested in new organisations, it often subsequently helps them with resource mobilisation in order to ensure their sustainability. UNITAID could adopt this model: assisting the MPP to find new funding sources while offering ongoing support.

The UNITED KINGDOM praised the discussion about future funding of the MPP and said that it is the Board's responsibility to evaluate these issues. He suggested that the MPP should landscape future funding opportunities and diversifying into non-HIV areas, while the UNITAID Secretariat could evaluate the value for money provided by the MPP's proposal for its core work in HIV.

The EXECUTIVE DIRECTOR A.I. agreed that more work is needed to evaluate the impact of MPP's work. He clarified the Executive Board instructions were to request the MPP to submit a 5 year proposal for funding its core business and to conduct feasibility studies alternative funding options and non-HIV areas of work and, if so, what the timeframe for this was. NORWAY confirmed this instruction. She pointed out that the UNITAID funding for the MPP does not expire until the end of 2015 and so there is time to prepare the proposal for Executive Board Consideration in December 2014 and the feasibility studies for the April 2015 Board consideration.

The CHAIR OF THE EXECUTIVE BOARD asked for the Resolution text to be amended to reflect the Board's approach.

DECISION

The EXECUTIVE BOARD *adopted by consensus* Resolution n°4

Closure of the meeting

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

The open session of EB20 closed at 14.45 on Friday, 13 June 2014. The Executive Board then went into a closed session until the end of the meeting.

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
BRAZIL	– Alt.: Jorge Bermudez
COMMUNITIES LIVING WITH THE DISEASES	– Violeta Gracia Ross Quiroga – Alt.: Kenly Sikwese
FRANCE	– Philippe Meunier – Alt.: Marianne Barkan-Cowdy
FOUNDATIONS (GATES)	– Blair Hanewall
NGO's	– Tido von Schoen-Angerer – Alt.: Brook Baker
NORWAY	– Kari Marjatta Hoel – Alt.: Kjetil Aasland
SPAIN	– Gonzalo Vega Molina – Alt.: Miguel Casado Gomez
UNITED KINGDOM	– Jason Lane – Alt.: Sarah Boulton
WHO	– Hiroki Nakatani

OTHER MEMBERS OF DELEGATIONS

ASIAN COUNTRIES – Republic of Korea	– Ganglip Kim
BRAZIL	– José Roberto de Andrade Filho
FRANCE	– Stéphane Renaudin – Margot Nauleau

UNITED KINGDOM	– Donal Brown
	– Ross Leach
WHO	– Issa Matta
COMMUNITIES LIVING WITH THE DISEASES	– Nelson Otwoma
NGOs	– Khalil Elouardighi
	– David Deakin
LIAISON OFFICER, CIVIL SOCIETY	– Jessica Hamer

PROPOSAL REVIEW COMMITTEE

CHAIR	– Andy Gray
VICE-CHAIR	– Stephanie Simmonds

PARTNERS (OBSERVERS)

THE GLOBAL FUND	– Mark Dybul
	– Christopher Game
MEDICINES PATENT POOL	– Greg Perry
	– Chan Park
	– Esteban Burrone
	– Sandeep Juneja
STOP TB PARTNERSHIP	– Joel Keravec
UNAIDS	– Carlos Passarelli
OFFICE OF THE CHAIR	– Laurence Thurion

UNITAID SECRETARIAT

Executive Director, a.i.	– Philippe Duneton
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
Executive Assistant, Executive Office	– Susanna Volk
 <u>On Specific Agenda Items</u>	
Communications Officer	– Clare Courtney
HIV Portfolio Manager, Operations	– John Cutler
Technical Officer, Operations	– Jane Galvao
Events Officer, Communications	– Sarah Mascheroni
Resource Mobilization Officer	– Gulmira McHale
Technical Officer, Operations	– Yamuna Mundade
Technical Officer, Market Dynamics	– Carmen Perez-Casas
Programme Monitoring Officer, Operations	– Kate Strong
Technical Officer, Market Dynamics	– Karin Timmermans