

Unitaid Executive Board Meeting 27th Session 7-8 June 2017 London I & II meeting room Starling Hotel Geneva

Agenda item 3

Minutes of the 26th Executive Board Meeting (13-14 December 2016)

Table of Contents

Executive Summary	3
1. Opening of Meeting	4
2. Adoption of Agenda (including any points for AOB)	4
3. Minutes from previous meeting EB25, 22-23 June 2016	4
4. Report from the Executive Director	4
Discussion	6
5. UNITAID Strategy 2017-2021	
5.1 Strategy 2017-2021	8
Discussion	
5.2 Key Performance Indicators	9
Discussion	
5.3 Investment Plan 2017-2018	
Discussion	
5.4 Resource mobilization	
6. Governance	12
7. Integration across the three diseases in the context of the attainment of SDG3	12
Discussion	13
8. Report from the Policy and Strategy Committee	15
9. Report from the Finance and Accountability Committee	15
10. Area for Intervention: HIV self-testing	16
Discussion	17
11. Intellectual Property Approach	
Discussion	19
12. Restricted Session: Discussion on the risks related to the Area for Intervention "Enabling Preventive TB treatment for high risk groups"	20
13. Grant Portfolio Update	20
14. Governance	20
14.1 Calendar of UNITAID Board and committee meetings for 2017	20
14.2 Governance Working Group	
15. AOB & closure of the Executive Board meeting	21
15.1 Meeting closure	21
Appendix: List of Participants	

Executive Summary

- The agenda for EB26 was adopted.
- The minutes from the 25th Executive Board were approved, subject to the addition of a point on the importance of intellectual property in stimulating innovation.
- Board Members noted the report of the Executive Director and congratulated him and the Secretariat for their work and achievements in 2016
- The Executive Board congratulated and thanked the Secretariat for the work to develop the new strategy, including changes introduced at the meeting, and adopted Resolution 1: UNITAID Strategy 2017-2021
- The Executive Board congratulated and thanked the Secretariat for developing clear and concise strategic and operational KPIs and adopted Resolution 2: Strategy 2017-2021: Key Performance Indicators
- The Executive Board thanked the Secretariat for the analysis of the 2017-2018 investment plan and suggested that projections beyond two years be developed
- Board Members thanked the WHO Assistant Director General for his
 presentation on WHO's work on integration, elimination and the Sustainable
 Development Goals. Board Members looked forward to working closely with
 WHO and other partners to achieve the elimination targets for the three
 priority diseases and integrating with the broader health and development
 agenda of the SDGs
- Board Members noted the report of the 16th Policy and Strategy Committee, thanked the Secretariat for update on progress and looked forward to a discussion of the plan to review the New Operating Model at the next PSC meeting
- The Executive Board adopted Resolution 3: UNITAID 2017 Budget
- The Executive Board noted the report of the 17th Finance and Accountability Committee and of the joint FAC/PSC session
- The Executive Board thanked the Secretariat for the thorough analysis and adopted Resolution 4: HIV Area for Intervention "Expanding access to HIV self-testing in LMICs"
- The Executive Board adopted Resolution 5: Area for Intervention related to Intellectual Property "Supporting the use of TRIPS flexibilities"
- The Executive Board adopted Resolution 6: Appointment of the Chairs and Vice-Chairs of the standing Committees of the Board
- The Executive Board adopted Resolution 7: Calendar of UNITAID Board and committee meetings 2017
- The Executive Board adopted Resolution 8: Governance Working Group

1. Opening of Meeting

The Executive Board Chair opened the 26th Meeting of the Executive Board at the Starling Hotel, Geneva, Switzerland at 09:35 on 13 December 2016 and welcomed Board Members, observers and the Secretariat to the meeting. He specifically welcomed new Board Members or Alternates: the Alternate Board Member for Brazil (Mr. Alexandre Santos Fonseca), the Board Member and Alternate Board Member for France (Ambassador Michèle Boccoz and Mr. Jean-François Pactet-excused) and the Alternate Board Member for the Bill and Melinda Gates Foundation (Mr. Andrew Jones, as replacement to Susan Nazzaro during her maternity leave).

He highlighted his highest respect for the legacy left by the founding Chair and the work and competence of the Secretariat. He is very committed to UNITAID and its objectives and underlined that the issue of access to medicines was now set within the context of the Sustainable Development Goals (SDGs) which emphasized a comprehensive approach to health and development. Since his election as Chair, he had met with the UN Secretary General elect, the President of Chile, and Ministers from France and Spain during which he had stressed the importance of UNITAID's role and position within the new sustainable development framework. He had also liaised and worked closely with the Board Vice-Chair on various issues related to UNITAID and in preparation for this Board meeting.

2. Adoption of Agenda (including any points for AOB)

The agenda for EB26 was adopted.

3. Minutes from previous meeting EB25, 22-23 June 2016

The Representative of the United Kingdom requested that the important role of intellectual property in stimulating innovation be specifically highlighted under section 10 "UNITAID's approach to intellectual property".

The minutes from the 25th Executive Board were approved, subject to the addition of a point on the importance of intellectual property in stimulating innovation.

The Representative of the Gates Foundation requested that draft minutes be circulated to Board Members within weeks after conclusion of each meeting in preference to weeks preceding the next meeting.

4. Report from the Executive Director

The EXECUTIVE DIRECTOR gave an overview of the developments in 2016 which he considered to have been pivotal for UNITAID. It was a year in which UNITAID's strategic role had been consolidated, its capacity to deliver had been improved and reinforced, and the interactions with grantees redefined. Consolidating UNITAID's strategic role had involved coordination with multiple partners working in the global health arena as well as countries and industry partners. He cited specific examples of missions to Cameroon, Kenya and Senegal which had provided an opportunity to interact with governments and civil society as well as local representatives of UN agencies and donor countries. A meeting in India had brought together both government and private sectors, including representatives of manufacturers of generic medicines who had welcomed the opportunity to learn more of UNITAID's

mission and ways of working. This was expected to lead to improved collaboration with the generic industry.

Relations with technical, funding and product development partners had been particularly strong during the year which had resulted in a shared vision and clear understanding of the distinct and complementary roles and strengths of the different organizations. This means that UNITAID is now operating synergistically with others to address development challenges to ultimately benefit the poorest and most vulnerable. The Executive Director highlighted the work on engagement with civil society at global, regional and country levels, which is critical to the ultimate success of UNITAID investments and actions. Most of UNITAID's active grants included elements of civil society engagement at country level. Strong local engagement and support were essential if interventions were to be successfully scaled-up and sustained beyond the closure of the catalytic UNITAID interventions.

The restructuring of the Secretariat and increases to staff had resulted in increased capacity to deliver high quality and technically sound grants. More than 30 new staff had been recruited, orientated and trained in the past 18 months and integrated into a solid and balanced Secretariat that was dedicated to ensuring the success of UNITAID. The new operating model, grant development and management systems are working well and ensure a consistent and coordinated approach to all operations. The Executive Director cautioned that pressure on staff remained high and that the senior management team was concerned about the potential for staff burnout.

The year had also seen the interactions with grantees redefined. Strong emphasis was now placed on fostering relations in each country between the grantee and government, civil society organizations, Global Fund Country Coordinating Mechanisms (CCMs), PEPFAR and other development partners. This ensured that innovations are well integrated with other development activities in the country, fostering local ownership of the results and facilitating eventual transition and scale-up. A recently completed survey of grantees had provided solid evidence that the new operating model was working well, with 99% of respondents reporting that the partnership to bring innovation to low and middle income countries was effective or very effective. This was considerably higher than the 42% of respondents in a similar survey conducted in 2014.

Looking forward to 2017, the Executive Director noted that major changes in leadership were underway in donor countries as well as in global health institutions, accompanied by a changing approach to development, exemplified by the broad scope of the Sustainable Development Goals. While these changes presented challenges, they were also opportunities. In particular, the transition from external donor funding-as an emergency response to the three diseases- to partnerships to foster long-term domestic investment in health and development, underlined the need for innovative products and solutions developed under the UNITAID model. UNITAID is well positioned with its portfolio of innovative, sustainable and cost-effective solutions to improving health and reducing inequities.

The new UNITAID strategy had been developed during 2016 through intensive reflection and discussion with partners and the Executive Board throughout the year. The results of this work were to be presented at this Board meeting, together with draft Key Performance Indicators, an Investment Plan and a first draft of the Resource Mobilization Plan.

Discussion

BOARD MEMBERS welcomed the Executive Director's report, thanked and congratulated him and the Secretariat for the work achieved, in particular the intensive work to develop the new strategy and the comprehensive consultation process.

Specific comments raised by Board Members included:

- The Representative of Brazil underlined the importance of effective engagement with governments from recipient and donor countries and other development partners so that UNITAID's investments could have lasting impact. She noted that Brazil was very interested in UNITAID's approach to intellectual property which would be discussed during the Executive Board meeting. In addition, Brazil welcomed moves to expand the UNITAID donor base but stressed the importance of maintaining an appropriate balance of developed and developing country representation in UNITAID's governing bodies.
- The Representative of the Communities Living with the Diseases commented on the importance of engaging with and fostering dialogues with affected communities who were critical agents for change and partners in local ownership of projects. UNITAID must continue to invest in civil society to catalyse sustained demand for its innovative products and services. She recalled the very successful community dialogue in Senegal in October and shared a few key messages to the Board: importance of information for increased ownership, community involvement from the start, and importance of the social, economic and political context, among others.
- The Representative of the United Kingdom thanked the Executive Director for his report and congratulated the Secretariat on their achievements. She was pleased to report that the UK had conducted two reviews of UNITAID during 2016, both of which had very positive outcomes and reflected the quality of the work undertaken by the Secretariat and the Executive Board. In the 2016 Multilateral Development Review, UNITAID was ranked amongst the top 9 of the 35 organizations assessed and was rated A+ (Exceeded expectation) in the 2016 annual review. She noted the positive feedback given by grantees to the UNITAID survey, but proposed that areas where ratings and responses were less favourable be carefully examined in order to identify areas for improvement.
- The Representative of France stressed the need for innovation in global health and underlined the importance of country ownership so that products introduced through UNITAID's investments were scaled-up and sustained for the long-term benefit of their populations. She commended the Executive Director on his attention to the changing global health landscape.
- The Representative of Chile thanked the Secretariat for their work and commended the Chair on his visit to her country which had included meetings with the President and Ministers of Finance and Development. Such discussions were important to foster support for UNITAID at the highest political level. She had benefitted from participating in the UNITAID visit to Cameroon together with representatives of France, the United Kingdom, civil society and communities. The three-day visit had provided a valuable opportunity to interact with local partners and civil society.

- The Representative of Korea underlined the importance of engagement with countries and cited the successful visit of senior UNITAID staff to her country earlier in the year and interactions with innovators in industry and academia. Good press coverage of the meetings had catalysed the public's interest in UNITAID and thus facilitated continued support for contributing to UNITAID budget.
- The Representative of the Foundations joined other delegations in congratulating the Executive Director and the Secretariat for the excellent work and achievements in 2016 as well as the strong interactions with donors, development partners, implementers, civil society and grantees. She cautioned that the enthusiasm and dedication of staff needed to be balanced with excessive workload and possible burn-out. She noted that several other organizations, such as the Global Fund and PEPFAR, were developing their own market dynamics analysis capabilities and asked how this may impact on UNITAID's historical role and capacity in this area.
- The Representative of the Non-Governmental Organizations congratulated the staff on their hard work and dedication, and commended the Secretariat for successfully operationalising the relationships with civil society. He also requested that the results of the grantee survey be analysed in greater detail to identify areas where improvements in performance could be made.

In response, the EXECUTIVE DIRECTOR thanked Board Members for their comments and support as well as the constructive and open working relationships that had been developed between Board Members and UNITAID staff. In respect of specific items raised by Board Members, the Executive Director:

- Welcomed the participation of Board Members in field visits to countries with whom UNITAID worked and proposed that all Board Members should participate in at least one field visit annually. He undertook to develop an agenda and schedule for planned field trips to facilitate coordination.
- Reported that the report on the grantee survey would be available shortly.
- Noted that civil society engagement was critical for UNITAID's success and continued to evolve.
- Considered that each of the development partners mentioned by the Foundations Representative had somewhat differing perspectives on market dynamics. UNITAID and Global Fund's teams have regular meetings on those topics and the expertise of both organisations should be regarded as complementary. However, the issue deserved to be discussed in detail.
- Noted that a positive outcome of the visit to Senegal had been the increased knowledge about UNITAID's work and products by civil society organisations, in particular by those who participated in the Global Fund Country Coordinating Mechanism (CCM). He noted the importance of finding ways to increase key in-country stakeholders' awareness about UNITAID.
- Thanked France for the recent announcement by the President of their contribution for 2016.

The Chair noted that while those who knew about UNITAID's work were strong advocates and ambassadors for its work, UNITAID remained little known outside its core constituents. He proposed that regional coordinating mechanisms, such as

SADC and UNASUR, be explored as ways to increase awareness of UNITAID. He also noted that it was important to stress that UNITAID worked within an agreed broader development framework embodied by the Sustainable Development Goals yet had a distinct constitution, method of working and mandate that complemented other development partners.

Board Members noted the report of the Executive Director and congratulated him and the Secretariat for their work and achievements in 2016.

5. UNITAID Strategy 2017-2021

5.1 Strategy 2017-2021

THE SENIOR ADVISER TO EXECUTIVE DIRECTOR provided an overview of the development of the 2017-2021 Strategy which was tabled in almost final form for consideration by the Executive Board (document UNITAID/EB26/2016/3). The work had started with the functional review of UNITAID in 2014 which led to an analysis of different options presented at the Strategic Review discussed at the 23rd Executive Board meeting in November 2015. This helped define UNITAID's long-term vision which was further refined during the Executive Board Special Session in March 2016. Consultations on the Strategy included bilateral meetings with Board Members, and specific interviews and consultations with development partners, particularly on the potential to broaden UNITAID's scope to include issues of access within Reproductive, Maternal, Neonatal and Child Health (RMNCH). The Executive Board decided at the 25th meeting in June 2016 that UNITAID's focus should remain on the three priority diseases and however decided to expand the mandate into RMNCH with a view to supporting integrated approaches with the three diseases. Since EB25, the Secretariat had continued to consult widely to refine elements of the Strategy, including discussions with Board Members, at disease-specific international meetings, with partner organizations, during in-country consultations, and through an on-line open consultation. This work had resulted in an alignment on the understanding of the global health landscape, and buy-in to the UNITAID mission, strategic objectives and investment commitments, and to UNITAID's ambition to support integrated approaches to health. The Strategy was supported by a strong platform to deliver over the next five years with clear institutional positioning, an efficient operating model, a robust grant management system, a strong organization and a new communication strategy. A separate document succinctly summarising the case for investment in UNITAID was under development as a complement to the Strategy. This document would bridge between various documents and be used primarily for fundraising with new and current donors.

Several additional comments had been received from Board Members in the weeks and days preceding the Executive Board session which further sharpened the focus and language in the document. The SENIOR ADVISER TO EXECUTIVE DIRECTOR presented these proposed changes which included references to UNITAID's founding principles in the constitution, refining definitions of effective markets, universal health coverage, anti-microbial resistance, partnerships, and RMNCH.

Discussion

The Chair thanked the Secretariat for the clear summary of the process leading to the document presented to the Board and considered that the most recent proposed changes strengthened the Strategy. Board Members congratulated the Secretariat on the excellent work to develop the strategy and thanked them for the constructive and inclusive consultation process. This had resulted in a crisp and focussed document which explained clearly UNITAID's purpose, position and role and the principles guiding its work. The document would serve UNITAID well for the next five years.

Specific additional comments were made on qualifying 'innovation in global health' as 'innovation for access in global health', the variety of civil society institutions and their differing roles according to disease area and context within which access barriers were addressed, and the limitations of gross national income as a proxy for need. Several Board Members commented that the Executive Summary required some additional changes before it could be used as a free-standing document. Requested changes were integrated and the Executive Summary was accordingly redrafted by the Secretariat between sessions of the Board and integrated into a revised document (UNITAID/EB26/2016/3/Rev1) tabled for approval.

The Executive Board congratulated and thanked the Secretariat for the work to develop the new strategy, including changes introduced at the meeting, and adopted Resolution 1: UNITAID Strategy 2017-2021

5.2 Key Performance Indicators

THE TEAM LEAD, RESULTS presented the draft Key Performance Indicators (KPIs, document UNITAID/EB26/2016/4). The purpose of KPIs is to demonstrate impact, aid with institutional positioning, and support direction setting and accountability. The KPIs are divided into nine strategic and ten operational KPIs. Strategic KPIs tell the full story of UNITAID's impact, covering how UNITAID invests on behalf of the poorest and underserved populations (KPIs 2.1 and 2.2), catalyze innovation (3), overcome market barriers (4), secure funding (5.1), leading to scale up in coverage of better health products and approaches (5.2); this should ultimately lead to increased public health impact (1.1), efficiencies and savings for health systems (1.2), which deliver positive returns overall (1.3). The TEAM LEAD, RESULTS noted that KPI 1.3 had been discussed at length in prior consultations with Executive Board Members and at the 16th Policy and Strategy Committee in October, in particular in relation to assigning a monetary value to public health impact. The Secretariat sought to allay concerns on using different monetary values for public health impact in different countries and contexts by using weighted average values across all countries in scope of UNITAID. Moreover, the Secretariat proposed that KPI 1.3 would never be used as a sole criterion for prioritization between interventions, nor would there be a minimum threshold for investments. Targets for 2017 and provisional targets for 2021 have been developed and would be updated as new grants were added to the portfolio. In addition, KPIs would also be supplemented by "Impact Stories", which would enable the communication of more details on UNITAID's impact, which is hard to measure in quantitative KPIs, such as how UNITAID has supported improvements in the quality of life of individuals, strengthened health systems, and sped up the introduction of better health products.

The ten operational KPIs reflected different aspects of the Secretariat's efficiency, resource mobilization, the grant development and implementation process, and management. Clear and ambitious, although achievable, targets were proposed for each.

Discussion

BOARD MEMBERS congratulated and thanked the Secretariat for developing a clear and concise set of KPIs which communicate well the catalytic effect of investments and the indirect public health impact of UNITAID's work. The KPIs are useful in tracking organizational performance and can support resource mobilization efforts. Questions were raised about how the Mission-level KPIs would be measured in practice, in particular whether the KPIs would be subject to independent external scrutiny.

Serious reservations were expressed about KPI 1.3 despite the Secretariat's reassurances. Assigning a common monetary value to public health impact was not considered satisfactory by some Executive Board delegations as it raises questions about appropriate country or regional weights and may not be harmonized with UNITAID's focus on addressing inequities in access for the underserved and most vulnerable within individual countries. There would be considerable discomfort in using this KPI for evaluating proposals and setting priorities between projects. In addition, several Board Members expressed reservations about translating public health impact, such as lives saved, into a monetary value as this was contrary to a Human Rights approach that considered every human life to have intrinsic value.

However, other Board Members noted that the Return on Investment metric was commonly used in the field by other funding agencies and governments who work closely with UNITAID.

Some Board Members highlighted concerns that the two KPIs measuring reducing inequities in access (2.1: Investing for the poorest, and 2.2: Investing for the underserved) appeared to be inconsistent with the constitutional requirement that at least 85% of commodities purchased should be spent on low income countries, and no more than 10% and 5% on lower middle and upper middle income countries, respectively. Other Board Members took a different viewpoint on the interpretation of the KPIs in relation to the constitution and noted that the targets for KPIs 2.1 and 2.2 were not the key issue in respect of ensuring consistency with the Constitution.

In response, the Secretariat thanked the Executive Board for its feedback and indicated that the KPIs should be used collectively to assess UNITAID's performance and no single indicator used in isolation. In estimating results to report on the KPIs, the Mission indicators would be calculated on the basis of evidence at the point of grant closure, and would be supported by analysis conducted during independent end-of-grant evaluations. Furthermore, the Secretariat is aware of, and keen to explore the use of, well-developed models across HIV, TB and malaria (such as the Spectrum model) to precisely estimate the post-grant impact of UNITAID's investments. It was re-iterated that KPI 1.3 was not intended to be used for priority setting. The baseline for the operational KPIs would be set using performance data from 2017.

In summary, the Chair noted that there was good consensus among Board Members on the ten operational KPIs and six of the nine strategic KPIs. He proposed that the Vice-Chair convene a small working group of interested Board Members to consider potential solutions to KPIs 1.3, 2.1 and 2.2.

The Vice-Chair reported back on the outcomes of the working group, noting that there had been a constructive and fruitful discussion between a sub-set of Executive Board delegations and the Secretariat. This led to minor revisions to the KPIs reflected in the Revised Annexes A and B of document UNITAID/EB26/4. The revised proposal clarified how KPI 1.3 will be calculated, and the scope of KPIs 2.1 and 2.2. In addition, the proposed resolution included an explicit statement that KPI 1.3 shall not be used as a factor to allocate new resources. Revised Annexes A and B were deemed acceptable by the Executive Board as part of the resolution.

The Executive Board congratulated and thanked the Secretariat for developing clear and concise strategic and operational KPIs and adopted Resolution 2: Strategy 2017-2021: Key Performance Indicators

5.3 Investment Plan 2017-2018

THE TEAM LEAD, STRATEGY presented an overview of estimated commitments and income for 2017-2018 based on currently available information on the grants under development, proposed new Areas for Intervention (AfIs) and potential AfIs that may be launched over the two years. The annual grant pipeline was estimated at\$350 million plus \$30 million operational expenses. Available funds included \$227 million in uncommitted funds at end 2016 and \$140 million estimated 2017 contributions (\$13 million shortfall). The TEAM LEAD, STRATEGY noted that an update to the original pre-read document was issued to reflect, for example, changes to projections based on the most recent EB e-votes, as well as critical internal review of realistic expectations for a dynamic pipeline. Figures presented reflect the pre-read document update. If these projections were fully realized, this gap could be filled by calling for deposit of the United Kingdom's 2015 Promissory Note (\$48 million), mobilizing resources or reducing the amounts in the planned pipeline. Projections further into the future were less certain but assumed an annual grant pipeline of \$350 million in 2018 (\$300 million thereafter) and assumed that the 2016 and 2017 United Kingdom's Promissory Notes would be accessed in 2018. The TEAM LEAD, STRATEGY noted that the investment plan is a snapshot of current projections, but a work in progress, and subject to change. Fluctuations may be expected due to savings from closing grants, budget reductions during grant negotiations, or extended grant negotiations, for example. With a narrow difference between projections and available funds, it is possible that the United Kingdom's promissory note may not be accessed in 2017. In all cases, the Secretariat remains committed to negotiating high-quality, rigorous, and timely grants.

Discussion

BOARD MEMBERS thanked the Secretariat for the analysis and projections which had been requested by the Board at previous meetings. They appreciated the transparency of the projections and the opportunity to discuss the challenges openly. Comments covered the following issues:

• The REPRESENTATIVES OF NORWAY, NON-GOVERNMENTAL ORGANISATIONS AND BRAZIL noted that not calling for the deposit of the UK 2015 Promissory Note might complicate mobilization of resources from other donors who may perceive that additional funds were not required.

- The REPRESENTATIVES OF THE NON-GOVERNMENTAL ORGANISATIONS AND BRAZIL
 pointed out that it was clear that considerable Secretariat resources had been
 devoted to development of the new strategy and associated documents, while
 at the same time implementing the new operating model and managing new
 grants and as a consequence current disease narratives may need updating.
- The REPRESENTATIVES OF THE FOUNDATIONS, NON-GOVERNMENTAL ORGANISATIONS, BRAZIL AND THE UNITED KINGDOM noted that projections over a two-year time frame were important and useful, but a longer-term vision of the funding requirements for potential investments was needed for a more complete analysis.
- The Representatives of the Non-Governmental Organisations, Brazil and the United Kingdom pointed out that the Investment Plan could benefit from projecting more than two years forward, particularly when considering the longer-term funding pipeline. Longer projections in the Disease Narratives may help with prioritizing investments within each disease area as funding allocations could be temporarily withheld in favour of potential high-quality high-impact projects expected in a subsequent year.

In response, the Secretariat thanked Board Members for their observations and noted the extensive and ongoing analysis undertaken to establish and inform Areas for Intervention (including Disease Narratives and landscapes published on an ongoing basis). Projections beyond two years are in development, and will be used to guide updates to the Investment Plan as required. Director, Finance and Administration noted that the majority of contributions were received in the last quarter of each calendar year so the carryover at the beginning of the year was used to fund new grants. It remained possible that the UK 2015 Promissory Note would be required to fund new projects in 2017 if there was insufficient cash in hand.

The Executive Board thanked the Secretariat for the analysis of the 2017-2018 investment plan and suggested that projections beyond two years be developed.

5.4 Resource mobilization

Board Members, Alternates and the Secretariat met in restricted session.

6. Governance

Board Members, Alternates and the Secretariat met in restricted session.

7. Integration across the three diseases in the context of the attainment of SDG3

The CHAIR welcomed Dr Ren Minghui, World Health Organisation Assistant Director General for HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases (HTM) and invited him to address the Board.

The WHO ASSISTANT DIRECTOR GENERAL FOR HTM discussed the transition from the 2000-2015 Millennium Development Goals (MDGs) to the 2015-2030 Sustainable Development Goals (SDGs) and their implications for the work of WHO and partner

organizations. While the health-related MDGs had addressed specific diseases in developing countries and favoured disease focussed solutions, the SDGs were much broader and addressed the health needs of all people in all countries. There were strong links between the different goals, with the health goal, SDG3, Good Health and Wellbeing, central to the SDG framework. Universal Health Coverage, one of the goals within SDG3, provided a unifying framework for WHO's approach and that of the HTM Cluster. Dr Ren attributed the major successes achieved under MDG6 in the fight against HIV/AIDS, tuberculosis (TB) and malaria to consensus around clear goals, practical strategies supported by better data and monitoring, collaboration between different actors, and research and innovation. The HTM Cluster was focussed on SDG 3.3 to end the epidemics of AIDS, TB and malaria for which clear goals aligned with the SDG 2030 vision had been set. Achieving the goals required increased partnership within WHO and with external partners, a transition to country ownership for sustainability, and greater emphasis on research and innovation. Success in ending the epidemics of HIV, TB and malaria plus those of sexually transmitted infections and viral hepatitis required universal health coverage - equity in access to services, sufficient quality of essential health services, and protection against financial risk. The work of HTM with countries concentrated on promoting use of global strategies, policies and frameworks, supporting adaptation and adoption by countries of key WHO guidelines, supporting countries to strengthen systems to monitor program performance, and leverage partners, including UNITAID, to provide effective technical support to countries. Specific issues of current interest to the UNITAID Executive Board include exploring the use of antiviral medications and injection technologies for HIV prevention, optimizing diagnostics and treatments for TB and latent TB, and market analysis to drive price reductions. Synergies to end the HIV, TB and malaria epidemics could be achieved by working across several platforms and leveraging interventions that addressed multiple goals, such as prevention of mother to child transmission of HIV (PMTCT), HIV testing and diagnosis, safe injection, blood safety and infection control. Fostering strong links with broader sexual and reproductive health services, preventing substance abuse and addressing gender-based violence was important to ensure the end the three epidemics by 2030. Dr Ren concluded his presentation by stressing that disease-specific programmes presented entry points for cross-cutting interventions with a focus on sustainability and health systems strengthening. People-centred services were necessary to prevent and treat co-infections, reach key populations, testing, and delivering services and programmes to the community. He considered that partnerships between WHO and specific health and development programmes were key to success.

Discussion

The CHAIR thanked WHO Assistant Director General for HTM for his summary of WHO's work to end the HIV, TB and malaria epidemics and its focus on a comprehensive and integrated approach to health.

The Representative of the Communities Living with the Diseases thanked Dr Ren for the presentation and strongly supported the approach to integration, particularly at the primary health care level. She was pleased to have heard the 'mantra' "no one left behind" in the context of WHO's approach to universal health coverage. Communities had introduced this language to the Boards of UNAIDS and the Global Fund and welcomed its adoption by WHO. However, she pointed out that the talk needed to be followed by concrete action not to leave anyone behind, citing the

example that access to life-saving medicines was restricted in some countries by intellectual property rights.

The Representative of Brazil noted that the SDG framework was a universal development agenda and no longer a development agenda for the 'global South'. This required countries and UN agencies also to address problems in the 'global North'. It was important to note that several other SDGs had implications for WHO's and UNITAID's work (for example SDGs 1: Poverty, 2: Hunger and food security, 5: Gender equality and women's empowerment, 6: Water and sanitation, 17: Partnerships). One of the targets within Goal 3 (Target 3.8: Achieve universal health coverage, including access to safe, effective, quality and affordable essential medicines and vaccines for all) was directly relevant to WHO and the UNITAID Executive Board discussions, yet the means of reaching the target were poorly defined. WHO had much to contribute to the UN Interagency Task Team on Science, Technology and Innovation for the SDGs. Moreover, the report of the UN Secretary General's High-Level Panel on Access to Medicines should be tabled for discussion at the World Health Assembly and at a future UNITAID Executive Board meeting.

The UNAIDS Deputy Executive Director congratulated the Chair on his election and the selection of the United Kingdom for the position of Vice-Chair. He reported that UNAIDS was a coordinating body of 11 UN agencies which sets policies, provides data for decision making, and promotes civil society involvement and a human rights approach to access to health services and commodities. He noted that many adverse health outcomes were influenced by human rights – lack of access to drugs for key populations was directly linked to discrimination and lack of sexual rights. Similarly, the SDGs had broadened to address those who had been excluded from the successes of the work to reach the MDG targets. A Human Rights approach plus engagement with and involvement of Civil Society were essential if any progress was to be made towards the SDG 2030 goals. He invited the Secretariat to present the new UNITAID Strategy to UNAIDS staff and governing bodies.

The Representative of the Non-Governmental Organizations welcomed the opportunity to hear WHO's perspective on the SDGs, but had not heard any mention of health literacy and its importance for generating demand for improved health services and better access to life-saving medicines. This required community members to learn how to navigate the health system and become active agents for change in health policy and health system design.

The EXECUTIVE DIRECTOR reported that there was strong and active interaction between UNITAID and WHO staff at the director and technical levels, as well as at country level. UNITAID was now working actively with WHO Country Offices to foster relations with governments and civil society to ensure that innovations have local support and are eventually adopted by countries.

In response, the WHO ASSISTANT DIRECTOR GENERAL FOR HTM noted that implementing the SDG agenda was a complex process and welcomed the collaboration and partnerships necessary to achieve the goals. WHO fully recognised the importance health literacy as knowledge about health underpinned the behaviour changes by individuals and communities that were central to improved health outcomes.

Board Members thanked the WHO Assistant Director General for his presentation on WHO's work on integration, elimination and the Sustainable Development Goals. Board Members looked forward to

working closely with WHO and other partners to achieve the elimination targets for the three priority diseases and integrating with the broader health and development agenda of the SDGs.

8. Report from the Policy and Strategy Committee

The Chair of the Policy and Strategy Committee summarized the key issues that had been discussed at the 16th meeting on 5 October 2016. She highlighted:

- The presentation and discussion on the draft Key Performance Indicators.
- Endorsement of Clinton Health Access Initiative (CHAI) as the proposed lead implementer on the project to introduce rectal artesunate for the treatment of severe malaria.
- Endorsement of the proposal to extend the period of appointment for current Project Review Committee members until the end of 2017.
- The preliminary discussion of the grant approval process in advance of the formal in-depth review to be completed in 2017 and proposed adaptations to the 'go-ahead' review stage.
- The discussion on solicitation of new ideas (in lieu of open calls for proposals) and the fact that the Secretariat will further develop an implementation mechanism and report on progress to the next PSC meeting.
- The discussion on UNITAID's approach to addressing access through nonstate actors, which is to be reviewed following the implementation by WHO of its Framework for Engagement with Non-state Actors (FENSA), to ensure a consistent approach.
- The review of PSC Terms of Reference and development of a PSC Work Plan to improve the operational performance of PSC to be prepared by the PSC Chair.

The REPRESENTATIVE OF THE NON-GOVERNMENTAL ORGANISATIONS requested more information on grantees' perspectives on the new operating model.

The Senior advisor to Executive Director responded that Secretariat was excited by the potential for new opportunities to arise from the solicitation of new ideas and would define and launch the process in early 2017. The full review of the new operating model was being outlined and the Secretariat looked forward to presenting the approach at the next PSC. Board Members agreed to discuss the plan for the review at the next PSC meeting.

Board Members noted the report of the 16th Policy and Strategy Committee, thanked the Secretariat for update on progress and looked forward to a discussion of the plan to review the New Operating Model at the next PSC meeting.

9. Report from the Finance and Accountability Committee

The Chair of the Finance and Accountability Committee summarized the key issues that had been discussed at their 17th meeting on 4 October 2016. These included the proposed 2017 Budget which presented a 9% increase over the 2016

budget, driven by a 17% increase in Secretariat costs due to recruitment of 15 new staff and an additional US\$ 1.2m for Monitoring and Evaluation (the newly proposed Grant Performance System for grant oversight and assurance).

The Executive Board adopted Resolution 3: UNITAID 2017 Budget

The Chair of the Finance and Accountability Committee reported that the FAC had been presented with a funding forecast through 2018 and an update to the Resources Mobilization Framework for 2017 – 2021 which had been discussed earlier in the Executive Board agenda.

An overview of the updated risk management assessment and internal review plan for 2016-2017 had been presented to the joint FAC/PSC session. Members of the Committees noted that important first steps had been taken to implement the organizational risk management framework, regular updates were to be received by the committees to monitor evolution of organizational risk, and updates on the internal review conducted by Moore Stephens would be provided to the committees for review together with the follow-up of recommendations.

The Executive Board noted the report of the 17th Finance and Accountability Committee and of the joint FAC/PSC session

10. Area for Intervention: HIV self-testing

The CHAIR welcomed Dr Gottfried Hirnschall, Director WHO HIV and Global Hepatitis Programme for this agenda item.

THE TECHNICAL MANAGER, STRATEGY introduced the new Area for Intervention (AfI) on HIV self-testing. While the number of HIV-infected people on antiretroviral treatment (ART) had increased substantially, there has been little progress in increasing the proportion of HIV-infected people diagnosed, or reducing the number of new infections. Low uptake of HIV testing occurred in almost all epidemic settings and particularly affected key populations, adolescents, young women and men. These groups had limited interaction with health services and feared stigma and discrimination. HIV self-testing technologies first became available in 2013 and UNITAID supported a pilot introduction project in Malawi, South Africa, Zambia and Zimbabwe in partnership with PSI. Preliminary results from first phase of the Self-Test AfRica (STAR) project showed high demand among first-time tester, adolescents and men, strong linkages to prevention and care following the test and no adverse events. In addition, the yield of approximately one new HIV infection diagnosed for every 75 people tested compared very favourably with other approaches to HIV testing in the STAR pilot countries. HIV self-testing provided an opportunity rapidly to expand testing to meet the 2020 HIV diagnosis and treatment targets and there was strong political momentum to expand beyond demonstration projects. In addition, WHO had now made a strong recommendation for countries to adopt selftesting based on the emerging results from STAR Phase 1. Currently there is no market for self-testing kits in low- and middle-income countries – with the existing market mostly due to volumes achieved through the UNITAID/PSI STAR project. Demand is very limited due to current prices, which in turn are not reduced in the absence of demand. New products from different manufacturers were poised to enter

the market, provided a market is created. Further investment is required to increase demand and provide technical support for delivery of self-test kits and ensure proper linkages to prevention and care services. The proposed new AfI would build on previous UNITAID investments in this area and complement other strategic investments made under the previous operating model, and those by other partners as described in the presentation.

THE DIRECTOR WHO/HIV reported that the UNITAID-funded STAR phase 1 project had demonstrated that HIV self-testing was acceptable, feasible and safe and there were several different ways to distribute the tests appropriately. Updated WHO guidelines on self-testing were released in World AIDS Day and several test kits had been prequalified by WHO, or assessed by the UNITAID/Global Fund Expert Review Panel for Diagnostics (ERPD). It was anticipated that a second phase of introductory projects, if at scale, would catalyse policy change and uptake beyond the early adopter countries, resulting in a greater number of men and adolescents testing themselves, increasing the market for self-test kits and ultimately leading to price reductions. He strongly supported the proposed AfI and noted that expansion of testing was key to reaching the 90-90-90 targets by 2020.

Discussion

BOARD MEMBERS welcomed the analysis and presentations and were very supportive of continued investments in this area. Specific comments on the background document and scope of the proposed AfI included:

- The Representatives of the United Kingdom, France, the Foundations, and Communities living with the diseases indicated that the scope of the proposed AfI should be broadened to include countries beyond the four involved in the first STAR project.
- They also pointed out that consideration should be given to assessing whether
 there was a role for UNITAID also to catalyse market access to HIV self-testing
 in middle-income countries which also had low testing uptake in high-risk and
 underserved populations. This would provide valuable generalizable
 information on ways to overcome market barriers from a more diverse range
 of settings.
- The Representatives of the United Kingdom and France estimated that it was not clear that the ambition to reach price parity between self-test and provider-based test kits was either realistic or necessary. The Representative of the Non-Governmental Organisations noted that it may be useful to identify the minimum cost at which quality-assured products could be made available.
- The Representatives of the United Kingdom, France, Norway and the Non-Governmental Organisations noted that the volume guarantees and advance market commitments mentioned in the document may not be the right instruments to catalyse market expansion of these particular products and flexible arrangements might be needed.
- The Representatives of France, Korea, Communities living with the diseases and Norway noted that it was critical to ensure access to follow-up tests, care and treatment services for those who tested positive, as well as continued HIV-prevention support for those who tested negative. While HIV

self-testing might reduce some of the barriers to testing, stigma and discrimination persisted at all levels of the testing, care and treatment process. Overcoming stigma at the first step would be of little value unless it was also addressed at subsequent steps, highlighted the REPRESENTATIVE OF THE NON-GOVERNMENTAL ORGANISATIONS.

- The Representative of the Communities living with the diseases noted that consideration should be given to the types of linkage and support provided to those who self-tested HIV negative, for example access to post-exposure prophylaxis. Experience from the STAR Phase 1 project showed that many users self-tested following a recent high-risk sexual encounter.
- The Representatives of the Communities living with the diseases, the Non-Governmental Organisations and African Countries noted that as with all interventions, community support was critical to success and expanded uptake. Appropriate educational and promotional actions at community-level should be included in any projects supported.

The Executive Board thanked the Secretariat for the thorough analysis and adopted Resolution 4: HIV Area for Intervention "Expanding access to HIV self-testing in LMICs"

11. Intellectual Property Approach

The Technical Manager, Strategy introduced the discussion on Intellectual Property (IP) by recalling that IP had been identified as a gap and a challenge in several disease narratives, contributing to lack of affordability and lack of appropriate treatment formulations. The paper on UNITAID's IP approach had been presented at the 25th Executive Board meeting and had been amended to reflect the comments received. In line with the request by the Board, the Secretariat had opened an on-line consultation to solicit ideas about potential actions through which UNITAID could address IP barriers.

The on-line consultation received 36 responses. After filtering, following a similar process to that used for disease-specific Areas for Intervention, three potential opportunities for investment had been identified – patent quality and patentability criteria, a patent opposition facility, and a platform or policy laboratory.

While all countries applied the same basic patentability criteria (novelty, inventiveness and industrial applicability) there was variation in how these criteria were applied. Low quality, secondary patents on antiretroviral medications can delay generic competition and development of appropriate fixed-dose combination formulations after expiry of the primary patents. The first potential opportunity focused on improving patent quality by complementing patent examiners' awareness of the public health implications of low quality, secondary patents through workshops, information sharing and policy dialogues. This would require limited investment but had a potentially large long-term return on investment.

The suggestion of a 'patent opposition facility' was conceived as a self-financing mechanism to conduct oppositions to relevant secondary patents in priority countries. This would reduce the number of low quality patents, allow earlier market entry by generic manufacturers and result in savings due to price reductions. A

proportion of profits from early entry of generic manufacturers or from the cost savings accruing to countries and/or external donors were envisaged to sustain the facility once it had been established with seed funding. This idea is attractive from the perspective of sustainability; however, there were outstanding questions on how to implement such a mechanism.

The third idea of a platform or policy laboratory pertained to a mechanism to provide rapid expert technical support to countries when IP barriers threatened or were found to block access to affordable medications. It could, optionally, also comprise the provision of rapid but limited financial support for such activities. The scope of such a mechanism remained to be defined.

Discussion

The Chair thanked the Secretariat for a thought-provoking and thorough analysis of the issues and enquired about the other ideas that had emerged from the on-line consultation but had not been presented. The Technical Manager, Strategy explained that some submissions contained similar ideas and had been combined. She recalled that a list was provided in Annex 3 of document EB26/2016/9, and indicated that those presented to the Board were considered by the Secretariat to be of highest relevance and priority for further UNITAID action.

Board Members thanked the Secretariat for the updated document on UNITAID's Approach to Intellectual Property which presented a comprehensive and balanced analysis of the issues and was a good foundation for UNITAID's work in this area.

Board Members commended the Secretariat on the consultative process to solicit innovative ideas to address IP barriers to affordable access, and on the disciplined, analytical approach that resulted in the identification of three potential opportunities for investment. Many Board Members expressed that they would be in favour of opening a call on all three opportunities.

The REPRESENTATIVE OF THE NON-GOVERNMENTAL ORGANISATIONS noted that the consultation had been for a limited period and was restricted to single page summaries. By contrast, the UN Secretary General's High Level Panel on Access to Medicines had a longer consultative process and accepted submissions up to 10 pages. The report from the High Level Panel should be scrutinised for additional ideas that might be suitable for UNITAID investment.

Several Board Members spoke in favour of bold and strong action on IP issues, particularly with regard to supporting countries use compulsory licensing and other flexibilities under the framework of the Doha Declaration on the Trade-Related Aspects on Intellectual Property Rights (TRIPS) Agreement and Public Health which featured in the second paragraph of the UNITAID constitution. Members noted that the Medicines Patent Pool was an extremely valuable and well recognized product of UNITAID investment which had proven its value in accelerating access to affordable medicines to protect public health. Members called for similarly bold action to support use of TRIPS flexibilities when IP barriers impeded the protection of public health, as stated for example in the Sustainable Development Goals declaration.

Some Board Members noted that they had been personally involved in application of TRIPS flexibilities to protect public health and concurred that this was a complex and time consuming activity. However, the threat of compulsory licensing had been very instrumental in reaching agreements with IP holders on affordable access to life-saving medicines. In accordance with UNITAID's constitution and founding

principles, this appeared to be a priority area for UNITAID to catalyse action and support countries to use TRIPS flexibilities judiciously to protect public health.

Several Board Members reiterated that they would be in favour of a broad call pertaining to all TRIPS flexibilities.

In discussion of the draft resolution, Board Members raised issues about the process for revising draft resolutions. The Chair requested that a fully transparent and inclusive process be followed. The Board adopted a revised resolution which contains a specific reference to the Constitution.

The Executive Board adopted Resolution 5: Area for Intervention related to Intellectual Property "Supporting the use of TRIPS flexibilities"

12. Restricted Session: Discussion on the risks related to the Area for Intervention "Enabling Preventive TB treatment for high risk groups"

Board Members, Alternates and the Secretariat met in restricted session.

13. Grant Portfolio Update

There was insufficient time to address this agenda item which was deferred.

14. Governance

The Executive Board adopted Resolution 6: Appointment of the Chairs and Vice-Chairs of the standing Committees of the Board

14.1 Calendar of UNITAID Board and committee meetings for 2017

The proposed dates for governing body meetings in 2017 were reviewed. The Executive Board Retreat day in June will be confirmed subsequently if deemed necessary.

The Executive Board adopted Resolution 7: Calendar of UNITAID Board and committee meetings 2017

14.2 Governance Working Group

A proposed resolution to establish a Governance Working Group with the representative of Norway as Chair supported by the Executive Board Vice-Chair was reviewed together with the list issues to be considered. The Chair stressed that the Working Group's mandate was to focus on procedural issues and that all proposals needed to be discussed and agreed with the full Board.

The Executive Board adopted Resolution 8: Governance Working Group

15. AOB & closure of the Executive Board meeting

No other business was raised.

15.1 Meeting closure

The Chair thanked Board Members for a constructive meeting that had discussed and agreed several very complex and difficult issues, in particular the Strategy 2017-2021, Key Performance Indicators and Intellectual Property. The process and eventual resolutions reflected the flexibility and pragmatism of the Board.

The 26th session of the Executive Board was adjourned at 17:20 on 14 December 2016.

Appendix: List of Participants

BOARD MEMBERS

CHAIR H.E. Celso Amorim

VICE-CHAIR (United Kingdom) Sarah Boulton

Alt: James Droop

Additional members of delegation:

Emma Foster

CHILE H.E. Jaime Moscoso

Alt: Rosalia Framil

AFRICAN COUNTRIES Alt.:Khalid Atlassi

ASIAN COUNTRIES – Republic of Korea Un-Yeong Go

Additional members of Delegation

Jongkyun Choi

BRAZIL H.E. Ms Regina Maria Cordeiro

Dunlop

Guilherme Patriota

Alt: Alexandre Santos Fonseca

Additional members of delegation:

Lucas Sversut Juliana Gomes

COMMUNITIES LIVING WITH THE

DISEASES

Violeta Gracia Ross Quiroga

Alt.: Kenly Sikwese

Additional members of delegation:

Wim Vandevelde Nelson Juma Otwoma

John Rock

Alexandra Volgina Anatoli Leshanok

FRANCE Michèle Boccoz

Additional members of delegation:

Catherine Dauphin-Llorens Marie-Anne Mortelette

FOUNDATIONS (GATES)

Blair Hanewall

Alt.: Andrew Jones

NGOs Brook Baker

Alt.: Diarmaid McDonald

Additional members of delegation:

Robin Jacob Morgane Ahmar Khalil Elouardighi Thiru Balasubramaniam Mohga Kamal-Yanni

Austin Arinze Obiefuna

Ludmila Maistat

Philip Waweru Mbugua

Katy Athersuch Sharonann Lynch Charles Gore

David Ruiz Villafranca

Subrat Mohanty David Deakin

NORWAY Bjørg Sandkjær

Additional member of delegation:

Jens Plahte

WHO Minghui Ren

Alt.:Issa Matta

Gottfried Hirnschall (Director, HIV/AIDS and Global Hepatitis

Programme)

Mario Raviglione (Director, Global TB

Programme)

PARTNERS (INVITED GUESTS)

UNAIDS Luis Loures

Carlos Passarelli

PROPOSAL REVIEW COMMITTEE Andy Gray (Chair)

RESOURCE PERSONS

Boston Consulting Group Mathieu Lamiaux

Paulo Goncalves Julien Saur Fanny Berthaud Charlotte Defretin Quentin Le Gland

UNITAID SECRETARIAT

Executive Director Lelio Marmora

Deputy Executive Director Philippe Duneton

Director, Finance and Administration David Curry

Director, External Relations Mauricio Cysne
Head of Communications Andrew Hurst

Director, Operations Robert Matiru

Team Lead, Strategy Janet Ginnard

Senior Adviser to Executive Director Sanne Fournier-Wendes

Senior Legal Officer Sonia Lees-Hilton

Team Lead, ResultsVincent BretinTeam Lead, OperationsJudith PolskyTeam Lead, OperationsEva Nathanson

Manager, Value for Money Ross Leach

Technical Manager, Strategy Karin Timmermans
Technical Manager, Strategy Carmen Perez Casas

Technical Officer, Strategy Olawale Ajose

Board Support:

Board Relations and Governance Manager, Marina Hue

External Relations

Governance Officer, External Relations Oksana Koval
Partnerships Officer, External Relations Laetitia Sieffert