



13th Meeting of the UNITAID Executive Board

10-11 November 2010, WHO – HQ Geneva

Minutes

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1. Adoption of the Agenda

The meeting began at 09:00 on Wednesday 10 November 2010 and was opened by its VICE CHAIR, Luciano Parodi (Chile). He welcomed members of the Executive Board and the staff of the Secretariat to the thirteenth meeting and thanked the Secretariat for organizing the meeting and preparing the documents. He explained that the Chair, Mr Philippe Douste-Blazy would not be able to attend the first day of the meeting owing to a personal matter.

BRAZIL requested that the Executive Session be moved to earlier in the day on day two, owing to time limitations.

DECISION

The Executive Board adopted the agenda as amended during the meeting.

2. Report from the Executive Secretary

The Executive Secretary welcomed participants to the meeting and said that 2010 had been an important year for UNITAID. However, key challenges still remained. The main priority over the coming months was to secure funding, including multi-year pledges. Over the previous six months, many positive outcomes had been achieved. A memorandum of understanding (MoU) with India had been signed in relation to tuberculosis diagnostics and the "Mother-Baby Packs" to prevent AIDS transmission from pregnant women to their babies had been launched in Kenya in conjunction with UNICEF. Further MoUs would be signed soon in the areas of PMTCT extension and the paediatric tuberculosis project. With regard to market dynamics, recruitment was ongoing to fill the outstanding positions, and work was being carried out to, *inter alia*, determine UNITAID's support role with other organizations. The Proposal Review Committee (PRC) had been established and the first meeting held in October 2010. Further progress had also been made in respect of monitoring and evaluation and the market intelligence system. In addition, the Medicines Patent Pool Foundation (MPPF) had been established and the first patent placed in the pool. Finally, the Secretariat was working to fill the positions created in the Human Resources Plan and the five-year independent evaluation of UNITAID was planned for 2011.

3. Minutes from the twelfth meeting of the UNITAID Executive Board

DECISION

The Executive Board approved the minutes from the twelfth meeting of the UNITAID Executive Board without comment.

4. Pledge session to review Contributions for 2011

The CHAIR OF THE FINANCE AND ADMINISTRATION COMMITTEE (FAC), Mr Patrice Debré (France) took the Chair during the pledging session. He stressed the importance of the session and requested that Executive Board Members announce their pledges.

The representative of the REPUBLIC OF KOREA explained that his country was not in a position to make a multi-year pledge owing to its budgetary procedure. However, it was able to make a single-year pledge of US\$ 7 million.

The representatives of BRAZIL, NORWAY, SPAIN and UNITED KINGDOM stated that they would also be unable to make multi-year pledges owing to budgetary constraints and/or the current position in the budgetary cycle of the country. Norway, Spain and the United Kingdom were also not in a position to make pledges for 2011, although it was hoped that at the appropriate time in their countries' budgetary cycles it would be possible to make such a pledge. However, a conditional pledge for 2011 was received from Brazil (Brazilian Reais 20,646,000, approximately US\$ 12 million). The draft Bill relating to that pledge was currently under discussion by the Senate of Brazil, and the pledge would be confirmed following approval of the draft Bill.

The CHAIR, speaking as the member for FRANCE, stated that his country was able to make a multi-year base pledge of € 110 million for 2011, 2012 and 2013. He hoped that France's commitment to multi-year pledges would encourage other donors to make similar pledges in future. He called for further development of the transition strategy and the establishment of clear definitions of public health impact and market impact in order to allow better analysis of UNITAID's competitiveness in different markets.

The representatives of the COMMUNITIES LIVING WITH THE DISEASES, NGOs and WHO, as well as the Executive Secretary, congratulated and thanked the countries for their pledges.

DECISION

The Executive Board welcomed the one-year pledge made by the Republic of Korea (US\$ 7 million for 2011), the multi-year pledge made by France (a minimum contribution of €110 million for 2011, 2012 and 2013) and the statements by the delegations of Brazil, Norway, Spain and United Kingdom that pledges would be made as soon as possible, in accordance with government budgetary cycles.

The VICE CHAIR, Mr Luciano Parodi (Chile), resumed the position of Chair of the meeting.

The MEMBER FOR FRANCE, speaking in his capacity as Chair of the FAC, informed the Board that following the pledges from the Republic of Korea and France, the total funding available for projects would be approximately US\$ 180 million. The FAC, in its earlier extraordinary session, discussed the proposed budgets for both the Office of the Chair and the Civil Society Delegations. Regarding the former, the FAC recommended that the Chair be asked to provide a detailed list of expenses, not exceeding US\$ 250,000, and that the Board takes a decision on that budget the following day when the Chair would be present. The FAC had also endorsed a budget of US\$ 147,500 for the Civil Society delegations, subject to a review by the NGOs on the way in which the delegations contributed towards achieving the aims of UNITAID (i.e. communication, facilitating transition in certain countries). This would be included in a Letter of Agreement with Oxfam, in its capacity as Civil Society focal point.

5. Report of Policy and Strategy Committee

The member for NORWAY, in her capacity as Chair of the Policy and Strategy Committee (PSC) presented the committee's report to the Board, which included the following:

- At its last meeting of 21 October 2010, the PSC addressed:
 - An update on the PRC;

- Prioritization;
- Monitoring and evaluation framework;
- Market dynamics;
- Research and development;
- Executive Board retreat;
- Owing to time constraints, the PSC did not discuss:
 - Operations (postponed to a teleconference on 4 November 2010);
 - Key Performance Indicators (KPIs);
 - Transition strategy;
- Update on the PRC:
 - A successful first meeting on 18–19 October 2010;
 - The PRC comprised 20 experts with a wide range of skills and experience;
 - The group reviewed four proposals and two concept notes;
 - A small working group was established to review guidance papers;
 - The PRC required eight or nine weeks to review a proposal;
- Human Resource Plan:
 - WHO policy has not hindered UNITAID recruitment;
 - The Secretariat had been requested to review the issue further in developing UNITAID's own Human Resource plan;
- Prioritization (PSC decision):
 - The PSC requested that the Secretariat produce a framework for prioritisation along with details of the steps required and provide this material for consideration at the Board retreat;
 - The PSC recommended that the Board, at EB13, endorse the creation of a prioritization process to support all UNITAID activities, which would be developed by the Secretariat, who would draw on relevant consultants as needed. Work to develop the prioritization framework would include review of lessons learned from prioritization activities in other organizations, consultation with Board Members, the development of a background paper and specific questions to be presented to the Board via a facilitated discussion at the Board retreat.
- Market dynamics:
 - UNITAID is the first organization to adopt a market approach to improving public health:
 - No precedent; UNITAID would continue to define its approach;
 - Markets are dynamic, so UNITAID must also be dynamic and flexible;
 - UNITAID is well positioned to be a leader in that area, but further work was needed in order to:
 - Institutionalize the approach across all UNITAID activities;
 - Improve coordination with other organizations to leverage comparative advantages and to share resources and intelligence;
 - Develop the means to liaise with country recipients to understand needs and implications;
 - Work closely with communications to disseminate the approach and success;
 - PSC decision:
 - A full framework on Market Dynamics should be developed for the next PSC meeting;
- Monitoring and evaluation framework (PSC decision):

- The PSC endorsed the framework for the implementation of the Monitoring and Evaluation framework. It should be ensured that:
 - The Monitoring and Evaluation framework can demonstrate its link to the UNITAID Strategy;
 - Consistent terminology be used throughout;
 - It achieves its objectives in providing the information needed;
- Research and Development:
 - Further to the implementation of the Strategy, the following action needed to be taken:
 - Identify new developments;
 - Address first whether UNITAID should invest in research and development and what impact could be achieved across the whole pharmaceutical chain;
 - Develop new terms of reference (by the Secretariat, for the next PSC meeting);
 - The terms of reference process would cover the duration of the Strategy 2010–2012;
- Operations:
 - Teleconference was held on 4 November 2010;
 - The PSC welcomed the presentation and noted improvements in the reporting;
 - Further work was needed with regard to:
 - Reporting of trends;
 - Ensuring clear noting of the dates to which figures referred;
 - PSC comments:
 - A greater use of qualitative data was requested;
 - The red and green lights related to projects should be highlighted;
 - A more strategic reporting approach should be taken;
 - PSC decision:
 - Further work to improve the quality of reporting in line with the comments made should be done before the PSC meeting;
- Mid-term review:
 - Work on the mid-term review was due to commence;
 - The PRC would be included in this work;
- Follow-up to Implementers' Meeting:
 - Three points were noted from the recommendations:
 - Increase financing of operational costs;
 - Strengthen the national supply and procurement system by increasing skills and capacity;
 - Support engagement of civil society in the implementation of projects at the country level;
 - PSC decision:
 - The PSC requested that these points be addressed at the Board retreat, in the context of the Strategy and prioritization;
- Board retreat:
 - Dates decided:
 - 29 March 2011: Partner/Stakeholder meeting;
 - 30–31 March 2011: Executive Board retreat
 - Good facilitation would be required; PSC members were invited to put forward names;
 - Further thought was needed on which partners to invite;
 - PSC decision:

- The PSC recommends that the Board endorses the revised document outlining the activities and programme for the retreat.

Opening the discussion on the PSC report, some members felt that the pace at which results were reported to the Board by the Secretariat should be accelerated, if possible. Currently, results were reported annually in June for the previous year, which left little time for countries to note the data and complete their own internal budgetary processes before making pledges in November. If the timing could be changed so that results were presented in the first quarter of each year, it may be possible to generate more support for UNITAID and to encourage pledges, particularly multi-year commitments, to be made. One suggestion was to encourage project proponents to report earlier so that the Secretariat could consolidate results sooner. One member noted, however, that accelerating the process should not compromise the results that it was hoped would be achieved regarding both prioritization and monitoring and evaluation. He felt that the Board should take a greater leadership role in those areas; tasks could be assigned to the PSC, for example, and not to the Secretariat.

One member noted that it would also be beneficial to accelerate the timeline set for the work on the prioritization plan. Prioritization was essential to UNITAID's work and currently the Board had US\$ 270 million worth of projects to consider and no prioritization framework against which to assess them. Another member felt that it would take perhaps six to nine months to gain a robust prioritization framework, with the AGFP (Advisory Group on Funding Priorities) in place, a fully functioning PRC and support from the Secretariat; however, the Board had a lot of time and a large amount of money that it could spend on projects between now and then and the key issue was how to develop an interim framework that would allow the Board to spend that money rationally and not on a first come first served basis.

On the mid-term review, members asked when they could expect reviews to be presented. Linked to that was a question on auditing of projects, as other organizations occasionally carried out such auditing and it had proved beneficial.

a) *Update on the establishment of the Proposal Review Committee*

Regarding the update on the PRC, members welcomed the news of its successful first meeting and the good balance that had been achieved in terms of the expertise of the professionals, as well as their geographical origin and gender.

Responding to comments that the eight to nine weeks allocated to review a proposal seemed a long time, the CHAIR OF THE PRC clarified that the period began from the proposal's submission to the Secretariat, which then spent approximately three weeks on the pre-screening process and on obtaining any necessary clarifications from the project proponents. PRC members then had around two weeks to complete their review, which left either one or two weeks between the PRC meeting and the Board meeting. The Secretariat's role was key, as it screened for completeness and filled in the first of the review forms. Proposals were only sent to the PRC for review once they had fulfilled those initial completeness requirements.

One member felt that too many proposals were still being sent to the PRC for review that did not contain any quantitative targets for market impact. Given the importance of market impact and value for money, as specified within UNITAID's strategy, any proposals that did not refer to those elements should not be passed to the PRC by the Secretariat.

The Board emphasized the need to clarify what it expected from proponents and the need for clear guidelines. Members were encouraged that the PRC aimed to establish a small working group to discuss and provide input to the process to improve the tools and guidance on how proposals should be constructed and how they should be ranked. The Secretariat noted that the process to refine the criteria would begin shortly and revised forms would be available for comment by Board Members at the Board retreat. Following the inputs obtained by members, the drafts would be discussed at the next PSC meeting, to be finalized shortly thereafter at the next Board meeting. It was essential that all members were able to agree on what was meant by market impact and value for money and on what they expected to see in proposals at a quantitative level, as the current guidelines did not make this clear.

Several members also felt that it would be useful to allocate a time at each Board meeting where the PRC could report on the review process and comment on general issues. This would allow the Board to provide feedback on the PRC review and how it felt the review fitted in with UNITAID needs.

b) *Prioritization framework*

The SECRETARIAT gave a presentation on the prioritization of UNITAID projects, which included the following:

- It was important to discuss how to improve public health and market impact ;
- Projects must be selected and their success measured using a more robust approach;
- More information was needed on the state of the market at the time of prioritization, as well as a clear idea of what the market should look like at the end;
- UNITAID's approach to date has been sufficient, but the challenge was to achieve the desirable outcomes of that approach (lower price, ensure quality, increase availability, facilitate delivery and improve acceptability of formulations) in the long term, as not all those outcomes were feasible in the different markets, and could end up having a negative long-term impact;
- It was vital that the prioritization framework was consistent in all areas of UNITAID's work;
- The proposed approach to establish a prioritization framework included three sets of tools and guidelines incorporating a revised market impact framework. Those tools should be discussed by the Board at the Executive Board retreat during 2011;
- The next steps were as follows:
 - Key informant interviews, involvement of PRC working group, drafting of a background paper and development of tools to be completed by March 2011;
 - Tools and paper to be presented and discussed with the help of a facilitator to guide discussions with pre-determined questions based on background work at the Executive Board retreat in March 2011;
 - Incorporation of comments and suggestions from the Executive Board retreat into all documents and tools, to be presented at the next meeting of the PSC in April 2011; and
 - Incorporation of the comments and suggestions from the PSC meeting into all documents and tools, to be presented at the fourteenth meeting of the Executive Board in June 2011.

In response to comments from members, the representative of the Secretariat explained that it was important that the framework be flexible, but that a basic approach needed to be established to analyse what the market looks in order to allow the Executive Board to make informed decisions within the business model. The framework needed to allow analysis of project value within the decision-making process.

Several members agreed that it was sensible to not issue a call for project proposals before the prioritization framework had been finalized. One member questioned whether it would be possible to speed up the process to allow a call for proposals to be issued earlier. It was also stressed that the prioritization framework was a vital tool and therefore it was important that the Secretariat have the appropriate funds and human resources to ensure the success of that work.

DECISION

The Executive Board adopted draft Resolution no. 3 (doc UNITAID/EB13/2010/R3) on Prioritization Framework, as amended by members during the meeting.

c) Monitoring & Evaluation framework

The SECRETARIAT gave a presentation on the Monitoring and Evaluation framework, which included the following:

- The Monitoring and Evaluation framework would:
 - Promote accountability;
 - Promote learning feedback and knowledge sharing.
- Current monitoring and evaluation tools:
 - Standard set of KPIs: to measure performance over time;
 - Logical Framework Approach: to improve project monitoring indicators, planning and management;
 - Mid-term and end-of-project evaluations: to monitor partner performance and achievement of outcomes;
 - Market Intelligence Information System: to measure impact and inform project selection.
- A timeline for the monitoring and evaluation framework was given, beginning in the fourth quarter of 2010 (October) and ending in the fourth quarter of 2012, which included the following elements:
 - KPIs;
 - Logical Framework Approach;
 - Partner validation tool: planning outcomes;
 - Review of guidelines for concept notes and project proposals (with assistance from PRC);
 - Mid-term and end-of-project evaluation: external reviewers;
 - Accountability Framework;
 - Market Intelligence Information System;
 - Project monitoring database setup and update;
 - Work plan to assess efficiency and effectiveness of projects at country level.
- The UNITAID project reporting cycle was shown, which included the following elements:
 - Key Performance Indicator (KPI) report: 30 June each year (consolidation and analysis of partner data);
 - Operations:
 - Partner reporting: semi-annual and annual basis (as established in MoUs with partners).
 - Market Dynamics:
 - Market Intelligence:
 - Analysis of project impact;

- Setting priorities for the future.
 - UNITAID semi-annual reporting update: 31 December.

Update: reviews and evaluations:

- External mid-term reviews:
 - Requests for proposals (RFP) for review of eight projects launched in July 2010:
 - Five proposals were received and reviewed by a selection panel;
 - Three consultancies were chosen to perform the reviews.
 - Results are expected by the first quarter of 2011.
- End-of-project evaluations:
 - Three projects are due for end-of-project reviews;
 - RFP will be launched in the coming weeks.
 - Lessons learned from mid-term review process:
 - Distribute to more than 26 consultancies;
 - Longer timeframe for submission of applications;
 - Suggestions of recommended consultants welcomed.
- Next steps:
 - Logical Framework Approach to project planning and management;
 - Data dictionary/common language to be developed;
 - Project monitoring indicators being refined;
 - End-of-project evaluations to be completed.

Members reiterated earlier comments on the need to accelerate the reporting process, if it was possible to do so. The Secretariat responded that the reporting cycle did pose some challenges. Partners reported on annually, as set out in their agreements with UNITAID; those reports were received by March each year, at which point they were consolidated by the Secretariat and hence presented to the Board in June. Noting that both the Secretariat and the Board would welcome any changes to the reporting process that would also positively impact the number of pledges confirmed, the Secretariat reaffirmed its aims for the coming year to develop a more comprehensive approach to obtaining data from partners, to receive more timely and higher quality submissions and to increase the speed at which the data were assessed. Within that context, it may be possible to receive another form of report before the end of each year, which could be consolidated and presented to the Board in March or April. The SECRETARIAT said that it would give more consideration to the issue and report back to the Board at a later date on how it could accommodate the comments made and meet the timeline.

Members turned to consider draft Resolution 2, on the Monitoring and Evaluation framework and agreed to adopt it.

DECISION

The Executive Board adopted draft Resolution no. 2, on the Monitoring and Evaluation framework.

6. Report of the Finance and Administration Committee

Introducing the item, the CHAIR OF THE FAC, Mr Patrice Debré (France) recalled that it had been agreed by the FAC that it would decide on how much money was available for calls for tenders once a year. He also stressed that the current period should not be used to launch such calls for tenders.

a) Update on funding capacity

The SECRETARIAT gave a short presentation on funding capacity, including the following key points:

- New projects can be approved up to 180 million US\$ on the basis of the 2011 contributions from France and the Republic of Korea;
- Between 2006 and 2010, 50% of funding had been allocated to HIV/AIDS, with the remainder divided between Malaria (26%), TB (16%) and Transversal (8%);
- Many partners, such as UNICEF, were United Nations entities and so were covered by the single-audit principle, meaning it would be impossible for UNITAID to audit those entities;
- Multi-year commitments even at stable level could allow for improved project design and partnerships in the context of clear priorities and an appropriate funding policy framework;
- The FAC recommends that whenever possible, donors should make multi-year pledges to UNITAID to enable strategic funding decisions.

Members stressed that the budget available for projects should be released once each year and decisions should be taken on which projects to fund at that time. Furthermore, it was vital that better efforts were made with regard to partner communications. It should be made clear to countries by the partners that the funding comes from UNITAID.

In response to questions from members, the Secretariat explained that it required guidance from the Executive Board regarding the possible repartition of funding between the three disease areas and between countries.

DECISION**The Executive Board noted the update on Funding Capacity.****b) Proposed budget 2011**

The SECRETARIAT gave a presentation on the proposed 2011 budget, which included the following:

- Revenue estimate based on past levels of pledges, and interest income would be lower owing to the current low cash reserves;
- Expenditure estimate is very conservative and only includes approved projects;
- Secretariat budget is based on unit work plans and is therefore a results-based budget;
- The expenditure budget for 2011 is fully funded;
- Outstanding issues had included the budget for the office of the Chair and the budget for civil society delegations, which had been agreed upon during the special session of the FAC earlier that day;
- Typically, project expenses represent more than 90% of the budget, however owing to the issues related to funding capacity, the project expenses for the 2011 budget only represented 85% of the total figure;
- Expenses for consultancy and staff costs had increased since 2010 owing to the implementation of the Human Resources Plan and the work on Market Intelligence System.

In response to comments from members regarding the increased expenses for the Secretariat and projects, the SECRETARIAT explained that the Secretariat budget was developed based on the previous portfolio and was based on a fully operative Secretariat, and the increase in expenses was mainly related to the increased work of the Market

Dynamics team and the Market Intelligence System. With regard to project expenses, in budgeting for those expenses it had been presumed that the projects would continue on the same level as the previous year.

One member questioned whether there were opportunities for savings within the budget that would not affect the running of the Secretariat, perhaps in the area of travel costs. Responding to this, the SECRETARIAT explained that the travel costs budget covered costs for travel of consultants, some Executive Board Members and consulting partners. The increase in travel costs was linked to the increase in consultancy, in particular for the planned 5-year evaluation of UNITAID. In addition, the Human Resources plan approved at the twelfth meeting of the Executive Board in June 2010 contained provisions for increased work in the area of external relations which required funding.

One member requested a comparison with 2009 budget as well as that for 2010, which also contained information on the percentage changes from year to year. Responding to a question on UNITAID's hedging strategy from the same member, the SECRETARIAT explained that written pledges are immediately hedged, meaning that when the money is received, the rate is as close as possible to the rate at the time the pledge was made. The Secretariat also explained that the expense estimates related the MPPF were based on the budget received from the Foundation itself.

It was also questioned why there was a substantial difference between the end of year balance for 2010 and the start of year balance for 2011. It was explained that the end of year balance was an estimation based on approved projects by April 2010 and the start of year balance was a projection. In April 2010, it had been expected that all project funding would have been disbursed by the end of 2010, however owing to changes in the funding disbursement cycle for one project, the figure had changed. The change was also, in part, a result of savings within the Secretariat budget for 2010.

DECISION

The Executive Board adopted draft Resolution no. 4 (doc UNITAID/EB13/2010/R4) on the Proposed Budget for 2011, as amended by members during the meeting.

The Executive Board adopted draft Resolution no. 1 (doc UNITAID/EB13/2010/R1) on Support to Civil Society delegations, as amended by members during the meeting.

The Executive Board adopted draft Resolution no. 9 (doc UNITAID/EB13/2010/R9) on Support to Office of the Chair, as amended by members during the meeting.

c) *Update on Human Resources Plan*

The SECRETARIAT gave a presentation on the Human Resources Plan, including the following key points:

- The launch had been delayed owing to the need to obtain WHO approval beforehand, however the new structure took effect from 1 October 2010;
- 20 of the 46 vacant positions had not been filled by staff on fixed-term contracts;
- WHO had suspended recruitment for four key positions and had requested confirmation from the Executive Board to resume the process;
- Hundreds of applications had been received for the advertised positions;

- The main priorities for recruitment were to staff the Market Dynamics team, the Operations team and the Finance team.

The Executive Secretary expressed concerns about the fact that the application period had closed for two of the four positions for which WHO had suspended recruitment; and that such a suspension could harm UNITAID's reputation. He had not agreed with WHO's decision to suspend recruitment and had requested the opinion of members of the Executive Board. To date, he had received messages of support from the African Union, Brazil, Chile, the Communities living with the diseases, France, the Gates Foundation, the NGOs and the Republic of Korea. Therefore, he requested the Executive Board to authorize WHO to resume the recruitment process for those four positions.

The REPRESENTATIVE OF WHO gave a short explanation of why recruitment had been frozen for those positions. As a result of the number of positions being opened within UNITAID, it was important that best management practices were observed. The main issue at the time of suspending recruitment for those positions was that there were a high number of departments where the leadership was changing. Therefore, the decision was taken to freeze recruitment until a more suitable time.

One member expressed concerns about the process followed by the Secretariat in requesting the Board's advice as it had been unclear whether the Chair had been involved in the discussion and whether the process followed by the Secretariat had been procedurally appropriate. However other members felt that it was important to continue the recruitment process as soon as possible.

In response to the comment from WHO regarding the possibility of the Executive Board adopting a resolution authorizing WHO to re-open recruitment, some members felt that such a resolution was unnecessary as a resolution authorizing the recruitment of persons to fill, *inter alia*, those positions had been adopted at the twelfth meeting of the Executive Board in June 2010.

DECISION

The Executive Board noted the update on the Human Resources Plan.

The Executive Board reconfirmed its previous decision and adopted draft Resolution no. 8 (doc UNITAID/EB13/2010/R8) on the Positions reporting directly to Executive Secretary, as drafted by members during the Executive Session on 11th November 2010.

d) Update on the Administrative Service Agreement with WHO

The SECRETARIAT gave a presentation on the administrative service agreement with WHO, which included the following:

- When UNITAID was audited for 2008–2009, the auditors highlighted that there was a gap in the MoU between UNITAID and WHO. This was due to the fact that UNITAID now had its own financial identity, although not all liabilities would necessarily be reported as relevant to UNITAID;
- Therefore, a draft amendment to the MoU has been developed stating that in the MoU any liabilities related to staff or procurement issues were covered, but any other contingent liabilities were not.

Some members reported that they were seeking internal legal advice on the issue and so were still unable to make a decision on the amendment. In response to comments from one member, the representative of WHO explained that the WHO Partnership Policy was not affected by the update. He also stressed that as a result of the hosting agreement between UNITAID and WHO, all UNITAID agreements were, by default, agreements entered into by WHO on behalf of UNITAID. The amendment was related to issues that do not fit under staff or procurement, such as the MoUs with the MPPF or the Millennium Foundation. In response to a question regarding the update of liability provisions in the MoUs with donor governments, it was explained that it was possible that amendments would have to be made to the existing MoUs with the five founding donor countries, and, if possible, a parallel instrument could be drafted to cover all other donors.

As a result of members' lack of readiness to make a decision on the issue, it was agreed that discussion would be postponed to a future meeting.

e) *Update on Audit*

Owing to time constraints, the Executive Board did not discuss the update on audit.

f) *Update on the accountability framework*

Owing to time constraints, the Executive Board did not discuss the update on the accountability framework. Board Members were referred to the information contained in the relevant Board meeting preparatory documents.

g) *Update on resource mobilization*

The SECRETARIAT gave a presentation on the Resource Mobilization Plan, which included the following:

- Resource mobilization remains a key challenge for UNITAD;
- There had been a low number of multi-year commitments;
- Currently, the main goal was to encourage Japan to become a member, particularly since no new members had enrolled since Cyprus in 2008;
- However, it was important to note that additional payments had been initiated by several African countries, including Mali. Cameroon and the Congo would also shortly be in a position to make a donation;
- It was vital that the technical capacity of the Secretariat should be enhanced through the implementation of the HR plan;
- The position of Assistant to the Chair had been suspended at the Chair's request;
- The FAC recommendation to the Executive Board was as follows: the Resource Mobilization Task Force should be revived and should include representatives from the FAC, the PSC and the Secretariat;
- The role of the Task Force would be to contribute to the design and implementation of a Resource Mobilization strategy for UNITAID. The Secretariat would be tasked with setting up this Task Force.

Several members stressed that it was vital to find new sources of funding, since securing funding from tax was not always fruitful and expressed concerns that there had been no new donors since 2008. It was clear that a new approach was needed in order to secure funding, through, for example, the Resource Mobilization Task Force. FRANCE emphasized that it was important that the Resource Mobilization Task Force be used effectively. Some members explained that they were working to encourage the proliferation of the so-called 'Robin Hood Tax', a tax on currency transactions of which UNITAID would be one of the beneficiaries. One member expressed concerns that the 'Robin Hood Tax'

would only be marginally effective in raising funds as many important countries were opposed to it.

The UNITED KINGDOM paid tribute to Cameroon, Congo and Mali for their momentous achievement of contributing or being able to contribute to UNITAID and suggested that some form of public recognition of that fact, for example a special award, could be given to act as an incentive for other developing countries. He also suggested that a letter could be sent from UNITAID to existing donors, thanking them for their contributions. Members felt that the idea had merit. The NGOs recalled the Thank You Campaign that had taken place in France and wondered whether there were plans to resume that campaign. It was suggested by the COMMUNITIES LIVING WITH THE DISEASES that another way of encouraging developing countries to contribute to UNITAID would be to state that a proportion of that funding would be made available for the countries to address issues based on their particular needs. Members also requested more information about what was being done to encourage Japan to contribute to UNITAID.

DECISION

The Executive Board noted the update on Resource Mobilization.

The Executive Board adopted draft Resolution no. 10 (doc UNITAID/EB13/2010/R10) on the Resource Mobilization Task Force.

7. Transition – a partner perspective

The SECRETARIAT gave a brief presentation on the transition of projects, which included:

Transition Strategy:

- UNITAID projects:
 - Are time-limited and catalytic;
 - Address market shortcomings;
 - Impact the market;
 - Exit after impact, leaving benefits achieved for others to continue;
 - Minimize risk of patient treatment stock-outs.

Current Portfolio status:

- The two CHAI HIV/AIDS projects were the most challenging in terms of transition, owing to their magnitude, or time-limited issues;

Transition:

- Particularly relevant in the HIV/AIDS niche;
- Need partners who could absorb costs:
 - Global Fund to Fight AIDS, Tuberculosis and Malaria;
 - The United States President's Emergency Plan for AIDS Relief (PEPFAR);
 - National resources.

The REPRESENTATIVE OF THE CLINTON HEALTH ACCESS INITIATIVE (CHAI) gave a presentation on the UNITAID-CHAI antiretroviral (ARV) treatment projects, transition update and next steps, which included the following:

- In 2006, CHAI became the implementing partner for the UNITAID paediatric and second-line HIV/AIDS projects;
 - Projects were time-limited and intended to catalyse a sustained market impact;

- Projects were not intended to create a parallel, permanent funding stream for commodities;
- Project goals:
 - Improve the market through pooled procurement to:
 - Lower prices;
 - Increase the number of high-quality suppliers;
 - Accelerate the entry of new improved products.
 - Close the gap between the rates of adult and paediatric patients on treatment.
- CHAI secured funds from other donors to carry out complementary activities and ensure a leveraged impact of UNITAID funds;
 - UNITAID funding created the marketplace for paediatric ARVs;
 - UNITAID catalysed a significant impact on the market for second-line treatments;
 - The additional CHAI funding was designed to carry out complementary activities on both the supply side and demand side of the market.
- The results have been significant;
 - At least US\$ 290 million in cost savings;
 - Price reductions:
 - Paediatric ARVs: 80–90% reduction for the most used regimens;
 - Second-line ARVs: 57% average reduction;
 - Early infant diagnosis reagents: 23% reduction.
 - Patients served:
 - More than 250,000 paediatric patients reached: a five-fold increase since 2005;
 - More than 67,000 adult second-line patients reached.
- CHAI began the transitioning process in 2008; however, the global context has changed and a looming funding for ARV treatment has made transitioning more difficult;
 - Global HIV/AIDS financing mechanisms are constrained, driving the need for bridge funding:
 - The Global Fund asked countries to take 10% reductions in Rounds 8 and 9;
 - For Round 10, the amount pledged falls short of the lowest funding scenario provided to donors by the Secretariat in May;
 - PEPFAR has flat-lined funding.
- CHAI has endeavoured to transition despite the global context;
 - Substantial efforts have been made to provide technical assistance to countries regarding Global Fund applications (supported 8 countries in Round 8, 12 in Round 9 and 8 in Round 10);
 - CHAI has continued to work with other partners and governments to find alternative funding;
 - Work with the US Government, UNICEF and local governments has led to more rapid transition in Guyana, Namibia, Papua New Guinea, Rwanda and Zimbabwe;
 - Progress is being made in Nigeria and Swaziland to transition to government funding;
 - CHAI will continue to coordinate with partners through the Coordinated Procurement Planning (CPP) mechanism.
- Paediatric bridge funding will be needed in many countries to avoid treatment interruptions in 2011; fewer countries will need support in 2012;

- 2011 paediatric bridge funding request: US\$ 81.1 million;
- 2012 paediatric bridge funding request: US\$ 62.8 million.
- Half of countries will require bridge funding for second-line products in 2011, in line with the US\$ 120 million approved by the UNITAID Board in 2009 for 2010–2011;
 - 2010–2011 adult 2I bridge funding and ATV/r tail request: US\$ 120.4 million;
 - 2012: most countries will have transitioned; preliminary and conservative estimates have been made, which will be reassessed following the approval of Round 10 funding.
- During the bridge period, CHAI will pursue important market dynamic goals to ensure ongoing impact of UNITAID funds, including:
 - Second-line: drive widespread registration and improved supplier performance.
- Transitioning the paediatric projects too quickly could increase the risk of supply disruption; CHAI is working closely with partners to address this;
- While responsibly transitioning the projects, CHAI will pursue important goals to achieve even more;
 - Transition next steps:
 - Continue working with partners and governments to secure alternative funding;
 - Reassess funding needs post Round 10 approvals;
 - Increase efforts to coordinate with partners to build in-country capacity for procurement and supply chain management transition;
 - Identify correct pooling mechanism for paediatric ARVs post-transition to avoid supply disruption.

Responding to questions from members on transition, the REPRESENTATIVE OF CHAI said that many lessons had been learned about the transition process since the paediatric and second-line HIV/AIDS projects; it was necessary to start considering transition at the very inception of a programme, not after. CHAI had begun to transition in 2008 but had received some criticism from alternative funding sources complaining that they had not necessarily been informed at the start of the programmes on how they might take over the funding streams later on.

The MEMBER FOR THE NGOS noted the need to evaluate how transition options would affect the fragmented market, as the potential effects of that would need to be addressed. Voluntary pooled procurement was one way to address market fragmentation but a way would need to be found to establish it in the longer term, as it could provide UNITAID with an effective transition strategy. Although projects were, by nature, time-limited, colleagues at the country level were urging UNITAID not to exit without ensuring that they were leaving behind a sustainable market.

It was essential that, moving forward, clear and concise forms were presented to project projects, with guidelines from UNITAID on what was expected from projects in terms of a transition strategy, market impact and value for money. Providing that information should have significant impact on the transition process; UNITAID should make it clear that bridge funding was not a viable transition option, the current CHAI projects under discussion were an exception, not the norm, and bridge funding would only ever be considered as a last resort.

Some members commented on the large sums of money needed for bridge funding, as it risked virtually exhausting UNITAID's funding capacity for the foreseeable future. CHAI was asked whether there was a need to provide incentives for the organization to seek alternative sources of funding in order to avoid the need for UNITAID to continue to provide bridge funding for extended periods of time; the REPRESENTATIVE OF CHAI responded that being part of the procurement chain for long periods caused tensions for his organization owing to its particular business model and, as such, it was also in CHAI's interests for the transition of projects to take place as soon as possible and not to extend bridge funding for longer than necessary.

The REPRESENTATIVE OF CHAI responded to several other questions put to him by members; on whether or not it was easy to encourage countries to include second-line and paediatric ARVs in their applications to Global Fund Rounds, he said that it varied by country, although it had generally been harder in earlier Rounds. If the Board so wished, he could provide more detailed information at a later date. It had been noted that discussions on transition should be held with alternative funding sources at the inception of projects; it was CHAI's view that both UNITAID and the relevant implementing partner should conduct those discussions. The SECRETARIAT recalled that both the Global Fund and PEPFAR had been informed when the paediatric and second-line ARV projects had begun in 2007 and agreements with CHAI had established that transition would begin the following year. However, the implications of programmatic implementation had meant that CHAI had needed more money from other funding sources in order for the projects to have success at country level. In addition to that, the changes in the global financial situation had also impacted the capacity of other organizations to take over project funding, thus creating further challenges with regard to transition.

Members had noted that the countries involved in the current CHAI projects fell into two categories: those with no alternative sources of funding, and for which UNITAID bridge funding would be essential, and those where alternative sources had in fact been found, but where there were issues related to cash flow, meaning that the provision of funds to those countries may be delayed by some months. Given the two distinct categories, the Board felt that they required different solutions, particularly as the latter accounted for around US\$ 30 million of the proposed budget and may not require UNITAID if another solution could be found. The REPRESENTATIVE OF CHAI said that he could provide more detailed information at a later date on those countries and the category into which each one fell.

Responding to questions from the member for the Communities Living with the Diseases on PEPFAR taking over the funding stream, country responses to that and the responsibility of countries in that process, the REPRESENTATIVE OF CHAI said that those were broader questions than CHAI was able to raise in discussions with ministries of health, which were limited to technical issues. Some countries did contribute towards ARV funding and some ministries of health had also taken control of procurement and supply chain management, but several were unwilling to take on that role as the primary driver of procurement, tendering and other key elements required to scale up programmes. That unwillingness on the part of some remained a concern for CHAI.

In response to questions on intellectual property issues by the member for Brazil, the REPRESENTATIVE OF CHAI replied that his organization was not helping Brazil to procure any products. Instead CHAI was providing analytical support to the country on how to optimize manufacturing processes.

8. Report and recommendations of the Governance Working Group

a) *Revised Board Operating Procedures*

The MEMBER FOR FRANCE, speaking in his capacity as CHAIR OF THE GOVERNANCE WORKING GROUP (GWG) recalled the in-depth discussions that had been held on revising the Board Operating Procedures. The revised document aimed to increase the efficiency of the Board and to eliminate any ambiguities. Some of the key elements included in the text were: i) procedures for decision-making by Board members in between Board meetings, ii) the provision that two-thirds of members would constitute a quorum and two-thirds majority must be reached for a vote to be carried out in the event that members do not reach consensus, and iii) that delegations should not exceed five persons.

Members highlighted some issues relating to the draft Board Operating Procedures, including that the annual performance review of the Executive Secretary had been included (as foreseen by the UNITAID by-laws) in a previous draft of the document but not in the current version; Board Members should therefore consider whether they wished to incorporate that provision. The Board should also bear in mind that, while the majority of the GWG agreed on the Executive Secretary term of office as one four-year term, renewable for a further three years, this was not a consensus decision.

One member, referring to paragraph 7 c) of the Board Operating Procedures, on additional delegates, advisers and observers, said that his delegation would like all Board Members, rather than only the Board Chair, to be involved in consultations on inviting observers. He also felt that the final list of observers should be sent to members much sooner than 24 hours before a meeting; it should be sent two or three weeks ahead, along with other preparatory documents. Responding, the WHO Legal Adviser recalled the GWG decision that the list of observers was to be sent to Board Members for information purposes rather than to request their input. As such, if the Board wished to change that provision so that all members participated in the decision on observers, with the list being sent three weeks before rather than the day before the meeting, it would no longer be possible to consider last minute requests on meeting observers.

Another member raised the matter of the taking of minutes during restricted Executive Sessions and said that someone should be responsible for that task, regardless of whether the Board wished to make the minutes public, as there should be a record of what was said during those sessions. The WHO Legal Adviser responded that it was not common practice for restricted sessions to have minutes, but that the Board Operating Procedures did stipulate that, at the Board's discretion, the Chair could appoint a member to prepare such minutes.

The Board turned to discuss the issue of voting either by teleconference or by email; one member felt that the Board may wish to consider stricter rules than were provided for in the Board Operating Procedures, such as funding decisions could be made by a vote by teleconference, but that email voting should be restricted to non-funding decisions. The Secretariat noted, however, that the majority of Board decisions implied a funding decision and by choosing not to vote electronically on such matters, the Board may limit its capacity to act, particularly if a teleconference was not possible at the relevant time.

The MEMBER FOR THE GATES FOUNDATION requested time with the Secretariat to discuss certain parts of the text that the Foundation's legal counsel had felt could be strengthened. Board Members agreed to postpone a decision on the revised Board Operating Procedures until those discussions had taken place and any necessary amendments had been incorporated into the document.

DECISION

Following discussions between the Secretariat and the member for the Gates Foundation, and the incorporation of proposed amendments into the document, the Board adopted Resolution no. 11, on the Board Operating Procedures.

b) Terms of References for the Advisory Committee on Funding Priorities

Board Members welcomed the draft terms of reference for the AGFP, noting in particular that the group represented a key step towards defining a clear prioritization strategy within the organization.

Regarding paragraph 2.2 of the terms of reference, questions were raised on the reference to the work streams of both the AGFP and PRC; members emphasized that while the two groups were distinct, their work should be complementary and dialogue may be necessary between the groups. Some members felt that the wording of paragraph 2.2 should be amended to better reflect those points, while one member proposed that reference be made elsewhere in the text to the PRC (perhaps at the beginning or in another paragraph of the section on Structure and Size), which would mean that paragraph 2.2 could be deleted altogether.

It was noted that the terms of reference did not make explicitly clear the process with which the AGFP would be involved, namely that the AGFP would provide its advice and recommendations to the PSC, which would in turn discuss and then pass that information to the Board, which would then take a decision. The language of the terms of reference should be modified to make clear that process.

The MEMBER FOR THE GATES FOUNDATION received wide support for the proposal that the prioritization process within UNITAID should be reviewed as a whole, perhaps six months after the AGFP had begun functioning. It would be important to assess the roles of the various components (e.g. the AGFP, PRC, Secretariat) and how they complemented each other in regard of the three levels of prioritization that were being developed (organizational, strategic and proposal).

The MEMBER FOR THE NGOS felt that paragraph 1.1 should include clarification on the relationship between the AGFP and the Secretariat, especially the Market Dynamics team. The Secretariat thus proposed to include a new sentence at the end of the paragraph that would read: "The AGFP works in close collaboration with the Secretariat, particularly with respect to Market Dynamics and Operations". Members agreed to accept that proposal.

The Board extensively discussed paragraph 4.2, particularly in regard of concept notes (unsolicited or otherwise) and the role that the AGFP would or would not have in receiving and reviewing them. Several members felt that the review of concept notes would be the sole purview of the PRC and the reference in the AGFP's terms of reference should therefore be removed. While the AGFP should advise on priority areas and niches, some members felt that it should not receive current proposals or concept notes, as their review was not within the mandate of the AGFP and that the group should not state whether or not it approved those proposals or notes. However, the AGFP should have full access to all archived material of UNITAID, including past proposals and concept notes, when formulating advice to the Board – via the PSC – on strategic matters. That advice would include areas of interest, not necessarily within the three disease areas, that the AGFP felt would be worth pursuing and for which a request for proposals could be issued. In order to avoid any ambiguity over the phrasing in paragraph 4.2, the Board agreed to delete the words "unsolicited concept notes" and instead include the words "explore ideas", on the understanding that the experts within the AGFP would know where to source the relevant information that they might be seeking.

Board Members emphasized the importance of not discouraging proponents of either innovative or urgent projects from submitting proposals to UNITAID. However, it was noted that the two categories would need to be addressed in different ways. For urgent, time-sensitive projects, it would logically not be possible to issue a request for proposals, as that process would delay any urgent action from being taken. Instead, AGFP members should be contacted and informed of the need to assess such a proposal and to advise promptly on whether that action should be taken.

Turning to the draft Resolution, members agreed to include a reference to the proposal for the review of the prioritization process, to take place six months after the AGFP had begun functioning.

DECISION

The Executive Board adopted draft Resolution no. 12, on the Advisory Group on Funding Priorities, as amended by members during the meeting.

c) *Conflict of interest principles for the UNITAID Executive Board*

Owing to time constraints, the Executive Board did not discuss conflict of interest principles for the UNITAID Executive Board.

The Vice Chair thanked Board Members for their day of discussions and the meeting rose at 19:10.

9. Election of the Chair of the Executive Board

Following the reopening of the meeting at 08:50 on Thursday 11 November 2010 by the CHAIR, the VICE CHAIR outlined the procedure for election of the Chair of the Executive Board contained in the Procedures for the Election of the UNITAID Board Chair, adopted by the Executive Board at its twelfth meeting in June 2010. Following this, the representative of France, who had nominated Mr Philippe Douste-Blazy, gave a short explanation of why he felt Mr Douste-Blazy was a suitable candidate for the position. A restricted session, for Board Members and limited members of the Secretariat only, was then held, in which Mr Philippe Douste-Blazy was elected Chair of the UNITAID Executive Board by acclamation.

DECISION

The Executive Board elected Mr Philippe Douste-Blazy to the position of Board Chair by acclamation and adopted draft Resolution no. 5 (document UNITAID/EB13/2010/R5) on Election of Chair of Executive Board.

The CHAIR expressed his thanks to the Board for his re-election and affirmed his commitment to establishing UNITAID as a key player in the public health sphere and increasing awareness of the importance of innovative financing. The current economic crisis meant that it was vital to find further sources of innovative financing. It was important for UNITAID to: increase public awareness of its existence and emphasize how it differed from other similar organizations; focus on specific niches; improve and increase cooperation with both donor and beneficiary countries; and increase coordination between the Executive Board and the Secretariat.

10. Communications

Owing to time constraints, the Executive Board did not discuss the update on communications.

11. Key Performance Indicators for 2010 and 2011

Introducing the item, the CHAIR reminded the Board that the KPIs for 2010–2012 had been approved at the twelfth meeting of the Board and had been adopted for the current term of the UNITAID Strategy. The only outstanding issue was to agree on the yearly baselines.

The SECRETARIAT gave a short presentation on key performance indicators, including the following key points:

- Baselines and milestones were a useful tool to allow full discussion of KPI results;
- New indicators and milestones had been established in all three areas:
 - Area 1 – Implementation of 2010-2012 strategy:
 - Two new indicators and milestones concerning progress reports relating to market tracking and transition of projects, respectively.
 - Area 2 – Organizational effectiveness:
 - Two new indicators related to the percentage of grants spent by implementing partners and Board member training, respectively;
 - One new milestone on Board member training.
 - Area 3 – UNITAID contributions to country health:
 - Three new indicators and milestones relating to the number of lives saved through UNITAID provision of medications, the identification of sources of support and operational costs, and the percentage of implementing partners that have signed MoUs with governments within the first 3 months of the project.

Members expressed appreciation for the work of the Secretariat on KPIs and acknowledged that many discussions had been held on the issue. Work on the KPIs was an ongoing and fluid process, and the KPIs themselves would develop and become more focused over time. It was important to learn from the previous process of establishing the KPIs. Some members proposed that for future drafting of KPIs, a small drafting group should be established comprising members of the PSC in order to agree on the KPIs and present a consolidated document to the Board.

Some members had specific comments regarding the indicators and milestones. BRAZIL questioned what would be measured by the new indicator 1 in area 1, as it seemed to be more of a source of verification than an indicator. He also questioned the use of the phrase ‘as relevant’ in the text of the milestone, as milestones are, by definition, relevant. With regard to the indicator on the optimization of UNITAID’s governance, a more suitable indicator would be to measure the implementation of Executive Board decisions. NORWAY expressed concerns that not all comments made by members at the twelfth meeting of the Executive Board had been incorporated into the final document. An example of this was the indicator related to staff performance review. She felt that the percentage of staff undergoing their performance review was not a relevant indicator of organizational effectiveness. It would be more important to show, for example, what actions were taken in cases of poor performance. As a result of these concerns, it was suggested that the draft Resolution be amended to include language related to the further discussion of KPIs at the fourteenth meeting of the Executive Board in 2011.

DECISION

**The Executive Board adopted draft Resolution no. 6 (doc
UNITAID/EB13/2010/6) on Key Performance Indicators 2010, as amended by
members during the meeting.**

12. Update on Market Intelligence and Operations

The SECRETARIAT gave a short presentation on market intelligence and operations. The key points were as follows:

- Portfolio overview:
 - The majority of HIV/AIDS funding was allocated to paediatric and second-line anti-retroviral drugs, 42% and 45% respectively, with the remaining 13% allocated to PMTCT;
 - 87.2% of funding was given to lower income countries, with the remaining 12.8% divided between lower middle income countries (9.6%) and upper middle income countries (3.2%);
 - Disability-adjusted life year (DALY) comparisons and the top ten recipient countries were included according to niche;
 - Information on trends by disease area was also provided, including information on the estimated number of patients treated for or protected from the three diseases between 2007 and 2009;
- Since the twelfth meeting of the UNITAID Executive Board in June 2010, two projects had been approved, in the areas of paediatric TB and PMTCT respectively. Projects were currently being developed by partners;
- An MoU had been signed with India for a TB project, and there were several MoUs pending, for the following projects: PMTCT Extension, ESTHER, TB SRF and Paediatric TB.
- A plan showing the reporting cycle for partners to report on projects was shown, the key points were as follows:
 - Partners report to UNITAID twice a year, in semi-annual and annual reports;
 - Project cycles were being aligned so that all partners would report on a calendar year, from 01 January to 31 December:
 - The calendar year cycle means that annual reports from partners were due in March/April for the previous year (i.e. 01 January-31 December 2010 reports will be due in March/April of 2011);
 - The Secretariat will assess the information provided by the partner and verify whether it is consistent with partners' semi-annual reports and any other information available about the project, and UNITAID statistics (trends in treatments, costs, price reductions etc.) are put together, analysed and used in the annual report on KPIs to the Board. The statistics are finalized on 30 June of each year;
 - Partner reporting, secretariat assessment, and KPI data feed into the Market Intelligence system.
- Information on the following market levers was also included:
 - Access;
 - Availability;
 - Quality.
- Many challenges remained including, *inter alia*:
 - Looking for market impact on products of public health importance, i.e. the sustainability of market gains;
 - Availability of predictable funding;
 - Monitoring results at the country level;
 - Securing achievements and scaling up, beyond UNITAID support;
 - Maintaining interest of manufacturers in low volume products.
- Implementation of the UNITAID 2010-2012 Strategy would continue in the following areas:

- Organizational framework;
- Project implementation;
- Sustainable impact;
- Demonstrate value for money.
- The Market Intelligence System was a tool to monitor the impact of UNITAID-funded projects and to provide information to allow informed decision making.
- It was based on the current WHO database, but UNITAID will work with different partners, including WHO, ANRS, FIND and Boston University, to produce different levels of analysis of data.
- The database will be UNITAID branded.

Several members suggested that more detailed analysis of the data would be useful from an operational standpoint in order to help UNITAID decide on, *inter alia*, which countries to focus on. With regard to this issue, the representative of the AFRICAN UNION stressed that it was vital to work with all of the most vulnerable countries and questioned why UNITAID currently only worked in seven of the most vulnerable countries. She requested further information on the possible issues with partners and governments that had an effect on the issue and offered to work with the Secretariat to analyse and address the trend. In response to this, the representative of the SECRETARIAT explained that the decision on which countries to focus on had been taken a few years previously and had been based on niches and government readiness and willingness to implement the project. However, she also stressed that the implementation of a prioritization framework would have an effect on those decision and, furthermore, if UNITAID had a closer relationship with countries and was better able to assess country-level data, it would be easier to decide where to focus resources.

a) *Report on the implementation of projects approved by the Executive Board*

Members expressed their appreciation for the detailed presentation, but some members suggested that more detailed information on prices and the number of patients treated would be useful. However, members were aware that it was often difficult to obtain qualitative data from partners, so further discussion regarding the nature of UNITAID's relationship with implementing partners was needed. The representative of the SECRETARIAT stressed that the information provided in the report was based on the semi-annual reports, and it was therefore difficult to provide new information since June. As a result of this, information on prices and numbers of patients had not been included as no new information had been received since the twelfth meeting of the Executive Board in June.

With regard to questions on the current TB projects, the Secretariat explained that 80% of TB funding was being invested in multi-drug resistant tuberculosis (MDR-TB) and that the 1st line project has already transitioned.

In response to specific comments from members on the relationship between the Affordable Medicines Facility – malaria (AMFm) and Assured Artemisinin Supply System (A2S2), the representative of the SECRETARIAT explained that although no formal link existed between the two initiatives, the increased provision of Artemisinin would lead to increased production of artemisinin-based combination therapy drugs (ACTs).

With regard to the roll-out of the PMTCT "Mother-Baby Pack" by UNICEF, several members expressed serious concerns about the lack of publicity about UNITAID's involvement in the project. Neither the pack itself or the articles and press releases on the implementation of the project by UNICEF made any reference to UNITAID as the source of funding.

DECISION

The Executive Board noted the report on implementation of projects.

b) *Update on the Market Intelligence project*

With regard to the Market Intelligence project, several members said that the structure of the system was highly complex, and that the value and the roles of the different partners were unclear. Members requested further information on the project.

DECISION

The Executive Board noted the update on the Market Intelligence Project.

13. Update on the implementation of the Medicines Patent Pool Foundation (MPPF)

The EXECUTIVE DIRECTOR OF THE MEDICINES PATENT POOL FOUNDATION presented an update on the MPPF:

Transition update:

- Held first Medicines Patent Pool Board meeting in September 2010:
 - Appointed Price Waterhouse Coopers as auditors;
 - Adopted management controls and operational policies;
 - Appointed Executive Director;
- Rented and furnished office space;
- Identified and contracted service providers:
 - IT; logo/brand; website; human resources; insurance and finance;
- Began staffing and recruitment efforts:
 - UNITAID staff is in the process of transitioning from UNITAID to the MPPF;
 - Active recruitment for additional staff is underway.
- Received UNITAID initial funding of US\$ 550,000.

Patent holder engagement and legal aspects:

- Patent holder engagement:
 - First licence agreement with the United States National Institutes of Health (US NIH) in September 2010;
 - Continued engagement with patent holders;
 - Currently investigating the impact of different royalty calculation methods with a view to ensuring broad geographical scope for patent licences.
- Legal:
 - UNITAID, in conjunction with World Intellectual Property Organization (WIPO), hosted a workshop on Licensing Terms and Conditions with globally recognized legal and licensing experts (September);
 - Retained law firm on a pro bono basis to provide legal services on licence drafting, negotiation strategy, technical patent analysis, etc. discussions with two other law firms for pro bono support are ongoing;
 - Established collaboration with the European Patent Office on patent information;
 - Provided comments to the United States Patent and Trademark Office on incentives for humanitarian licensing.

US NIH became the first to licence patents to the Pool:

- Overview of licence:

- A patent family relating to the use of a class of protease inhibitors, including darunavir.
- Patent owner: research by NIH National Cancer Institute and University of Illinois, Chicago (1999);
- Licence conditions:
 - Licence text is publicly available;
 - Licence to benefit all low- and middle-income countries;
 - Royalty-free.
- Additional information:
 - Licence is not enough to clear legal path to generic production:
 - NIH and the MPPF are discussing additional licences.
- The NIH licence received strong political support, including from the White House Office of Science and Technology Policy.

Engaging key stakeholders and the public:

- Patent Pool presented at international events;
- Briefings for interested stakeholders: governments, National Agency for AIDS Research (ANRS), and others;
- UN Human Rights Council resolution welcomed the creation of the MPPF by UNITAID (September).

Both the EXECUTIVE DIRECTOR and BOARD CHAIR OF THE MPPF thanked the UNITAID Board and Secretariat for their continued support and for managing the complex transition process, including the moving of some staff members from UNITAID to the MPPF.

The CHAIR emphasized the significance of the NIH agreement, as it was likely that many other patents were stored away in similar research institutes or universities following discoveries by researchers. The NIH agreement highlighted the potential extraordinary results that could be achieved if the MPPF were able to form agreements with other such institutes. In that context, the CHAIR proposed that a day of meetings be held, in February 2011 if possible, in a city such as London or New York, to promote the MPPF and to discuss licensing, universal access to medicines, and the politics behind the issues, with the heads of other research institutes, universities, NIH representatives, WHO representatives and other relevant entities from around the world. A similar meeting had been set up between the Executive Director and Chair of the MPPF and representatives of CNRS, ANRS and others. Several members expressed their support and enthusiasm for such a day and the opportunity to promote and give visibility to the MPPF and to engage other organizations in its work.

Responding to questions posed by Board Members, the EXECUTIVE DIRECTOR OF THE MPPF first noted that the institutes holding patents, such as the NIH, did continue to pay the necessary patent fees, even after the MPPF obtained the licence. She went on to explain that the MPPF was collaborating with WIPO; a group of experts had been formed but the collaboration was on a technical level, not a political level.

All policies put in place within the MPPF had been shared with the UNITAID Secretariat and the MPPF had benefited substantially from the support provided by the Secretariat in developing and refining those policies and ensuring that they met current applicable standards. That support would also be crucial to the MPPF in its daily activities and as it moved forward. It would continue to focus on working with pharmaceutical companies that held the relevant intellectual property that would enable the production of better-adapted and low cost medicines and improve the quality of life of those people living with HIV/AIDS and other diseases.

14. Update on the findings and recommendations of the Proposal Review Committee

The CHAIR OF THE PRC provided details to the Board on the PRC review process; proposals were first screened by the Secretariat and then referred to the PRC, with each proposal being allocated to four reviewers: two from the relevant disease area, once from market dynamics and one from another relevant area. Following the review, and input by the reviewers at the PRC meeting, the whole panel provided comments before reaching consensus. At the PRC's first meeting, the UNITAID Market Dynamics team also provided input on the current market landscape, which the group found particularly useful.

PRC Members had emphasized the importance of the confidentiality of discussions and had welcomed the open and safe environment in which they were able to comment freely. They had also recognized the need to streamline the proposal review process and had noted the need for more robust financial information.

The PRC had reviewed four proposals and two concept notes.

a) *Clinton Health Access Initiative Paediatric Transition Operational Plan*

The CHAIR OF THE PRC read out the main points of the summary of comments and recommendations of the PRC on the proposal, which had been provided to Board Members.

Members raised questions on the budget requested as it had increased from US\$ 76.8 million in the exit year to US\$ 81.1 million. This was of particular concern as the true cost of project implementation was often higher than estimated and therefore impacted on cost effectiveness. The Chair of the PRC clarified that the increase in the budget was due to increased use of lopinavir and ritonavir, in accordance with new guidelines. The drugs were more expensive than those previously used, as the production process was more difficult and CHAI had therefore not been able to achieve the same level of market price reduction.

Several Board Members recalled the earlier discussions following the presentation made by the representative of CHAI, when it had been noted that there were two types of country: those with no alternative funding source, which would require UNITAID funding (category one), and those that had secured alternative funding but were experiencing cash flow issues (categories two and three). It was emphasized again that those categories would require different solutions in regard of funding. One member proposed that funding be approved for Category 1 countries up to around US\$ 50 million, but that, for Category 2 and 3 countries, CHAI first work with those countries to secure alternative solutions to the cash flow issue. If there were no other means of resolving the issue, the Board would then grant green light status to funding. Board Members wished the draft Resolution to be amended to reflect that agreement.

Members of the Board also found that, in terms of monitoring and evaluation, partners should report more effectively so that the market impact of a proposal could be better assessed. In that regard, it was proposed that the draft Resolution be amended to include the condition that information must be provided on indicators for monitoring and evaluation and the market impact of the intervention.

The Board agreed that this was an important project and that the proposal should be supported, on the basis that the relevant conditions were set. To-date, CHAI had been an effective and efficient partner, the project had been successful and it had received a high profile in political terms.

Following further discussions by Board Members outside of the meeting on the amendments to be made, the draft Resolution was amended to take into account the comments made. Upon review of the modified text, the Board agreed to adopt draft Resolution 13.

DECISION

The Executive Board adopted draft Resolution no. 13, on UNITAID-funded Paediatric HIV/AIDS Treatment Project Extension (CHAI) for the period 2011–2012, as amended by members during the meeting.

b) Second UNITAID Paediatric Tuberculosis Project: First-line drugs to treat paediatric tuberculosis

The CHAIR OF THE PRC drew the Board's attention to the comments and recommendations of the PRC and read out some of the key points that had been made.

Noting the current high pill burden for some children, one Board Member emphasized the need for better-adapted fixed dose combinations (FDC), as such formulations would be key in improving the currently poor outcomes of HIV/AIDS and tuberculosis treatments. However, the proposal needed to provide greater clarity on targets for when those new FDCs would be achieved.

A number of Board Members considered that, while the proposal seemed a good one, a lack of strategic prioritization within UNITAID at the current time made it difficult to assess whether the proposal represented the best option for tuberculosis funding, particularly in terms of value for money and market impact.

It was found by some that the proposed cost per treatment (US\$ 11), sounded quite high, but the Chair of the PRC clarified that this was due to an increase in dosage. PRC Members had considered that the cost was reasonable, compared with that which had been recommended in previous guidelines. The Chair of the PRC also noted that the change in policy, as set out in the new WHO guidelines, would not be enough alone to impact the market and incentivize the production of the new paediatric FDCs; without that intervention, the manufacturers would meet the new WHO recommendations by breaking tablets and using parts of the dosage for adult formulations, thus maintaining the high pill burden for children.

The Board agreed that it could adopt the draft Resolution on the condition that the proponents provide clarification on the issues raised by both the PRC and Board Members. The draft Resolution was amended accordingly.

DECISION

The Executive Board adopted draft Resolution no. 7, on Second UNITAID Paediatric Tuberculosis Project (GDF, StopTB Partnership Secretariat, WHO), as amended by members during the meeting.

c) PASCAL viral load testing and WHO viral load testing

- **Partnership for a sustainable access to quality and affordable viral load testing in resource-limited settings (France Coopération Internationale (FCI) & PASCAL consortium)**

- **Improved HIV/AIDS Monitoring: Pilot Expanded Access to Quality and Affordable Viral Load Testing in Three Low-income Countries (WHO)**

The CHAIR OF THE PRC read out the key points that had been made in the comments and recommendations of the PRC of both proposals. He noted the background to the two viral load proposals; at the previous Meeting of the Executive Board, Board Members had considered three separate proposals, submitted by CHAI, PASCAL and WHO, and had requested the proponents to explore ways to work together to produce one comprehensive proposals that was innovative and with a wide geographical scope. Since that time, CHAI had withdrawn from the process. The PASCAL and WHO proposals, although complementary and without overlap, had retained quite different approaches to viral load testing; as such, the PRC had reviewed them as two separate proposals.

Board Members questioned why the proponents had chosen not to work together, particularly as both had scaled down their proposals to the extent that there would be a much reduced market impact of both. The Chair of the PRC informed Board Members that the WHO proposal had taken the approach of working with proprietary closed systems, while PASCAL had proposed a more innovative, although riskier, open-system approach. It would have been difficult to merge those approaches and the proponents would not necessarily have provided better results in terms of numbers. If CHAI had remained in the process, the scales of the project(s) may have significantly changed but CHAI had stated that it would not continue in the process unless it could be sure of the transition strategy and that there would be other major sources that could take over the funding. However, at the current time, that was not the case and on that basis CHAI felt it could not proceed.

Recalling the PRC recommendation that the Board should consider a further review of the viral load landscape, the Chair of the PRC noted that the situation had changed dramatically since UNITAID had launched its request for proposals two years ago to promote viral load testing and improve access, and a new request for proposals might give rise to more advanced proposals in terms of innovation and technology. Without UNITAID intervention, the market had already changed significantly enough for some tests to appear at a lower cost per test (approximately US\$ 10) than was achievable through the two proposals under consideration.

Board Members expressed support for the principle of an innovative open-system approach, as proposed by WHO, but felt strongly that neither proposal could be taken any further currently, owing to, among other things, the low market impact that would be achieved and the low value for money. However, Board Members noted the urgent need for improved viral load testing, given its potential impact on public health, and it was agreed that, once the new prioritization framework was in place in the near future and new, clear forms and comprehensive guidelines could be provided to proponents on project proposals, viral load should be certainly be reconsidered and prioritized by the Board.

While agreeing with the PRC recommendation not to fund either proposal, the Board clearly stated that it did not wish to permanently rule out further viral load project proposals. Board Members wished the two draft Resolutions on the viral load proposals to be redrafted to make it clear that the Board would reconsider viral load in the coming months, through a new request for proposals.

DECISION

The Executive Board adopted draft Resolution no. 14, on Partnership for a Sustainable Access to Quality and Affordable Viral Load Testing in resource-

limited settings (France Coopération Internationale (FCI) & PASCAL consortium), as amended by members during the meeting.

DECISION

The Executive Board adopted draft Resolution no. 15, on Improved HIV/AIDS Monitoring: Pilot Expanded Access to Quality and Affordable Viral Load Testing in Three Low-income Countries (WHO), as amended by members during the meeting.

e) *Concept Notes*

The CHAIR OF THE PRC drew attention to the information provided to Board Members in the summary of comments and recommendations of the PRC on the Concept Notes under discussion, noting in particular the recommendation that both a full proposal should be requested for both. The Chair of the PRC noted that the PRC did not review the four Concept Notes that had previously been reviewed by the Interim Expert Advisory Group (IEAG) and considered by the Board at its twelfth meeting.

Some Board Members expressed support for the PRC recommendation to request full proposals from the proponents of not just the two Concept Notes currently under consideration but also the four that were discussed at the previous Board Meeting. However, others did not think that requesting those six proposals was in UNITAID's interests in terms of its strategy and prioritization. If proponents were to be invited to submit full proposals, the proponents may expect funding to be approved, which the Board could not guarantee at that time. The six proposals amounted to approximately US\$ 280 million, which would bind up UNITAID funds for at least a few years. While the Concept Notes put forward a number of interesting and innovative ideas across a number of areas, some Board Members found that it would be more appropriate to issue requests for proposals on the topics covered by the Concept Notes (e.g., viral load testing, female condoms, tuberculosis and multidrug-resistant diagnostics, malaria etc) and hold a competitive process. Such a process would allow the PRC to review a number of proposals on a particular topic, using the new prioritization framework once in place, and to report to the Board on how the proposals ranked in terms of market impact, value for money and impact on public health. The Board would then be in a better position to assess proposals in a rational manner and not on a 'first come, first served' basis.

The Executive Board decided not to adopt a draft Resolution on Concept Notes. There was general consensus on waiting until the new prioritization framework has been put in place within the next six months before drafting clear and comprehensive requests for proposals. The CHAIR OF THE PRC also agreed with this approach, but recommended that it be made clear to proponents of the six concept notes that a request for proposals would be issued, and that before that time, UNITAID was not in a position to allocate funding. The proponents would then be free to take their proposals elsewhere and seek other sources of funding, if they so wished.

15. Follow up on Resolution 19 from the twelfth meeting of the UNITAID Executive Board

The member for NORWAY gave an update on the preparations for the Executive Board retreat and partner consultations to be held in March 2011. She thanked the members of the PSC for their contributions to the discussions, particularly the NGOs and Brazil for the proposal that a session should be held on funding and funding predictability. There were four issues that needed further discussion and development. First, was the current framework suitable and comprehensive enough to be used as a working document during the

preparations of the retreat? Second, it was important to agree on a facilitator for the meeting, either from the list of suggested facilitators proposed by the Secretariat, the Gates Foundation, NGOs and Norway or from other suggestions by Board Members. Third, the Board needed to agree on the partners that should be invited to attend the retreat. Fourth, would the PSC be required to liaise between the facilitator and the Executive Board?

It was agreed that, owing to time constraints, discussion of those issues would be held within a small group of PSC members, including the Gates Foundation, WHO and NGOs, with input from the Secretariat, and that a final framework would then be submitted to the Board. It was suggested by the NGOs that the PSC should develop criteria to guide decisions on which recipient countries and partners should be invited to attend the retreat.

DECISION

The Executive Board adopted draft Resolution no. 16 (document UNITAID/EB13/2010/R16) on the Board retreat and partnership meeting.

16. Update on the independent Review of the Millennium Foundation and Voluntary Solidarity Contribution Project

The representatives of Dalberg Global Development Advisors gave a short presentation on the Independent Review of the Millennium Foundation and Voluntary Solidarity Contribution (VSC) Project. The key points were as follows:

- Significant implementation steps had been completed, but the results had not tallied with the predicted results.
- The key issues were:
 - There was limited awareness of the MASSIVEGOOD brand;
 - The size of the market was smaller than anticipated;
 - Partners were less willing to participate, and consumers less willing to donate; and
 - Building a fundraising brand was time consuming and costly.
- The main lessons learned were:
 - Changes to the strategy should have been implemented in a more timely manner in response to emerging information;
 - The Board and Secretariat required greater industry and start-up experience; and
 - A soft launch or pilot project should have been launched prior to the main launch in order to assess and mitigate the risks.
- The possible next steps for UNITAID were:
 - a) To implement the current scope;
 - b) To expand the current scope;
 - c) To outsource implementation to a new partner; or
 - d) To exit the project.
- The recommended course of action was to work with partners or outsource the operation as it reduced the risks and shared the costs through working with partners.
- A number of key strategic questions still needed to be answered, including:
 - What is the revenue potential of each option?
 - What is the implementation timeline for each option?
 - What are the key risks?
 - What revenues are expected?

The REPRESENTATIVE OF THE MILLENNIUM FOUNDATION expressed his appreciation to Dalberg Global Development Advisors for their analysis and stressed that it was vital for the project's success that the Executive Board send a positive message to the Executive Board

of the Millennium Foundation. Two key issues remained with the project: the brand, and private sector involvement.

The NGOs suggested that the project should focus solely on the online market, i.e. online travel agencies and airlines. In response to this, the REPRESENTATIVE OF THE MILLENNIUM FOUNDATION said that if the market stayed as it was, then the maximum potential revenue from the online markets would be US\$ 200 million, 20% of which could feasibly be reached within the first six months to a year. However, it would be impossible to guarantee that such a level of revenue would be reached.

In response to comments from members regarding the next steps for UNITAID's support of the VSC project, the REPRESENTATIVE OF THE MILLENNIUM FOUNDATION urged the Executive Board to be more proactive in its support for the project. The first nine months of the project had been spent negotiating the MoU, and more political and communications work was needed to ensure the success of the project.

17. Calendar of Board meetings for 2011 and 2012 and other events requiring Board Members

Following discussions by Board Members, the Executive Board agreed that the Secretariat would find alternative dates for the committee meetings scheduled in May 2011 and would submit the proposed dates to Board Members in writing. The Board therefore agreed not to adopt draft Resolution no. 19 (document UNITAID/EB13/2010/19) on Dates of UNITAID Official Meetings.

18. Any other business

As there was no other business, the CHAIR closed the meeting at 18:40 on Thursday 11 November 2010. A closed session of the Executive Board was held immediately following the closure of the meeting.

Annex 1 - List of Participants

MEMBERS

- | | |
|---|---|
| CHAIR | - Mr Philippe Douste-Blazy |
| CHILE | - Vice Chair. Mr Luciano Parodi |
| AFRICAN COUNTRIES | - Mrs. Tanya Prayag-Gujadhur |
| ASIAN COUNTRIES – Republic of Korea | - Mr Joo-il Lee
- <u>Alt.</u> : Mr Pil-woo Kim |
| BRAZIL | - Mr Carlos Alberto M. Den Hartog
- <u>Alt.</u> : Ms Maria Luisa Escorel
- Dr Carlos Passarelli
- Mr Bruno Neves
- Ms Maria Eugenia Ferraz do Amaral Bodra |
| FRANCE | - Prof Patrice Debré
- Mr Stephane Renaudin
- Ms Genevieve Chedeville-Murray |
| CONSTITUENCY OF FOUNDATIONS
- BILL AND MELINDA GATES
FOUNDATION | - Mr Girindre Beeharry
- <u>Alt.</u> : Ms Susan Navarro |
| NGOS | - Dr Mohga Kamal Yanni (Oxfam)
- <u>Alt.</u> : Ms Kim Nichols (African Services Committee)
- Mr Khalil Elouardighi (PLUS, Coalition International Sida)
- Ms Jessica Hamer (Oxfam)
- Mr Louis Da Gama (Global Health Advocates) |
| COMMUNITIES LIVING WITH THE
DISEASES | - Dr Esther Tallah
- <u>Alt.</u> : Mr Nelson Otwoma
- Mrs Blessina Kumar |
| NORWAY | - Mrs Sissel Hodne Steen |

SPAIN	- Ms Kirsten Myhr
	- Mr Miguel Casado Gómez
	- Mr Javier Parrondo
UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND	- Mr Gavin McGillivray
	- <u>Alt.</u> : Mr Carlton Evans
WHO	- Mr Alex Ross
	- <u>Alt.</u> : Mr Issa Matta
	- Dr Winnie Mpanju-Shumbusho
PROPOSAL REVIEW COMMITTEE	- Dr James McIntyre
PARTNERS	
THE CLINTON HEALTH ACCESS INITIATIVE (CHAI)	- Mr Inder Singh
ESTHER	- Dr Gilles Raguin
FIND	- Dr Giorgio Roscigno
MEDICINES PATENT POOL FOUNDATION	- Dr Ellen 't Hoen
	- Dr Charles Clift
MILLENNIUM FOUNDATION – INNOVATIVE FINANCE FOR HEALTH	- Mr Bernard Salomé
	- Ms Donna Catliota
	- Mr Henk Mulder
	- Ms Maud Biton
ROLL BACK MALARIA PARTNERSHIP (RBM)	- Dr Awa Marie Coll-Seck
	- Mr Julian Fleet
	- Dr Jan Van Erps
THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA	- Prof Michel Kazatchkine
UNAIDS	- Dr Paul de Lay
OBSERVERS	
NGOs AND COMMUNITIES LIVING WITH THE DISEASES	- Mercy Douala (REMED)
	- Diarmaid McDonald (Stop AIDs Campaign UK)

- Anton Kerr (International HIV/AIDs Alliance)
- Janice Lee (Médecins Sans Frontières)
- Katy Athersuch (Médecins Sans Frontières)
- Elodie Jambert (Médecins Sans Frontières)
- Billie-Jean Nieuwenhuys (Stop AIDS Alliance)
- Charles Allotey (Health Access Network Ghana)
- Casco Mubanga (NZP +)
- Rosemary Mburu (KANCO)

UNITAID SECRETARIAT

- Dr Jorge Bermudez (Executive Secretary)
- Dr Philippe Duneton (Deputy Executive Secretary)
- Dr Raquel Child (Director, Market Dynamics and Operations)
- Ms Brigitte Laude (Director, Administration and Finance)
- Ms Brenda Waning (Coordinator, Market Dynamics)
- Ms Daniela Bagozzi (Senior Adviser, Communications)
- Mr Edward Vela (Senior Adviser)
- Mr Paulo Meireles (Acting Coordinator of Operations)
- Mr Frederic Martel (Board Relations Officer)
- Ms Louise Kleberg (Technical Officer, Proposal Review Committee and Advisory Committees)
- Ms Gelise McCullough (Technical Officer)