



Fifteenth Meeting of the UNITAID Executive Board
11–12 December 2011, Ministry of Foreign and European
Affairs, Paris, France

Minutes

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1. Welcome and opening of the Session

The VICE CHAIR OF THE EXECUTIVE BOARD, Mr Eduardo Gálvez (Chile), opened the meeting at 9.20 a.m. and welcomed all members. Upon his arrival, the CHAIR OF THE BOARD, Mr Philippe Douste-Blazy, expressed thanks to the French Ministry of Foreign and European Affairs for hosting the meeting and for continuing to support UNITAID.

He said that the unique character of UNITAID meant that it was well placed to serve as an example to others at a time of financial crisis. The UNITAID model had seen many successes and served the whole international community in reducing the price of medicines. Nevertheless, it was clear that in the context of the crisis the organization should continue to ensure that resources were used as effectively and efficiently as possible. Many other organizations and entities were now recognizing the importance of innovative financing mechanisms, especially after seeing the example of UNITAID and, notably, the Group of Twenty (G-20) had acknowledged the importance of establishing a financial transaction tax. It was hoped that funds coming from such a tax would in future be used to help many poorer countries in a number of areas.

The multi-annual commitments that had been pledged to UNITAID by some of its Board members were greatly valued, as they provided sustainability of funding and helped to ensure that momentum was maintained. The Chair welcomed the news that other members intended to establish multi-annual commitments in the near future and encouraged others to follow suit.

Despite the discussions that would take place during the meeting on a range of items, there were still challenges to be addressed as UNITAID moved forward in its work. These included: how to act strategically but also leave enough flexibility to take advantage of opportunities as they arose; how to better plan for long-term sustainability through effective transitioning of projects; and how to respond to increasing demands and expectations while maintaining a small but effective Secretariat.

2. Adoption of the Agenda

Board members agreed to adopt the provisional agenda without amendment.

DECISION

The Executive Board adopted the provisional agenda.

3. Minutes of the 14th session of the Executive Board

Board members had no comments on the minutes of their previous meeting, of 5–6 July 2011, and approved them without amendment.

DECISION

The Executive Board approved the minutes of its previous meeting.

4. Overview of Progress since the 14th Executive Board meeting

a) *Report of the Chair*

The CHAIR said that recent months had been testament to the far-reaching support and interest that UNITAID enjoyed among civil society, donors, implementing agencies, academic institutions and, increasingly, the private sector. Expectations of UNITAID were high and the organization needed to ensure that it did all it could to achieve the anticipated results. To that end, UNITAID would need to continue its close collaboration with partners, as well as to develop new alliances, in order to remain dynamic and ensure that needs were met. UNITAID should be encouraged by the new donors that had come forward from Africa and Asia, especially those who were also beneficiaries of UNITAID's work.

There were certain politically controversial topics that required the attention of the Board, but it should not avoid debates on those topics; instead it should use the discussions as a chance to refine approaches and accept the need to take some risks in order to remain innovative.

b) *Report of the Executive Director*

The EXECUTIVE DIRECTOR thanked the French Ministry of Foreign and European Affairs for inviting UNITAID to hold its Board meeting in Paris. He welcomed the new Board members for France (Ms Mireille Guigaz and her alternate Mr Philippe Meunier) and Brazil (Mr Jorge Bermudez) and thanked outgoing French Board member Mr Patrice Debré for his support to UNITAID in recent years.

In the current global public health context, UNITAID's role was more important than ever, as the financial crisis meant that there was an ever growing need to develop clear and effective strategies and for interventions to be as effective and efficient as possible at as low a cost as possible. UNITAID had seen many successes across the three disease areas, but a number of challenges remained and UNITAID needed to give careful attention to how to respond most effectively to those challenges in the coming years.

In the area of HIV/AIDS, the 2011 Political Declaration on HIV/AIDS made in New York had mobilized the international community in the objective to increase access to treatment from 6 million to 15 million people by 2015. It was an ambitious goal, however, as no additional financing was available. There therefore needed to be further reductions in the price of medicines, so that more people could be treated with the same amount of funding. Furthermore, many of those 15 million did not know that they had the virus and UNITAID needed to work to ensure access to affordable and accurate tests. The paediatric antiretroviral (ARV) market had been non-existent before UNITAID's intervention, but now with the number of paediatric cases decreasing, the organization needed to take care not to become a victim of its own success. Work needed to be done to coordinate the purchase of paediatric ARVs, so that manufacturers remained mobilized and continued their production. UNITAID also had an essential catalytic role to play in the production of adapted diagnostic tests and in the late stage development of products to aid their entry to the market and in overcoming regulatory obstacles. The role of the Medicines Patent Pool is also essential in the development of new products, as its involvement would aid the implementation of Treatment 2.0 and would help create the optimum market conditions for implementing the 2011 Political Declaration on HIV/AIDS.

In malaria, UNITAID had succeeded since 2006 in increasing the number of registered manufacturers of artemisinin-based combination therapies (ACTs) from one to eight, leading to a considerable price reduction. UNITAID also partnered the Affordable Medicines Facility – malaria (AMFm), whose concept of a global subsidy to make drugs available to people in the poorest countries was one of the most innovative interventions in the malaria market. The challenge was to ensure that the AMFm remained effective, efficient and sustainable. In addition to supporting access to diagnostics and medicines, UNITAID also needed to ensure that long-lasting insecticidal nets (LLINs), as a tool for prevention, were available without stock-outs.

In tuberculosis, UNITAID had supported access to first- and second-line treatments, as well as rotating stockpiles, but new and innovative interventions were foreseen in tuberculosis, including new technologies for diagnosis. UNITAID needed to ensure it was present and able to support those technologies and new treatments that were due to become available in the coming years.

Despite many successes, factors such as the global financial crisis had put into question the ability of the international community to sustain a public health response at the required scale. Yet the dangers of scaling back that response were well known and so focus needed to shift toward the most strategic and efficient interventions, so that more could be done with the same level of funds. UNITAID's strength in that area and its catalytic and innovative presence meant that others increasingly sought its expertise in market impact and stabilization. It was therefore essential that UNITAID remained responsive and effective, with good management and clear strategies. The organigram of the Secretariat's structure had been revised, to give authority and responsibility to managers, in order to ensure that. A new communications strategy would help make UNITAID better known and would help to show that innovative financing delivered results; all actors in the market needed to know of UNITAID's work and that those with new products and technologies could be supported. A new website would be launched within six months. A functional review was to take place to ensure that each position was relevant and that all staff members were working to their full capacity.

UNITAID needed to continue to act as a laboratory and trendsetter in innovation and to advocate for the future of innovative financing. The organization had recently supported a study on financial transaction tax and had produced an implementation guide so that all countries wanting innovative financing measures could see what steps to take and what results they could expect.

The REPRESENTATIVE OF BRAZIL said that all UNITAID Board members were agreed on the need for access to medicines and lower prices. However, there were still some matters on which members had not yet achieved consensus, particularly those issues on UNITAID's agenda that had the potential to become controversial, such as the quality of drugs or the Patent Pool. On those issues, the Executive Director would need to be cautious, as he spoke on behalf of the organization and needed to remain aware of political sensitivities. Brazil looked forward to working with the new Executive Director and to his assistance to the Board in developing policies and strategies.

5. Report of Finance and Administration Committee

The REPRESENTATIVE OF THE UNITED KINGDOM, in his capacity as CHAIR OF THE FINANCE AND ADMINISTRATION COMMITTEE (FAC) explained that he would be presenting the update from the FAC. However, he said he would be asking the

Secretariat to present the HR issues because it would be for the Board to decide whether to accept the Secretariat's recommendations, which were not recommendations coming from the FAC.

a) Proposed Budget 2012

The REPRESENTATIVE OF THE UNITED KINGDOM, presented the proposed budget for 2012, including projected revenue of US\$ 288m for 2011, contributions from donors, and expenses for the governing bodies, Secretariat, projects (including Special Projects and Secretariat Initiatives) and budget provision. The proposed budget could be broken down as follows:

- Governing bodies: USD 2.03 million;
- Secretariat: US\$ 25.2 million;
- Projects, special projects and Secretariat initiatives: US\$ 168 million;
- Budget provision (to be used only following budget reallocations requiring close scrutiny): US\$ 1.6 million.

The SECRETARIAT provided more detail on the human resource plan, including the foreseen changes to the UNITAID staff structure, and how those changes would affect the budget. Some increases to the number of staff members in the Market Dynamics and External Relations teams were proposed. Overall, the proposed changes would see the number of Secretariat staff increase from 48 to 62 persons.

The CHAIR OF THE FAC said that the Committee had endorsed the budget for final Board approval, but had raised concerns over the increases in staff costs at a time of financial constraint. He emphasized that the role of the FAC was not to pre-approve the budget before Board discussion but to test the assumptions that had been put forward by the Secretariat and to ensure that the figures were accurate before reporting to the Board, which would then take the final decision as to whether or not to approve the budget proposals.

The REPRESENTATIVES OF BRAZIL, FRANCE AND NORWAY indicated that their countries would soon be making their contributions to UNITAID. The REPRESENTATIVE OF SPAIN explained that Spain continued to support UNITAID and would fulfil the pledges it had already made to the organization. However, it was currently experiencing great financial difficulties and discussions on future commitments would be taken up by the in-coming Spanish Government after January 2012. The REPRESENTATIVE OF THE CIVIL SOCIETY DELEGATIONS in particular welcomed the contributions that had been or would soon be made to UNITAID, especially given the financial difficulties faced by some countries, as well as the news that a number of African countries had joined UNITAID's list of donors.

Many members, including FRANCE, NORWAY AND KOREA expressed general support for the budget proposals, but raised concerns over the Secretariat's intentions to increase its staff numbers, especially given global financial constraints and the fact that many organizations were currently trying to reduce numbers of staff. The REPRESENTATIVE OF FRANCE acknowledged the importance of communication activities but said that France nevertheless had some concerns about the projected expenditure proposed in the budget. He said that it was very important for France to be coherent in the face of the economic crisis. Whilst France understood the need for some supplementary expenses in 2012, it was noted that the 2011 budget was not fully spent, so France could see no reason to increase from the level agreed for 2011.

The REPRESENTATIVE OF NORWAY expressed support for France's comments and called for a discussion on the strategy for the staffing of the Secretariat. In particular, NORWAY was uncomfortable regarding the timing of the increase in external relations activities. NORWAY therefore proposed that a final decision on exact numbers for increased staff should only be set once the 5-Year Evaluation had been completed and the strategy approved for 2013–2015.

The REPRESENTATIVE OF THE GATES FOUNDATION expressed broad support for the proposed budget, noting that the growth was in the right places. However, she said that within the Gates Foundation, they tended to believe that additional staffing should not be approved until at least 90% of existing positions have been filled. She therefore supported Norway and suggested that smaller Secretariat growth should be approved initially. A further review of numbers could take place at a later stage, depending on the needs identified in the context of the Strategy. The REPRESENTATIVE OF ASIAN COUNTRIES said that she echoed the comments of the Constituency of Foundations, requesting the Secretariat to prioritize the HR Plan. The NGOs said they felt comfortable with the staffing proposals.

Responding specifically to the points made by France, THE CHAIR said that the work of the Market Dynamics Team was used by the Global Health Community and not UNITAID alone. He argued that the seven additional UNITAID posts which were proposed in this area would therefore enable the Global Fund to cut its costs. However, the REPRESENTATIVE OF THE UNITED KINGDOM cautioned against using UNITAID money to make up for any shortfall in the funds of the Global Fund. He said it would be difficult for the UK to accept that France and the UK were being asked to channel even more money to the Global Fund, as in doing so they would simply be making up for the shortfalls of countries which are not part of UNITAID. Nevertheless, he said that the UK was broadly supportive of the Budget, including the proposed increases in staffing, although the proposed implementation might be too fast.

Responding to some of the comments, the EXECUTIVE DIRECTOR said that he understood that the Secretariat might be proposing to increase staffing to an optimal level too quickly. However, in response to the comments of the Gates Foundation, he clarified that while the current human resource plan had specified 48 positions, the Secretariat's current staffing level was above capacity (52 persons), as it had needed to bring in a number of people on short-term contracts, to ensure it met expectations and demands. In addition, some of the positions that were now being requested reflected the fact that previously frozen recruitment processes were now unfrozen. He assured members that the Secretariat was very careful to ensure that all the proposed positions were needed. Nevertheless, the Secretariat could look to expand more slowly, particularly in the areas of communications and external relations. .

The Board had previously requested a robust market dynamics capacity within the Secretariat in order to analyse markets and, as a result of that, a strong team with a high level of expertise was now in place. However this came at a premium, as there were few people globally with the appropriate experience and expertise of analysing developing country markets and assessing the levels of goods and commodities needed and how to make them available at the lowest possible price. The budget therefore needed to reflect the cost of that market dynamics team, otherwise the Secretariat would not be able to produce the analyses and the results that were required, not only for use by the Board but also by many other partners.

Responding to a question from WHO, he confirmed that the budget for the proposed staff increases did include other potential costs, such as indemnities and

severance pay. UNITAID was committed to ensuring that whatever happened, no financial burden would be placed on WHO itself. He also welcomed the suggestion from WHO that outsourcing could provide some of the needs in the areas such as market dynamics at less cost and said that the Secretariat would explore the option further.

Following questions on the provisions budget, he explained that the move of the Secretariat was accounted for in that, but it was hoped that the provision would not need to be used as WHO had indicated that it might be able to relocate UNITAID to another part of the headquarters building. The provision would only need to be used if that was not the case and the Secretariat had to move elsewhere. FRANCE commented that relocation would not be reasonable at this time and funds must not be used for that purpose.

The REPRESENTATIVE OF THE GATES FOUNDATION has seen remarkable impact of the support provided to the civil society delegations and suggested to extend support to members of the Board other than the civil society delegations on a more principle-based approach, such as those from implementing missions or implementing groups or those representing a large number of countries and that could be useful for the FAC to consider putting a principle on how UNITAID support delegations. The REPRESENTATIVE OF NGOS said that her delegation could provide information on the model that it used for preparing its requests to the Board.

The EXECUTIVE DIRECTOR said that the proposed budget could be revised following the comments made by members regarding the Secretariat budget. Certain budgeted expenses could be postponed until after 2012 and some recruitment in the area of communications and external relations could also be delayed. The Gates Foundation had also indicated previously that it may provide extra funds to help with establishing the strategy for 2013–2015 and, in that case, the budget could be reduced further.

Following proposed revisions to the proposed budget, the Executive Board agreed to approve the budget for 2012.

DECISION

The Executive Board adopted by consensus Resolution No. 9 on the Budget for 2012 (document UNITAID/EB15/2011/R9) and Resolution No. 2 on Office of the Chair of the Board: Budget 2012 (document UNITAID/EB15/2011/R2)

The CHAIR OF THE FAC gave a presentation to the Board on risk management at UNITAID and a proposed action plan for set of activities to be taken in that regard in 2012 in the areas of governance and management.

He then provided information on UNITAID's funding capacity, explaining that the FAC had requested the Secretariat to provide scenarios for a fixed minimum annual funding ceiling. The FAC had also noted the importance of taking into consideration all present and future risks and opportunities when determining funding levels. Financial decision-making needed to be finely balanced, as having too little or too much funding capacity could have unwanted consequences. UNITAID used a tool whereby funding capacity indicated how much the organization could potentially invest and the project funding ceiling indicated how much the organization should invest. Based on the current situation, UNITAID's funding capacity stood at US\$ 533 million and, after accounting for risk mitigation and reserving funds for certain particular expenses, such as potential project extensions and diagnostics proposals, the current project funding ceiling stood at US\$ 107 million. The

Secretariat provided scenarios for future funding capacity if multi-year and annual contributions remained at current level and if those contributions dropped to 70% of the current level.

DECISION

The Executive Board adopted by consensus and Resolution No. 3 on Risk Management (document UNITAID/EB15/2011/3)

b) Funding decision framework

The CHAIR OF THE FAC gave a brief presentation on the proposed funding decision framework and said that, in its discussions, the FAC had emphasized the need to ensure consistency in how all types of projects were considered and to also allow the Secretariat sufficient flexibility to approve some cost or no-cost extensions without having to put them before the Board each time.

The Secretariat had provided three scenarios for those extensions and, after an in-depth analysis, recommended that the more appropriate term “change requests” be used instead of cost or no-cost extensions, and that all such requests should first be analysed to establish whether or not they warranted the development of a new project.

After welcoming the three proposed scenarios, the REPRESENTATIVE OF THE GATES FOUNDATION requested that the framework be modified to ensure that it made explicitly clear that all projects and special projects would be approved and reviewed according to the same criteria and also that the PRC would have a clear role in reviewing both.

After comments by the REPRESENTATIVE OF ASIAN COUNTRIES that Scenario 1 seemed the most appropriate as it respected Board decisions but also allowed some flexibility to the Secretariat, the Executive Board agreed to approve the funding decision framework, specifying that Scenario 1 would be implemented.

DECISION

The Executive Board adopted by consensus Resolution No. 1 on UNITAID Funding Decision Framework (document UNITAID/EB15/2011/R1), specifying that Scenario 1 should be followed

6. Report of Policy and Strategy Committee

a) PSC and FAC terms of reference and related governance reforms

The CHAIR welcomed the new Executive Board member for France, Ms Mireille Guigaz, who had taken over the role as Chair of the Policy and Strategy Committee (PSC). He expressed sincere appreciation for the work of the previous member, Mr Patrice Debré and read out a letter to the Executive Board from Mr Debré.

The REPRESENTATIVE OF FRANCE gave a brief update on the work of the PSC, including the following key points and recommendations:

- The PSC had discussed the terms of reference for the Committee and brought them into line with those of the FAC;

- The PSC felt that the standing committees that were not active should be disbanded and their mandates should be divided among the remaining committees;
- The PSC suggested that the consultative forum should be held every two years;
- The call for proposals for diagnostics had yielded 10 projects that would submit full proposals to the Proposal Review Committee (PRC), with the Executive Board taking the final decision in 2012;
- The PSC recommended that a call for letters of intent (LOIs) in the reactive route should be issued in early 2012, and for the proactive route in the second half of 2012.

The Executive Board considered the draft Resolution on the PSC and FAC terms of reference and related governance reforms.

The REPRESENTATIVE OF THE GATES FOUNDATION, supported by the UNITED KINGDOM, suggested that the FAC should not be renamed as the Finance and Audit Committee as audit was a very important element and the best practice was to separate the finance and audit roles within an organization in order to ensure the independence of the audit process. Further discussion of that issue was needed by the FAC, and it would be useful if the FAC could be briefed by the WHO Auditor to enhance its understanding of the implications of such a name change. Responding to this, the EXECUTIVE DIRECTOR explained that the finance and audit functions were clearly separated within the Secretariat and that the Finance and Audit Committee would only be responsible for reviewing the performance and results of the audits. However, it would be possible to review the issue further at a later meeting if preferred. The WHO LEGAL OFFICER added that the auditing of UNITAID was the responsibility of WHO, but that it would be possible to consult with the Committee on the audit activities.

The EXECUTIVE DIRECTOR, responded to the concerns expressed by the Communities Living with the Diseases regarding the disbanding of the Communications Committee. He explained that in the past, there had been uneven performance by the Secretariat in the area of Communications, so the Board had become involved. However, in principle, Communications is a Secretariat issue. The Secretariat was in the process of developing a new Communications Strategy that would address gaps and improve communications activities within the Secretariat. Since the Secretariat was now active, the Board should wait in order to judge the results.

THE REPRESENTATIVE OF BRAZIL stressed that although the main administrative functions should be within the purview of the Secretariat, but that it was important that the language in the terms of reference be clear that certain administrative aspects, such as the human resources plan, required Executive Board approval. The NGOs added that, in light of the absence of funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) for transition of projects, the FAC, in collaboration with the PSC, should carry out a full analysis of the portfolio.

DECISION

The Executive Board adopted by consensus Resolution No.10 on the PSC and FAC Terms of Reference and related Governance Reforms (document UNITAID/EB15/2011/R10), as amended during the meeting.

7. Update on the 5-Year Evaluation of UNITAID

The CHAIR OF THE INDEPENDENT STEERING COMMITTEE (ISC) gave a short update on the 5-Year Evaluation. The ISC had taken into account the request from the Executive Board to assess UNITAID's performance with the goal of identifying how UNITAID could strategically leverage its strengths to increase its impact on markets and catalyze improved public health outcomes. It would also consider the previous evaluations carried out by the United Kingdom and France when undertaking the evaluation as well as UNITAID's mid-term and final project evaluations. The draft timetable and projected budget had been reviewed. The budget had incorporated the hiring of an additional expert in areas specified by the Executive Board. In addition, the terms of reference for selection of the working-level evaluation team had been developed. The request for proposals had been widely disseminated, including through Board members, and to date, 20 firms of varying sizes had announced their intention to submit proposals.

Responding to the presentation, the REPRESENTATIVE OF THE COMMUNITIES LIVING WITH THE DISEASES said that the terms of reference for the 5-Year Evaluation should include reference to the incorporation of the results of the in-country reviews of projects carried out by the Community Support Team and the evaluation of the functioning of the Executive Board. In addition, the evaluation team should also include media and market experts and it was important that the PSC should guide the evaluation process.

The CHAIR expressed his appreciation for the work of the ISC to date and requested that the evaluation also look at innovative financing. He also suggested that it would be useful to include an economist on the Committee because the world was currently trying to find a new financial model.

8. Review of processes to update the Strategy 2013–2015

The SECRETARIAT gave a brief update on the development of the strategy for 2013–2015. The process should take one year, and it would be important to bear in mind the current strategy and the work that had been completed to date in areas such as market intelligence, market dynamics and operations. The results of the 5-Year Evaluation would be instrumental in guiding the development of the new strategy, when they became available. In order to start the process and ensure that it would be effective, it was necessary to develop terms of reference for the development of the strategy, and the member for the Constituency of Foundations had agreed to work with the Secretariat on that issue, as he had prior experience in that area. It was expected that the deliverables for the project would be developed by December 2012. It was also important that time be allocated to allow review of the terms of reference and deliverables by the Executive Board.

The REPRESENTATIVES OF ASIAN COUNTRIES and NORWAY welcomed the proposal to include time for review by the Executive Board in the timeline for the strategy review and development process. The REPRESENTATIVE OF ASIAN COUNTRIES added that it would be useful if the new strategy could be submitted to the PSC and Executive Board earlier than planned, in order to ensure that there was time for an in-depth review. Several members welcomed the proposal that the results of the 5-Year Evaluation should be used when developing the new draft strategy and REPRESENTATIVE OF NORWAY suggested that, given the importance of that evaluation, discussion by the Executive Board of the new draft strategy should take place after the results of the 5-Year Evaluation had become available.

Responding to the comments, the EXECUTIVE DIRECTOR emphasized that the 5-Year Evaluation, development of the new strategy for 2013–2015 and the reforms of the Secretariat were all inter-linked and, as a result, he was unsure whether it would be possible to accelerate the strategy development process further than planned. It was important to take into account the 5-Year Evaluation and therefore it would be vital to wait until the results were made available.

The Executive Board considered the draft Resolution on the review of processes for the update of the strategy 2013–2015.

DECISION

The Executive Board adopted Resolution No. 4 on Review of processes for the update of the Strategy 2013–2015 (document UNITAID/EB15/2011/R4)

9. Update on Operations

a) Report on implementation of projects

The SECRETARIAT gave a presentation of the status of current UNITAID projects approved by the Executive Board, including information on the achievements, trends in medication uptake by disease area, the next steps for those projects that were due to finish in the near future, the effectiveness of partners, and the next steps for the Operations team.

The REPRESENTATIVE OF ASIAN COUNTRIES encouraged the Secretariat to develop a better project management system in order to better assist implementing partners to submit their reports in a timely manner and welcomed the results from the mid-term review of projects.

10. Update on the Call for Letter of Intent for Diagnostics

The SECRETARIAT gave a presentation on the call for letters of intent (LOIs) for diagnostics. The proponents of those LOIs that had successfully passed the initial Secretariat screening process had been requested to submit full proposals by 19th January 2012, which would then be screened by the Secretariat and submitted to the PRC for full analysis. At present, the total cost of the ten proposals that had passed the initial process was in the region of US\$ 330 million; however, thanks to the landscape analysis carried out by the Secretariat, it had been possible to negotiate a lower budget. The presentation also included information on the proposals by disease area and information on the failed LOIs. It was felt that the new LOI process had been successful and had led to proposals that supported UNITAID's market impact framework. The process had also attracted a number of new proponents. The Secretariat would continue to update and refine its approach to project selection and prioritization, taking into account the lessons learned from the call for proposals for diagnostics.

The REPRESENTATIVE OF ASIAN COUNTRIES welcomed the success of the LOI process but expressed concern that 6 out of 10 of the successful LOIs came from existing partners. The Secretariat should take steps to disseminate calls to an increased number of potential partners. The REPRESENTATIVE OF THE GATES FOUNDATION said that a number of the successful LOIs could be seen as complimentary to existing UNITAID-funded projects. The Chair added that it was

important to make UNITAID an effective and efficient player on the global stage and to show that UNITAID had significant market impact. Therefore, he welcomed the new developments and proposals in diagnostics. It would also be useful to see a more detailed analysis of the HIV/AIDS landscape.

Responding to the comments made by the Asian Countries, the SECRETARIAT explained that although 6 out of 10 of the successful LOIs were led by existing partners, all the proposals included consortiums, including 13 new partners.

11. HIV/AIDS Diagnostics Technologies: supporting market entry

The SECRETARIAT gave a presentation on supporting market entry for novel HIV diagnostics technologies. Since the last meeting of the PSC, the Secretariat had made a concerted effort to increase its understanding of the market space, through interviews and meetings with developers, academics and global health organizations. It had been noted that there was currently no global registration process to help streamline the in-country registration processes. There was currently a funding gap in this area as many devices only received funding grants in the early development stage and private funding was difficult to access. This led to fewer products reaching the market, limited competition and limited incentives to enter the market. There were a number of short- and long-term options for UNITAID intervention, such as providing support for companies for late-stage field evaluations (short-term) and contributing to the establishment of a global body to assess the quality of new products (long-term). It would be important to ensure that any short-term UNITAID input would substantially alter the path to market. The Secretariat was investigating potential funding sources, such as co-financing approaches and other innovative funding options. With regard to the proposal review process, it would be useful to include experts from the diagnostics industry in that process, for example in a PRC subgroup. The Secretariat would develop an implementation plan for market entry support, including a timeline for consideration of proposals by the Executive Board.

The REPRESENTATIVE OF ASIAN COUNTRIES expressed concern that any potential grant from UNITAID in this area would only have a short impact. The NGOs said that if the product was needed by the market then any UNITAID intervention would be worthwhile, however it would be important to ensure that UNITAID would receive good access to the product once it had reached the market.

With regard to the registration issues, the REPRESENTATIVE OF NGOS said that it had received information that the main problems were the lack of registration and the registration requirements, which highlighted the need for a strong WHO prequalification process. The REPRESENTATIVE OF ASIAN COUNTRIES said that that UNITAID should play a significant role in the development of any global quality assurance mechanism. Lessons could be learnt from how WHO had evaluated and endorsed the GeneXpert system, as this was a very efficient process.

Turning to the draft resolution, WHO proposed an amendment to include reference to consultation with technical partners, including WHO, which members agreed to include.

DECISION

The Executive Board adopted by consensus Resolution No. 5 on support for products in late stage field evaluation and registration (market entry) (document UNITAID/EB15/2011/R5), as amended during the meeting

12. Presentation of WHO's strategy on prequalification

The WHO ASSISTANT DIRECTOR-GENERAL FOR INNOVATION, INFORMATION, EVIDENCE AND RESEARCH gave a presentation on the WHO strategy on prequalification, in which she explained that the current service was mainly used by United Nations procurement agencies and organizations such as the Global Fund and was mainly employed for vaccines, immunization devices and diagnostic tests. The key challenges for developing an organization-wide prequalification policy included the growing workload, funding constraints, inefficiencies in the process, conflicts of interest, internal and external communication and the need for a quality management system. Any new prequalification policy should be equitable, inclusive, practical and feasible and should be self-sustainable with regard to funding. It was also important to attract new funding and develop innovative solutions. A number of stakeholders and industry representatives had been consulted regarding the new policy, which had produced a number of recommendations. The next steps included communicating the report to the WHO Director-General and harmonizing procedures across all prequalification teams.

A number of members expressed concern that it appeared that WHO was moving towards handing prequalification responsibilities over to national regulatory authorities. The CHAIR stressed that the current trend was to approach issues such as prequalification from a global or regional, rather than national, perspective. In addition, prequalification was a very technical issue and should not be solely the responsibility of countries, particularly low-resource countries. The NGOs suggested that in the long term, regional centres could be the best solution. In addition, she expressed concern that the Essential Medications department of WHO would be severely affected by the internal reforms being undertaken. THE REPRESENTATIVE OF BRAZIL explained that there were a number of national regulatory agencies working together in the Latin American and Caribbean region by carrying out joint activities and inspections. He also asked whether the results of the consultations would also be submitted to the WHO Governing Bodies. THE REPRESENTATIVE OF COMMUNITIES LIVING WITH THE DISEASES questioned whether WHO envisaged providing support to developing countries to develop some kind of regional process. THE REPRESENTATIVE OF FRANCE, echoing a number of members, stressed the importance of having a neutral regulator to, inter alia, oversee conflict of interest situations.

The representative of the ROLL BACK MALARIA PARTNERSHIP said that his organization attached great importance to the prequalification of diagnostics tools and a potential partnership would create an enabling environment for prequalification and standardization activities. WHO could count on Roll Back Malaria and other partners for support in that area.

Responding to a comment by BRAZIL regarding a prequalification section within the Pan-American Health Organization (PAHO), the WHO ASSISTANT DIRECTOR-GENERAL FOR INNOVATION, INFORMATION, EVIDENCE AND RESEARCH explained that there were discussions ongoing with PAHO regarding a possible prequalification role, but at the present time, the only office doing prequalification activities was WHO headquarters. In addition, the WHO prequalification activities were not meant to take the place of regional networks, but rather provide advice on safety, as many countries did not have the capacity to regulate that area. Addressing the concerns regarding to a move towards national regulation, she explained that WHO would continue to play a role in prequalification for as long as it was needed, but it would continue to provide assistance to countries to strengthen their national regulatory authorities and develop regional regulatory authorities. There were currently no plans to submit the results of the consultations to the WHO Governing

Bodies, however the Director-General would consider the results and decide the next steps. In response to a question from the CHAIR regarding funding, she explained that WHO had been advised that it needed to develop a new funding mechanism involving internal and external sources. The current funding model for prequalification, which was based on grants, was not sustainable, and since prequalification was a service, it should be funded as such.

13. Update on UNITAID ACT forecasting outcomes

The REPRESENTATIVE OF THE BOSTON CONSULTING GROUP gave a presentation on malaria medicines landscaping and forecasting and said that the firm had been commissioned by the Secretariat to develop a landscape that mapped current and future trends in disease burden, product development and market evaluation for malaria medicines. In his presentation he provided a market overview, explained current market shortcomings and identified possible market interventions. Market shortcomings existed in the areas of availability, quality, affordability, acceptability and delivery of medicines, but a number of potential interventions existed with short-term objectives (improving access to quality and affordable treatments), medium-term objectives (stabilizing supply and demand for ACTs) and long-term objectives (ensuring sustainable ACTs and affordability and limiting resistance and over-treatment).

Several members welcomed the presentation and the highly detailed and informative level of data that had been provided. The REPRESENTATIVE OF THE GATES FOUNDATION in particular requested that more information be provided in future on the cyclical nature of artemisinin, given that it was a plant-based product, and how that affected the market, and on the potential impact that semi-synthetic forms would have on the market.

The REPRESENTATIVE OF NGOS expressed grave concerns over the situation earlier in the year when the huge numbers of orders for ACTs had led to shortages and speculation in the raw materials market. Careful examination was needed of the role that the AMFm and, by extension, UNITAID had played in the destabilization of that market. The situation had raised serious issues regarding management and oversight.

The REPRESENTATIVE OF THE ROLL BACK MALARIA PARTNERSHIP said that one important factor to consider in the global ACT landscape was the number of people who received ACTs, the number that actually needed ACTs and the extent to which those figures overlapped, as it was very difficult to measure effectively how many people who needed ACTs actually received them. To resolve that, one important step was to prioritize reducing the waste of ACTs; some opportunities did exist in the public sector to scale up access to rapid diagnostic tests (RDTs), although the cost of RDTs was still three to four times that of ACTs.

Other factors that needed to be addressed included improving access to ACTs in remote areas through the public-sector health systems; many people in those areas did receive anti-malarial treatments through private sector channels and some stakeholders thought that private-sector pipelines should be enhanced to ensure that ACTs reached those in need. Others believed that public-sector capacity should be strengthened, including through increasing numbers of community health workers.

Responding to the NGOs, he said that the forecasts for demand for treatments in the first two years of the AMFm (approximately 300 million) had been made known to the UNITAID Board, the Global Fund as well as retailers and manufacturers. However, the situation earlier in the year had arisen as a result of manufacturers not expecting such large scale up of the AMFm and therefore not placing orders for artemisinin in line with the forecasts made. The potential problems in scaling up were anticipated by UNITAID, RBM and WHO, leading to the creation of the Assured Artemisinin Supply System (A2S2), which helped to provide a further 26 tons of artemisinin, or approximately 55–60 million treatments. Increased confidence among other manufacturers at that point led to the production of approximately a further 30–50 million treatments. Without the existence of A2S2 the situation would certainly have been dire, with many orders disrupted, the suspension of the AMFm and shortages in many countries. However, any serious destabilization of the market had been avoided and the steps taken meant that no such situation would arise in the coming year.

The NGOs welcomed the clarifications provided and the assurances that such a situation would not arise again in future but reiterated that UNITAID's role comprised ensuring that the AMFm was scaled up in such a way as to not disrupt the raw materials market, even for a short period, or to increase the cost of those materials.

The DIRECTOR OF THE AMFm said that, based on the best information currently available, and after independent price tracking exercises by Health Action International, the retail prices of AMFm subsidized ACTs had reduced significantly in all countries and were less expensive than comparative therapies. In addition, ACTs were now between 1.5 and 3 times the price of non-ACT treatments, which was well within the benchmark set for what would be considered a success after the first year of the AMFm. The current information also showed that availability was now very high in the private sector and that price and penetration in remote areas had reached good levels, while recent studies had shown that the uptake of subsidized ACTs was disproportionately high among illiterate persons and households.

The AMFm model had shown that it had the capacity to bring a product to periphery areas at very reduced costs, meaning that the same mechanism could now potentially be used to do the same for RDTs. In the short term, however, such a mechanism would not bring about the same level of reduction in the price of RDTs as had been seen with the ACTs; in fact in the short term the prices would likely increase, but over the longer term total costs would decrease significantly.

The REPRESENTATIVE OF THE COMMUNITIES LIVING WITH THE DISEASES said that a number of monotherapies still existed in many countries despite the fact that they should have been eliminated as a result of AMFm's presence in those countries. She asked the AMFm to put in place measures to ensure elimination of monotherapies, including in non-AMFm countries, as they continue to jeopardize the treatment of malaria.

14. Update on Medicines Patent Pool Foundation

The EXECUTIVE DIRECTOR OF THE MEDICINES PATENT POOL FOUNDATION (MPPF) gave a presentation to the Board, including information on the review of its first year's milestones, the current status of negotiations with patent holders, the products that were a priority for the Patent Pool, and the four-year plan for core activities.

She provided more detailed information on the recently signed licence agreement between the Patent Pool and Gilead, including on its geographic scope. The Gilead licence had since been out-licensed to two generic pharmaceutical companies and the Patent Pool was in discussion with others.

After one year of activity of the Patent Pool, a number of companies had shown interest in licensing to the Pool or taking licences from the Pool. Political and public support for the Pool was essential in being able to advance negotiations, and it was clear that company engagement was an ongoing process, as three amendments had already been made to the Gilead licence since it was first agreed. The transparency of the agreements signed so far was a key achievement but would continue to require the appropriate management of responses and queries from other stakeholders.

The REPRESENTATIVE OF BRAZIL raised its concerns over the limited geographic scope of the Gilead licence agreement and the fact that the agreement provided for significant geographical limitations regarding the countries in which manufacturers were authorized to use the technology licensed by Gilead. Brazil recognized the importance of any agreement made with the Medicines Patent Pool but could not accept those that favoured or discriminated against certain countries of manufacture. Ministers in Brazil had agreed on the need for the participation of all countries that were capable of producing medicines within the scope of the agreement as a key element of reducing costs and improving access. They were disappointed that Brazil itself could not engage in the manufacturing of generic products, as the agreement had limited production to a small number of generic manufacturers in India, thus diminishing the capacity of the agreement to increase competition. The message from the Brazilian Government was that it would not be prepared to support future agreements if their scope did not extend to all low- and middle-income countries and all manufacturers.

The DELEGATION OF BRAZIL concluded by underlining the sensitive nature of this issue for Brazil and explaining that they had been instructed to read out a letter addressing these issues, which had been sent by Brazil to the Chair of the UNITAID Board. The letter was read and was therefore read out during the meeting and the text of that letter can be found in Annex 2 to this report.

Responding to a question from the NGOs on whether Gilead was also aware of Brazil's views on the agreement, Brazil confirmed that it had recently taken part in a forum at which a representative of Gilead was also present and had taken the opportunity to voice its concerns on the licence agreement.

The EXECUTIVE DIRECTOR OF THE MPPF welcomed the comments made by Brazil and the strong desire that the country had to use its production capacity for the manufacture of generic products under Patent Pool licensing agreements. It was hoped that Brazil would be able to contribute in future to filling some of the gaps that currently existed in the production of ARVs.

While the Memorandum of Understanding with the MPPF made reference to geographic scope including low- and middle-income countries, she underscored the fact that the voluntary nature of licensing agreements with the Patent Pool would lead to some limitations. The guiding principle of the work of the MPPF, however, was to ensure that no country excluded from the scope of agreements was ever worse off as a result of those agreements. Efforts also continued to be made to

improve upon agreements and to provide incentives to companies to extend the geographic scope, both for the production and consumption of products.

Moving on to respond to questions put forward by the NGOs regarding the collection of royalties and potential conflict of interest, the DIRECTOR OF THE MPPF said that its Board had discussed the option of forgoing the collection of royalties. The amount of royalties that could be gained from the licensing agreement with Gilead was only very small (US\$ 8000 over four years), which the Foundation did not believe would give rise to any conflict of interest. However, it did take the perception of conflict of interest very seriously and was willing to reconsider the collection of royalties if it was felt that it was not appropriate.

Responding to questions from the REPRESENTATIVE OF THE GATES FOUNDATION on both the milestones and staffing of the MPPF, she said first that, on the milestones, there was certainly a need to define them further, which would be done in collaboration with UNITAID and once further guidance had been received. She welcomed the suggestion by the Constituency of Foundations that, in future, milestones should focus first on the objectives on the Patent Pool to deliver new products to the market and to reduce costs, rather than setting targets for the number of licences to be signed, for example. Such an approach was in line with the priority setting work that had been done by the MPPF. With the support of experts from WHO, WIPO and others, the Patent Pool had looked at medicines prioritization and had matched it with potential intellectual property barriers, which would help to further guide the formulation of milestones in future.

On staffing, she said that the original numbers specified had been informed by the design of other patent pools, but it had not been possible to make a direct comparison as their work was very different and they were mostly housed in larger commercial corporations with a high level of resources. The proposed expansion of the Secretariat of the MPPF by seven people was in response to the increased workload that was envisaged. However, the final number was not yet set in stone and any expansion would depend on what progress was achieved in negotiations and licence agreements.

15. Proposals for funding decision

The meeting resumed at 9.10 a.m. on Tuesday 13 December 2011 in a restricted session.

Introducing the item, the CHAIR thanked Professor James McIntyre for his work as Chair of the PRC. As Professor McIntyre had accepted the position of Chair of the Advisory Group on Funding Priorities (AGFP), the Vice Chair of the PRC, Mr Andy Gray, would take over steering the Committee.

a) *Update on findings and recommendations of the Proposal Review Committee*

The CHAIR OF THE PRC gave an update on the work of that Committee, explaining the process followed by the Committee when considering proposals. The most recent reviews had been the first using the new review sheets, meaning feedback from the Executive Board on the sheets was needed. The PRC had also expressed concern regarding the amount of time allocated to them for review of the proposals. With regard to the specific proposals, he reminded the Executive Board that the additional information that had been requested regarding the proposals had

already been received for the AMFm cost extension request, and the Medicines Patent Pool Foundation Proposal. There had been a move to incorporate PRC review of proposals as one of a number of elements of the information presented to the Executive Board. That approach had a number of positive and negative aspects and would require further discussion. The PRC had discussed the proposals and had agreed to submit three for consideration by the Executive Board. It had been considered that proposal for an extension to the A2S2 project required further clarification from the partner before it should be submitted to the Executive Board for consideration.

b) Proposals

i. Paediatric HIV/AIDS Treatment Project

The CHAIR OF THE PRC summarized the Committee's review of the Clinton Health Access Initiative (CHAI) proposal for an extension of its Paediatric HIV/AIDS Treatment Project. He explained that the main issue related to the cancellation of the Global Fund's Round 11 funding, but that CHAI had put forward a well-organized proposal regarding transition. The PRC was in favour of the extension of the project, although it had concerns about how CHAI would manage the shrinking market, how the extension for second-line treatment would be handled and how to maintain the market impact gained after the end of the CHAI project.

The REPRESENTATIVE OF THE UNITED KINGDOM questioned whether an up-to-date, real-time analysis of market data could be included in the information provided to the Executive Board. He welcomed the proposal review process used by the PRC but expressed concern about the way that the information was presented to the Executive Board, as the current method suggested that the PRC had serious concerns about the proposal, while in fact, the majority of those concerns had already been addressed by the proponent. The CHAIR OF THE PRC responded that it was important to find a balance between completing the reviews on time and presenting the information. The clarifications requested were usually submitted to the Executive Board for approval prior to being sent to proponents, although that had not happened for the proposal in question, as there had not been sufficient time. That approach had been successful, and should be considered in future, but it would be important to factor in additional time for the PRC to review the clarifications received, either by teleconference or in person.

The Executive Board considered the draft Resolution on the UNITAID funded paediatric HIV/AIDS treatment project – extension for 2012 funding.

Questions were raised regarding the view of the PRC on the effect of the Prevention of Mother to Child Transition (PMTCT) project would have on the paediatric market and of the potential risks for transitioning in 2012. The CHAIR OF THE PRC acknowledged that a detailed analysis of the effect of the PMTCT project was needed. The alternate for the NGOs, supported by the REPRESENTATIVES OF THE GATES FOUNDATION and the COMMUNITIES LIVING WITH THE DISEASES, said that it was important to take a strategic view of the project and that UNITAID should remain involved in the area for the next few years. A key issue in future would be how to address problems that arose in countries after successful transition of the project.

The REPRESENTATIVE OF THE GATES FOUNDATION raised questions regarding the approach planned by CHAI for countries that were reliant on Round 11 funding from the Global Fund, and the rate of disbursement of funding to CHAI in previous years. The SECRETARIAT explained that a new disbursement process was being

tested with CHAI, in which funds were transferred as soon as CHAI was ready to distribute to suppliers. That had led to lower levels of disbursement, but not reduced performance. Responding to a question posed by the CHAIR regarding monitoring of results in the field, the SECRETARIAT explained that it was in the process of implementing a number of review processes, with the cooperation of CHAI, in areas such as the purchase system used and the distribution of medication. The Secretariat had notified CHAI of its wish to receive reports from the field more quickly, and CHAI had cooperated fully with that. Moreover the process of receiving reports from the field differed for United Nations agencies, to which the CHAIR responded that it was important that it was made clear to such agencies that transparency regarding activities on the ground was vital. The CHAIR requested that at the next Executive Board meeting, a discussion should be included on reports from the field.

DECISION

The Executive Board adopted Resolution No. 6 on the UNITAID funded paediatric HIV/AIDS treatment project – extension for 2012 funding (document UNITAID/EB15/2011/R6)

ii. AMFm Phase 1 cost extension

The CHAIR OF THE PRC summarized the Committee's review of the AMFm extension proposal submitted by the Global Fund to Fight AIDS, Tuberculosis and Malaria. The initial review had raised a number of issues related to the timeline and the need for increased focus on rapid diagnostics tests. Further consultation with the partner had occurred and clarification of issues had been received, but the PRC felt that additional clarification was required on the price difference and the situation with the other donor for the project. However, the PRC felt that it was important that the phase one of the project should be completed to allow a full evaluation.

Concerns were expressed regarding the lack of UNITAID representation in the governance of AMFm and the REPRESENTATIVE OF FRANCE insisted that the issue should be reflected in the draft Resolution. The REPRESENTATIVE OF NORWAY suggested that it may be more effective for UNITAID to have a normal role rather than being Chair or Vice-Chair, as had previously been the case, as it would allow the UNITAID to express its views more fully. Members also had concerns regarding the level of funding and the speed at which the funding was used.

The REPRESENTATIVE OF the UNITED KINGDOM said that the UK wants to see Phase I completed but is agnostic regarding Phase II. The UK will evaluate Phase I before deciding on Phase II.

The REPRESENTATIVE OF THE GATES FOUNDATION said that they were incredibly supportive of Phase I but did not yet know about Phase II. She explained that Gates supported AMFm indirectly, through the funding of CHAI's participation (i.e. funding of research and the ACT Watch). However, since Gates was primarily a product funder, rather than a market dynamics funder, they did not have the funds in their budget to invest in AMFm directly.

Regarding governance, the REPRESENTATIVE OF THE GATES FOUNDATION said there was no need for UNITAID to be involved in the governance to manage this grant to the Global Fund, although for different reasons it would be essential that UNITAID have a seat on the Global Fund's Market Dynamics Committee.

DECISION

The Executive Board adopted Resolution No. 7 on the Affordable Medicines Facility – malaria extension proposal (document UNITAID/EB15/2011/R7), as amended during the meeting.

Following the end of the restricted session, and at the invitation of the Chair, the REPRESENTATIVE OF THE AMFm, took the floor. He expressed appreciation for the decision of the Executive Board to continue co-funding AMFm and said that he was satisfied with the progress made by the project, in particular the reduction of price by 40% in some countries as a result of private sector investment and public sector co-financing. He also welcomed the cooperation between UNITAID and the Global Fund.

iii. Medicines Patent Pool Foundation (2012–2015)

The CHAIR OF THE PRC summarized the Committee's review of the funding request for the MPPF. He explained that since the MPPF had originated from within UNITAID, the PRC had not reviewed the initial proposal and had a specific mandate with regard to its review activities for proposals received from the MPPF. That mandate was to review and provide comments on the business plan of the MPPF, rather than reviewing its progress. The Committee had requested a number of clarifications, which had been received prior to the meeting and included in the documentation provided to the Executive Board. The PRC still had a couple of concerns regarding key performance indicators (KPIs) and staffing, which had also been raised by Executive Board members during the discussion of the agenda item on the update from the MPPF.

THE REPRESENTATIVE OF NGOS said there were strong feelings within the NGO Constituency that a strong, functioning Patent Pool was needed but there was nevertheless disappointment with the first licence, particularly regarding the limited geographical scope and restrictions on production sites. Standard terms and conditions should be developed for licences. The NGOs also wanted the Patent Pool to engage much more actively with civil society at large.

The NGOs called the payment of royalties to the Patent Pool by licensors to be dropped from the Pool's business model, as this was resulting in the perception of a conflict of interest. They also underlined the importance of ensuring that countries do not use the Patent Pool as an excuse to do nothing else to address access to medicines – e.g. for failing to implement the TRIPS flexibilities.

The REPRESENTATIVE OF NGOS said that ultimately, they wanted the Patent Pool to succeed, so it was important to give it a four year funding commitment, subject to the Secretariat agreeing Milestones each year. The Board would give guidance on those Milestones.

The CHAIR responded by asking the NGO delegates to ensure they represented an effective communication channel for NGOs. The REPRESENTATIVE OF NGOS responded that the NGO delegation took the process of engaging with stakeholders very seriously. She said it was fair to say that civil society wanted to see the Patent Pool concept tested. The NGO delegation would prefer civil society stakeholders to address any concerns through them but could not prevent civil society from making direct contact.

The REPRESENTATIVE OF FRANCE said that France supported the NGO's view that there should be an annual review of the Patent Pool by the Board. The CHAIR also agreed with this.

THE REPRESENTATIVE OF BRAZIL suggested the amendment of the draft Board Resolution to include a fourth condition requiring the assessment of satisfactory performance by the Patent Pool to be based on the Milestones and the principles set out in the Board Resolution of 5 February 2010. THE REPRESENTATIVE OF CHILE supported Brazil's position

THE REPRESENTATIVE OF THE GATES FOUNDATION said that the Gates Foundation agreed with Brazil that the funding of the Patent Pool should be conditional on the attainment of Milestones. He said that the Gates Foundation had some ideas regarding those Milestones.

Regarding the requested funding, he said that the Gates Foundation could not understand any need for the requested increase in the Patent Pool's budget of US\$6 – 7m per annum because there were insufficient supporting details. He therefore put forward three options for considerations: (1) approve the funding ceiling then work with the Secretariat to refine the necessary budget; (2) approve a lower budget (e.g. US\$18 – 20m), with the possibility that a further request could be submitted by the Patent Pool if it was required; or (3) approve the ceiling then establish a process of yearly Board approved disbursements. The Gates Foundation favoured the second of their proposed options, arguing that it would give the Board more flexibility, whilst reflecting UNITAID's continued support for the Patent Pool, as well as the desire for it to succeed.

The REPRESENTATIVE OF COMMUNITIES LIVING WITH THE DISEASES said they supported Brazil's position because more competition would lead to more access and lower prices. They also supported the definition of Milestones for the Patent Pool. In addition, the representative of COMMUNITIES LIVING WITH THE DISEASES said they wanted more parties to have a say during the Patent Pool's negotiations, including civil society and countries.

As there was some disagreement on the exact wording of the draft Resolution, it was agreed that informal consultations would be held to resolve the issues.

Following informal consultations on the draft Resolution, it was explained by the WHO LEGAL OFFICER that draft Resolution requested the MPPF to submit its annually updated Work Plan and Budget to the Secretariat and that both documents would be subject to Executive Board approval.

DECISION

The Executive Board adopted Resolution No. 8 on the funding request for the Medicines Patent Pool Foundation (document UNITAID/EB15/2011/R8), as amended during the meeting.

16. Medicines landscape progress report

Following the end of the restricted session, the SECRETARIAT gave an update on the development of the medicines landscape analysis, including information on the methodology used; an overview of the emerging findings, trends, challenges and opportunities by disease area; and the next steps that would be taken.

The CHAIR expressed appreciation for the work performed by the Secretariat and suggested that the results of the landscape analysis should be published in a medical journal such as Nature or The Lancet.

17. Presentation on future opportunities in the tuberculosis niche

The REPRESENTATIVE OF THE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT (TB Alliance) gave a presentation on opportunities in the tuberculosis market. He focused on current market shortcomings, noting the evolution of drug-sensitive tuberculosis therapies and that markets have never been adequately prepared to adopt tuberculosis therapies, and went on to assess both the adult and paediatric markets. Currently in the adult market, therapies were too long and complex, there were issues relating to second-line drugs, diagnostics were inadequate and tuberculosis advocacy was ineffective. The paediatric market, meanwhile, was a largely neglected area, as market dynamics almost never justified commercial investment. The market was also highly complex and required considerable expertise across multiple areas.

There were however, a number of opportunities in both markets, including through attaining a higher impact by meeting all or most of the characteristics of the target profile of new regimens. In particular, there was much potential for a new regimen, which was expected to come onto the market within the next few years. In the paediatric markets, one of the key goals of lowering market entry barriers was envisaged through a paediatric centre of excellence which would involve the participation of several stakeholders, including national tuberculosis programmes, regulatory authorities, WHO, pharmaceutical companies, academic centres and funders.

Responding to questions from BRAZIL on the development of new products and the geographic scope of their availability once they were brought to market, the REPRESENTATIVE OF THE TB ALLIANCE said that the organization demanded concessionary pricing and held negotiations on potential costs from the beginning of its involvement with any new product. Those negotiations on pricing needed to ensure that competitive manufacturing was maintained and that any manufacturer was able to make at least a small profit and not driven out of the market. Concessions were usually agreed for all but so-called highly developed countries, as part of the incentive for pharmaceutical companies was that they could continue to make higher profit in those countries while agreeing to concessions elsewhere.

In response to a question from the REPRESENTATIVE OF THE UNITED KINGDOM on the scalability of injectable treatments, he said that when looking at the factors of patient compliance, patient acceptance, health-care system costs, and treatment costs, there was currently no injectable treatment available that could compete with oral bioavailable tablets in those areas. While injectable treatments were theoretically scalable, they were much more expensive and harder to deliver and store, and did not provide the same level of results that were seen with other forms of treatment.

The REPRESENTATIVES OF NGOs and WHO welcomed the idea of a paediatric centre of excellence but said that it should not duplicate the work of other similar entities, instead it should seek to take advantage of the work already done by others.

Responding to other comments by the REPRESENTATIVE OF NGOs on introducing drugs quickly but responsibly, the REPRESENTATIVE OF THE TB ALLIANCE

said that in some countries there was a high level of government involvement which helped to ensure rapid adoption and uptake by the market and also helped local industry to play its part.

THE REPRESENTATIVE OF WHO greatly welcomed the approach advocated by the TB Alliance in looking at multidrug regimens, especially as it would help address multidrug resistant tuberculosis and was also keen to support UNITAID in its role in preparing markets for new treatments.

18. Update on Resource Mobilization

The EXECUTIVE DIRECTOR provided an update on resource mobilization at UNITAID. He explained that UNITAID raised approximately US\$ 320 million each year, which allowed it to impact on the price of commodities, to ensure supply and to drive the production of new and affordable quality treatments. However, in future the organization would need to raise US\$ 500 million in order to cover all planned activities and to have greater impact. To achieve that level of funding, a strategic and phased approach would be needed, including preserving and securing the existing resource base, exploring new donors, advocating for further innovative financing mechanisms (including a financial transaction tax), and raising funds in the private sector. A strong external relations department would be needed to ensure that sufficient levels of resources could be mobilized, along with continued coordination with the Millennium Foundation and regular reporting to the FAC and Executive Board.

In response to a query from CHILE, the EXECUTIVE DIRECTOR explained that a Report had been commissioned from “99 Partners” by the Secretariat on the Financial Transaction Tax and this would be circulated to the Board.

The REPRESENTATIVE OF AFRICAN COUNTRIES noted the importance of holding an event in Africa to raise awareness among countries about UNITAID and the air tax. Those countries that already had experience of the air tax should share their experiences with others and explain the benefits of the air tax and how other countries could implement it.

The REPRESENTATIVE OF CHILE commented that countries needed evidence that an air tax would not deter tourists or affect airlines’ trade. The REPRESENTATIVE OF FRANCE responded that a French company had carried out a review of all airlines operating in France and had published a short article on UNITAID and how the funds raised through the air tax were used. Crucially, the article had stated that the tax had had no negative impact on air traffic and trade.

A number of members emphasized the need for UNITAID’s communications capacity to be strengthened. The CHAIR said that a viral campaign would also be valuable, as young people, who were most receptive to innovative financing, could be targeted with a short video on UNITAID, what it did, how it raised funds and where it spent its resources.

The CHAIR, responding to questions from the REPRESENTATIVE OF NGOS on the Secretariat’s capacity to carry out work, especially in the area of resource mobilization, now the budget had been adjusted and the Secretariat’s budget reduced, said that the situation would be reviewed throughout the year to ensure that the budget was able to support all of the Secretariat’s needs, especially in Market Dynamics, where further recruitment might be needed.

The CHAIR also explained that good progress had been made with regard with regard to Japan's intention to implement an air tax, though it was likely that revenue would be split between post-tsunami redevelopment efforts and UNITAID.

The REPRESENTATIVE OF THE UNITED KINGDOM said there was a need to prioritize UNITAID's resource mobilization efforts. He said that focusing on India and China would instinctively seem more worthwhile than targeting small African countries. The CHAIR responded that every country that joined UNITAID as a donor, no matter how much of a contribution that they could make, increased number of countries involved, making it easier to persuade others to join. In addition, there was a greater potential for South-South cooperation, with an increased number of African countries participating in UNITAID.

19. Review of business plan from the Millennium Foundation focusing on corporate fund raising

The MANAGING DIRECTOR OF THE MILLENNIUM FOUNDATION explained that the Foundation's Board had reviewed the Foundation. The MASSIVEGOOD Voluntary Solidarity Contribution Project and had agreed that that the project should be discontinued. All partners had been informed of that decision and the Millennium Foundation had now let go most of its staff. It was seeking to vacate its offices.

While the project had not been as successful as hoped, the technology that had been developed to allow donations to be made was now a valuable tool that could be used by other partners. UNICEF in particular was very interested in integrating the tool into its existing campaigns. Initial talks with Amadeus, the company that owned the tool, had been positive, with Amadeus agreeing to provide the tool to UNICEF for free and to provide the necessary support. There was also a possibility that the Millennium Foundation could benefit financially from the loaning of the tool to other partners.

The question now was now which direction the Millennium Foundation should take. The proposed Business Plan was that it should pursue private sector fundraising from larger companies and corporations, who could make substantial donations that could be used by UNITAID. One such opportunity that had already arisen was with the Chinese company HNA, which owned Hainan Airlines, the biggest private airline company in China. A Letter of Intent between HNA and the Millennium Foundation was due to be signed later that day and the contribution made by HNA would be transferred by the Millennium Foundation, as a donation UNITAID. It was hoped that a pipeline of similar opportunities could be built. The Foundation would be focusing primarily on countries such as China and India, where an increasing number of entities had the funds and the capacity to support UNITAID.

Once the Millennium Foundation had fully closed down the Voluntary Solidarity Contributions Project and had paid all outstanding bills, it would have US\$ 2.5 million remaining in its accounts. One option was to use those funds to finance a small Secretariat, of only one or two people dedicated to operations for the proposed private sector fundraising. The funds could then be used to grow the pipeline of opportunities for future financial donations.

Responding to questions put forward by the REPRESENTATIVE OF BRAZIL, the MANAGING DIRECTOR OF THE MILLENNIUM FOUNDATION clarified that the funds from the agreement with HNA would go in their entirety to UNITAID. However, in the future, it

would be necessary to decide whether the Millennium Foundation should take a small percentage of any donations received, in order to fund its operations, or whether the total amount of all donations should go to UNITAID, who would then allocate an agreed amount to the Millennium Foundation to cover operations. With regard to the Foundation's plans for the near future, more detailed proposals would be available following the upcoming meeting of the Millennium Foundation's Board. However, it was hoped that the Foundation would soon be able to follow up on other private sector opportunities. The Foundation would also need to develop incentives or a 'value proposition' for private sector company donations, as they would only contribute if they received something in return, such as public relations exposure.

Members noted the need to ensure the best use of resources and the REPRESENTATIVE OF BRAZIL questioned whether UNITAID itself could fundraise among the private sector, without the need for the Millennium Foundation to take on that role. The EXECUTIVE DIRECTOR responded that unlike UNITAID, the Millennium Foundation could receive donations tax free, meaning that more funds would be available for UNITAID. The MANAGING DIRECTOR OF THE MILLENNIUM FOUNDATION also explained that developing relations within the private sector and building a pipeline of opportunities took a considerable amount of time and effort, to which UNITAID itself might not have the capacity to devote resources.

Members generally supported the proposed business plan of the Millennium Foundation, but nevertheless drew attention to a number of issues. THE REPRESENTATIVE OF FRANCE said that France considered the Foundation's existence could only be justified if it was used to channel private sector funds to UNITAID with minimum administrative costs of the Foundation. In particular, he specified that under no circumstances should any funds be earmarked by donors, so as to allow UNITAID complete flexibility in how it allocated its resources. He also said it would be for UNITAID to communicate the existence of the Millennium Foundation and the Foundation should not carry out any communication activities itself.

The REPRESENTATIVE OF NGOS also raised concerns over the future possibility of private sector entities wishing to have greater relationship with UNITAID and representation on its Board.

Responding to a question from the United Kingdom, the MANAGING DIRECTOR OF THE MILLENNIUM FOUNDATION clarified that there were no legal implications to the Foundation changing its business model, as its Statutes specified that its purpose was to raise funds for UNITAID, without dictating precisely how that should be done. Its purpose therefore had not changed.

20. Calendar of Board meetings for 2012 and 2013 and other events requiring Board participation

The VICE-CHAIR took the place of the Chair for discussion of this item. A number of members requested that an Executive Board Retreat should be held later in spring 2012. The REPRESENTATIVE OF THE GATES FOUNDATION suggested that discussion of meeting dates should be conducted and agreed upon via email. The REPRESENTATIVES OF AFRICAN COUNTRIES, BRAZIL and FRANCE said that it was important to agree on dates for meetings, particularly the Executive Board Retreat as soon as possible.

21. Address from the French Minister of Foreign and European Affairs

The French Minister of Foreign and European Affairs was unable to attend the meeting due to time constraints. A representative of the Minister attended the meeting on Monday 12 December 2011 and welcomed the Executive Board members to the Ministry of Foreign and European Affairs. He said that the work of UNITAID was being followed very carefully by the French Government and other partners as it was of great importance to the international community and welcomed the progress UNITAID had made in its work.

22. Any other business and closure of the Session

At the invitation of the CHAIR, the CHAIR OF THE EXECUTIVE BOARD OF THE GLOBAL FUND took the floor. He explained that the first stage of the governance reforms within the organization had been completed and that the Global Fund had three standing committees in the areas of strategy, finance and operations and audit. There were also technical ad-hoc committees, such as the AMFm Committee and the Market Dynamics Committee, although the final structure for such committees had yet to be agreed upon. He stressed that although AMFm was hosted by the Global Fund, there were many other stakeholders, and Global Fund did not have overall ownership of the project.

A delegation of representatives of the Chinese company HNA, headed by Mr Chen Feng, was briefly presented to the Board and the CHAIR warmly welcomed HNA's intention to collaborate with the Millennium Foundation for the benefit of UNITAID.

The CHAIR expressed appreciation for the efforts and contributions made by Ms So Rie Lee (Asian Countries) during her membership of the Executive Board.

As there was no other business, the CHAIR thanked participants and closed the meeting at 17:10 on Tuesday 13 December 2011.

Annex 1 – List of Participants

BOARD MEMBERS

- CHAIR - Dr Philippe Douste-Blazy
- VICE-CHAIR CHILE - H.E. Mr Eduardo Gálvez
- Alt.: Dr Guy Fones
- AFRICAN COUNTRIES - Alt.: H.E. Mr Luc-Joseph Okio
- BRAZIL - Alt.: Dr Jorge Bermudez
- FRANCE - Ms Mireille Guigaz
- Alt.: Mr Philippe Meunier
- NORWAY - Ms Sidsel Bleken
- Alt.: Mr Harald Storbekkrønning
- SPAIN - Mr José Luis Solano Gadea
- UNITED KINGDOM OF GREAT
BRITAIN AND NORTHERN
IRELAND - Mr Carlton Evans
- Alt.: Ms Samrita Sidhu
- CIVIL SOCIETY NETWORKS –
COMMUNITIES LIVING WITH THE
DISEASES - Dr Esther Tallah
- Alt.: Mr Nelson Otwoma
- NGOs - Ms Kim Nichols
- Dr Tido von Schoen-Angerer
- CONSTITUENCY OF
FOUNDATIONS – BILL AND
MELINDA GATES FOUNDATION - Alt.: Ms Susan Navarro
- WHO - Dr Hiroki Nakatani

OTHER MEMBERS OF DELEGATIONS

- ASIAN COUNTRIES – REPUBLIC
OF KOREA - Ms Sorie Lee
- BRAZIL - Mr Elio Cardoso
- FRANCE - Mr Gustavo Gonzalez-Canali
- Ms Marina Hue
- Mr Stephane Renaudin
- CONSTITUENCY OF
FOUNDATIONS – BILL AND
MELINDA GATES FOUNDATION - Mr Richard Wilder

COMMUNITIES LIVING WITH THE DISEASES & NGOs	- Ms Jessica Hamer
NORWAY	- Ms Kirsten Myhr
WHO	- Mr Issa Matta - Dr Marie-Paule Kieny - Dr Paul Nunn
PROPOSAL REVIEW COMMITTEE	- Prof James McIntyre
INDEPENDENT STEERING COMMITTEE – 5YE	- Ms Johannah-Joy Phumaphi
PARTNERS	
THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA	- Prof. Michel Kazatchine - Mr Humberto Laudares - Mr Igor Oliynyk - Dr Olusoji Adeyi
ROLL BACK MALARIA PARTNERSHIP	- Dr Jan Van Erps
MEDICINES PATENT POOL FOUNDATION	- Ms Ellen 't Hoen - Mr Chan Park
MILLENNIUM FOUNDATION – INNOVATIVE FINANCE FOR HEALTH	- Mr Henk Mulder
SPECIAL INVITEES	
BOSTON CONSULTING GROUP	- Mr Mathieu Lamiaux
THE GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT	- Mr Melvin Spigelman
OBSERVERS	
NGOs AND COMMUNITIES LIVING WITH THE DISEASES	- Mr Louis Da Gama (Global Health Advocates) - Mr Casco Mubanga (Network of Zambian People Living with HIV/AIDS) - Mr Mayowa Joel (Communication for Development Centre) - Ms Rosette Mutambi (HEPS Uganda) - Ms Carol Nyirenda (CITAM+ Zambia) - Mr Jamie Love (KEI) - Ms Olive Edwards (Jamaican Network of Seropositives)

- Mr Stephen McGill (Stop AIDS Liberia)
- Dr Mohga Kamal Yanni (Oxfam)
- Ms Pauline Londeix (Act up Paris)
- Ms Katy Athersuch (Médecins sans Frontières)
- Mr Khalil Elouardighi (Coalition Plus)
- Ms Mercy Douala (REMEDI)

UNITAID SECRETARIAT

- Dr Denis Broun (Executive Director)
- Dr Philippe Duneton (Deputy Executive Director)
- Dr Raquel Child (Director, Market Dynamics and Operations)
- Ms Brigitte Laude (Director, Administration and Finance)
- Ms Brenda Waning (Coordinator, Market Dynamics)
- Mr Edward Vela (Senior Adviser to the Executive Director)
- Ms Sonia Hilton (Legal Adviser)
- Mr Frederic Martel (Strategy & Planning Officer; Acting Board Relations Officer)
- Ms Louise Kleberg (Technical Officer, Proposal Review Committee and Advisory Committees)
- Ms Gelise McCullough (Technical Officer)
- Ms Vibhu Garg (Executive Officer)
- Ms Susanna Volk (Executive Board Assistant)
- Ms Carole Ballon (Assistant)

Annex 2 – Letter from Brazil to the Chair of the Executive Board regarding the Medicines Patent Pool Foundation

Brasília, 29 July 2011

H.E. Mr. Philippe Douste-Blazy

Chairman of the Executive Board of UNITAID

Mr. Chairman,

We received with interest the announcement of 12 July 2011 of the first license agreement signed between the Medicines Patent Pool Foundation and a private pharmaceutical company with the purpose of allowing the production of medicines for HIV/AIDS and hepatitis B treatment in an amplified scale. Nevertheless, we are concerned with the absence of Brazil and other countries in the scope of the instrument.

While recognizing that the agreement is an important step towards improving access to medicines, we hope to count with the good offices and determination of Your Excellency to ensure that, in the future, the principles of non-exclusivity and non-discrimination, as well as transparency in the decision-making process, will be strictly observed. These principles are essential for the achievement of the public health goals of the UNITAID-MPP partnership, as established in the Memorandum of Understanding signed in September 2010. Competition in the pharmaceutical market and the reduction of international asymmetries in innovation and production capacities constitute the most effective mechanism to reduce the price of medicines.

In Brazil, we have been able to accumulate significant experience with public policies aimed at ensuring universal access to health, which include treatment of HIV/AIDS and hepatitis B. At the basis of these policies lies a strategy of development and innovation of industries in the health sector, which comprises structural actions that have placed our country in a position of acknowledged capacity in the production of medicines, notably generics. Furthermore, through various cooperation programs, we have been sharing national practices in the field of public health and access to medicines with other developing countries, from which many have benefited. Any form of arbitrariness and exclusivity in production does not contribute to overcome global asymmetries in technology.

We are convinced that the participation of all countries capable of producing medicines in the scope of the agreements

signed by Medicines Patent Pool is a key element to reduce costs, improve access to medicines and to ensure the full realization of the right to health. The absence of some countries and their large populations from the recently signed agreement calls into question the efficacy and the objectives of the Medicines Patent Pool. Non-exclusivity, non-discrimination and transparency are fundamental values to ensure the assistance of the populations most in need.

In brief, we reaffirm the need for all countries members of the Executive Board of UNITAID to be consulted before any strategic decisions are taken, including the signing of agreements, so as to preserve the constitutional principles of the organization. We also stress the commitment of the Brazilian government to improve global access and production of essential medicines as well as to ensure that intellectual property rights do not prevail over the right to health.

With this, we express our expectation that future agreements signed by the Foundation will fully enshrine these principles, which are vital for the realization of our common aspirations.

Cordially,

Antonio de Aguiar Patriota

Minister of Foreign Relations of Brazil

Alexandre Padilha

Minister of Health of Brazil