

## **Review of hosted partnerships**

### **Review of Unitaid**

#### **Report by the Director-General**

1. The present report is submitted in line with the request made by the Executive Board to its Programme, Budget and Administration Committee in decision EB132(10) (2013) in respect of the regular review of arrangements for hosted health partnerships.
2. This report summarizes the contribution of Unitaid to improved health outcomes, the harmonization of its work with the relevant work of WHO and the Secretariat's interaction with the partnership.
3. Unitaid was established in September 2006 pursuant to a Memorandum of Understanding between WHO and the five founding countries, namely, Brazil, Chile, France, Norway and the United Kingdom of Great Britain and Northern Ireland.
4. The Board of Unitaid is composed of representatives of each of the five founding countries in addition to one representative of Spain, one representative of African countries (South Africa), one representative of Asian countries (Republic of Korea), one representative of the constituency of foundations (Bill & Melinda Gates Foundation), two representatives of civil society networks and one representative of WHO as a non-voting member.

#### **CONTRIBUTION TO IMPROVED HEALTH OUTCOMES**

5. The mandate of Unitaid is to “contribute to scale up access to treatment for HIV/AIDS, malaria and tuberculosis for the people in developing countries by leveraging price reductions of quality drugs and diagnostics, which currently are unaffordable for most developing countries, and to accelerate the pace at which they are made available”.<sup>1</sup> Since 2006, it has committed over US\$ 2 billion to investments in promising health solutions so that partner organizations can scale them up and make them widely available.

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<sup>1</sup> Unitaid Constitution: adopted by the Executive Board on 6 July 2011 (<https://unitaid.eu/assets/UNITAID-constitution.pdf>, accessed 26 February 2018).

6. The mission of Unitaid for 2017–2021 is to “maximize the effectiveness of the global health response by catalyzing equitable access to better health products”.<sup>1</sup> Its projects endeavour to fill the gap between the late-stage development of health products and their widespread adoption. By ensuring that innovative ideas come to fruition in the real world, Unitaid helps innovators to address the needs of underserved populations.

7. Unitaid aims to make the global response on HIV/AIDS, tuberculosis and malaria more effective. In order to do so, it identifies ways to prevent, treat and diagnose HIV/AIDS and coinfections, tuberculosis and malaria more affordably, effectively and quickly. It transforms game-changing ideas into practical solutions, making it possible for countries and major funders to deliver universal health coverage across the three critical dimensions, namely: population (who is covered), services (which services are covered and the quality of those services) and cost (how much of the cost is covered). Its actions are based on its strategic objectives, as follows:

- innovation – to connect innovators who develop better health products with people who need them, both by using existing commodities in new ways and by developing new products and approaches;
- access – to overcome barriers to access to innovative health products that can deliver more with less, by leveraging its market expertise and working in partnership;
- scalability – to create the right conditions for scale-up so that better health products reach all those who need them, working with partners at every stage to ensure that its projects scale up successfully through countries and major funders.<sup>2</sup>

8. There is one global health response. As one of many players engaged in that response, Unitaid is connected to its partners and works to ensure coordination between them around its projects, having made an investment commitment to “succeed in partnership”.<sup>1</sup>

9. Unitaid works closely with WHO’s disease departments, for example through the enabler projects financed by Unitaid and implemented by the respective departments. These projects aim to ensure that outputs from Unitaid’s investments in the areas of HIV, hepatitis C virus, tuberculosis and malaria are translated into public health policy and have global impact. WHO’s technical departments are uniquely positioned to assume this task, given the mandate, capacity and expertise of WHO in developing normative guidance; its strong, constructive linkages with health ministries in Member States; and its ability to serve as a global convener of key stakeholders. As such, WHO serves as a catalyst for major policy shifts within countries; such shifts, in turn, have a demonstrated and substantial impact on implementers and markets.

10. Moreover, Unitaid provides a significant proportion of the funding to the WHO prequalification programme to address the lack of affordable, adapted, quality-assured health products for use in low- and middle-income countries which delays progress towards global health targets.

11. The following recent examples illustrate the impact of Unitaid investments on the delivery of better health outcomes, on a path to universal health coverage.

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<sup>1</sup> Unitaid. Strategy 2017–2021 ([https://unitaid.eu/assets/Unitaid-strategy-2017-2021\\_Dec-2017.pdf](https://unitaid.eu/assets/Unitaid-strategy-2017-2021_Dec-2017.pdf), accessed 26 February 2018).

<sup>2</sup> Unitaid. About us – strategy (<https://unitaid.eu/about-us/strategy/#en>, accessed 26 February 2018).

- *Optimal antiretrovirals.* Unitaid is investing in a number of projects designed to accelerate access to optimal HIV regimens that control the virus more quickly, have fewer side-effects and are less likely to develop drug resistance than alternatives. Access to these regimens can improve the quality of life of people living with HIV, as well as simplifying the delivery of HIV care in settings where resources are limited. Moreover, the treatments are affordable, costing US\$ 75 per person annually; they could cost even less at scale, which would improve the efficiency of public spending. By 2021, an additional 5 million people living with HIV could be treated from the same funding by scaling up access to optimal regimens. These projects are also supported by the WHO Department of HIV/AIDS through the enabler investment made by Unitaid.
- *Paediatric tuberculosis care.* Until the end of 2015, appropriate paediatric tuberculosis treatments were not available. Caregivers had to cut or crush multiple, bitter-tasting pills in order to administer correct doses to children, leading to poor adherence to treatment and, ultimately, to poor health outcomes. Through the TB Alliance, Unitaid supported the introduction of affordable, appropriately-dosed, child-friendly tuberculosis medicines that meet WHO guidelines for childhood treatment to ensure that no one is left behind. Since December 2017, more than 700 000 treatment courses of these new formulations have been ordered by almost 80 countries.
- *Preventing malaria in children during high transmission seasons.* Unitaid invested in a project to demonstrate how to deliver seasonal malaria chemoprevention (SMC) cost-effectively in the Sahel region for children aged under 5 years. The results of this investment, through the Malaria Consortium and Catholic Relief Services, are very positive. Over two years of delivery across seven countries in the Sahel, the ACCESS-SMC project is estimated to have averted more than 5 million cases of malaria, 150 000 severe cases and more than 30 000 deaths in children aged under 5, typically at a cost of less than US\$ 3.50 per child. Furthermore, a joint effort among partners culminated in the production of sweetened, dispersible tablets that are more palatable to children. Four of the seven project countries have already transitioned to Global Fund funding. At full scale, the public health and economic impact could be even higher, as SMC has the potential to reach 30 million children globally every year.
- *Prequalification of medicines and diagnostics.* Since its inception, Unitaid has provided significant financial support to the WHO prequalification programme, thereby contributing to the prequalification of more than 200 medicines and over 60 diagnostics for HIV/AIDS, hepatitis C, tuberculosis and malaria. The programme has also generated tangible benefits to public health in low- and middle-income countries, through facilitating capacity-building and collaboration between regulators, accelerating access to urgently needed medical products through the collaborative procedure for national registration and contributing to market sustainability and lower prices by increasing fair competition among quality products.

## **HARMONIZATION OF THE PARTNERSHIP'S WORK WITH THE RELEVANT WORK OF WHO**

### **WHO cross-cutting enabler grant**

12. In late 2017, WHO and Unitaid concluded a cross-cutting enabler grant. Prior to the signature, Unitaid grantees communicated their support needs directly to the relevant WHO departments, without knowing what complementary support the Organization already provided to other projects with the

same funding source. This situation created the risk of duplication or overlap of activities, as well as inefficiencies where opportunities to leverage and/or coordinate efforts were missed.

13. The WHO enabler grant approach eliminates these risks and inefficiencies by streamlining thematic activities (such as those on HIV, tuberculosis, malaria and prequalification) under a single WHO grant agreement that provides for common planning. At the same time, it sets them in a performance framework that improves the benefit derived from Unitaid funding as well as the quality of the outputs, outcomes and impact of WHO's enabling support to Unitaid's grants. Key benefits of the approach are:

- a more systematic, streamlined and consistent approach to WHO support, with greater transparency and visibility for WHO activities in each area of intervention;
- cost-savings and efficiency gains realized through working directly with WHO rather than via a third-party grant implementer;
- a performance-based approach with specific, measurable, achievable, relevant and time-bound (SMART) key performance indicators;
- focused support that targets activities that would not otherwise have been implemented by WHO and are deemed critical to enabling the success of Unitaid's grants and contributing to WHO's normative function.

14. The funding committed by Unitaid to the enabler grant as well as its support to WHO for the RTS,S malaria vaccine pilot implementation programme amounts to more than US\$ 60 million.

## **Malaria**

15. The malaria enabler grant signed in December 2017 facilitates WHO's support to two existing Unitaid grants: Community-based access to rectal artesunate for malaria and Transforming intermittent preventive treatment for optimal pregnancy (TIPTOP). WHO provides technical support to project partners and ministries of health to ensure quality implementation and supports the transition from projects that establish evidence for policy-making to policy adoption and programme implementation at country level.

16. Unitaid, together with the GAVI Alliance and the Global Fund to Fight AIDS, Tuberculosis and Malaria, is providing support to WHO in connection with the introduction of the world's first malaria vaccine in pilot projects in three sub-Saharan African countries. RTS,S acts against *Plasmodium falciparum*, the most deadly malaria parasite globally and the most prevalent in Africa. Vaccinations are anticipated to begin in mid-2018.

17. At its December session in 2017, the Unitaid Board requested its secretariat to launch a call for proposals in the area of intervention of the integrated management of childhood fever. The secretariat emphasized the rationale for this area of intervention, namely that:

- integrated management of fever can improve malaria case management;
- many children with malaria are coinfecting with other conditions which require effective treatment;

- appropriate treatment of non-malarial fevers is needed to improve rational drug use and mitigate resistance;
- many of the signs and symptoms of severe diseases are common across diseases.

18. This call supports the work of WHO to improve child survival, address the threat of drug resistance and reduce wastage and inefficiencies to improve fever case management.

## **Tuberculosis**

19. The Global Tuberculosis Programme enabler grant for US\$ 7.4 million was signed in December 2017 for four years, supporting Unitaid-funded projects in the areas of intervention of childhood tuberculosis, latent tuberculosis infection and multidrug-resistant tuberculosis. Activities under the WHO/Programme enabler grant will support and facilitate the implementation of Unitaid funded projects within its mandate in order to leverage innovation for global health in the field of tuberculosis and contribute to country efforts towards the achievement of targets under all three pillars of the End TB Strategy.

20. Unitaid's grantees aim to reduce paediatric morbidity and mortality from tuberculosis through cost-effective and decentralized childhood diagnostic approaches that will enhance case-finding and the development of service delivery models to improve tuberculosis case detection and management among children. The Global TB Programme will provide a global platform that will facilitate project coordination, provide technical assistance to address implementation bottlenecks and ensure that results feed into WHO guideline development processes and have a global impact beyond the project countries.

21. In addition, the Global TB Programme will support the dissemination and uptake of up-to-date global guidance on programmatic management of latent tuberculosis infection in the project countries; facilitate sharing of best practices and experiences at the country, regional and global levels; promote research for latent tuberculosis infection; and provide a platform for coordination and systematic information-sharing between the different stakeholders.

22. Unitaid has also funded projects aimed at the development and introduction of new treatment and diagnostic strategies for cases of multidrug-resistant tuberculosis. These projects are geared to generate valuable clinical and observational evidence that will inform WHO's policies and implementation guidance and help adoption and scale-up by countries.

23. As a Unitaid partner, WHO is concerned by the fact that a significant number of proposals in respect of multidrug-resistant tuberculosis failed to obtain Unitaid funding in 2017. It has underscored with the Unitaid Board the need for Unitaid to launch a new call for proposals focusing on multidrug-resistant tuberculosis as soon as possible, with a view to beginning disbursements under grants resulting from such a call in time for the United Nations General Assembly in 2018.

## **HIV/AIDS**

24. The enabling grant between Unitaid and WHO started 1 June 2017. The enabling grant aims to address critical gaps across four workstreams:

- enabling and accelerating uptake of new antiretroviral regimens for HIV treatment for affected populations;
- enabling scale-up of pre-exposure prophylaxis with linkage to HIV testing in a range of settings and populations;
- enabling scale-up of innovations for the diagnosis and monitoring of HIV;
- enabling scale-up of best service delivery approaches to diagnose hepatitis C infection and deliver hepatitis C treatment to persons with HIV coinfection.

25. The project will create a policy environment that accelerates access to new technologies and approaches for HIV/hepatitis C diagnosis and treatment as well as pre-exposure prophylaxis for HIV. The project will enable outputs from Unitaids' investments in the areas of HIV and hepatitis C to be translated into public health policy and ultimately have global impact. WHO's technical expertise in HIV and hepatitis treatment, prevention and diagnostics and its access to strategic information for both drug and diagnostic demand and uptake can enable the outputs from Unitaids' investments to reach their full potential in terms of impact and scale.

26. On 1 October 2017, the enabler grant was amended to include a new component, namely, HIV self-testing. This amendment builds on the work undertaken by WHO in the context of the first phase (2015–2017) of the HIV Self-Testing Africa (STAR) Initiative. It includes further support through the second phase (2017–2019) and, more broadly, to all other Unitaids investments in HIV self-testing, as well as alignment and collaboration with and support for cross-project/programme activities with other HIV self-testing projects supported by national programmes and other donors in all regions.

### **Prequalification**

27. Unitaids has been one of the main supporting partners for WHO's prequalification of medicines and in vitro diagnostics activities. The current grant enables WHO to prequalify products in Unitaids disease areas and to ensure sustained supply of quality applications as well as post-marketing monitoring of these products. WHO continues to work with Unitaids to enable shorter times to market for quality-assured products, through collaborative registration procedures and regional harmonization initiatives. There is increasing focus on supporting innovation and enhancing performance and sustainability. WHO is appreciative of Unitaids' past support and is particularly encouraged by Unitaids' engagement in current activities to streamline reporting activities and strategic planning.

### **Antimicrobial resistance**

28. Unitaids invests in addressing the challenge of resistance to medicines and preventives for HIV/AIDS, malaria and tuberculosis and through these investments it directly and indirectly supports the antimicrobial resistance agenda. Institutionally, Unitaids is well placed to share its experience in funding innovation to tackle resistance (including in the following areas: testing through TB GeneXpert diagnostics; paediatric tuberculosis; multidrug-resistant tuberculosis; investments in clinical trials for emerging antiretrovirals; next generation indoor residual spray). In addition, Unitaids is a member of the Ad Hoc Interagency Coordination Group on Antimicrobial Resistance, co-chaired by the WHO Director-General and the Deputy Secretary-General of the United Nations.

## **WHO'S HOSTING RELATIONSHIP WITH THE PARTNERSHIP**

29. In 2016, the WHO Director-General issued generic hosting terms for WHO hosted partnerships. The hosting terms, which apply to Unitaid, were developed through a consultative process with all WHO hosted partnerships. They set out the operational framework for WHO's hosting and administration of formal partnerships in the context of the WHO Constitution, together with the Organization's Financial Regulations and Financial Rules, Staff Regulations and Staff Rules, Manual provisions and applicable policies, procedures and practices (including WHO technical norms, guidelines and procedures), and any relevant resolutions of WHO's governing bodies. Specific adaptations to these WHO rules as applicable to hosted partnerships are contained in the hosting terms.

### **Human resources**

30. Through special procedures agreed by the Director-General, representatives of the Unitaid Board participate in the selection panel for its Executive Director. The delegation of authority to the Executive Director to implement administrative matters in WHO's Global Management System comes directly from the Assistant Director-General for Communicable Diseases.

31. The Unitaid secretariat currently comprises 89 positions, with 64 staff members on fixed-term and continuing appointments and no staff at the regional and country levels. Staff members are subject to WHO Staff Regulations and Staff Rules.

32. Staff members are normally assigned exclusively and solely to support Unitaid and, as such, should their positions be abolished they are not eligible for reassignment elsewhere within WHO. However, some current partnership staff members have reassignment rights within WHO. All liabilities incurred for any staffing decision and for the abolition of positions are borne by the partnership, which has been setting aside funds to meet such liabilities.

### **Programme and financial management**

33. The Unitaid budget is separate from that of WHO and is approved by the partnership's Board. The 2018 Unitaid operating budget, approved by the Board at its December meeting, was for US\$ 30.2 million.<sup>1</sup> The partnership produces a full financial statement to its Board for approval. The WHO Office of Internal Oversight Services serves as Unitaid's internal auditor.

34. In order to ensure full and flexible coverage of Unitaid-specific risk and activities, an external firm competent in the field of risk management and international audit has been retained by Unitaid and the Office of Internal Oversight Services to deliver internal reviews to Unitaid, either in the form of assurance (audits) or advisory/consulting engagements. An annual internal review plan is prepared by the external firm and reviewed by the Office of Internal Oversight Services.

35. With respect to procurement, Unitaid is compliant with WHO's Financial Rules and Regulations and contracts for goods and services are submitted to the WHO Contract Review Committee in accordance with WHO policies.

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<sup>1</sup> Unitaid. Resolution No. 3: approval of the 2018 Unitaid budget ([https://unitaid.eu/assets/UNITAID\\_EB28\\_2017\\_R3\\_Approval-of-the-2018-Unitaid-budget.pdf](https://unitaid.eu/assets/UNITAID_EB28_2017_R3_Approval-of-the-2018-Unitaid-budget.pdf), accessed 27 February).

36. The Unitaid secretariat is expected to relocate towards the end of 2018 to the newly built Health Campus building that will primarily be occupied by the Global Fund to Fight AIDS, Tuberculosis and Malaria and the GAVI Alliance but is also expected to accommodate the secretariats of the Stop TB and Roll Back Malaria partnerships. In view of the fact that WHO will enter into the sublease on behalf of Unitaid, Unitaid has agreed to indemnify WHO for any financial costs or future possible claims associated with the sublease.

### **Resource mobilization and cost recovery**

37. Unitaid mobilizes its own resources from governments and philanthropic foundations. Since its establishment in 2006, it has received over US\$ 2.5 billion, primarily from eight donors. The top three donors that account for approximately 89% of overall contributions are France (50%), United Kingdom of Great Britain and Northern Ireland (29%) and Brazil (10%). Unitaid has been actively working on the development of its donor base in order to increase its reach, broaden the perspectives of its Board and mitigate the risk of reliance on a few key contributors.

38. With respect to cost recovery, resolution WHA63.10 (2010) endorsed a partnership policy that seeks reimbursement for all costs incurred by WHO in providing hosting functions to partnerships. In this regard, a new methodology implemented in 2016 apportions applicable administrative and management costs to partnerships based on their relative weight of staff costs. The rationale for doing so is that staff costs are a major cost driver of administration and management costs, given that they occupy space, utilize information technology infrastructure and benefit from security services. Using this methodology, the budget for hosting costs for 2018 is approximately US\$ 1.425 million.

### **Communications**

39. Unitaid is compliant with WHO policies on communications and coordinates its communication activities with WHO's Department of Communications. In 2017, a new Unitaid logo was developed in consultation with stakeholders and WHO. As required by WHO, Unitaid includes an appropriate reference to WHO in its external communications. The Unitaid website was recently updated and is maintained in coordination with WHO, as appropriate.

### **Other organizational policies**

40. In accordance with WHO policy, all research proposals involving human participants that will require funding or other support from WHO must be submitted to its Ethics Review Committee. As Unitaid expands its portfolio to fund research projects with an operational research component involving human subjects, it is increasingly interacting with the Review Committee. However, given that the capacity of the Committee is limited and given the diversity and complexity of Unitaid proposals, the requirement to submit such proposals for review has proved challenging on occasion. WHO is working with the Unitaid secretariat to explore how the procedure can be streamlined and facilitated to meet the Unitaid requirements while ensuring compliance with WHO policy.

41. WHO's accountability and internal control frameworks apply to hosted partnerships. In this respect, Unitaid communicates its main risks to WHO's Office of Compliance, Risk Management and Ethics. The risks identified are assessed in accordance with WHO's risk evaluation criteria and included in the risk reports. Unitaid is also bound by WHO's ethical principles, as well as its policies on declarations of interest and on whistle-blowing and protection against retaliation.

42. In view of the fact that the Unitaid secretariat derives its legal personality from WHO, all Unitaid grant agreements and agreements with third parties are also subject to review and clearance by WHO's Office of the Legal Counsel.

**CONCLUSION**

43. The review of Unitaid indicates that both Unitaid and WHO have benefited from the hosting arrangement, in particular through the enabler grant framework but also through Unitaid grants, which have generated valuable data that is contributing to WHO's normative function.

44. Unitaid is a well-focused, organizationally strong partnership that supports a compelling programme of work that is aligned with and supportive of WHO's overall goals. The review also confirms that the platform provided by WHO as a hosted partnership gives Unitaid significant convening power among relevant stakeholders and a robust accountability framework, and enables it to access decision-makers at global, regional and national levels through an extensive network of WHO regional and country offices.

**ACTION BY THE EXECUTIVE BOARD**

45. The Board is invited to note the report.

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