

## **Review of hosted partnerships**

### **Review of Unitaid**

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

1. In accordance with Executive Board decision EB132(10) (2013), the Programme, Budget and Administration Committee periodically reviews the 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 Unitaid.
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.

#### **CONTRIBUTIONS TO IMPROVED HEALTH OUTCOMES**

4. 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\$ 3 billion to investments in promising health solutions so that partner organizations can scale them up and make them widely available.
5. The mission of Unitaid for 2017–2021 is to “maximize the effectiveness of the global health response by catalysing equitable access to better health products”.<sup>2</sup> Its projects endeavour to fill the gap between late-stage development of health products and their widespread adoption. By ensuring that innovative ideas come to fruition in the real world, Unitaid helps countries and donors to address the needs of underserved populations.

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<sup>1</sup> Unitaid Constitution: adopted by the Executive Board on 6 July 2011 and amended on 21 June 2018 (<https://unitaid.org/assets/UNITAID-Constitution-revised-version-15-June-2018.pdf>, accessed 5 April 2022).

<sup>2</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 5 April 2022).

6. Unitaid aims to make the global response to HIV, tuberculosis and malaria more effective. In order to do so, it identifies ways to prevent, treat and diagnose HIV and coinfections, tuberculosis and malaria more affordably, effectively and quickly. Unitaid's strategic objectives are:

- 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 to ensure that projects scale up successfully through countries and funders.

7. Unitaid works closely with WHO, such as through the enabler projects financed by Unitaid and implemented by relevant WHO programmes. These projects aim to ensure that outputs from Unitaid's investments in 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 stakeholders.

8. Moreover, Unitaid provides a significant proportion of 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.

9. Unitaid is coming to the end of its current strategy, which began in 2017, and is developing a new strategy for 2022–2026. During the 2017–2021 strategic period, its investments provided more than 110 million people with better health products and approaches. Unitaid-supported products and approaches have averted 560 000 deaths and 17 million cases or infections. Furthermore, its work has resulted in cost savings of US\$ 2.3 billion for global health efforts. The return on investment of Unitaid projects is high, with the benefits representing between four times and over one hundred times the initial cost. Evidence of its impact will increase as Unitaid investments over the last five years are fully concluded.

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

- *Optimal antiretrovirals.* Unitaid projects are 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. It is estimated that, by 2025, 94% of all people living with HIV on first-line antiretroviral therapy (over 20 million people) will use a dolutegravir-based regimen.<sup>1</sup> By 2030, the global savings achieved by using optimal HIV regimens in low- and middle-income countries could exceed US\$ 5 billion.
- *Paediatric tuberculosis care.* Until 2016, appropriate paediatric tuberculosis treatments were not available. Caregivers had to cut or crush multiple, bitter-tasting pills to administer correct doses to children, leading to poor adherence to treatment and poor health outcomes. Unitaid

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<sup>1</sup> Clinton Health Access Initiative, 2021 HIV Market Report (<https://3cdmh310dov3470e6x160esb-wpengine.netdna-ssl.com/wp-content/uploads/2021/10/2021-CHAI-HIV-Market-Report.pdf>, accessed 5 April 2022).

supported the introduction of affordable, appropriately dosed, child-friendly tuberculosis medicines that meet WHO guidelines for childhood treatment. Since December 2017, more than 1 million courses of these new tuberculosis treatments have been ordered by 117 countries.<sup>1</sup>

- *Preventing malaria in children during high transmission seasons.* Unitaid invested in a project to demonstrate how to deliver and scale up seasonal malaria chemoprevention for children aged under five years in the Sahel region. Significant progress has been made in increasing access to seasonal malaria chemoprevention across the Sahel region, with more than 33 million children receiving this treatment in 2020, a 33-fold increase since 2013.<sup>2</sup>
- *Prequalification of medicines and diagnostics.* Since its inception, Unitaid has provided substantial financial support to the WHO prequalification programme, thereby contributing to the prequalification of more than 200 medicines and over 60 diagnostics for HIV, hepatitis C, tuberculosis and malaria. The programme has also generated tangible benefits to public health in low- and middle-income countries, by 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. It is estimated that the WHO prequalification programme enables access to quality-assured products for up to 400 million additional people, as well as a large donor-funded market of about US\$ 3.5 billion in quality, safe and effective products. The return on investment is estimated to be between 30 and 40 times the initial cost for the prequalification-enabled donor-funded market, across all products, vaccines and diagnostics.

## Unitaid's positioning and strategic priorities during the pandemic of coronavirus disease (COVID-19)

11. Unitaid is a leading partner in the Access to COVID-19 Tools Accelerator (ACT-A):

- **The ACT-A therapeutics pillar.** Unitaid co-leads this partnership for the development, manufacture and equitable distribution of new treatments – pharmaceutical therapeutics as well as medical oxygen – to mitigate the impact of COVID-19 and ensure treatments are adapted for global use. It also leads the ACT-A Oxygen Emergency Taskforce, launched in early 2021. Unitaid works closely with WHO in these roles, assuring quality and developing clinical, implementation and allocation guidance and frameworks to support equitable access.

<sup>1</sup> See <https://www.tballiance.org/child-friendly-medicines> (accessed 5 April 2022).

<sup>2</sup> WHO, World malaria report 2021 (<https://www.who.int/publications/i/item/9789240040496>, accessed 5 April 2022).

- **The ACT-A diagnostics pillar.** Unitaid contributes to increasing access to and the affordability and availability of COVID-19 diagnostics, working alongside the FIND alliance for diagnostics, the Global Fund and WHO. It is uniquely positioned to provide targeted support for both diagnostics supply and demand, ensuring that the most appropriate products for low- and middle-income countries are developed and commercialized, with adequate access secured, and introduced to countries in a timely manner.
- **The ACT-A Health Systems Response Connector.** Unitaid works with WHO, the World Bank and the Global Fund within the Health Systems Response Connector, to support the rapid uptake and use of effective diagnostics and therapeutics.

## **COVID-19 investments to date**

12. Since the start of the pandemic, Unitaid has invested US\$ 194 million in the response: US\$ 39 million for therapeutics, US\$ 65 million for diagnostics, US\$ 83 million for emergency oxygen and US\$ 7 million for cross-cutting areas such as intellectual property. These investments were funded by resources mobilized for COVID-19 (US\$ 129 million), complemented by core Unitaid funding (US\$ 65 million).

13. As at 31 December 2021, Unitaid had committed US\$ 83 million to the ACT-A Oxygen Emergency Taskforce. This included funding the emergency procurement of oxygen supplies; technical assistance to more than 20 countries, including support in completing Global Fund applications; market-shaping to increase the supply of liquid oxygen; repairing broken equipment; and building capacities.

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

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

14. In 2017, WHO and Unitaid concluded a five-year enabler grant with WHO's HIV, tuberculosis and malaria departments. Through the enabler mechanism, WHO provides technical support to Unitaid project partners and ministries of health to deliver high-quality clinical and implementation research; accelerate development of policies and guidelines based on evidence generated from the projects; and adopt and scale up better health products and approaches in countries. Unitaid committed US\$ 46 million to the HIV, tuberculosis and malaria enabler grants between 2017 and 2022.

### **HIV**

15. The enabler grant between Unitaid and WHO on HIV and its coinfections and comorbidities, such as hepatitis C and cervical cancer, comprises seven workstreams:

- accelerating uptake of new antiretroviral regimens for HIV treatment for affected populations;
- enabling access to a package of life-saving medicines and diagnostics for opportunistic diseases in patients with advanced HIV disease;
- promoting the scale-up of innovations for the diagnosis and monitoring of HIV, which has, for example, helped to reduce the costs of early infant HIV diagnostics and decrease the time to treatment initiation;

- enabling access to HIV self-testing to reach and sustain high HIV testing rates and to help turn the course of the epidemic;
- ensuring the scale-up of HIV pre-exposure prophylaxis with linkage to HIV testing in a range of settings and populations;
- enabling the scale-up of best service delivery approaches to diagnose hepatitis C infection and delivering hepatitis C treatment to persons living with HIV coinfection;
- reducing cervical cancer illness and death by expanding access to better and more affordable tests and treatments.

## **Malaria**

16. The malaria enabler grant facilitates WHO's support in three areas:

- pre-referral treatment with rectal artesunate suppositories for suspected cases of severe malaria in children under the age of six years, in order to demonstrate how treating children before they are referred to a hospital or health centre can save lives;
- intermittent preventive treatment of malaria among pregnant women via a network of community health workers;
- vector control to reduce malaria transmission, such as through the use of insecticide-treated bed nets, long-lasting insecticide sprays, spatial repellents and preventive medicines.

## **Tuberculosis**

17. Unitaïd works with the Global Tuberculosis Programme in the areas of childhood tuberculosis, tuberculosis preventive treatment and multidrug-resistant tuberculosis. Activities under the enabler grant contribute to country efforts to fulfil the commitments made in the political declaration of the high-level meeting of the United Nations General Assembly on the fight against tuberculosis in 2018.

### **Cooperation beyond the cross-cutting enabler grants**

18. **The WHO prequalification programme:** Since 2006, Unitaïd and WHO have worked closely together to facilitate access to medicines that meet unified standards of quality, safety and efficacy. In 2009, cooperation also started on the prequalification of diagnostics. This cooperation has resulted in more than 200 medicines and over 60 diagnostic tools being prequalified for HIV, hepatitis C, tuberculosis and malaria. Unitaïd has contributed a total of US\$ 157 million to WHO's Department of Essential Medicines and Health Products for this work.

19. **High-quality research:** To ensure that Unitaïd-funded research protects the dignity, rights and welfare of research participants, Unitaïd cooperates with WHO's Research Ethics Review Committee. Over the last four years, more than 120 research protocols have been reviewed by the Committee. Unitaïd and WHO are also working together to improve research ethics review processes.

20. **New malaria vaccine:** Since 2017, Unitaïd, Gavi, the Vaccine Alliance and the Global Fund to Fight AIDS, Tuberculosis and Malaria have worked closely with WHO to introduce the world's first malaria vaccine through pilot projects in Ghana, Kenya and Malawi. In October 2021, based on the results of these pilot projects, which immunized more than 800 000 children, WHO recommended the

widespread use of the vaccine to prevent malaria in children in regions with moderate to high transmission. Unitaïd is supporting the project financially, with US\$ 13 million committed up to 2023.

21. **Integrated management of childhood fever:** Unitaïd supports innovations in the integrated management of childhood fever, which is linked to malaria, with technical support provided by WHO's Child Health and Development Unit. The tools developed enable health workers to identify children who require immediate medical attention and, as such, avoid irrational use of medicines, including antibiotics.

22. **Childhood medicines:** Unitaïd plans to support the work of the Global Accelerator for Paediatric Formulations Network to ensure better childhood variants of, ultimately, all essential medicines. In order to achieve this, Unitaïd will draw on its pioneering work with WHO in the area of paediatric HIV medicines and the more than US\$ 1 billion it has invested in ground-breaking innovations to treat children living with HIV, tuberculosis and malaria.

23. **Maternal health:** Unitaïd is working with the Special Programme of Research, Development and Research Training in Human Reproduction to improve the management of postpartum haemorrhaging, with a grant expected to be concluded before mid-2022. Additional innovative work to improve the prevention and treatment of pre-eclampsia is also being considered.

24. **Long-acting technologies:** Unitaïd is working to ensure that long-acting medicines are introduced more quickly and remain available, with the current focus on medicines to cure hepatitis C, prevent malaria and latent tuberculosis and prevent and treat HIV. WHO provides technical support and plays a key role in the advisory committee of Unitaïd's project on long-acting medicines for malaria, tuberculosis and hepatitis C, which facilitates information-sharing and alignment with global long-acting product development and commercialization efforts.

25. **Antimicrobial resistance:** Unitaïd has always been at the forefront of the fight against antimicrobial resistance, bringing innovative solutions to prevent, diagnose and treat diseases more quickly, cheaply and effectively to low- and middle-income countries. Unitaïd was a member of the Ad Hoc Interagency Coordination Group on Antimicrobial Resistance, which was convened by WHO and led the work on innovation in this area. At present, Unitaïd has more than 30 antimicrobial resistance-related investments, representing 65% of its portfolio and totalling US\$ 900 million.

26. **Global Action Plan for Healthy Lives and Well-being for All:** Under WHO's leadership, Unitaïd works with 13 other global health agencies to accelerate progress towards the health-related Sustainable Development Goals.

27. **Pan American Health Organization (PAHO):** Unitaïd works with PAHO and its Revolving Fund for Strategic Public Health Supplies to improve access to quality-assured, safe and effective medicines and other essential public health supplies at reduced cost. Unitaïd and PAHO also work with public health institutes in South America to improve the management of Chagas disease.

## WHO'S INTERACTION WITH UNITAID

### Hosting arrangements

28. In 2016, the WHO Director-General issued generic hosting terms for WHO hosted partnerships. The hosting terms, which apply to Unitaïd, were developed through a consultative process with all WHO hosted partnerships.

## **Human resources**

29. 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 Director-General of WHO.

30. The Unitaid secretariat currently comprises 93 positions, with 74 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.

31. 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**

32. The Unitaid budget is separate from that of WHO and is approved by the Unitaid Executive Board. The 2021 Unitaid operating budget, approved by the Board at its December meeting, was for US\$ 32.2 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.

33. In order to ensure full and flexible coverage of Unitaid-specific risks 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.

34. 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.

## **Resource mobilization and cost recovery**

35. Unitaid mobilizes its own resources from governments and philanthropic foundations. Since its establishment in 2006, it has received over US\$ 3.6 billion, primarily from eight donors, in support of its core work. The top two donors, which account for 81% of overall contributions, are France (58%) and the United Kingdom of Great Britain and Northern Ireland (23%).

36. In response to the COVID-19 pandemic, Unitaid as co-lead of the ACT-A therapeutics pillar has mobilized an additional US\$ 177 million to date, with US\$ 115 million from current donors (of which 48% from Norway and 41% from France) and US\$ 62 million from new donors: Canada (45%), Germany (37%), Italy, Portugal and the Wellcome Trust (16%). An overhead cost of 2% for current donors and 7% for new donors is charged on these contributions in order to enable Unitaid to resource the additional staff needed to respond to the resulting increase in investments.

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<sup>1</sup> Unitaid. Resolution No.3: approval of the 2021 Unitaid Budget ([https://unitaid.org/assets/UNITAID\\_EB37\\_2020\\_R3\\_Unitaid-2021-Budget.pdf](https://unitaid.org/assets/UNITAID_EB37_2020_R3_Unitaid-2021-Budget.pdf), accessed 5 April 2022).

37. 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. Using this methodology, hosting costs for 2021 were approximately US\$ 2 million.

## **Communications**

38. Unitaid works in close collaboration with WHO as a key communications partner. In 2021, jointly supported efforts took place throughout the year, with regular stepping up of WHO campaigns and messages and participation in several joint events, webinars and workshops. To mark the anniversary of the adoption of WHO's global strategy to eliminate cervical cancer and reconfirm its commitment in that regard, Unitaid took part in an official WHO press conference and supported the campaign across platforms. In autumn 2021, Unitaid was pleased to welcome WHO's recommendation on the widespread use of the world's first malaria vaccine in conjunction with Malaria Vaccine Implementation Programme partners, Gavi, the Vaccine Alliance and the Global Fund. In addition, as part of their ongoing efforts to raise visibility and mobilize efforts to tackle the COVID-19 pandemic, Unitaid, WHO and all other ACT-A partners have been in close and continuous coordination.

39. Unitaid remains compliant with WHO policies on communications and coordinates its communications activities with WHO's Department of Communications. As required by WHO, Unitaid includes an appropriate reference to WHO in its external communications. The Unitaid website is regularly updated and maintained in coordination with WHO, as appropriate. A request for proposals is currently being developed to revamp Unitaid's website, by leveraging the latest technological and design trends and tools, with a view to improve the user experience, make information more easily accessible and increase visibility.

## **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 Research 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.

## **ACTION BY THE EXECUTIVE BOARD**

43. The Board is invited to note the report.

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