

Q&A for Submission of Proposals

Specific Questions related to the Call “Supporting the use of TRIPS flexibilities and other intellectual property-related solutions to facilitate access to health products”

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| Question Answer |
| Are there any lessons from Unitaid’s earlier projects on TRIPS flexibilities and access to medicines could inform proposals for future projects? | An independent evaluation of the work of the projects on TRIPS flexibilities can be found [here](https://unitaid.org/assets/Joint-Portfolio-End-of-grant-evaluation-Supporting-the-use-of-TRIPS-Flexibilities.pdf). This evaluation has been conducted by independent, external evaluators. Unitaid’s approach to evaluations, and previous reports, can be found [here](https://unitaid.org/evaluations/#en). Unitaid is not bound by the recommendations, which will be considered alongside other inputs.  |
| If the Theory of Change section has more than one outcome (as per the Results Framework document), would the proper/preferred way of dealing with this be to encapsulate them in a single outcome, or would it be permissible to add a separate row for an additional outcome? | In instances where proponents have more than one outcome in their theory of change, please add additional outcomes to the logframe annex. Please ensure consistency between the logframe and the theory of change. |
| Should the work focus on one of the programmatic priorities (HIV/TB/Malaria/women and children health/response to global health emergencies)? Or could our call also focus on general access to medicines policy and the use of TRIPS flexibilities? | With regard to activities falling under Area 1, the proposal should focus on products that are relevant to Unitaid’s Programmatic Priorities. It could relate to multiple or all Programmatic Priorities. With regard to activities falling under Areas 2, 3 and 4, the focus can be broader / can be on general access to health products. |
| Is advocacy included in this Call for Proposals? | Yes, advocacy is included under Area 2 (focused on advocacy for the use of TRIPS flexibilities and other approaches to prevent, remove or overcome IP-related barriers) and under Area 4 (broader advocacy in favour of policies and solutions that facilitate access to and uptake of health products in LMICs, now and in the future).  |
| Work on local production capacity need IP and tech transfer work as well, could that be part of the proposal? | Work to support local production under this Call should focus on intellectual property issues and challenges. This can include, for example, addressing IP-aspects that can facilitate technology transfer (e.g. addressing barriers posed by trade secrets). Non-IP related aspects of local production, for example training of staff on using a new technology, while very important, are outside the scope of this Call.  |
| Would facilitating vaccine manufacturing capabilities in LMICs, be in scope? | Please see answer to previous question.  |
| Are HIV-associated non-communicable diseases in scope?  | Most HIV-associated non-communicable diseases, while obviously important, are not currently a primary focus area for Unitaid. There are some exceptions, such as cervical cancer. Also, it is possible that this may change over the course of the period covered by Unitaid’s Strategy 2023-2027.  |
| Unitaid’s Programmatic Priorities include women’s health. Would that include cancer?  | While all issues pertaining to women’s health are important, Unitaid’s work on women’s health is currently mostly focused on maternal and reproductive health. In addition, Unitaid is working on cervical cancer. It is however possible that this may change over the course of the period covered by Unitaid’s Strategy 2023-2027. |
| If the Executive Board gives the go ahead second half of May, how big are the chances of getting the final approval as well? Is there still a chance that your proposal will be declined after the Executive Board second half of May have agreed, not to get the funding? How big is that chance?  | The Executive Board may decide not to fund a project, even after the go-ahead has been given; however, the intent is to fund and in most cases the project will be funded. |
| What more is required after the Executive Board approves second half of May?And is there a chance that proposals will not get the total amount of funding requested? (but only a part) | Following a ‘go-ahead’ decision by Unitaid’s Executive Board, the proponent would work with the Secretariat to develop a full, detailed proposal. The proponent will also be expected to address comments from the reviewers and the Executive Board and Proposal Review Committee. This could result in the budget being modified, or in some activities being adjusted.  |
| Can we be part of more than one proposal?  | Yes, an organization or individual can take part in more than one proposal.  |

General Questions

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| Question Answer |
| What is the proposal process under the Unitaid Operating Model? | 1) Once a Call is issued, applicants are invited to attend a webinar on a date specified in the call for proposals text. The webinar presents the call scope, content, and process and answers questions submitted ahead of time using the online webinar registration form. Webinar attendance is not a mandatory requirement, however is strongly encouraged as it allows proponents to obtain further information and ask questions. A webinar recording is posted on the call for proposals web-page for all those unable to attend real time.2) Full proposals must be submitted electronically using theUnitaid proposal form by the indicated closing date.3) Proposals received are then assessed and eventually submitted to the Joint Review Committee (JRC), composed of representatives of the Unitaid Secretariat and the Proposal Review Committee (PRC).4) The recommendations of the JRC must be endorsed by the Unitaid Board for a “go-ahead” to start developing a grant agreement. This endorsement does not mean and should not be perceived as involving any obligation on the part of Unitaid to fund the project.5) Successful applicants receive a formal “go-ahead” for their proposal and will be requested to develop it into a full grant agreement.6) The full grant agreement is reviewed by the JRC and submitted to the Unitaid Board for funding approval.For further details please refer to the Unitaid Proposal Process document that can be found at <http://unitaid.org/calls> |
| Can a proposal that includes middle-income countries in scope be submitted? | Yes. While the primary focus of Unitaid investments is in low-income countries, proposals that include middle-income countries in scope are eligible. In principle, Unitaid looks for proposals that accrue benefit to those most in need (e.g., those in low-income countries, vulnerable populations). To this end, proposals should clearly demonstrate the use of innovative and sustainable approaches and are expected to outline a concrete and clear pathway to results and impact. Applicants should also demonstrate that their proposal is feasible and that they have the capacity to implement it.Across its portfolio of projects, at least 85% of Unitaid funds dedicated to commodity purchase must be spent in low-income |

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|  | countries. Middle-income countries are also eligible for inclusion in Unitaid-funded projects, however for any proposed project that includes a greater than 15% proportion of funding for commodity purchases in middle-income countries, the justification should be clearly stated, in line with the objectives of the Call for Proposals. Wherever possible, funding in middle-income countries should be used to increase access to commodities for vulnerable groups. Proposals focused on middle income countries will need to explain how low and lower-middle income countries will benefit from the interventions, at least indirectly, and what efforts will be made to ensure these indirect benefits materialize. |
| Can a proposal that focuses only on one or two countries be submitted? | Yes, in certain circumstances. Unitaid works through market-based interventions to have global market and public health impact. This may require work in more than one or two countries. However, an intervention in a single country (or in a very limited number of countries) can be supported when the proponent can make the case, with clear supporting evidence, that such an intervention could have global impact or when the problem addressed is regional in nature. |
| Who can submit a proposal? | Unitaid interventions are delivered through implementers; that is, Unitaid does not implement interventions directly and has no in- country presence. For proposals that include country implementation, proposal submitted should demonstrate that the organization has the capability and capacity to deliver the proposed work in project countries and that the intervention will have a global/regional effect. |
| Are NGOs and civil society organizations eligible to submit a proposal?  | Yes. Unitaid can provide grants to NGOs and civil society organizations. All Unitaid implementers must demonstrate their established capacity to manage their project. |
| Can a consortium submit a proposal? | Yes, a consortium approach may be considered for the project implementation purposes. However, projects should be as lean as possible. Any consortium approach should have a strong lead organization with overall responsibility for project implementation. |
| What constitutes a consortium? | A Consortium is a group of partners who have agreed to implement the project together on the basis of clearly defined agreements, which set out the basis on which all but the lead implementer is a sub-grantee with no direct legal relationship to Unitaid. Entities orindividuals providing services to the project on a commercial basis are service providers and not Consortium Members. Partners collaborating on the implementation of the project but that are not active part of the project design and execution are not to be considered members of the consortium but will be identified as collaborating partners. |
| Which organization would Unitaid prefer to have in the lead for a consortium project proposal? | Should the establishment of a consortium for the project implementation purposes be necessary and substantiated, the selection of the lead agency/ organization in a consortium application is at the discretion of the consortium members. It should be noted that the lead of a consortium has overall responsibility for project implementation, including coordination of consortium members and communications with/reporting to Unitaid. They are also often the main route of funding. In determining the most suitable lead, consideration should be given to each of these factors to identify |

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|  | which organization is best suited to deliver on each of them and assume overall responsibility for project activities. The capacity of the lead organization to manage the consortium and to report will be key at all stages of the project implementation. |
| Can an organization respond with more than one proposal in the capacity of lead organization? | Yes. Organizations can certainly respond with more than one proposal as lead organization. However, the organization must have the capability to deliver on any proposal they submit. Organizations must provide robust justification for the configuration of any consortium proposed, including the relative roles and responsibilities of members in achieving the goals detailed in each proposal. |
| Can a consortium member, a service provider or a collaborating partner participate in several proposals under the same call for proposals? | Yes, consortium members, service providers and collaborating partners can participate in several proposals under the same call for proposals. |
| Does Unitaid support R&D projects for pharmaceuticals and diagnostics? | Subject to call scope, Unitaid can support some late-stage R&D activities. Unitaid interventions typically focus on formulation or final product field validation where a product is about to reach the market. However, Unitaid carefully monitors the pipeline for innovative new products that may be “game changers” in the market in order to support entry, enable future scale-up and have public health impact. Note: Late-stage R&D activities are not within the call scope of this current call for proposals. |
| Can I contact Unitaid for further guidance on proposal development? | Unitaid provides guidance on the application process and the application forms. Questions should be addressed to Grant Applications Manager at proposalsunitaid@who.intIn the interest of fairness and transparency, Unitaid does not provide guidance to individual organizations on substantive issues for responding to each particular call beyond what is available in the call text, associated documents published on the Unitaid website or through webinars announced in the call text. |
| What is the typical timeframe for Unitaid projects? | Unitaid makes catalytic investments. The timeframe is typically 3 to 5 years, including transition and sustainability plan. |
| Is there a limited grant size? | Unitaid considers funding size in light of Unitaid's strategy, available funds, investment required for impact, and existing portfolio of projects. As a general principle, Unitaid aims to fund projects that are targeted and ‘lean’ – that is, scoped at the minimum size required to achieve the desired market impact and public health effects and demonstrate value for money. |
| Do Unitaid grantees automatically benefit from tax exemption for the importation of goods? | Unitaid encourages the grantees to take all measures to secure tax and customs duty exemptions for all expenses incurred, especially regarding purchase of commodities with delivery to project countries. It should be noted that many of our grantees are successful insecuring such exemptions. |
| Products must comply with Unitaid Quality Assurance Policy to be eligible for procurement. Are there any other conditions to be met? | Conditions on procurement within Unitaid grants may vary according to the commodity purchased, and detailed procurement conditions are typically finalized during grant development. Regarding quality assurance, as a general rule, Unitaid has harmonized its policy with those of other major partners, such as the Global Fund or PEPFAR. As a result, Unitaid typically requires that product be WHO Prequalified, authorized for use by a Stringent Regulatory Authority (SRA), or |

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|  | reviewed and permitted for use by the Expert Review Panel (ERP) as described in the Unitaid Quality Assurance guidelines https://unitaid.org/assets/UNITAID\_QA-of-health- products\_August2014.pdf |
| A high-burden country makes and buys its own local medicine, which is not WHO- prequalified or registered bya recognized stringent regulatory authority (SRA). Would Unitaid require that any project work it funds be used to increase demand only for product that is WHO- prequalified or SRA- registered? | Unitaid welcomes efforts to improve access to better, quality-assured treatment. Unitaid requires that any product procured with its funds conform with the Unitaid Quality Assurance guidelines as stated in https://unitaid.org/assets/UNITAID\_QA-of-health- products\_August2014.pdf - i.e., that products are WHO-prequalified or approved by a recognized SRA. In addition, in funding activities not directly related to product procurement, Unitaid still emphasizes the importance of quality assurance to 1) ensure that people in need receive appropriate, quality-assured medicines and diagnostics and 2) contribute to improving market health and stability for quality- assured health products. |
| What about rights-based projects, like patent law reform? | While Unitaid considers rights-based approaches important, Unitaid works through a market-based approach. The two approaches are not mutually exclusive, but the language used to present the issues, and the way to estimate and articulate impact can be considerably different. Nevertheless, one may wish to consider including elements related, for example, to the use of intellectual property flexibilities to bring down prices in quantifying impact. |

Questions Related to Submission of Proposals

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| Does Unitaid provide samples of proposal submissions? | No; however, the submission form provides a useful guidance on how proponents should approach each section of the proposal form. |
| Does GANTT chart need to include monthly planning for the full duration of the project? | At the proposal stage proponents are requested to provide quarterly planning and monthly planning only for the first year of the project. The monthly planning can be indicative at this stage and if the proposal receives “Go-Ahead” decision, a more detailed planning will need to be done during the grant agreement development process. |
| What level of detail should the budget contain? | At the stage of submission of a proposal an indicative but realistic budget estimate will have to be prepared using the budget template that can be found at <http://unitaid.org/calls> |
| What are the rules regarding the, indirect or overhead costs? | Unitaid agrees to fund a fair share of general administrative expenses linked to the general running of the head office administration of the different consortium members. Such expenses should primarily include expenses associated to head office corporate functions which support the entire operations (e.g. general management, human resources, finance, accounting, legal, internal audit, riskmanagement) as well as expenses linked to the general running of headquarter infrastructures (e.g. facility, information systems). Unitaid has established the following maximum levels:- 2% on commodity expenses;- 13% on other project expenses. |

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|  | Any expenses linked to fundraising and lobbying activities are excluded from such general administrative expenses and are not funded by Unitaid. When projects are implemented through a consortium of organizations, Unitaid only accepts general administrative expenses of either the lead grantee or the sub-grantee and does not support overlapping layers of general administrative expenses.There is no differentiation in the funding approach based on the type of entity. |
| Is there a list of cost category allowable/non-allowable for inclusion in the proposal budget? | Yes, Unitaid uses a standard expense classification. It can be found in the proposal budget form (Annex 3) that is available on Unitaid website ([http://unitaid.org/calls).](http://unitaid.org/calls%29) |
| Should budget be segregated by sub-grants? | Budgets of sub-awards to partners should be detailed using the proposal budget form (section 1, table Budget by organization). |
| Is there an audit requirement (do we have to plan some budget for audit orevaluation that would be contractually requested)? | Unitaid requires the grantees to engage with an audit firm to carry out annual financial audits during the project implementation and until the end of the project. The lead applicant should therefore include financial audit costs in the annual budgets. Such financialaudit would normally include reasonable assurance engagements and agreed-upon procedures on specific areas. The estimated value of audit costs should be based on prevailing market rates. |
| Is co-funding, required or recommended and if yes, at which level? | Co-funding is not a mandatory requirement; however, proponents are encouraged to include this information in the proposal.Please note that Unitaid defines co-funding as funding secured from other funding sources in addition to the Unitaid project funding to accomplish the Unitaid project outputs. Other funding source that will be used to finance activities which will support but not directly contribute to the achievement of the outputs should not be treated, and therefore not included, as co-funding.Please note that the budget form asks you to indicate the co-funding source (Section 2 of the form), if applicable, and if the co-funding is confirmed or anticipated. |
| What analysis on impact and value for money needs to be included in the proposal? | The proposal must plausibly demonstrate a clear analysis of the expected market and public health impacts and how the proposal would contribute to goals and targets set in respective disease strategies by WHO and other partner organizations. A more detailed guidance on impact assessment can be found at <http://unitaid.org/calls> |
| The goal and outcome in the log-frame template (Annex 1) is already pre-populated with a standard goal. Can this be changed? | Yes, proponents are free to change the goals and outcomes. The pre- populated goals and outcomes are only included to be a guide for the level and type of statements Unitaid is expecting. |

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| Can more than 5 risks be listed under the Section 4 of the application form? | Unitaid would like to encourage proponents to identify the most critical risks for the implementation of the project instead of presenting a large list of potential risks. |
| Do Annexes 5, 6, 7 and 8 need to be completed for all members of consortium? | The Annexes 5, 6, 7 and 8 need to be filled for the lead agency only. |
| What type of governmental bodies can sign the “Country engagement support letters”? | These letters can be signed by any relevant government body based on the proposed work and target countries. |
| Does Unitaid provide feedback on the JRC deliberations at the end of the proposal review process? | Unitaid proposal processes do not include the process of appeal. Letters are sent to inform each proponent of the result of the review and indicate decisions and rationale. In some cases, Unitaid may provide additional feedback at its discretion. |