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TO : Deans/Directors/Department Chairs/Faculty/REPS

FROM : ARMANDO C. CRISOSTOMO, MD. MHPEd
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SUBJECT : Unitaid: Accelerating impact of long-acting technologies in low- and middle-income countries.

We are pleased to announce that Unitaid is now accepting proposals entitled "Accelerating Impact of Long-acting technologies in low- and middle – income countries".

Under this call, Unitaid is soliciting proposals to support development of long-acting products of medicines to treat and/or prevent diseases affecting LMICs, notably HIV, HIV coinfections/comorbidities, TB, and malaria, with broader consideration for management of antimicrobial resistance (AMR).

You can visit this link: <https://unitaid.org/call-for-proposal/accelerating-impact-of-long-acting-technologies-in-low-and-middle-income-countries-lmics/#en> for more detailed information and downloadable forms.

The deadline for submission of proposals online is on April 23, 2019 12 noon CET. For inquiries, kindly coordinate with the Research Grants Administration Office (rgao@post.upm.edu.ph, 567-2054)

Thank you for your continued interest in health research and development.

 / CALLS FOR PROPOSALS

Call for Proposals: Accelerating impact of long-acting technologies in low- and middle-income countries

The objective of this call for proposals is to speed the development of existing medicines, into long-acting products, for treatment and prevention of diseases including HIV and its coinfections/comorbidities, tuberculosis (TB) and malaria.

Context

Safe and efficacious medicines are available for the prevention and treatment of major diseases, but their effectiveness can be compromised by poor treatment completion. Lack of adherence can worsen clinical outcomes, leading to increased mortality, persistent transmission and increased drug resistance in the case of antimicrobials and antivirals. Analyses of treatment and prevention of HIV, malaria, and TB within public health programs show wide disparities in rates of completion, especially among specific populations and regions.^[1]^[2]^[3]^[4]^[5]

Currently, most medicines in use require daily intake of oral tablets. Reasons for limited levels of adherence include: pill burden; duration of treatment (e.g., antiretrovirals (ART), maintenance phase for treatment of drug susceptible TB); stigma (e.g., treatment of TB, prophylaxis or treatment of HIV); discontinuation in access to health care for key populations (e.g. hepatitis C (HCV) treatment in people who inject drugs); and supply and programmatic issues. In addition, treatment interruptions are frequent in asymptomatic people (e.g., TB or malaria prophylaxis, HIV pre-exposure prophylaxis (PrEP) or ART).

Long-acting products have revolutionized other fields, such as schizophrenia and contraception, and could dramatically change the response to other major diseases affecting LMICs.

While not yet approved, long-acting products at various stages of development have been identified through wide-ranging consultations^[6] and landscaping^[7]^[8]^[9] that hold promise to dramatically transform the management of HIV and its co-infections/comorbidities, TB, or malaria, among other disease areas.

However, in the absence of intervention, an extensive time-lag for these new technologies to be available in LMICs can be expected. Therefore, Unitaid aims to support interventions that can accelerate development of game-changing long-acting solutions for global health impact.

Call scope

Under this call, Unitaid is soliciting proposals to support development of long-acting products of medicines to treat and/or prevent diseases affecting LMICs, notably HIV, HIV coinfections/comorbidities, TB, and

malaria, with broader consideration for management of antimicrobial resistance (AMR). Proposals should include the following elements:

- repurposing critical standard-of-care medicines into long-acting products, examples of such products may include injectables, implants, oral dosing technologies, or other;

AND

- enabling sound commercialization to facilitate subsequent uptake and scale in LMICs for resulting products. Considerations include: capacity for adequate and quality-assured production; regulatory strategy for LMICs; licensure and pricing strategies that can facilitate introduction and broad access in LMICs.

Proposals submitted should clearly demonstrate the fit with the objectives set out above, the expected impact and value for money, as well as, the complementarity to similar projects in this area.

Applicants are encouraged to consider products that can be introduced in the market within three to five years (i.e. products that could be eligible for purchase by major funders and countries as relevant and supply capacity created to address demand sufficiently by the end of this timeframe).

Topics which are out of scope for this Call include: a) proposals seeking the development of long-acting products including new chemical entities (NCEs), or new indications for approved drugs, that require full clinical development prior to submission to regulatory approval; b) proposals aiming to implement and/or deliver products at scale.

Proposals that include more than one product, leveraging investments across product-categories, and collaborative partnerships including industry are welcomed. Proposed project governance should consider the integration of a scientific advisory board.

Submission and format of proposals

Proposals, including all annexes, should be submitted electronically to proposalsUnitaid@who.int. A full proposal consists of the following documents:

- Proposal form [\[template, 160 KB\]](#)
- Annex 1: Log frame [\[template XLS, 50 KB\]](#)
- Annex 2: Timeline GANTT chart [\[template XLS, 35 KB\]](#)
- Annex 3: Budget details [\[template XLS, 23 KB\]](#)
- Annex 4: Organizational details and CVs of key team members [\[no template\]](#)
- Annex 5: Support Letters (not mandatory) [\[no template\]](#)
- Annex 6: Declaration of relevant interest [\[template DOC, 21 KB\]](#)
- Annex 7: Applicable ethics, anti-discrimination and environmental policies [\[template DOC, 21 KB\]](#)
- Annex 8: Declaration regarding tobacco and arms entities [\[template DOC, 25 KB\]](#)
- Guidance on Impact Assessment [\[PDF, 450 KB\]](#)
- Financial Guidelines for Unitaid Grantees [\[PDF, 1,2 MB\]](#)
- Report on the global technical consultation meeting: 1-2 November 2018 [\[PDF, 136 KB\]](#)

Please note that our email system accepts messages up to 8 MB in size. For submissions exceeding this size, please consider splitting attachments in several messages.

Your proposal and potential queries receive personal attention: submitting your application at least a day before the deadline allows providing feedback on its completeness. You will receive answers to your queries at any

one stage of the application review process. Please send your queries to the Grant Application Manager at proposalsUnitaid@who.int

You will find further guidance in the [Unitaid proposal process document](#) [PDF, 100 KB]

Downloads are available in this link:

<https://unitaid.org/call-for-proposal/accelerating-impact-of-long-acting-technologies-in-low-and-middle-income-countries-lmics/#en>



Q&A for Intention to Submit Proposals (ISP) and Submission of Proposals

General Questions

Question	Answer
What is the proposal process under the Unitaid Operating Model?	<ol style="list-style-type: none">1) Once a Call is issued, applicants communicate their Intention to Submit Proposal (ISP) by the date indicated in the call. They can do so by filling in the form, available on Unitaid's web site at http://www.unitaid.org/calls. ISP submission is not a mandatory requirement, however is strongly encouraged as it allows Unitaid to provide initial feedback on whether the proposed project could match the call requirements.2) Full proposals must be submitted electronically using the Unitaid 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. <p>For further details please refer to the Unitaid Proposal Process document that can be found at http://unitaid.org/calls</p>
Can a proposal that includes middle-income countries in scope be submitted?	<p>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.</p> <p>Across its portfolio of projects, at least 85% of Unitaid funds dedicated to commodity purchase must be spent in low-income countries. While middle-income countries are not ineligible for inclusion in Unitaid-funded projects, there are overall limits on</p>

	Unitaid funding that can be dedicated to commodity purchases in these countries. For any proposed project that includes a greater than 15% proportion of funding for commodity purchases in middle-income countries, this needs to be clearly justified in the proposal as being essential to the realization of the project objectives. Wherever possible, funding in middle-income countries should be used to increase access to commodities for vulnerable groups.
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.
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 eligible to submit a proposal?	Yes. Unitaid can provide grants to NGOs. 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 or individuals 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 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.
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.int In 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 and associated documents published on the Unitaid website. In some cases, webinars may be arranged.
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 does not specify minimum or maximum grant sizes. 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 in securing 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 reviewed and permitted for use by the Expert Review Panel (ERP) as described in the Unitaid Quality Assurance guidelines https://unitaid.eu/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 by a 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.eu/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 to. 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 Relating to ISP Submission

How can ISPs be submitted? By email, post or diplomatic pouch?	If you intend to submit a proposal, we invite you to complete and send the intention to submit form to proposalsunitaid@who.int . The form can be found on our internet site: Call for Proposals (http://unitaid.org/calls)
Can proponents share ISP or proposal details with others while under review by Unitaid?	There are no Unitaid policies or rules that preclude a lead organization from sharing information on an ISP or proposal submitted to Unitaid while the ISP or proposal is under review. As the owner of the ISP or proposal you are free to share ISP or proposal content both pre- and post-submission. However, when sharing ISP or proposal information, it is important to emphasize that there is no guarantee of funding at either the ISP or proposal stage.
Does the ISP submission form exist in French? If not, can the form be filled out in French?	The ISP submission form is only available in English, however the ISP can be prepared in English or French.
Should the ISP be submitted in English or in French?	ISPs are reviewed in either language. However, at the next stage, proposals would need to be submitted in English.

Questions Related to Submission of Proposals

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?	There is no need to have budget at the ISP stage. 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?	<p>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, risk management) as well as expenses linked to the general running of headquarter infrastructures (e.g. facility, information systems).</p> <p>Unitaid has established the following maximum levels:</p> <ul style="list-style-type: none"> - 2% on commodity expenses; - 13% on other project expenses. <p>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.</p> <p>There is no differentiation in the funding approach based on the type of entity.</p>
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).
Should budget be segregated by sub-grants?	Budgets of sub-awards to partners should be detailed using the proposal budget form (section 1, table <i>Budget by organization</i>).
Is there an audit requirement (do we have to plan some budget for audit or evaluation 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 financial audit 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?	<p>Co-funding is not a mandatory requirement; however proponents are encouraged to include this information in the proposal.</p> <p>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.</p> <p>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.</p>
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.
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 6, 7 and 8 need to be completed for all members of consortium?	The Annexes 6, 7 and 8 need to be filled for the lead agency only.
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.