# Call for Proposals announcement text

# Summary

Unitaid is pleased to announce a Call for Proposals for the Area for Intervention: **Accelerating impact of long-acting technologies in low- and middle-income countries (**LMICs).

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.

For the purpose of this call, Unitaid defines ‘long-acting products’ to mean sustained/extended release products that allow slow absorption of administered drugs maintaining their effects over long periods of time (i.e., over a week for oral products, over a month for injectables and other devices such as implants, patches or rings). The expected change in public health impact for the new products, compared to current daily oral formulations, would need to be explained in each case as it differs depending on disease and indication.

# 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]](#footnote-1),[[2]](#footnote-2),[[3]](#footnote-3),[[4]](#footnote-4),[[5]](#footnote-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 productss 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]](#footnote-6) and landscaping[[7]](#footnote-7),[[8]](#footnote-8),[[9]](#footnote-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 s 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.

**PROCESS FOR PROPOSAL SUBMISSION**

*Note: If selected, applicants should plan to be available for a face-to-face kick-off meeting with Unitaid, in Geneva, between 22-31 July (exact date tbc). In addition, successful applicants should plan to have sufficient human resource capacity available to advance a first draft of the project plan by early September.*

When developing a proposal, please note the following resources:

* Answers to frequently asked questions relevant to proposal development (this document is regularly updated), please [click here](http://www.unitaid.eu/images/call_proposals/QA-ISP-Proposals_14_04_2016.pdf);
* Unitaid’s preliminary rationale for working in this area for intervention, please [click here](file:///I:\UnitData\Market%20Dynamics%20II\1%20HIV\8%20Call%20for%20proposals%20and%20go%20ahead\2017%20ST\Call%20for%20proposal).

Unitaid works through market-based interventions to achieve global market and public health impact. Proposals should clearly demonstrate the use of innovative and sustainable approaches to address key public health problems.

Applicants should be clear about the underlying assumptions made in their proposed approach, ad should highlight any major risks or other factors that may affect the delivery of results. Finally, proposals are expected to outline a lean, concrete and clear pathway to results and impact.

The proposed implementing agency needs to demonstrate capacity/prior experience implementing projects of this nature, including capacity to address concerns of and seek input and buy-in from key civil society groups at all stages of the proposal.

All proposals received will be considered, but Unitaid reserves the right to not fund all the areas outlined in this call. Funding may be allocated to more than one successful proponent.

**Important dates:**

If you intend to submit a proposal, please complete and send the [[intention to submit (ISP) form](http://unitaid.org/images/call_proposals/january_2017/Intention_to_submit_proposal_form.doc) DOC, 30 KB] to [proposalsUnitaid@who.int](mailto:proposalsunitaid@who.int) **by 4 March 2019.**

The closing date for receipt of full proposals **is 23 April 2019**, at **12:00 noon Geneva (Switzerland) time**. Applications received past the indicated deadline will not be considered.

**N.B. A proposal is considered submitted only once you receive an e-mail message of confirmation of receipt from Unitaid.**

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

* Proposal form [template]
* Annex 1: Log frame [template]
* Annex 2: Timeline GANTT chart [no template]
* Annex 3: Budget details [template]
* 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]
* Annex 7: Applicable ethics, anti-discrimination and environmental policies [template]
* Annex 8: Declaration regarding tobacco and arms entities [template]
* Guidance on Impact Assessment
* Financial Guidelines for Unitaid Grantees

**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](mailto:proposalsunitaid@who.int)

You will find further guidance in the [Unitaid proposal process document](https://unitaid.eu/assets/Proposal-process-2018.pdf)

1. . Bezabhe WM *et al*. Adherence to antiretroviral therapy and virologic failure. [Medicine](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4839839/). 2016 Apr; 95(15): e3361. [↑](#footnote-ref-1)
2. . Shargie EB *et al*. Determinants of treatment adherence among smear-positive pulmonary tuberculosis patients in Southern Ethiopia. PLoS Med 2007; 4(2): e37 [↑](#footnote-ref-2)
3. . Sandgren *et al*. Initiation and completion rates for latent tuberculosis infection treatment: A systematic review. BMC Infectious Diseases 2016 16:204 [↑](#footnote-ref-3)
4. . Bruxvoort K *et al*. How patients take malaria treatment: A systematic review of the literature on adherence to antimalarial drugs. 2014 PLoS ONE 9(1): e84555. [↑](#footnote-ref-4)
5. . Siddiqui MR *et al*. Adherence to Artemisinin Combination Therapy for the treatment of uncomplicated malaria in the Democratic Republic of the Congo. [F1000Res](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4406189/). 2015; 4: 51. [↑](#footnote-ref-5)
6. Unitaid Technical Consultation Meeting: Bringing innovation to the frontline for impact—long-acting solutions to prevent and treat major infectious diseases, 1-2 November 2018, Geneva. [↑](#footnote-ref-6)
7. Medicines Patent Pool and Unitaid intellectual Property Report on Long-Acting Technologies, <https://medicinespatentpool.org/uploads/2018/12/MPP-Unitaid_Intellectual-property-report-on-long-acting-technologies.pdf> . [↑](#footnote-ref-7)
8. Marmora L *et al.* Long-acting technologies for infectious diseases in LMICs. Lancet (2018) 392(10158):1610-1611. [↑](#footnote-ref-8)
9. Unitaid Compendium of Technical and Market Information: Bringing innovation to the front line for impact—long-acting technologies for the prevention and treatment of major infectious diseases, November 2018. ADD link once published [↑](#footnote-ref-9)