



TOGETHER TO HEAL

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In reply please
refer to:

Your reference:

Dr Marcos Espinal
Executive Secretary
Stop TB Partnership
World Health Organization
Avenue Appia 20
1211 Geneva 27

REM-UNITAID-001
390490
2007-02-16
FILE

10 January 2007

Dear Dr Espinal,

**UNITAID Project Support for Paediatric TB, 2006/Q4 and 2007 -
Global Drug Facility (GDF)**

Reference is made to your proposal to UNITAID for support of a Paediatric Tuberculosis (TB) project for 2006/Q4 and 2007 endorsed by the Board of UNITAID and a Plan of Action and Deliverables attached hereto as Annex 1 (collectively referred to as "the Project"). Annex I is an integral part of this Letter of Agreement.

Although it is estimated that about 10% of TB cases are in children, paediatric TB has been largely neglected, with little focus on the specific treatment needs of children. As a result, no paediatric tuberculosis products are currently pre-qualified. Nor have child-friendly formulations yet been approved. These needs are not being funded by other existing programmes.

UNITAID is an international drug purchase facility to accelerate access to high-quality drugs and diagnostics for HIV/AIDS, malaria and tuberculosis in high-burdened countries.

UNITAID is hosted and administered by the World Health Organization



**World Health
Organization**

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cc: Dr A. Asamoah-Baah, ADG/HTM
Dr Mario Raviglione, Director Stop TB
Mr Robert Matiru, Manager GDF

UNITAID is pleased to assist in a contribution of financial support for the Pediatric TB Project for 2006/Q4 and 2007 in the amount of USD 5,665,000. The contribution is payable in accordance with the schedule in paragraph 3, subject to your countersignature of this Letter of Agreement, and is made subject to the terms and conditions set out below.

Use of Funds and Duration of Agreement

1.1 The use of the contribution is restricted exclusively to provide appropriate-strength paediatric drugs for children under 15 years of age and ensure development of new child-friendly formulations for infants under 5 years of age. GDF is expected to use the contribution to fund the supply of approximately 150,000 paediatric TB drugs to children in about 20 countries by the end of 2007.

1.2 The starting date of the Project shall coincide with the date of the receipt of the contribution. GDF shall complete the implementation of the Project by December 31, 2007. The letter of agreement will remain in effect until such time as all the drugs procured under this Agreement have been satisfactorily delivered and until acceptance by UNITAID of GDF's final technical and financial reports.

2. Responsibility

2.1 UNITAID. UNITAID is responsible for the provision of funds for the Project, in accordance with the terms of this Agreement. It is anticipated that UNITAID's sustained funding will stimulate the production by manufacturers of appropriate-strength fixed dose combinations for children and catalyze development of child friendly formulations for children under 5 years of age. It is also expected that UNITAID's funding for pooled procurement would enable purchases to be made by GDF in sufficient volumes to generate significant price reductions.

2.2. GDF. GDF is responsible for the implementation of the Project in accordance with the Plan of Action and Deliverables for 2006/Q4 and 2007 as set out in Annex 1 and the budget expenditure pattern described in paragraph 4 below. Implementation, monitoring and evaluation and reporting of the Project will be conducted in accordance with GDF's existing procedures. (These procedures are updated from time to time utilizing mechanisms established for that purpose.)

A summary of GDF's procedures for grant application and review, supply and delivery, quality assurance, programme monitoring and evaluation, and reporting is provided in the Overview of Operations at Annex 2 hereof. GDF Guides and Monitoring Documents are also published on GDF's website at www.stoptb.org/gdf (or successor site designed by GDF). Related reporting requirements are set out in paragraph 8 below. A complete copy of GDF's standard operating procedures, including contracts and common operating procedures established with the relevant agents and suppliers, will also be provided to the UNITAID Secretariat.

3. Schedule of payments. The contribution shall be paid in advance to cover at least one year's operations in accordance with the following schedule: the initial installment of USD 864,000 shall be paid upon signature of this Letter of Agreement by both parties, and the balance of USD 4,801,000 shall be paid on 15 February 2007 subject to the completion of the following disbursement conditions:

- (i) signature of the contract(s) between GDF and procurement agent(s) responsible for the procurement of UNITAID funded drugs ; and
- (ii) signature of all grant agreements between beneficiaries and GDF.

4. Budget The Budget for the activities financed by the contribution is set out below:

Estimated Budget Breakdown - Paediatric TB Niche 2006/Q4 - 2007 (in USD)	
Drugs	4 081 632
Agent fees	167 118
Freight, Insurance & Quality Control	1 416 250
TOTAL	5 665 000

Any proposed change or reallocation over 10% of any budgeted expenditure heading or any new expenditure heading is required to have prior written approval from the UNITAID Secretariat.

5. **Price reduction.** It is understood that activities to be implemented in 2006/Q4 and 2007 are not likely to generate significant price reductions due to the relatively short timeframe under the Project. In order to achieve this objective, GDF would require sustainable funding in subsequent years. Sustainable funding would facilitate price reduction by enabling GDF to attract a sufficient number of suppliers to participate in competitive tenders based on the prospect of long-term supply contracts and high volume purchases.

6. **WHO Rules.** The operations of GDF and UNITAID in connection with this agreement shall be conducted and administered in accordance with the WHO Constitution, WHO's Financial and Staff Regulations and Rules, Manual provisions, and applicable policies, procedures and practices (the "WHO Rules") and with the terms of the Memorandum of Understanding (MoU) dated September 19, 2006 for the hosting and administration of UNITAID among Brazil, Chile, France, Norway, the United Kingdom of Great Britain and Northern Ireland, and WHO, in particular Annex C thereof entitled "Procurement Strategies and Procedures".

7. **Financial Administration and Accounting.** The funds and allotment(s) will be administered in accordance with the WHO's Financial Regulations and Rules, Manual provisions, and applicable policies, procedures and practices (the "WHO Rules"). The contribution will be made available through a transfer from UNITAID Trust Fund to WHO Voluntary Fund for Health Promotion (VFHP), sub-account for "Stop TB partnership" (XL53). Allotments issued from this contribution will bear the programme code "TUB", which corresponds to the WHO Area of Work for the Stop TB Partnership.

Any balance of the contribution under WHO VFHP that is outstanding at the time of completion of the Project or on earlier termination shall be held by the World Health Organization at the disposal of UNITAID, after all obligations incurred for the Project prior to such completion or termination have been fully liquidated. All contributions are subject exclusively to WHO's internal and external auditing procedures


In addition to the financial support of USD 5 665 000 to the Paediatric TB Project, an amount corresponding to 3% of the Project expenditure will be paid by UNITAID to WHO, directly from UNITAID Trust Fund, to cover programme support costs in accordance with World Health Assembly Resolution WHA 34.17 as provided in Annex D of the 19 September 2006 MoU.

8. **Reporting.** GDF shall provide to UNITAID in April 2007 an interim Progress report on the activities financed by the contribution (covering Q4/2006 and Q1/2007) and at the end of January 2008, an annual Progress report for 2007, together with interim financial statements of income and expenditures, describing the activities undertaken and the progress achieved. GDF will submit to UNITAID, annual Progress reports in the same content and format as it submits to its current donors to its Grant service line for 1st line adult TB Drugs, with additional sections as well as process/impact indicators for pediatric TB drug development and supply, covering the actions set out in Annex 1. All GDF Progress Reports are posted on the GDF website and can be accessed by UNITAID for review: <http://www.stoptb.org/gdf/whatIs/documents.asp>

A final certified statement of income and expenditures for the Project will be provided to UNITAID within ninety (90) days after settlement of all obligations for activities commenced prior to completion or termination of the Project. Reports to UNITAID are to be submitted to the Executive Secretary of UNITAID.

9. **Assignment.**

9.1 If during the term of the Project there is a change of the legal status of UNITAID, such as a change in the hosting or administering agency, GDF agrees to enter into an Agreement with that legal entity under the same terms and conditions as this Letter of Agreement if required by that entity: The new Agreement and this Letter of Agreement would be contiguous and simultaneous with the combined validity not exceeding that of the terms specified in paragraph 1.2 of this Agreement.



9.2 This Agreement will be binding upon the successors and assignees of the parties hereto, provided that nothing herein will permit any assignment without the prior written consent of the other party (such consent not to be unreasonably withheld).

10. **Resolution of Disputes.** In the unlikely event of a disagreement on any aspect of the interpretation or implementation of this Letter of Agreement, UNITAID and GDF will find a mutually acceptable method of finally resolving the disagreement. Any differences of opinion relating to the Project shall be resolved through good faith negotiation. Upon request, the reasons for the dissatisfaction will be set out in writing and the cause of the dispute will be discussed. If after further consultations, no satisfactory agreement can be reached to resolve the matter, either the UNITAID Board or GDF may terminate the Project, subject to the settlement of any outstanding obligations.

Upon the expiration or earlier termination of this Project agreement for any cause, the parties will negotiate in good faith with a view to agreeing on an orderly and ethical manner of winding down operations (including compliance with any outstanding reporting obligations and final reporting).

11. **Acknowledgement.** GDF will make an appropriate acknowledgement of the contribution in its Grant Agreements with recipient countries (as provided in Annex 1) and in its publications emanating from the Project. Any proposed reference to the contribution or the relationship between UNITAID and GDF will be agreed in advance. It is understood that any donor is entitled to refer to its donation in its internal documents and in its annual reports.

12. **Risk Review.** GDF will cooperate in the UNITAID Secretariat's periodic risk review and assessment from time to time.

13. **Publication.** GDF makes public its list of products and, subject to agreement with the respective manufacturer or supplier, will publish prices of all drugs and other products funded by UNITAID. All Stop TB Partnership annual reports, financial statements and GDF progress reports are posted on the Stop TB Partnership web site: <http://www.stoptb.org>. GDF reports are also available on the GDF website: <http://www.stop.tb.org/gdf>.

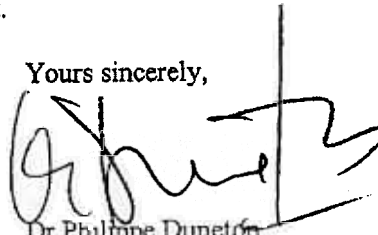
14. **Legal Status.** UNITAID is a collaborative drug purchase facility, which is not a legal entity and is hosted and administered by WHO. GDF is a project of the Stop TB Partnership, which is not a legal entity and is also supported by a hosting arrangement with WHO.

This contribution by UNITAID and the undertaking of the Project by GDF have been endorsed by, respectively, the UNITAID Executive Board and the Stop TB Partnership Coordinating Board. The contribution has also been reviewed by the Office of the Director-General of WHO and has been made subject to the normal WHO clearance procedures.

15. **Consultation.** At the request of any party or their representatives, consultations shall take place with reference to the implementation, modification or revision of this Letter of Agreement.

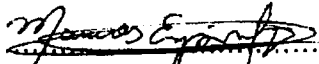
If this letter correctly describes your understanding of the provisions of this contribution, please countersign below and return it to the UNITAID Secretariat.

Yours sincerely,



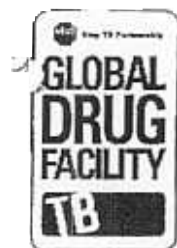
Dr Philippe Duneton
Interim Executive Secretary
UNITAID
Hosted and administered
by the World Health Organization

Acceptance:

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Dr Marcos Espinal
Executive Secretary
Stop TB Partnership
Hosted and Administered by WHO

Date: 12/01/2007



Annex 1: Plan of Action and deliverables for 2006/Q4 - 2007

1. Call for Proposals to eligible countries

Justification: In order to identify eligible countries for and determine interest in UNITAID funded paediatric TB drugs, a widely disseminated Call for Proposals is required.

Action: An unofficial call will be issued on September 20 followed by an official call after the 1st UNITAID Board meeting October 9-10, with a closing date of November 6 2006. It will be issued via the WHO Regional offices, Stop TB Partners and in the public domain (GDF website). GDF will make appropriate acknowledgement of UNITAID in the Call.

Indicator: Call for Proposals issued.

Status: *Completed*

2. Secure prices for initial supply of Paediatric TB drugs

Justification: Initial contracts for supply of paediatric TB drugs will be based on direct offers of price and volume solicited from eligible supplies. The GDF secretariat will secure prices of products for supply on a non-exclusive, term-limited basis in order to obtain initial industry commitment and achieve the short-term supply targets of 2007. Direct offers are necessary since there are too few suppliers at this stage for a competitive tender. The products for which prices will be secured will be, at least, appropriate strength paediatric Fixed-dose combinations (FDCs) and single formulations. Quality assurance of these products will be based on GDF's Provisional Quality Assurance Process, pending prequalification under WHO's prequalification programme.

Action: GDF will secure prices for the products in question by October 2006. Suppliers will be required to commit, in principle, to submit into the WHO Prequalification process paediatric TB drug dossiers, develop child-friendly formulations and participate in future competitive tenders.

Indicator: Prices offered and secured from more than one supplier.

Status: *Completed. GDF secured prices for four products from three suppliers based on its provisional quality assurance process. The suppliers have committed to submit paediatric product dossiers into the WHO prequalification process, develop child-friendly formulations and participate in future GDF competitive tenders provided sufficient volumes of TB drugs are purchased by GDF based on attractive supply projections and sustainable UNITAID funding for the same.*

3. Meeting of GDF Technical Review Committee to assess Proposals

Justification: The Technical Review Committee (TRC) of the GDF, an independent body of TB and drug management experts, provides objective, expert advice on country proposals and progress. The TRC assesses grant applications to the GDF and makes recommendations on the grants to the Stop TB Co-ordinating Board on which grant applications to accept, on the level and nature of the grant and on any country-specific conditions for support, and to WHO on the non-drug aspects of the programme requiring assistance.

Action: GDF's TRC will meet at its 14th session November 13-16 2006 at which all proposals received in response to the Call will be reviewed. Proposals recommended for approval will be reported to the UNITAID Board November 29-30 and submitted to the Stop TB Coordinating Board for final endorsement, in early December.

Indicator: TRC meeting is held and recommendations are made and documented on which grant applications to accept, on the level and nature of the grant and on any country-specific conditions for support.

Status: *Completed. The outcome of the TRC review of paediatric TB proposals was as follows:*

Proposals Received (19): Approved (14), Conditionally Approved (4), Not Approved (1). (* Final approval subject to clarification on one or more aspects of the proposal being received by the TRC and/or one or more recommendations of the TRC being followed.)*

Note - 16 proposals were submitted from Low Income Countries (LICs) and 3 proposals from Lower-Middle Income Countries (LMICS)

4. Stop TB Coordinating Board Review

Justification: Grant recommendations and other decisions of the TRC will be approved by the Stop TB Co-ordinating Board (via its Executive Committee or the delegated authority of the Executive Secretary of the Stop TB Partnership) in early December 2006.

Action: A copy of the list of approved grantees will be provided to the UNITAID Secretariat within 14 days of approval.

Indicator: List of approved grantees.

5. Conclude Grant Agreements with recipient governments

Justification: GDF will enter into Grant Agreements with recipient governments that provide, inter-alia, that the drugs supplied will only be used for treatment, free of charge, to TB patients and in treatment regimens and programmes following WHO guidelines, including the DOTS element of the Stop TB Strategy, and are subject to specified reporting and monitoring requirements. The Grant Agreement will acknowledge that UNITAID is the source of funding for the drugs and that the country's commitments under the Grant Agreement are made to UNITAID as well as to GDF.

Action: Conclude Grant Agreements between WHO/GDF and each recipient government provided that sufficient funding is approved by the UNITAID Board at its November 29-30 meeting and upon approval of the Stop TB Coordinating Board.

Indicator: Signed Grant Agreements between WHO/GDF and each recipient government, contingent upon funding commitment from UNITAID.

6. Contract with Procurement agent

Justification: GDF is responsible for coordinating the identification and selection of the agents involved in carrying out the supply chain and for placing and monitoring the progress of drug orders through to delivery. A GDF procurement agent will contract and coordinate the suppliers, quality control agents, laboratories and shipping and insurance agents needed, under GDF oversight. All GDF agents (including the Procurement Agent) and suppliers are selected through a transparent, competitive process and are required to comply with GDF designated quality standards which include but are not limited to WHO prequalification standards. As GDF is not a legal entity, legal engagements, it relies on its hosting arrangements with WHO, which enters into the necessary legal contracts for the benefit of GDF.

Action: Signature of contract between WHO/GDF and the recently selected procurement agent, GTZ International Services by early December.

Indicator: Signed Long Term Agreement between WHO/GDF and GTZ.

7. Issue Official Purchase Requests (OPRs) for paediatric TB drugs to GTZ

Justification: Upon signature of a Grant Agreement the GDF secretariat places an OPR with its procurement agent which forms the basis for (a) the Final Purchase Order which the agent will then issue to one or more suppliers to manufacture the required quantity of product(s) and (b) the quality control and delivery of the order to the recipient country.

Action: Issuance of OPRs as per GDF Standard Operating Procedures in December 2006 and 2007.

Indicator: Final signed OPRs issued.

8. Collaborate with WHO Prequalification programme to stimulate prequalification of paediatric TB drugs, including child-friendly formulations

Justification: No prequalified paediatric drugs, including child-friendly formulations, currently exist due to an undeveloped market for these products and therefore lack of industry interest in investing in prequalification.

Action: GDF to assist WHO's Prequalification team in 2007 in (a) identifying and prioritizing suppliers and products for prequalification in January 2007 (b) supporting capacity building initiatives (c) facilitating communication between GDF supply partners and the prequalification team (d) designing its tenders, to the extent possible, to reward suppliers of prequalified products and ultimately limiting its tenders to suppliers of prequalified products.

Indicator: Number of prequalified paediatric TB drugs, including child-friendly formulations (Target date and number will be set jointly with WHO prequalification team).

9. Launch tender and finalize Long term agreements with suppliers of Paediatric TB drugs

Justification: As per Action point 6 above. In addition: In order to stimulate price reduction, promote competition and ensure sustainable supply, a competitive tendering process among eligible suppliers will be issued in 2007.

Action: GTZ will issue a tender no later than end Q2 2007.

Indicator: Competitive tender issued, adjudicated and long term agreements concluded with suppliers (subject to acceptable tenders submitted).

10. Engage and negotiate with industry to produce and prequalify appropriate child-friendly formulations

Justification: There is a current lack of high-quality, prequalified child-friendly formulations and little momentum for development of the same. The value added of UNITAID in this niche is to ensure creation of appropriate paediatric formulations, not currently available, which are unlikely to be developed otherwise. GDF will engage industry to demonstrate the projected market volumes to be funded by UNITAID over a sustained period of time, clarify the types of product required and demonstrate the benefits to industry of collaborating with GDF and UNITAID.

Action: (a) Meet with interested industry players and potential suppliers at key meetings to promote paediatric TB drug prequalification and supply, including: bi-lateral meetings in Geneva, Sept., Oct. and Nov. 2006; International Congress of IUATLD, Paris, Oct. 31 – Nov. 4 2006; CPHI Suppliers meeting Mumbai, India, Dec. 1-3 2006; GDF supply stakeholders meeting Q2 2007; CPHI Suppliers meeting, Shanghai, China, June 2007.
(b) Provide a forecast to industry on the long-term sustainable volumes of paediatric TB drugs to be supplied via GDF based on UNITAID sustainable funding.

Indicator: Outcomes of meetings held and commitments from suppliers made.

11. Reporting to UNTAID

Justification: UNTAID shall be provided an interim progress report on the activities financed by the initial contribution. GDF submits annual Progress reports to its current donors to its Grant service line for 1st line adult TB drugs. GDF will submit the same reports to UNTAID with added sections as well as process/impact indicators for paediatric TB drug development and supply covering the actions set down in this Annex. All GDF Progress Reports are posted on the GDF website and can be accessed by UNTAID for review:
<http://www.stoptb.org/gdf/whatis/documents.asp>

Action: The interim report will be submitted in April 2007 (covering Q4/2006 & Q1/2007) and the first annual report, for 2007, will be submitted end January 2008.

Indicator: Final interim and annual reports submitted.

November 21 2006