



February 22, 2011

RE: RfP for Supply of UNITAID-Financed Pediatric OI drugs for period of June 2011 - February 2012

Dear Sir or Madam,

The Clinton Health Access Initiative ("CHAI"), formerly a division of the William J. Clinton Foundation, is collaborating with UNITAID, an international drug purchase facility hosted by the World Health Organization ("WHO"), to increase the affordability of critical pediatric medications for national HIV/AIDS treatment programs. The Board of UNITAID has given approval for the extension of the UNITAID-CHAI Pediatric HIV/AIDS Project (the "Pediatric Project" or the "Project") through December 31, 2011 and authorized the Executive Secretary to commit up to \$81,116,440 with a guarantee amount of up to \$54,000,000, to fund the purchase of specific pediatric ARVs and other commodities for certain developing countries. The products expected to be procured for the Project in 2011 include ARVs, drugs to fight opportunistic infections ("OI Drugs"), diagnostic tools and ready to use therapeutic food. In 2011 UNITAID is expected to consider the funding similar purchases for the Project in 2012.

The subject of this Request for Proposals ("RfP") is the procurement of OI Drugs for the Project in 2011, which is anticipated to total US \$ 2.8 million. The RfP initiated by this letter will determine the selection of suppliers and pricing for the OI Drugs (set forth in Schedule 2.A), from **June 1, 2011 through February 28, 2012**. Another process will be conducted in 2012 for supply and pricing of orders for OI Drugs for the twelve months following this period.

To this end, this RfP is requesting suppliers to submit Proposals for the OI Drugs set forth in Schedule 2.A, and serves to inform suppliers of the terms and conditions of selection. As explained more fully in Appendix 1, Section 3, bid proposals for each OI product that the supplier proposes to supply should specify product pricing, associated terms and conditions of sale, regulatory preparedness and willingness to abide by the conditions of the project. Offerors must prepare and submit their Proposals in accordance with Appendix 2 to this RfP (Specific Instructions to Proposers and Required Information for Responses).

The Proposal must be received **electronically or in hard copy by no later than 17:00 Central European Time (CET) on March 15, 2011 at the address below**. Faxed proposals are not acceptable.

Following submission, CHAI will proceed through a selection process that is more fully detailed in Appendix 1, Section 3 below. CHAI will confirm the eligibility of suppliers. Thereafter, based on several factors (including but not limited to price, regulatory status and willingness to abide by the conditions of the project), CHAI will select supplier(s) for each product.

The successful Proposer(s) will receive an award notification letter subsequent to final adjudication of the RfP. CHAI and the successful Proposer(s) would then agree on a date to begin the negotiation of a purchase agreement. The selection of eligible suppliers and negotiation of purchase agreements will be completed on a timeline to permit orders to be placed beginning in June 2011.

To this end, this RfP is being issued and consists of this cover letter and the following:

APPENDICES

1. Background Information on Roles and Responsibilities, Description of the Project, Supplier Selection Process and Evaluation Criteria
2. Specific Instructions to Offerors and Required Information for Responses

SCHEDULES

1. List of Beneficiary Countries of UNITAID-CHAI Pediatric Project
2. Dosage forms of OI Drugs to be Procured by CHAI for the Project and Initial Indicative Forecast of Product Volumes for 2011
3. Mandatory Eligibility Requirements of Suppliers
4. Standard Terms and Conditions of Product Procurement under the Project
5. Summary of Applicable UNITAID Quality Assurance Standard for OI Drugs Procured under the Project
6. Quality Control Requirements

All Proposals (including supporting documentation) are to be submitted to the following office:

<i>If by email, to:</i> nprakash@clintonhealthaccess.org
<i>If by post or courier, to the following address:</i> Clinton Health Access Initiative Attn: Nikhil Prakash F79 Green Park Main New Delhi, 110016 INDIA

Proposals:

Proposals must be made in accordance with the Specific Instructions to Offerors as detailed in Appendix 2.

Requests for Clarification:

Written requests for clarification in relation to the RfP must be submitted in writing via email no later than **March 1, 2011** to **nprakash@clintonhealthaccess.org** referencing 'Request

for Clarification: RfP for Supply of OI Drugs for the UNITAID-CHAI Pediatric Project' in the subject header. The CHAI team will respond to the request as quickly as possible, normally within the next working day. All relevant questions and related responses, as well as any amendments to the RfP, will be sent by email to all parties who received this RfP. It is the Offeror's responsibility to consult their email to ensure they are aware of and to acknowledge by email their receipt of the clarification.

CHAI may, at its discretion, ask any Offeror for clarification of any part of its proposal to assist in the evaluation and comparison of proposals. CHAI's request for clarification and the Offeror's response shall be in writing.

Modifications:

CHAI may issue a modification of the RfP documents at its own initiative or in response to a clarification requested by a Proposer. Any such modifications to the RfP documents shall be communicated to all Proposers at the same time.

RfP-related Expenses:

Offerors are solely responsible for their own expenses, if any, in preparing and submitting an offer in response to this RfP. This would include any cost incurred during oral presentations, functional demonstrations and subsequent meetings and negotiations.

Supplier Selection and Contract Award:

CHAI plans to select a successful supplier(s) by **April 22, 2011**, and a purchase agreement will be negotiated and executed soon afterwards to enable orders to be placed beginning in June 2011.

CHAI expects to award a contract resulting from this RfP to the responsible Offeror(s) whose proposal conforming to this RfP offers the greatest value in terms of the selection criteria. CHAI may (a) reject any or all proposals, (b) accept other than the lowest cost proposal, (c) accept more than one proposal, (d) accept alternate proposals, (e) waive informalities and minor irregularities in proposals received, or (d) cancel this RfP.

CHAI may award the contract on the basis of initial proposals received, without discussions or negotiations. Therefore, each initial Proposal should contain the Offeror's best terms from both financial and technical standpoints. CHAI reserves the right (but is not under obligation to do so) to enter into discussions with one or more Offerors in order to obtain clarifications or additional detail, to suggest refinements in the Proposal, or negotiate financial adjustments, including of price and scope.

CHAI will apply the evaluation criteria set out in this RfP but is under no obligation to reveal or discuss with any Offeror any further detail of how a Proposal was assessed, or to provide any other information relative to the selection process.

Offerors whose proposals are not selected will be notified in writing of this fact, and shall have no claim whatsoever for any kind of compensation.

This letter and its attachments shall not be construed as a contract or a commitment of any kind. This Request for Proposal in no way obligates CHAI to award a contract, nor does it

commit CHAI to pay any cost incurred in the preparation and submission of the proposal(s).

By submitting any materials or other information, Offerors warrant to CHAI that they have the right to provide the information submitted and that it is honest and accurate.

Thank you for your commitment to making opportunistic infection treatment available to children in developing countries affected by HIV/AIDS. We are eager to work with you to rapidly expand care to children living with HIV, in parallel with efforts to minimize the number of children who are born with the virus in the long-term.

We look forward to your reply no later than **March 15, 2011**.

Best regards,

Inder Singh
Executive Vice President Access Programs
Clinton Health Access Initiative (formerly, Clinton Foundation HIV/AIDS Initiative)

cc: Jorge Bermudez, Executive Secretary, UNITAID

APPENDIX 1

Background Information on Roles and Responsibilities, Description of the Project, Supplier Selection Process and Evaluation Criteria

The sections below provide additional information on the roles and responsibilities of UNITAID and CHAI, the Procurement Agent, Supplier and Beneficiary Governments and the process and criteria for the selection of suppliers and the procurement of products.

1. Roles and Responsibilities

1.1 UNITAID

UNITAID (www.unitaid.eu) aims to increase access to treatment for HIV/AIDS, malaria and tuberculosis for people in developing countries by lowering the price of high-quality drugs and diagnostics and accelerating the pace at which they are made available to patients in need. UNITAID uses predictable and additional funding to help generate steady demand for products. UNITAID is financed mainly by a solidarity contribution on airline tickets and supplemented with funds from Brazil, Chile, France, Norway, the United Kingdom and other donors. Governed by a board including donors, representatives of developing countries, representatives of nongovernmental organizations, and the World Health Organization (“WHO”), as its host and trustee, UNITAID is focusing its resources initially on “niche” areas for which the supply of key products remains limited and prices remain high, including pediatric and second-line ARVs and related medicines and commodities.

UNITAID funds will be used pursuant to WHO procurement principles, including best value for money, international competition and compliance with international quality standards.

UNITAID will be responsible for the consistent and timely provision of funding to enable the purchase and delivery of the specified pediatric and second-line ARVs for beneficiary countries, within budgets approved by the UNITAID board. (The beneficiary countries being supplied with UNITAID-funded products under these projects are specified in Schedule 1.) UNITAID has previously established in writing with beneficiary governments UNITAID’s role, the role of CHAI and the responsibilities and undertakings of the governments, for these projects. UNITAID will also engage in ongoing review of the financial and technical progress of the projects and evaluate the performance of partners.

1.2 Clinton Health Access Initiative (CHAI)

Established in 2002 by the U.S President Bill Clinton as the Clinton HIV/AIDS Initiative¹, CHAI was created to support the efforts of national governments to expand HIV/AIDS care and treatment. Today, CHAI supports programs, in partnership with governments, in more than 35 countries in Africa, Asia, Latin America and the Caribbean. CHAI has signed agreements with more than a dozen manufacturers to lower the prices of pharmaceuticals and diagnostics used to treat HIV/AIDS.

¹ As of January 1, 2010, the Clinton HIV/AIDS Initiative became a separate nonprofit organization called the Clinton Health Access Initiative (CHAI).

As part of the Pediatric Project, CHAI, representing UNITAID, will undertake negotiations with manufacturers and oversee the procurement of products. Based on the outcome of the selection process, CHAI will enter into legally binding purchase agreements (also referred to as “Master Supply Agreements”) with the selected suppliers. Master Supply Agreements will include the agreed price, which will represent the ceiling price for the duration of the Master Supply Agreement (i.e., through February 2012), at which the products will be supplied, upon placement of a purchase order (see section 3.4. below).

In the selection process, CHAI will apply appropriate strategies to enable the development of a healthy market that favors competition and sustainability, with reduction in prices. When feasible, the supply of any single product will be shared by more than one supplier to sustain competition and minimize risks associated with supply shortages and over-dependence on a single or limited number of suppliers. Other objectives are to engage with industry to stimulate the number of new eligible suppliers and an expansion of the registration of products (or waivers thereof) with the regulatory authorities of the beneficiary countries.

Under the terms of Memoranda of Understanding (“MoU”) between CHAI and beneficiary countries, CHAI will also be responsible for helping governments access products covered by the UNITAID projects – with activities including protocol review and guidance, product quantification, and support to national drug regulatory authorities for timely registration of products. CHAI will also be responsible for reporting to UNITAID on the progress of the projects, the performance of suppliers, and achievement of key objectives.

1.3 Procurement Agent

IDA Foundation (“IDA”), the designated procurement agent, has been contracted by CHAI and is operating under terms agreed with UNITAID, and will be responsible for purchasing, freight forwarding and quality control. In particular, IDA will order products from suppliers at or below the ceiling prices specified by the outcome of the process set forth in this letter. IDA will arrange with each specified supplier for the ongoing supply and distribution of products. IDA will then issue purchase orders, based on product quantifications completed in close collaboration with beneficiary governments. For purchased products, IDA will be responsible for quality control, including pre-shipment inspection and random batch testing. IDA will be responsible for ensuring product registration, port clearance and distribution to central medical stores (consistent with MoU signed between CHAI and beneficiary countries, which will typically commit the beneficiary countries to waiving import duties and taking responsibility for distribution of products to treatment sites). Finally, IDA will be responsible for timely payment to suppliers following the delivery of products according to the terms of awarded contracts.

1.4 Suppliers

Manufacturers who duly submit a Proposal in response to this letter and who meet the mandatory requirements listed in Schedule 3 will be considered eligible for participation in the selection process.

Suppliers selected by the outcome of the process set forth in this letter will be responsible for the following:

- manufacture of high-quality products;
- submission of dossiers for the registration of these products with the national drug regulatory authorities of the beneficiary countries;
- compliance with the applicable quality assurance standards and quality control procedures;
- delivery of these products at or below agreed ceiling prices for UNITAID-financed volumes to the beneficiary countries;
- timely delivery of products consistent with ongoing purchase orders; and
- adherence to other applicable terms and conditions of the Project.

Further information on conditions of eligibility of and participation by suppliers in the UNITAID-funded Pediatric Project is described below in [Section 3](#).

1.5 *Beneficiary Governments*

Consistent with agreements signed with UNITAID, as well as MoUs signed with CHAI, beneficiary countries will be responsible for the receipt and effective use of products covered in these projects. This will typically include responsibility for product registration by national drug regulatory authorities; quantification and order scheduling; receipt, port clearance and central warehousing; and distribution to treatment centers. This will also include accountability for rational use of products, including provision to patients consistent with international treatment guidelines, and effective supply chain management and monitoring. Beneficiary countries will be responsible for the provision of documents confirming product delivery and of agreed data for reporting of the consumption and use of products. They will also be responsible for paying (or facilitating the waiver of) duties and local costs for products covered by the project; to provide these products free of charge; to distribute them securely to avoid diversion; and to comply with international and national law. For a list of beneficiary countries of the UNITAID-funded Pediatric Project, see [Schedule 1](#).

2. Description of the Project

For Co-trimoxazole, a pool of suppliers -- at a minimum, a primary and secondary supplier -- will be selected. This approach may also be applied to the other OI drugs, to the extent deemed necessary for reasons of national regulatory status. IDA will issue purchase orders and pay participating suppliers at agreed prices for all volumes financed by UNITAID, consistent with the outcome of this process.

The pediatric OI Drugs covered by this process are specified in [Schedule 2A](#). Detailed packaging, labeling and insert requirements will be specified in ongoing purchase orders. CHAI will procure products indicated for use in pediatric HIV/AIDS care and treatment, consistent with WHO guidelines and national protocols. Initial indicative volumes of UNITAID-financed purchases of pediatric OI Drugs are included in [Schedule 2A](#). Historical order volumes by country for OI Drugs are included in [Schedule 2B](#). The countries for which procurement of pediatric OI Drugs will be conducted with UNITAID financing are specified in [Schedule 1](#). The process set forth in this letter will determine the ceiling prices and suppliers **for orders placed during the twelve month period beginning June 1, 2011.**

An additional process will be conducted next year for supply and pricing for the following twelve-month period.

3. Supplier Selection Process, Eligibility and Evaluation Criteria

This section outlines the mandatory eligibility criteria for participation in the supplier selection process, the procedural steps of the process and evaluation criteria.

In order to be considered eligible to participate in the selection process, suppliers must meet the mandatory eligibility requirements set out in Schedule 3.

3.1 *Request for Proposal*

CHAI is requesting from eligible suppliers an offer of pricing for each OI Drug proposed to be supplied including associated terms, conditions of sale, regulatory preparedness, minimum and maximum delivery lead times for each product, volume thresholds for prices and/or maximum available volumes.

An estimate of global product volume requirements is included as Schedule 2A. Schedule 2B shows historical order volumes by country for products included in this RfP. These data are provided to help inform suppliers' decision-making about pricing and prioritization of dossier submissions for beneficiary country registrations. Suppliers are advised to take their registration and regulatory status into account in gauging volume expectations.

3.2 *Screening for eligibility*

CHAI reserves the right to only consider proposals submitted by suppliers that meet the mandatory eligibility requirements detailed in Schedule 3. These requirements include:

- regulatory preparedness;
- compliance with UNITAID's quality assurance standards and quality control procedures; and
- adherence to other terms and conditions associated with the supply of the products.

Schedule 3 must be signed and submitted with the supplier's Proposal in response to this RfP, together with associated documentation (see Section 3 below). Proposers not complying with these mandatory criteria may be eliminated from the process.

For purposes of emphasis, your attention is especially directed to the requirements of Schedules 5, 6 and 7 relating to quality assurance standards and quality control procedures for the products to be supplied.

With regard to quality assurance standards, only OI drugs meeting standards and specifications in conformity with UNITAID's quality assurance policy, as outlined in Schedule 5 are considered acceptable for procurement funded by UNITAID.

With regard to quality control requirements, suppliers must also agree to adhere to the obligations set out in Schedule 6, including testing and pre-shipment inspections to be performed by a testing agency specified by CHAI and the related measures to be undertaken by suppliers to facilitate such inspections.

Actual orders placed under the program will be country-specific and placed on an ongoing basis for the current project period (**through till February 2012**).

Product delivery will be expected within eight weeks from time of agreement to a purchase order. Payment will be made to manufacturers within 45 days of delivery provided that satisfactory proof of delivery has been received.

3.3 *Selection of supplier and Selection Criteria*

The proposals from each eligible supplier will be reviewed and compared. For Co-trimoxazole, a pool of suppliers -- at a minimum, a primary and secondary supplier -- will be selected. The primary supplier will be granted preference over other suppliers in the order process. This approach may also be applied to the other OI drugs, to the extent necessitated by national regulatory status.

For any given product, in selecting the primary supplier, CHAI will take into consideration:

- the supplier with the lowest OI drug price;
- the suppliers' ability to supply to the countries in question (as determined by national registration status or waiver thereof);
- the suppliers average lead time to deliver the OI drugs;
- the suppliers ability and capacity to meet the indicative quantities of OI drugs required (based on historical data in Schedule 2B); and
- financial viability of the supplier.

3.4 *Contractual Agreements*

Each selected supplier will be required to enter into Master Supply Agreements with CHAI on behalf of UNITAID. Under the terms of such agreements, the selected supplier(s) will undertake to supply the products at or below the agreed ceiling prices in the quantities ordered upon placement of purchase orders by the designated procurement agent. The prices in the Master Supply Agreements will serve as the ceiling price for the duration of the agreements (i.e., through February 2012). Each selected supplier will be required to execute purchase orders placed by the selected procurement agent on standard conditions that are substantially the same as those set forth in Schedule 4.

APPENDIX 2

Specific Instructions to Offerors and Required Information for Responses

This section sets out the specific instructions to Offerors and the required information for responses.

A. SPECIFIC INSTRUCTIONS TO OFFERORS

1. Proposal Submission

All Proposals (including supporting documentation), must be submitted in Microsoft Word and/or Excel or PDF format. The Proposal must be received **electronically or in hard copy by no later than 17:00 Central European Time (CET) on March 15, 2011 at the address below**. Faxed proposals are not acceptable. As explained more fully in Section B below, bid proposals for each product that the company proposes to supply must specify product pricing, associated terms and conditions of sale, regulatory preparedness and willingness to abide by the conditions of the project.

All Proposals (including supporting documentation) are to be submitted to the following office:

<i>If by email, to:</i> nprakash@clintonhealthaccess.org
<i>If by post or courier, to the following address:</i> Clinton Health Access Initiative Attn: Nikhil Prakash F79 Green Park Main New Delhi, 110016 INDIA

1.1. Language and format

The Proposals shall be written in **English** and typed on letter size or A4 paper, single spaced with each page numbered consecutively. The Proposals must be in Microsoft Word and/or Excel or PDF format.

1.2. Validity

The proposal(s) must be valid for **90** days from the deadline for submission. CHAI will make its best effort to finalize selection during that period. In case the selection process has not been completed in this time CHAI may request Offerors to extend their proposal validity.

1.3. Delivery of Proposals

- (a) **Closing Date and Time:** All proposals in response to this RfP must be received **electronically or in hard copy by no later than March 15, 2011.**
- (b) Proposals which are submitted late or are incomplete or do not fully respond to this RfP may not be considered in the review process.
- (c) See additional instructions about the submission of proposals in the Cover Letter of this RfP.

B. REQUIRED INFORMATION FOR RESPONSES

Eligible suppliers that wish to supply must submit to CHAI by **no later than March 15, 2011 a proposal of volumes, prices and** the following information:

1. Proposal of prices and terms for the UNITAID-financed volumes associated with the beneficiary countries specified in Schedule 1. All prices should be quoted FCA Airport and it is preferred, but not mandatory, that prices be indicated in U.S. dollars. If quoted in a currency other than US dollars, prices must be accompanied by the exchange rate used.
2. The technical specifications for each product that the company proposes to supply to the Project.
3. Satisfactory evidence that the OI product is prequalified by FDA, WHO or other stringent regulatory authority, **OR**

If the OI product is not prequalified by a stringent regulatory authority, for each such product that the company proposes to supply, the company shall submit a completed Interagency Pharmaceutical Product Questionnaire **no later than March 15, 2011.**

4. The registration status (or waiver) in all beneficiary countries listed in Schedule 1 for each product that the company proposes to supply. For products not currently registered or submitted for registration, a detailed schedule of registration submissions is required for all such beneficiary countries.
5. A signed copy of Schedule 3 with the supplier's commitment to the conditions set out therein.

SCHEDULE 1

List of Beneficiary Countries of UNITAID-CHAI Pediatric Project in 2011

Angola
Benin
Botswana
Burkina Faso
Burundi
Cameroon
Cote d'Ivoire
Democratic Republic of the Congo
Ethiopia
Guyana
Haiti
India
Kenya
Lesotho
Malawi
Mali
Mozambique
Nigeria
Senegal
Swaziland
Tanzania
Togo
Uganda
Vietnam
Zambia
Zimbabwe

SCHEDULE 2.A

Dosage Forms of OI Drugs to be Procured by CHAI for the Project and Initial Global Forecast of Product Volumes for 2011

Note: The figures below represent initial global forecasts. A forecast of purchase volumes will be provided by CHAI to the selected suppliers.

Generic Name	Strength	Dosage Form	Pack Size	Indicative Order Volumes (April 1, 2011 – March 31, 2012)
Fluconazole	10mg/ml	Syrup	50ml bottle	5,800
	100mg	Tablets	10 Tablets or Capsules	6,600
	100mg	Capsules		
	200mg	Tablets	10 Tablets or Capsules	9,000
	200mg	Capsules		
Amphotericin B	50mg	Powder for injection	1 Vial	3,100
Amoxicillin with clavulanic acid	250mg/62.5mg/5ml	Powder for oral Suspension	100ml bottle	14,700
	500mg/125mg	Capsules	10 Capsules	17,100
Ceftriaxone	500mg	Injection	1 Vial	26,800
	500mg + WFI 5ml	Injection	1 Vial + 1 Amp	
	1g	Injection	Vial	33,800
	1g + WFI 10ml	Injection	1 Vial + 1 Amp	
Acyclovir	200mg	Tablets	25 Tablets	6,900
Cotrimoxazole	200+40mg/5ml	Suspension	60ml or 100ml bottle	1,397,800
	100+20mg	Tablets	1000 tablets	2,700
	400+80mg	Tablets	100 tablets	423,100

HISTORICAL VOLUMES FOR THE UNITAID PEDIATRIC PROJECT (in packs)

2008 order quantities:

Product	Angola	Burundi	Cameroon	China	Dominican Republic	India	Lesotho	Liberia	Malawi	Mozambique	Namibia	Papua New Guinea	Rwanda	Swaziland	Tanzania	Uganda	Vietnam	Zambia	Zimbabwe	TOTAL
Acyclovir 200mg	-	-	-	-	-	2,256	-	-	5,505	-	-	-	-	-	-	-	-	-	-	7,761
Amoxicillin with Clavulanic Acid 250mg/62.5mg/5ml	-	-	-	-	-	5,787	-	-	4,141	-	-	-	-	-	-	-	-	-	-	9,928
Amoxicillin with Clavulanic Acid 500mg/125mg	-	-	-	-	-	5,788	-	-	11,340	-	-	-	-	-	-	-	-	-	-	17,128
Amphotericin B 50mg Injection	-	-	-	-	-	-	-	-	388	-	-	-	-	-	-	-	-	-	-	388
Ceftriaxone 1g Injection	-	-	-	-	-	20,244	-	-	131,745	-	-	-	-	-	-	-	-	-	-	151,989
Ceftriaxone 500mg Injection	-	-	-	-	-	20,244	-	-	45,327	-	-	-	-	-	-	-	-	-	-	65,571
Cotrimoxazole (120mg)	-	-	-	-	-	-	-	-	-	-	-	-	2,563	-	-	600	-	-	-	3,163
Cotrimoxazole (240mg/5ml)	43,771	3,378	5,625	20,000	11,016	-	-	-	10,990	372,880	244,824	6,720	70,764	31,730	180,300	22,320	14,300	741,589	391,363	2,171,570
Cotrimoxazole (480mg)	30	1,438	3,869	-	4,562	-	5,540	1,200	10,084	217,395	84,000	-	27,413	6,530	-	51,108	3,300	-	47,399	463,868
Fluconazole Capsules 200mg	-	-	-	-	-	-	-	-	910	-	-	303	-	-	-	-	-	-	-	1,213
Fluconazole Suspension 10mg/ml	-	-	-	-	300	4,060	-	-	1,267	-	-	4,489	-	-	-	-	-	-	-	10,116
Fluconazole Tablets 100mg	-	-	-	-	-	3,610	-	-	1,898	-	-	604	-	-	-	-	-	-	-	6,112

2009 order quantities:

Product	Angola	Benin	Botswana	Burundi	Cameroon	D R Congo	Dominican Republic	India	Lesotho	Malawi	Mozambique	Namibia	Papua New Guinea	Rwanda	Senegal	Swaziland	Togo	Uganda	Zambia	Zimbabwe	TOTAL
Acyclovir 200mg	-	-	-	-	-	-	-	969	-	33,215	-	-	-	-	-	-	-	19,427	-	-	53,611
Amoxicillin with Clavulanic Acid 250mg/62.5mg/5ml	-	-	-	2,250	-	-	-	1,397	-	32,334	-	-	-	-	-	-	-	18,409	-	-	54,390
Amoxicillin with Clavulanic Acid 500mg/125mg	-	-	-	-	-	-	-	2,490	-	47,760	-	-	-	-	-	-	-	21,781	-	-	72,031
Amphotericin B 50mg Injection	-	-	-	113	-	-	-	-	-	2,797	-	-	-	-	-	-	-	4,705	-	-	7,615
Ceftriaxone 1g Injection	-	-	-	-	-	-	-	7,431	-	37,437	-	-	-	-	-	-	-	33,085	-	-	77,953
Ceftriaxone 500mg Injection	-	-	-	110	-	-	-	6,519	-	13,277	-	-	-	-	-	-	-	16,774	-	-	36,680
Cotrimoxazole (120mg)	-	-	-	-	-	-	-	-	-	-	-	-	-	1,846	-	-	-	5,387	-	-	7,233
Cotrimoxazole (240mg/5ml)	22,344	10,400	736,158	21,847	18,158	16,100	6,628	-	104,711	175,301	849,933	-	7,280	218,828	2,679	68,000	5,000	50,265	530,454	187,896	3,031,982
Cotrimoxazole (480mg)	380	3,000	49,599	3,619	10,475	6,692	2,822	31,155	19,580	81,028	221,684	75,000	-	34,254	572	29,725	2,098	143,654	-	-	715,337
Fluconazole Suspension 10mg/ml	-	-	-	-	-	-	300	1,267	-	9,464	-	-	7,856	-	-	-	-	2,430	-	-	21,317
Fluconazole Tablets 100mg	-	-	-	71	-	-	-	1,797	-	8,529	-	-	11,627	-	-	-	-	3,264	-	-	25,288
Fluconazole Tablets 200mg	-	-	-	30	-	-	-	-	-	21,020	-	-	5,830	-	-	-	-	25,616	-	-	52,496

2010 YTD order quantities (through November 30, 2010):

Product	Botswana	China	D R Congo	Haiti	India	Kenya	Lesotho	Malawi	Mali	Mozambique	Rwanda	Swaziland	Togo	Uganda	Vietnam	Zambia	Zimbabwe	TOTAL
Acyclovir 200mg	-	-	-	2,000	1,316	-	-	30,497	-	-	-	-	-	1,368	-	-	350	35,531
Amoxicillin with Clavulanic Acid 250mg/62.5mg/5ml	-	-	-	2,390	2,303	-	-	43,221	-	-	-	-	-	2,212	-	-	2,567	52,693
Amoxicillin with Clavulanic Acid 500mg/125mg	-	-	-	450	1,645	-	-	16,428	-	-	-	-	-	7,938	-	-	1,705	28,166
Amphotericin B 50mg Injection	-	-	-	491	-	-	-	300	-	-	-	-	-	1,242	-	-	691	2,724
Ceftriaxone 1g Injection	-	-	-	800	8,056	-	-	22,331	-	-	-	-	-	5,650	-	-	11,250	48,087
Ceftriaxone 500mg Injection	-	-	-	800	8,056	-	-	17,737	-	-	-	-	-	3,020	-	-	-	29,613
Cotrimoxazole (120mg)	-	-	-	-	-	-	-	8	-	-	2,292	-	-	2,898	-	-	-	5,198
Cotrimoxazole (240mg/5ml)	-	11,232	15,000	13,500	254,321	99,988	72,643	153,484	5,000	646,324	-	68,000	5,000	35,375	-	254,264	-	1,634,131
Cotrimoxazole (480mg)	1,335	-	8,000	11,000	63,265	-	-	37,660	-	122,987	31,879	38,800	-	128,808	5,000	-	-	448,734
Fluconazole Suspension 10mg/ml	-	-	-	400	4,194	-	-	3,436	-	-	-	-	-	909	-	-	-	8,939
Fluconazole Tablets 100mg	-	-	-	-	5,402	-	-	864	-	-	-	-	-	402	-	-	-	6,668
Fluconazole Capsules 200mg	-	-	-	-	-	-	-	-	-	-	-	-	-	121	-	-	-	121
Fluconazole Tablets 200mg	-	-	-	-	-	-	-	17,422	-	-	-	-	-	-	-	-	-	17,422

SCHEDULE 3

Mandatory Eligibility Requirements of Suppliers

Each supplier must meet the following conditions, with respect to each product it proposes to supply, in order to participate in the project. **Suppliers are required to sign and return a copy of this Schedule 3 with their Proposal** as confirmation of their commitment to supply in accordance with the terms and conditions set out herein.

1. Supplier agrees to supply OI products that conform to the quality assurance standards set forth in Schedule 5.
2. Supplier agrees to comply with the obligations set out in Schedule 6 relating to quality control requirements for all products delivered under the Projects.
3. Supplier shall provide to CHAI the registration status of the product (or waiver thereof), including the date of submission to or approval by each of these authorities, at the time of proposal and on an ongoing basis.
4. The shelf life for the product should be provided to CHAI at the time of proposal, and the dispatch of the product must be conditioned on a minimum of 75% of the total product shelf life remaining at the time of delivery.
5. For facilities in which the product is manufactured and records associated with its manufacture for UNITAID-financed volumes, the supplier must be willing to submit to a quality assurance audit by CHAI or its authorized representative or agent, which may include the selected procurement agent, prior to the first shipment of product and once per year thereafter.
6. Supplier must warrant to CHAI and UNITAID that the prices at which it proposes to sell product are not intended to be “predatory prices” or otherwise anti-competitive, and, in the event that CHAI or UNITAID has reasonable grounds to question this statement, the supplier will grant CHAI or its representative access to records sufficient for CHAI and UNITAID to resolve their concerns.
7. Supplier warrants that all products supplied to the UNITAID Pediatric Project shall be manufactured according to the same specifications that were approved by the relevant national drug regulatory authority (or, where relevant, are set out in an application for approval to such authority).
8. Supplier must confirm that it has the capacity to supply indicative volumes proposed.
9. Product(s) affected by an outstanding notice of concern, warning letter, import alert or other precautionary action by the WHO, U.S. FDA or other stringent regulatory authority, as designated by the International Conference on Harmonization (ICH), are ineligible for supply to the project. Suppliers are required to inform CHAI and UNITAID in the Proposal of any and all such actions against them by a stringent regulator, even if the action in question does not directly affect products covered in this RfP. CHAI and UNITAID reserve

the right to revoke a supplier's eligibility and suspend procurement at any time during the tender period if precautionary action affecting product(s) supplied to the project is taken by a stringent regulatory authority subsequent to supplier selection.

10. If a supplier is selected for a product, in case of failure by the supplier to perform under the terms and conditions of the purchase order, including but not limited to failure to make delivery of all or part of the goods by the agreed delivery date(s), the procurement agent may, after giving the supplier reasonable notice to perform and without prejudice to any other rights or remedies, exercise one or more of the following rights:
 - a. Procure all or part of the goods from another source(s), in which event the agent may hold the supplier responsible for any excess cost occasioned thereby;
 - b. Refuse to accept delivery of all or part of the goods; and/or
 - c. Terminate the purchase order.

11. Each selected supplier will be required to enter into a Master Supply Agreement with CHAI on behalf of UNITAID to commit to the agreed ceiling prices and terms on standard conditions consistent with applicable UNITAID requirements. In addition, each selected supplier will be required to execute purchase orders placed by the selected procurement agent on standard terms and conditions that are substantially the same as those set forth in Schedule 4.

These and other conditions associated with the supply of a product will also be included in the agreement(s) between the procurement agents and the supplier.

The terms and conditions described above are agreed and accepted.

Company Name: _____

Signed: _____

Typed Name: _____

Title: _____

Date: _____

SCHEDULE 4

Standard Terms and Conditions of Product Procurement Under the UNITAID-CHAI Pediatric Treatment Project

Manufacturer will enter into an agreement with Procurement Agent at or below the ceiling prices set forth in the Master Supply Agreement and on terms and standard conditions that are substantially the same as those terms and conditions set forth below.

1. Acknowledgement Copy

Acceptance of this purchase order (the "Purchase Order") shall form a binding contract with the Manufacturer, acknowledging (in writing or by email) receipt of the Purchase Order and its agreement to deliver the products by the date therein specified (the "Products"). The contract between the parties is subject only to the Master Supply Agreement and the terms and conditions detailed here below. In the event that any terms or conditions of this Schedule 5 conflict with any terms or conditions of the Master Supply Agreement, the terms and conditions of the Master Supply Agreement will take precedence and apply.

2. Delivery Terms

2.1 Delivery Date is to be understood as the time the Products must be available at the Delivery Location indicated on the Purchase Order in accordance with the agreed (INCOTERMS 2000). Manufacturer commits to a Delivery Date of no later than twelve weeks (absent specific agreement to the contrary) from the date of issuance of this Purchase Order, failing which the Procurement Agent reserves the right to amend or cancel the order and CHAI reserves the right to cancel the Agreement.

2.2 Manufacturer commits to submitting the following documents/information to the consignee by email or fax at least two (2) days before arrival of Products: (i) ship or flight details, (ii) Bill of Lading or Air Way Bill, (iii) pro forma Manufacturer's invoice, (iv) packing list, and (v) a Certificate of Analysis ("COA") for each batch manufactured under this Purchase Order (the COA, together with the items listed in (ii)-(v) above, each a "Document" and, together, the "Documents"). One of each of the documents will be attached to the consignment and one of each of the Documents will be placed inside shipping carton number 1 unless specified otherwise in the packing list due to particular packing needs.). Where a country requires that the invoice be certified by Chambers of Commerce in the Manufacturer's country, the Manufacturer shall submit such 'Chamberised' Invoices as part the shipping documents.

2.3 Manufacturer will submit to CHAI within 5 days of the arrival of the Product a proof of delivery to the delivery location indicated on the Purchase Order. CHAI through the Procurement Agent will also arrange for confirmation of the receipt of the products by the beneficiary country to be sent to CHAI by means of a written acknowledgement from the Country of its designee (the "Arrival Report").

3. Payment Terms

3.1 On fulfillment of the Purchase Order and the delivery terms noted in Section 2 above, unless otherwise specified in the Purchase Order, payment shall be made within 45 days of receipt of the Products and the proper submission of the Documents by the Manufacturer and confirmation of delivery to the agreed destination in the Beneficiary Country (“Delivery Location”) by means of an arrival report provided to CHAI. All prices should be stated FCA Airport or such other terms as are mutually agreed. The specified Incoterm (and related geographical location), as well as the identification of the Delivery Location would be designated by Procurement Agent and inserted into the individual Purchase Order. Manufacturer shall indicate the value of goods and components of Other Charges, such as Freight and Insurance, separately in each invoice. Manufacturer shall submit to CHAI actual bills from its freight forwarders and other freight and logistics vendors towards such Other Charges within 45 days of the Delivery of goods.

3.2 The prices for the products secured in the Master Supply Agreement are expected to remain ceiling prices for the duration of the Agreement.

3.3 Inspection by the Procurement Agent or its designated agent prior to shipment does not relieve the Manufacturer from its contractual obligations.

3.4 The Procurement Agent shall have a reasonable time after delivery of the Products to inspect them and to reject and refuse acceptance of Products not conforming to the Purchase Order. Acceptance of Products shall follow inspection and confirmation that the Products delivered meet the Terms and Conditions of the Purchase Order. Payment for Products pursuant to the Purchase Order shall not be deemed acceptance of the Products.

3.5 If, after inspection, the Products are not found to be conforming to the Purchase Order, the Procurement Agent shall reject such Products and shall (i) promptly contact Manufacturer regarding the non-conforming Products and (ii) negotiate for reimbursement of the cost of such Products. The Procurement Agent specifically reserves the right to deduct the payment made for such non-conforming Products and any costs incurred in connection with the replacement of such non-conforming Products from future payments due to Manufacturer.

4. Quality Assurance

4.1 All Products are required to be in compliance with national regulatory standards and prequalified by WHO or other stringent national regulatory authority, which includes compliance with standards for good manufacturing practices (“GMP”).

4.2 All products must conform to the quality assurance standard as set forth in Schedule 5 of the Manufacturer Letter.

5. Tax Exemption

To the extent that UNITAID or CHAI is exempt from all direct taxes and is exempt from customs duties in respect of articles imported or exported for its official use, then accordingly, the Manufacturer authorizes the Procurement Agent, acting on behalf of UNITAID, to deduct from the Manufacturer's invoice any amount representing such taxes or duties charged by the Manufacturer to Procurement Agent. Payment of such corrected invoiced amount shall constitute full payment by Procurement Agent. In the

event any taxing authority refuses to recognize the exemption status from such taxes, the Manufacturer shall immediately consult with the Procurement Agent to determine a mutually acceptable procedure for allocation of responsibility for payment of taxes. Manufacturer shall pay all taxes under this Section 5 when due, subject to reimbursement by the Procurement Agent, in the event that UNITAID or CHAI is found to be responsible for these taxes.

6. Export License

The contract is subject to the obtaining of any export license or other governmental authorization which may be necessary. It will be the responsibility of the Manufacturer to obtain such license or authorization, but CHAI will provide reasonable assistance upon request.

7. Risk of Loss, Terms of Shipment

All risk of loss, delay or damage in transit to the Products, as well as the cost of freight and insurance shall be borne by the Manufacturer until physical delivery to the Delivery Location.

8. Intellectual Property Warranties

Manufacturer warrants that the use or supply by CHAI, UNITAID, WHO or the Beneficiary Countries of the Products offered for sale under the Purchase Order do not infringe any patent, design, trade-name, or trade-mark. In addition, the Manufacturer shall, pursuant to this warranty, indemnify, defend and hold harmless CHAI and WHO/UNITAID, donors of resources being used to finance the Products from and against all claims, damages, losses, costs and expenses arising out of the alleged infringement of a patent, design, trade-name or trade-mark arising under or relating to the Purchase Order. CHAI shall promptly give notice to the Manufacturer of any such claims, damages, losses and costs and expenses and shall in such event cooperate in a reasonable manner with the Manufacturer.

9. Force Majeure

Force majeure as used in this Section 9 means acts of God, war (whether declared or not), invasion, revolution, insurrection, or other acts of a similar nature or force. In the event of and as soon as possible after the occurrence of any cause constituting force majeure, the affected Party shall give notice and full particulars in writing to the other Party, of such occurrence if that Party is thereby rendered unable, wholly or in material part, to perform its obligations and meet its responsibilities under this Purchase Order and that Party shall be relieved of these obligations and responsibilities for so long as such circumstances prevail. If a Party is rendered permanently unable, wholly, or in material part, by reason of force majeure to perform its obligations and meet its responsibilities under this Purchase Order, the other Party shall have the right to suspend or terminate this Purchase Order on the same terms and conditions as are provided for in the Master Supply Agreement.

10. Rights of Procurement Agent

In case of failure by the Manufacturer to perform under the Terms and Conditions of the Purchase Order, including but not limited to failure to obtain necessary export

licenses, or to make delivery of all or part of the Products by the agreed delivery date or dates, Procurement Agent may, after giving the Manufacturer reasonable notice to perform and without prejudice to any other rights or remedies, exercise one or more of the following rights (i) procure all or part of the Products from other sources, in which event Procurement Agent may hold the Manufacturer responsible for any excess cost occasioned thereby; (ii) refuse to accept delivery of all or part of the Products; and/or (iii) terminate the Purchase Order.

11. Product Warranty

11.1 Manufacturer warrants that the Products, as of the date of delivery: (i) comply with all laws, rules and regulations applicable to such Product; (ii) have been handled and processed so as not to be contaminated, adulterated, changed or rendered unsafe or unfit for its intended use; and (iii) are free and clear of any lien or encumbrance.

11.2 Manufacturer warrants that the Products, including adequate packaging, conform to the formula, specifications and standards as approved by, or as submitted to for approval by, the WHO and/or a stringent regulatory authority and are of merchantable quality and fit for the purposes for which such Products are ordinarily used and for purposes expressly made known to the Manufacturer by CHAI, and are free from defects in workmanship and materials. The Manufacturer also warrants that the Products are contained or packaged adequately to protect the Products.

11.3 Manufacturer shall bear sole responsibility for the validity of all test methods and appropriateness of all Product specifications. In addition, Manufacturer shall bear sole responsibility for all regulatory approvals, filings, and registrations and adequacy of all validation, stability, and preservative efficacy studies. Manufacturer further warrants that it shall obtain any and all necessary approvals from the appropriate National Drug Regulatory Authority (“NDRA”) to distribute and sell all Products under a specific Purchase Order. Manufacturer warrants that it shall obtain any and all necessary approvals from the WHO or US Food and Drug Administration (FDA) or stringent regulatory authority, for products as set forth in the applicable Purchase Order. If the Manufacturer is unable to obtain the necessary approval(s) as stated above, the Manufacturer shall have the option to reject the Purchase Order.

11.4 Manufacturer and CHAI shall co-operate to identify the applicable regulatory approvals required for Products under a specific Purchase Order or under anticipated Purchase Orders in accordance with the Master Supply Agreement.

11.5 Subject to the provisions set forth in the Master Supply Agreement, Manufacturer warrants that all Products manufactured, held for sale, sold and shipped pursuant to this Agreement shall have been manufactured and shipped by Manufacturer in substantial compliance with the United States Food, Drug and Cosmetic Act of 1938 (21 U.S.C. Section 201 et seq.) together with any regulations promulgated thereunder, including, without limitation, all Good Manufacturing Practices, in each case as amended from time to time.

11.6 Manufacturer warrants that all product design, labeling copy and artwork approved, designated or supplied by Manufacturer shall be in compliance with all Applicable Laws and governmental regulations and that such compliance is the sole responsibility of Manufacturer. Manufacturer hereby represents and warrants to the Procurement Agent that none of the formulas, components and artwork related to the

Product violate or infringe any patent, copyright, trademark or other intellectual property right of any third Party in Manufacturer's country or the destination country of the Product. Manufacturer shall notify the Procurement Agent of any patent or other intellectual property infringement claim against Manufacturer, relevant to the applicable Purchase Order at the time of acknowledgement of the Purchase Order and Procurement Agent shall have the option to proceed or cancel the Purchase Order at that time.

11.7 The Manufacturer warrants that the use or supply by Procurement Agent of the Products offered for sale under the Purchase Order does not infringe any patent, design, trade-name, or trade-mark.

11.8 Manufacturer shall be responsible for the costs and expense of any product recall resulting from Manufacturer's supply of defective products, and shall refund to Procurement Agent any payment for such Products.

12. Indemnity

12.1 Manufacturer agrees to indemnify, defend and hold the Procurement Agent, CHAI and WHO/UNITAID harmless from and against any claims, losses, liability, obligations, lawsuits, deficiencies, damages or expense of whatever nature, whether known or unknown, accrued, absolute, contingent or otherwise, including, without limitation, interest, penalties, reasonable attorney's fees, costs of investigation and all amounts paid in defense or settlement of the foregoing (collectively, "Loss"), suffered or incurred by the Procurement Agent as a result of the occurrence of, or arising out of, any breach of this Agreement by Manufacturer, including, but not limited to, any of Manufacturer's representations and warranties contained herein.

12.2 Manufacturer also agrees to indemnify, defend and hold the Procurement Agent, CHAI and WHO/UNITAID harmless from and against any Loss suffered or incurred by the Procurement Agent, CHAI and WHO/UNITAID arising out of or relating to: (i) any third Party product liability claim against any Product; (ii) any defects in any Product supplied; or (iii) any non-compliance by such manufacturer or Manufacturer with any technical requirements applicable to any Products supplied.

12.3 Manufacturer also agrees to indemnify, defend and hold the Procurement Agent, CHAI and WHO/UNITAID from and against all claims, damages, losses, costs and expenses arising out of the alleged infringement of a patent, design, trade-name or trade-mark arising under or relating to the Agreement.

12.4 Procurement Agent agrees to give prompt notice to the Manufacturer (the "Indemnitor") of any third-Party claim, action, suit, complaint or proceeding that might give rise to a claim based on the indemnity contained in this Section 12, stating the nature and basis of the claim and the amount thereof; provided, that no delay on the part of the Procurement Agent in giving any such notice shall relieve Indemnitor of any indemnification obligation hereunder unless, and then solely to the extent that, Indemnitor is materially prejudiced by such delay. Further, the Procurement Agent shall tender the defense of such claim to Indemnitor and the Procurement Agent shall provide reasonable assistance to Indemnitor in the defense of such claim.

13. Use of Name, Emblem or Official Seal of CHAI or WHO/UNITAID

The Manufacturer shall not, without prior written consent from CHAI, and/or WHO/UNITAID, as appropriate, advertise or otherwise make public the fact that it is a Manufacturer or in any other way affiliated with CHAI, WHO/UNITAID, President Clinton or the Projects, nor shall the Manufacturer, in any manner whatsoever use the name, emblem or official seal of CHAI, UNITAID, WHO, President Clinton, or any abbreviation of the name of CHAI, UNITAID, WHO and/or President Clinton in connection with its business or other activities. Any proposed public written reference to the relationship of the Parties or to UNITAID in connection with the Projects or to President Clinton (including his name, image, voice or likeness) will be agreed in writing in advance.

14. Liability Insurance

Manufacturer shall obtain or maintain adequate liability insurance covering the claims and liabilities referred to in Sections 8, 11 and 12 above.

15. Assignment and Insolvency

15.1 The Manufacturer shall not assign, transfer, pledge or make other disposition of this contract or any part thereof, or any of the Manufacturer's rights, claims or obligations under the Purchase Order except with the prior written consent of CHAI.

15.2 Should the Manufacturer be adjudged bankrupt, or be liquidated or become insolvent, or should the Manufacturer make an assignment for the benefit of its creditors, or should a Receiver be appointed on account of the insolvency of the Manufacturer, Procurement Agent may, without prejudice to any other right or remedy it may have under the terms of these conditions terminate this Purchase Order forthwith. The Manufacturer shall immediately inform the Procurement Agent and CHAI of the occurrence of any of the above-events.

16. Arbitration

Any dispute, controversy or claim arising out of or relating to this Agreement, including any question regarding this Agreement's existence, validity or termination or any breach of the same shall be settled by final and binding arbitration. Any arbitration pursuant to this provision shall be administered by the American Arbitration Association in accordance with its International Arbitration Rules. The place of arbitration shall be New York, New York. The language of the arbitration shall be English. The number of arbitrators shall be one, to be nominated jointly by the parties. If one arbitrator cannot be agreed upon by the parties within thirty (30) days of the notice of arbitration, then the arbitrator shall be appointed by the administrator of the American Arbitration Association. The parties shall bear their own attorneys', experts' and other fees and expenses in connection with any arbitration unless otherwise determined by the arbitrator. Any laws allowing or providing for a judicial review de novo of such arbitration are hereby waived, and the award of the arbitrator shall be final, binding and not subject to de novo review.

17. Privileges and Immunities of WHO/UNITAID

Nothing in or relating to the Contract shall be deemed a waiver of any of the privileges and immunities enjoyed by WHO or UNITAID under national or international law, convention or agreement, or submit WHO or UNITAID to any national court jurisdiction. Similarly, nothing contained herein shall be construed as conferring any responsibility or liability upon WHO or UNITAID in relation to or as a result of the supply of the products under this Purchase Order.

18. Request for Price Adjustment

The prices for the products are expected to remain fixed until February 28, 2012. Exceptionally, should a significant and sustained change in circumstances create a need for price adjustment, such adjustment shall be subject to the advance written approval of UNITAID. Such a request must be submitted to UNITAID, through CHAI, at least one month prior to the requested effective date, together with documentary proof of the circumstances that are claimed to warrant a price adjustment. While the request is under consideration by UNITAID and CHAI, the Manufacturer is expected to continue to supply the product without interruption at the originally agreed upon price. No retroactive price increases will be permitted for purchase orders already issued to and accepted by the Manufacturer.

19. Manufacturer Performance

Supplier will be evaluated based on its performance of obligations under the terms and conditions set forth in the Master Supply Agreement.

20. Labeling

20.1 The Projects, which are the subject of the Master Supply Agreement, shall be referred to, respectively, as the "UNITAID-CHAI Pediatrics HIV/AIDS Project 2011" and the "UNITAID-CHAI Second-line HIV/AIDS Project 2011".

20.2 All documents issued by the Manufacturer in connection with the supply or delivery of UNITAID-funded products or services (including but not limited to agreements with local providers) should clearly indicate they were funded by UNITAID.

20.3 To the extent permitted by applicable law or regulation, the Manufacturer will use best efforts to ensure that the packaging of products (with the exception of primary packaging) shall bear a label and/or text to indicate they were funded by UNITAID.

Dependent on the destination of the Products, the Manufacture will supply the Products, labeled in English and when applicable also in French, Spanish or Portuguese.

20.4 The shipping and other related documents for the Drugs shall be marked "*For UNITAID-funded Project: Free of Charge- Not for Sale,*" and shall state the name of the party to whom the Drugs are to be delivered, the Purchase Order number, and the Destination. This is to prevent, or aid in the prevention of, the Drugs being diverted from their intended recipient and use under the Project.

21. **Publication of Prices**

It is understood that UNITAID regularly reports to the public the prices paid by UNITAID for products procured with UNITAID support, including those agreed by CHAI with Manufacturers. The Manufacturer authorizes UNITAID to publicly disclose the prices for the products procured in relation to the Project as well as the name of the Manufacturer in question.

22. **Reporting of Ex Works Prices**

If the purchase price differs from the ex-works price, during the submission of price bids, the Manufacturer will provide to CHAI a written report of the price charged for each product supplied in the project on an ex-works price basis for purposes of monitoring and market analysis.

SCHEDULE 5

Summary of Applicable UNITAID Quality Assurance Standard for OI Drugs Procured in Pediatric Project

1. All Opportunistic Infection (OI) medicines procured under UNITAID-funded projects are required to be in compliance with national regulatory standards and prequalified by FDA, WHO or other stringent regulatory authority², which includes compliance with current Good Manufacturing Practice (cGMP)³.
2. In the case of single or limited-source pharmaceuticals, (a) the drugs must be either prequalified by WHO or approved by a stringent regulatory authority **by March 15, 2011** or (b) in case there is only one or no equivalent product that meets this condition, in such event: (i) a completed Interagency Pharmaceutical Product Questionnaire must be submitted no later than **March 15, 2011** and the product must be manufactured at a site that is compliant with WHO or stringent regulatory authority standards of cGMP², provided that the Ministry of Health of the beneficiary country concurs that the products may be supplied on the basis of the conditions set out in (b).

² A regulatory authority which is (a) a member of the ICH (as specified on www.ich.org); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).

³ Including the regulatory authority participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S). For PIC/S, refer to www.picscheme.org.

SCHEDULE 6

Quality Control Requirements

CHAI is responsible for ensuring proper quality assurance (“QA”) and quality control (“QC”) testing of products procured for the UNITAID Pediatric and Second-Line Projects. Testing and pre-shipment inspection will be performed by a testing agency (“TA”) specified by CHAI. The selection of TA and its qualifications shall be agreed with UNITAID. CHAI will be responsible for costs incurred by the testing agency. For QC testing the TA will randomly select 20% of batches of prequalified products and 40% of batches of non-prequalified products. The tests to be performed should include: appearance, identity, assay, related substances, mass uniformity and dissolution, unless justified otherwise.

1. Pharmacopoeial Monographs and Test Methods

Testing will be performed against an Acceptable Monograph, if available. An “Acceptable Monograph” is one that has: (i) been published in the US Pharmacopoeia or International Pharmacopoeia or (ii) has been published to the web sites of the US Pharmacopoeia or International Pharmacopoeia. In addition, testing against monographs published in other pharmacopoeia may be permitted by CHAI on a case by case basis.

Testing in the absence of a published monograph may be based on published methods, methods developed by the TA, or supplier developed methods. Supplier methods should be validated according to ICH guidelines and the supplier is responsible for providing a validation report. Further, the supplier is expected to support method transfer by providing relevant samples and necessary technical assistance to the TA. If a method is subsequently published by the US pharmacopoeia or the International Pharmacopoeia, the supplier shall change its testing methods to use the pharmacopoeial method within 120 days. CHAI will be responsible for final decisions regarding selection of test methods.

2. Samples and Working Standards

The Supplier is required to make available for collection by IDA, through its quality control laboratory, the following, at no extra charge, for every Batch (in case of Laboratory testing) and for every Shipment (in case of Pre-shipment Inspection), in order to enable proper testing:

- a) Samples for Laboratory Testing
- b) Samples for Pre-shipment Inspection
- c) Placeboes sufficient to test one batch.

The TA is responsible for maintaining reference materials required to perform testing. Primary standards may be obtained from pharmacopoeial organizations and used to establish working standards. Materials for working standards may be requested from suppliers and may be used for multiple batches. Crude samples of API with characterized levels of critical impurities may be used to quantify impurity levels in place of primary standards of these impurities. Such samples may be obtained from the supplier and may be used for multiple batches.

3. Retain Samples

The supplier is obliged to collect and maintain retain samples of Finished Dose Formulation (FDF) and API of every batch produced according to a Standard Operating Procedure (SOP) addressing such samples. The supplier is required to provide a copy of this SOP.

4. Certificates of Analysis

The supplier is responsible to supply Certificates of Analysis and packing lists of every batch to be supplied for the UNITAID Pediatric and Second-Line Projects. Supplier shall not ship the stocks unless Clean Report of Findings is received from the TA when a Pre-shipment Inspection has been conducted for the shipment.

CHAI reserves the right to test/ inspect every batch/ shipment.

5. PIC/s Audit reports

Suppliers are required to provide copies of PIC/S (or FDA) audit reports from the past 2 years:

- a. Copies of audit reports from the US FDA, UK-MHRA or WHO Geneva, if these agencies have audited the API and formulations manufacturing facilities in the last 2 years
- b. Copies of all PIC/S reports for the API and formulations manufacturing facilities in the last two years, if the US FDA, UK-MHRA or WHO Geneva have not audited the facility in the past 2 years

While existing audit reports may obviate the need for on-site inspection CHAI reserves the right to call for such an inspection. Examples of situations in which CHAI may conduct an audit include, but are not limited to, the following: after a PIC/S agency identifies problems in the facility, and/or if a limited number of PIC/S audits have occurred in the past 2 years.

6. Product Recall

Suppliers will be responsible for communicating, conducting, and paying for any product recalls that may be required. Suppliers are required to provide a copy of their Standard Operating Procedure (SOP) to be followed in case of a product recall.