

NATIONAL EMERGENCY RESPONSE COUNCIL ON HIV/AIDS



A NATION AT WAR WITH HIV/AIDS

TENDER DOCUMENT FOR TENDER

NUMBER 010 OF 2009/2010:

SUPPLY OF ANTIRETROVIRAL DRUGS

FOR

THE GOVERNMENT OF SWAZILAND

FOR THE PERIOD OF

MAY 2009 TO APRIL 2010

1. INTRODUCTION

The National Emergency Response Council on HIV/ AIDS (NERCHA) is a statutory Council of the Swaziland Government, established in December 2001. One of NERCHA key objectives are “The provision of comprehensive appropriate care and support for people infected and affected by HIV/AIDS”.

As Principal Recipient of the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF), NERCHA has set to organize the procurement and distribution of antiretroviral (ARV) drugs for the treatment of HIV infected people in Swaziland, according to the published “National HIV/AIDS Clinical Care Guidelines” Please note that under the Global Fund program, NERCHA is currently providing ARV treatment to 32,701 patients and anticipates providing treatment to 46,071 by the end of June 2009. In order to serve these patients appropriately Swaziland seeks reliable, high quality, affordable ARV treatment for its patients

In 2004 NERCHA and The Ministry of Health of the Government of Swaziland signed a Memorandum of Understanding with the Clinton Foundation HIV/AIDS Initiative (CHAI) to ensure access to high quality, affordable ARV treatment. As a member of the CHAI Procurement Consortium NERCHA and the Government of Swaziland is entitled to prices at or below the price ceilings indicated on the price list as updated (see <http://www.clintonfoundation.org/what-we-do/clinton-hiv-aids-initiative/information-center-resources>)

Further, the government of Swaziland will be eligible for any CHAI price ceilings renegotiated at or before the time of contract, but not yet included in this document.

This document serves to inform manufacturers of the processes, terms and conditions of the selection of suppliers, described in section 2 below, for the Global Fund and Government of Swaziland funded ARVs. A detailed list of drugs required is attached as **Annex A, and Annex B is a copy of the Standard Supplier Contract for your information.**

It is requested that interested manufacturers/suppliers respond to this invitation by no later than **10.00 am on 24th April 2009**. As explained more fully in sections below, bids must include bid notifications for each product that the company proposes to supply.

2. ROLES AND RESPONSIBILITIES

- a. SUPPLIERS– high quality, compliance with quality standards, delivery of product at agreed upon prices, and all additional eligibility criteria are met. The Tender should be complete and include all required information. If it does not include all required information the Tender Board may deem the Tender incomplete and ineligible for bidding.
- b. NERCHA – consistent with GF – Swaziland will engage suppliers in international competitive bidding and select the most cost-effective supplier who meets the minimum eligibility criteria described below in Section 3. NERCHA and the Government of Swaziland are responsible for the effective use of products, quantification and order placement, receipt, warehousing and rational use. The products will be provided free to patients.

3. SELECTION OF SUPPLIERS

- a. Both originator and generic suppliers are invited to submit their offers for the supply of ARV for the duration of the tender. As essential condition for their offers to be considered by NERCHA, Suppliers are required to provide the following information;
 - Price quotation in South African Rands for South African Tenderers, Emalangeni for Swaziland Tenderers and US\$ for other international Tenderers inclusive of freight and insurance (CIF)
 - Lead times
 - Any additional costs involved for the products to be delivered at Central Medical Stores(CMS) in Matsapha, Swaziland,
 - Suppliers must be willing to make a commitment to the maintenance of minimum eligibility for as long as they are supplying the necessary products to NERCHA and the Government of Swaziland
- b. If a supplier has any questions regarding the tender or specifications of the tender they should contact the following:

Lynette at procurement@nercha.org.sz (Procurement Manager)

and

teeboodee@yahoo.com(Pharmaceutical Supply Chain Management Officer)

4. MINIMUM ELIGIBILITY CRITERIA

- a. Any supplier submitting a bid should provide documentation that the Active Pharmaceutical Ingredient (API), and manufacturing facility and all other facilities from which ingredients are being used for the drugs are GMP certified;
- b. Supplier will agree to share the results of any audit by stringent regulatory agencies; including, but not limited to World Health Organisation (WHO), and the United States Food and Drug Administration (U.S. FDA) ,
- c. The Supplier should have gone through the process of dossier evaluation by WHO, FDA or other stringent regulatory authority before submitting a bid for this tender. Proof of such submission and /or the outcome of the evaluation should be attached to the bid. Should the Government of Swaziland request for the dossier, the supplier should produce a hard copy of proof of submission within seven (7) days of the receipt of said request,
- d. The supplier should competitively determine the time frame for delivery and include this in the bid for the tender. The maximum acceptable delivery time frame is six(6) weeks,
- e. Products supplied to Swaziland should have no less than two (2) years of total shelf line upon delivery and must be stable and retain their original characteristics as described in their monograph throughout their shelf life. For those items whose original shelf life is shorter than two years, they must have a remaining period of at least three quarters (3/4) of their original shelf life.
- f. For each product, assurance of capacity to supply up to 100% of the volumes. Orders will be placed quarterly and suppliers will be expected to supply all volumes ordered during the quarter. Partial deliveries will be accepted but they should be a third (1/3) of the total quantity ordered, and the balance delivered within the agreed upon delivery time
- g. Suppliers are required to provide for each product they propose to supply, evidence that they comply with the Global Fund Quality Assurance Policy by submitting the following documents:
 - For “A” classified products-Listed on WHO prequalification list;
 - For “B” classified products-Stringent NDRA Registration letter or Marketing Authorisation;
 - For “Ci” classified products- GMP Certificate issued by a stringent NDRA or WHO Prequalification letter certifying the compliance of the manufacturing site with WHO GMP requirements; and Proof of dossier submission to either WHO prequalification program along with acceptance letter to stringent NDRA for registration;
 - For “Cii” classified products – GMP certificate issued by a stringent NDRA or Prequalification letter certifying the compliance of the manufacturing site;

ANNEX A further provides space in which suppliers are to indicate the category under which their products fall.

All certificates and information will be duly assessed by the NERCHA Tender Board, who will have to be satisfied with regards to any potential Quality Assurance issues. In particular, we require that all products meet the Global Fund Quality Assurance Policy requirements; (see www.theglobalfund.org/en/about/procurement/globalfund).

5. TENDER EVALUATION PROCESS

The process for the assessment of the tenders received in response to the present tender will be as follows:

- All tenders received by the closing date will be checked against completeness of the information required under this invitation;
- Only complete tenders received by the closing date and including all the information requested in the present tender invitation will be considered for further evaluation;
- All tenders considered complete will be assessed by the NERCHA Tender Board in terms of Quality Assurance;
- As the main objective is the procurement of all products in the “National HIV/AIDS Clinical Care Guidelines”, there is the possibility that more than one supplier will have to be identified in order to secure supply for all required medication. However, preference will be made to select the least possible number of suppliers;
- Those products not raising quality concerns, and ranked in terms of Quality Assurance, pricing, delivery time and costs, reliability of supply (through references), availability and guarantees of future stock, availability of barcodes on products labelling and any other element considered important to achieve the best possible outcome from the clinical, financial and logistic point of view. It will then select the tender(s) considered more attractive and will contact the relevant supplier(s) to negotiate the final agreement(s).
- In case a satisfactory final agreement is not reached within a time considered reasonable, also in light of the extreme urgency to sustain treatment in the country, NERCHA Tender Board will select the tender considered to be the following most attractive and negotiate with the relevant supplier, and so on until it will be successful in reaching final agreement(s);

We anticipate that the selected supplier(s) presenting the best offer(s) and approved by the NERCHA Tender Board could become NERCHA Tender Supplier(s), to which all orders for ARV intended to be used for the ART Program, and agreed under this process, will be made for a period **of twelve months** after which another international tender will be run.

6. PAYMENT CONDITIONS

Payments will be made by NERCHA within 30(thirty) days of completion of delivery of a specific order and upon receipt of the correct invoices and customs declaration document. In case of part deliveries, payments will be processed and made only for items delivered of the specific purchase order.

7. FLUCTUATING QUANTITIES ORDERED

The quantities stated on the schedule are estimates as probable annual requirements based on rigorous national quantifications and are subject to fluctuations at the time of ordering.

For each Bid Document, a non refundable fee of US\$150.00 (For International bidders, and R250.00 for South African and Swaziland bidders) will be paid through electronic transfer to the following account:

Account Name: NERCHA ESCROW
Account Number: 62060796243
Branch Code: 280164
SWIFT CODE: FIRNSZXM

For proof of payment, bidders are requested to attach a copy of the swift payment instruction to their bankers or copy of the internet payment confirmation to the bid upon submission.

Attached is the Drug schedule marked Annex A on which suppliers are expected to make their quotations, and fill in all required information which shall be accompanied by relevant certificates and documents as mentioned in section 4 above.

8. SUBMISSION

Submissions should be made in two hard copies and one soft copy, and must reach NERCHA by mail (Courier Service) or hand delivered and dropped into the Tender Box situated at the Main Reception addressed as follows;

**THE TENDER BOARD
NATIONAL EMERGENCY RESPONSE COUNCIL ON HIV & AIDS
OFFICE # 5 COOPER CENTRE,
SOZISA STREET,
MBABANE
SWAILAND**

By no later than **10.00 am on 24th April 2009** and clearly marked; "CONFIDENTIAL RESPONSE TO TENDER 010 OF 2009/2010: SUPPLY OF ARV"

On the same day and time, submissions will be opened in public in the NERCHA Main Boardroom and Tenderers are requested to attend.

ANNEX A

PRODUCT DESCRIPTION	PACK SIZE	INDICATIVE ANNUAL QUANTITY REQUIRED	COUNTRY OF MANUFACTURE/ MANUFACTURING SITE	QUALITY STATUS IN RELATION TO GLOBAL FUND QUALITY ASSURANCE POLICY (Tick appropriately)				LEADTIME (DELIVERY TIME)	UNIT PRICE QUOTATION
				A	B	Ci	Cii		
NNRTI									
EFAVIRENZ(EFV)									
Capsules 200mg	90	41,703							
Capsules 600mg	30	39,886							
NEVIRAPINE (NVP)									
Tablets 200mg	60	118,075							
NRTI									
ABACAVIR SULPHATE (ABC)									
Tablets 300mg	60	7,000							
DIDANOSINE (ddi)									
Tablets 100mg	60	1,494							
Tablets 150mg	60	722							
Tablets 250mg	30	1,484							
Tablets 400mg	30	1,660							
LAMIVUDINE (3TC)									
Tablets 150mg	60	120,988							
STAVUDINE (d4t)									
Capsules 30mg	60	68,388							
ZIDOVUDINE (AZT)									
Capsules 100mg	100	7,844							
Tablets 300mg	60	42,394							
ZIDOVUDINE with LAMIVUDINE (AZT/3TC)									
Tablets 300/150mg	60	98,038							
AZT with 3TC and NVP									
Tablets AZT/3TC/NVP 300/150/200Mg	60	246,149							
AZT with 3TC Co-packed with EFV									
Tablets AZT/3TC 300/150MG co-packed with 600mg EFV	60	76,731							
STAVUDINE with LAMIVUDINE and Nevirapine									
Tablets 30/150/200mg	60	125,597							
SAQUINAVIR									
Capsules 200mg	270	146							

PRODUCT DESCRIPTION	PACK SIZE	INDICATIVE ANNUAL QUANTITY REQUIRED	COUNTRY OF MANUFACTURE/ MANUFACTURING SITE	QUALITY STATUS IN RELATION TO GLOBAL FUND QUALITY ASSURANCE POLICY (Tick appropriately)				LEADTIME (DELIVERY TIME)	UNIT PRICE QUOTATION
				A	B	Ci	Cii		
TENOFOVIR									
Tablets 300mg	30	14,575							
RETONAVIR									
Capsules 100mg	84	291							
RITONAVIR with LOPINAVIR									
Capsules Ritonavir 200mg with Lopinavir 50mg	120	14,831							

ANNEX B

STANDARD SUPPLIER CONTRACT (AGREEMENT)

Made and entered into by and between

NERCHA

(National Emergency Response Council on HIV/AIDS)

“the PURCHASER”

and

“the SELLER”

NOW THEREFORE THESE PRESENTS WITNESSETH:

1. EFFECTIVE DATE AND DURATION

1.1 The Effective Date of this Agreement shall be.....

1.2 This Agreement shall endure until it is terminated:

1.2.1 in terms of the provisions of clause 8 below; or

1.2.2 in terms of the provisions of clause 12 below; or

1.2.3 upon written notice given by the SELLER at least 180 (one hundred and eighty) days prior to such termination.

2. SALE

The SELLER will sell to the PURCHASER who will purchase the Product upon the terms and conditions set out therein.

3. PRODUCT

3.1 The Product to be sold by the SELLER to the PURCHASER is more fully described in the Schedule annexed hereto marked "A". In the event that the Tender award comprises more than 1 (one) product, the Schedules shall be marked "A1", "A2" and so on.

3.2 The Product will be manufactured and supplied in compliance with the provisions set out hereunder and the Product will :

be manufactured in compliance with Good Manufacturing Practices (“GMP”) as recommended by the World Health Organization (“WHO”); and

- 3.2.1 be manufactured at a manufacturing site included in the WHO list of pre-qualified products (under the heading of Procurement, Quality and Sourcing Project/Access to HIV/Aids/Drugs and diagnostics of acceptable quality) and be manufactured under valid regulatory approval of the manufacturing country; or
- 3.2.2 be manufactured under valid regulatory approval of the manufacturing country and be licensed for use and marketed in any country member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S); and
- 3.2.3 be supplied in a stable condition, retaining its original characteristics as described in their BP/USP monograph throughout its shelf life; and
- 3.2.4 be accompanied by a Batch Certificate or a Certificate of Analysis for each batch supplied; and
- 3.2.5 be supplied to the Delivery Point with a remaining shelf life of twenty-four months or at least not less than 3/4 (75%) of its total shelf life.

4. PACKAGING AND LABELLING

- 4.1 The Product shall be packaged in immediate and external containers suitable to withstand rough handling in transit and storage under conditions where temperatures may rise to 40 (forty) degrees centigrade and humidity may be as high as 75% (seventy five percentum);
- 4.2 The SELLER shall ensure that the Product is packed in such a manner so that the Product reaches the Delivery Point intact and undamaged, it being recorded that the SELLER shall be solely responsible for loss, damage or expense incurred by the PURCHASER due to insufficient or unsuitable packaging;
- 4.3 All containers and packing material supplied by the SELLER shall be non-returnable;
- 4.4 Any damaged or inferior or out of specification Product delivered to the Delivery Point shall be rejected by the PURCHASER and uplifted by the SELLER at the sole cost and expense of the SELLER who shall replace the rejected Product at its expense within a period of 72 hours of being advised of the rejected Product in writing by the PURCHASER of such rejected Product.
- 4.5 Each unit of Product shall be labelled with the following:
- 4.5.1 all primary containers as well as packaging cartons shall be labelled in English;
 - 4.5.2 the label shall consistently reflect the generic description and strength of the Product, notwithstanding the use of brand names. In the event of Products containing more than 1 (one)

ingredient, the generic name and strength of each active ingredient shall be clearly indicated;

4.5.3 the label shall show the quantity of the primary unit container, batch number, expiry date written in full, storage conditions, the barcode and barcode numbers as well as any other important information provided in a concise and ethical manner;

4.5.4 each primary unit container shall be provided with a package insert approved by the regulatory authority of the manufacturing country and in English;

4.5.5 the information on the package insert shall include details relating to :

- 4.5.5.1 Name;
- 4.5.5.2 Qualitative and Quantitative Composition;
- 4.5.5.3 Pharmaceutical Form;
- 4.5.5.4 Therapeutic Indication/s;
- 4.5.5.5 Posology and Method of Administration;
- 4.5.5.6 Contraindications;
- 4.5.5.7 Special Warnings and Special Precautions for Use;
- 4.5.5.8 Interactions with Other Medicinal Products and Other Forms of Interactions;
- 4.5.5.9 Use during Pregnancy and Lactation;
- 4.5.5.10 Use in Children
- 4.5.5.11 Effects on Ability to Drive and use Machines;
- 4.5.5.12 Undesirable Effects
- 4.5.5.13 Overdose
- 4.5.5.14 Pharmacodynamic Properties
- 4.5.5.15 Pharmacokinetic Properties
- 4.5.5.16 List of Excipients

- 4.5.5.17 Incompatibilities
- 4.5.5.18 Shelf Life
- 4.5.5.19 Special Precautions for Storage
- 4.5.5.20 Nature and Content of Container
- 4.5.5.21 Instructions for Use, Handling and Disposal
- 4.5.5.22 Date of Revision of the Text.

5. QUANTITY OF PRODUCT TO BE ORDERED AND ORDERING PROCEDURE

- 5.1 The quantity of the Product to be ordered, supplied and delivered for each batch will be set out on an order form issued by the PURCHASER.
- 5.2 The order form will only be valid and binding if signed by a person duly authorised thereto by the PURCHASER from time to time;
- 5.3 All orders will be dispatched by facsimile or electronically to numbers and/or addresses nominated by the SELLER from time to time. For the sake of confirmation only and on the understanding that the date of delivery of the orders by facsimile or electronically will be the date upon which the order becomes effective, the original order will be dispatched to such address by the SELLER by prepaid mail.

6. DELIVERY OF PRODUCT

6.1 All lawfully ordered Product shall be delivered by the SELLER within the agreed lead period for each supplier the date of placement of the order as provided for in 5.3 above:

6.2 Such delivery shall be:

- 6.2.1 to the Delivery Point which shall be the warehouse at the Central Medical Stores, Plot No.77, King Mswati III Avenue, Matsapha Industrial Sites, Matsapha, Swaziland;
 - 6.2.2 inclusive of all transport and delivery costs on the Carriage Insured Freight ("CIF") basis with all costs being paid in respect of the Product up to the Delivery Point;
 - 6.2.3 Free of any form of taxation or duties accruing to the PURCHASER or the Government of the Kingdom of Swaziland.
 - 6.2.4 Include a complete Batch Certificate of a Pharmaceutical Product issued by the manufacturer. The Batch Certificate shall include specifications of the final product at the time of the Batch release and the results of a full analysis undertaken on the batch in question,
- 6.3 The SELLER acknowledges that:
- 6.3.1 in the event of the delivery of any order being later than 14 (fourteen) days after the date stipulated in 6 above, the PURCHASER shall be entitled to deduct a sum equivalent to 2.5% (two point five) of the total Purchase Price as a penalty;
 - 6.3.2 thereafter, for every period of 7 (seven) days for which delivery is late thereafter, the PURCHASER shall further be entitled to deduct a sum equivalent to 1% (one percent) of the total Purchase Price as a penalty for each such period.

7. WARRANTY OF AVAILABILITY OF PRODUCT

- 7.1 The SELLER warrants stability and continuity of supply of Product and acknowledges and undertakes that it shall at all times have available for delivery to the PURCHASER at least a third (1/3) of the quantity of each Product ordered as part delivery, and the balance within the agreed upon delivery time.

7.2 The SELLER acknowledges that, a breach by it of the provisions of 7.1 or its failure to deliver any Product within the period stipulated at 6 above, will constitute a material breach going to the root of the contract entitling the PURCHASER to either immediately and without further notice cancel this Agreement and/or demand specific performance in which event the SELLER will, at its own expense, be obliged to source and supply Product with identical properties and specifications at its sole expense and in the event of the SELLER being unable to do so for any reason whatsoever within a period of 72 (seventy two) hours of it being required to do so, the PURCHASER shall be entitled to source Products with identical properties and specifications from any other supplier and the PURCHASER will be entitled to claim from the SELLER the difference between the agreed Purchase Price set out below and the actual sum paid for the replacement Product in terms hereof.

8. PURCHASE PRICE

8.1 The Purchase Price will be:

8.1.1 denominated in Swaziland Lilangeni (for local suppliers), South Africa Rand (for South African Suppliers) or United States Dollars (for International suppliers)

8.1.2 an amount not greater than the prices agreed between the Parties as specified in the Schedule annexed hereto marked "B". Insofar as the tender award consists of more than 1 (one) product, the Schedules shall be marked "B1", "B2" and so on.

9. PAYMENT OF THE PURCHASE PRICE

9.1 Payment of the Purchase Price will be made by the Purchaser within 30 (thirty) days of completion of a specific order and upon receipt of the correct invoices quoting the relevant purchase order, and custom declaration documents. In case of part deliveries, payment will be processed for items delivered.

9.2 Payment will be made less any taxes or withholding taxes which the PURCHASER is obliged to deduct from the Purchase Price at law for Swaziland Suppliers, where applicable.

10. WARRANTIES BY SELLER

10.1 The SELLER fully warrants that the Product will conform to all quality specifications and that no registered or unregistered intellectual property rights will be infringed by it arising out of the provisions of this Agreement.

10.2 The SELLER indemnifies the PURCHASER against any claim of whatsoever nature which may arise out of the use of the Product by any person and/or any claim which may arise out of the provisions of 10.1 above.

11. CONFIDENTIALITY

11.1 The SELLER undertakes to and in favour of the PURCHASER:

11.1.1 to protect the interests of the PURCHASER and the Government of the Kingdom of Swaziland and to treat as confidential all information coming into their possession relative to the activities and funding of the PURCHASER;

- 11.1.2 that they shall at all times keep secret and not give, disclose or divulge to any person any details relating to the volumes of Product purchased by the PURCHASER or any information relating to the recipients of the Product, unless specifically authorised in writing by the PURCHASER.
- 11.2 The Parties acknowledge that in this agreement they are unable to record all the arrangements that will govern their relationships between each other and accordingly they agree to co-operate and negotiate with each other in the settlement and implementation of the intents and purposes of this agreement and the settlement and agreement of the terms and conditions necessary to implement the arrangements contemplated herein. In their dealings with each other, they agree that they shall display the utmost good faith.
- 11.3 The Parties undertake at all times to do such things, perform all such actions and take all such steps to procure the doing of all such things and the taking of all such steps as may be open to them, and necessary for or incidental to the putting into effect or maintenance of the terms, conditions or import of this agreement.
- 11.4 The Parties acknowledge that the PURCHASER shall be entitled to make public the Purchase Price and to disclose it upon request to any other interested party.

12. BREACH PROVISIONS

- 12.1 In the event of the SELLER being in breach of any material provision of this Agreement, and failing to remedy such breach within a period of 7 (seven) days of receiving notice thereof in writing from the PURCHASER, the PURCHASER, without prejudice to any other rights

which it may have at law including the right to urgent interim relief,
shall be entitled to either:

12.1.1 forthwith cancel this Agreement without further notice, and
claim from the SELLER damages; or

12.1.2 claim specific performance.

12.2 In the event that the PURCHASER instructs its attorneys to take any
steps to enforce any rights under this Agreement, the SELLER accepts
liability for all costs incurred by the PURCHASER on the scale as
between attorney and its own client including collection commission.

12.3 The SELLER shall not be entitled to cancel this Agreement by reason of
a breach of the PURCHASER of any terms of conditions hereof unless
the breach is of a material term going to the root of the Agreement
and the PURCHASER has failed to remedy the breach within a period of
14 (fourteen) days after having received notice in writing from the
SELLER to do so and the breach in question cannot be remedied by the
payment of the sum of money.

13. DISPUTE RESOLUTION

13.1 Any deadlock, lack of quorum, dispute, question or difference arising at any time between the parties to this Agreement out of or in regard to any matters arising out of; or the rights and duties of any of the parties hereto; or the interpretation of; or the termination of; or any matter arising out of the termination of; or the rectification of this Agreement, shall be submitted to and decided by arbitration on notice given by either party to the other of them in terms of this clause.

13.2 Such arbitration shall be held in Mbabane, Swaziland in accordance with the rules of the Arbitration Act of Swaziland as amended, it being the agreed intention that, if possible, the arbitration shall be held and concluded within 60 (sixty) days after it has been demanded.

13.3 Save as otherwise specifically provided in this Agreement, the Arbitrator shall be, if the question in dispute is:

13.3.1 Primarily an accounting matter - an independent accountant of not less than 15 (fifteen) years standing;

13.3.2 Primarily a legal matter - a practising attorney or advocate of not less than 15 (fifteen) years' standing;

13.3.3 Any other matter - an independent and suitably qualified person, as may be agreed upon between the parties.

13.4 If Agreement cannot be reached on whether the question in dispute falls under 13.3.1, 13.3.2, or 13.3.3 above or upon a particular arbitrator in terms of 13.3 within 7 (seven) days after the arbitration has been demanded, then the applicable person at AFSA shall:

13.4.1 Determine whether the question in dispute falls under 13.3.1, 13.3.2 or 13.3.3;

13.4.2 Nominate the arbitrator in terms of the relevant sub-clause.

13.5 This clause shall constitute each party's irrevocable consent to the arbitration proceedings, and no party shall be entitled to withdraw herefrom or to claim at such arbitration proceedings that it is not bound by this clause.

13.6 Each of the parties hereby irrevocably agrees that the decision of the Arbitrator in the arbitration proceedings:

13.6.1 shall be final and binding on each of them; and

13.6.2 will be carried into effect; and

13.6.3 can be made an Order of any Court to whose jurisdiction the parties are subject.

13.7 The provisions of this clause shall not prevent or prejudice any party to seek urgent interim relief from a court of competent jurisdiction.

14. GENERAL

Field Code Chan

14.1 Each of the parties warrants that it has power to enter into this Agreement.

14.2 Waiver by either party ("the first party") of any right or default by the other party shall not affect or prejudice the first party's rights in respect of any other right or default nor any subsequent default of the same or of a different kind nor shall any delay or omission of the first party to exercise any right arising from any default affect or prejudice the first party 's rights as to the same or any future default.

Field Code Chan

14.3 This Agreement and the documents referred to in this Agreement constitute the whole agreement between the parties in relation to the subject matter covered and supersede any previous agreement between the parties in relation to such matters which shall cease to have any further effect. It is agreed that:

14.3.1 no party has entered into this Agreement in reliance upon any representation, warranty or undertaking which is not set out or referred to in this Agreement;

14.3.2 in the absence of fraud, no party will have any remedy in respect of any untrue statement, made to it or its representatives or agents, upon which it or they relied and such party's only remedy will be for breach of contract; and

14.3.3 this clause shall not exclude any liability for fraudulent misrepresentation.

14.4 ~~The invalidity or unenforceability of any part of this Agreement~~ shall not prejudice or affect the validity or enforceability of the remainder of this Agreement.

Field Code Chan

14.5 The parties agree that if during the validity of this Agreement:

14.5.1 any act or acts of the Government(s) of the countries within the Territory are enacted prescribing further requirements for or otherwise affecting this Agreement; or

14.5.2 a competent authority publishes or issues a statement or statements of further requirements governing the use of the Technology; or

14.5.3 any Court of competent jurisdiction delivers a judgment; and the effect of the above is in the reasonable opinion of the PURCHASER that non-compliance therewith would render or likely render this Agreement or any part of this Agreement invalid, voidable, illegal or unenforceable then the parties will immediately amend this Agreement or any relevant part of this

Agreement and will sign all documents as may be necessary to effect amendment so far as is necessary in the reasonable opinion of the PURCHASER and the SELLER or their attorneys or solicitors to avoid this Agreement being invalid, voidable, illegal or unenforceable.

14.6 The SELLER agrees that it will:

14.6.1 not describe itself as agent or representative of the PURCHASER except as expressly authorised by this Agreement, or otherwise in writing by the PURCHASER;

14.6.2 in all correspondence and other dealings not give reasonable grounds for a belief that it is acting as agent for the PURCHASER and not as principal for its own account;

14.6.3 not describe itself as or in any way indicate or hold itself out as a partner of the PURCHASER;

14.7 Neither the PURCHASER nor the SELLER shall be liable for any delay or failure to perform obligations hereunder where such delay or failure is due to circumstances beyond its control being an act of God, war, riot, civil commotion or any governmental restriction, order or regulation or statutory prohibition ("Force Majeure"). The party affected by such event shall promptly notify the other of the event and performance of the Agreement shall be suspended for the duration of the event of force majeure. Notwithstanding the foregoing provisions it is agreed the PURCHASER shall not thereby be relieved of its obligations to pay sums due under this Agreement accrued on or before the date of suspension unless it is the payment method which is delayed by such circumstances.

14.8 Any notice required to be given under this Agreement shall be in writing and shall be deemed validly served if delivered by hand or sent by facsimile (such facsimile to be confirmed by pre-paid registered post) to the facsimile number and address of the other party set out in this Agreement (or such other number and address as may have been notified) and any such notice shall be deemed to have been served if delivered by hand immediately or if sent by facsimile upon the expiration of 12 hours after dispatch.

PURCHASER:- NERCHA (National Emergency Response Council on HIV/AIDS)

Telefax No.: +268 404 1692/7300

Telephone No.: +268 404 1703 / 8
+268 404 1720 / 6

Postal address: P O Box 1937
Mbabane
Swaziland

SELLER:.....

Telefax No.:

Telephone No.:.....

Postal address:
.....
.....

15. **GOVERNING LAW AND JURISDICTION**

This Agreement is deemed to be made at Mbabane in the Kingdom of Swaziland and this Agreement and its construction, interpretation and enforcement is governed by the laws in force in the Kingdom of Swaziland.

The Parties consent to the non-exclusive jurisdiction of the Magistrate's Court in respect of any proceedings arising out of this Agreement.

16. **COSTS**

Each party shall bear its own costs of and incidental to the negotiations leading up to and the preparation and signature of this Agreement.

17. **AMENDMENTS**

This Agreement may only be amended by the mutual written agreement of both parties.

18. **NON-EXCLUSIVITY**

It is recorded that the SELLER shall not have the exclusive right to supply Product to the PURCHASER and the PURCHASER shall be entitled to enter into Agreements with other sellers relating to the Product simultaneously with this Agreement.

19. **SPECIAL PROVISION**

- 19.1 So as to specifically and effectively combat any unfair or unethical or unacceptable business practices and for the sake of transparency and accountability the SELLER undertakes that it will not, in respect of supply of any Product into the Kingdom of Swaziland to the PURCHASER or any other party, make any direct or indirect payment, gift, inducement, allowance or

any other disbursement which has any monetary value of any nature to any person or entity which is directly or indirectly, however remote, engaged in the affairs of the PURCHASER, the Government of the Kingdom of Swaziland or any other entity which is directly or indirectly involved in the supply of medical equipment, consumables, drugs or medicines into or in the Kingdom of Swaziland.

19.2 In the event that the PURCHASER is desirous of making a gift or contribution to an acceptable charitable or educational entity in Swaziland, it shall be entitled to do so with the written consent of the PURCHASER, which consent will not be unreasonably withheld.

20. **CONDITION PRECEDENT**

It shall be a condition precedent to this agreement becoming effective that the NERCHA Tender Board gives final approval to this transaction.

SIGNED by the parties on.....

AS WITNESSES:

1.

For and on behalf of the SELLER

2.

AS WITNESSES:

1.

**For and on behalf of
the PURCHASER**

2.

SCHEDULE "A"

the active ingredient is:

the brand name is:

the dosage form is:

the strength is:

the approved indication is: use in combination with other antiretroviral agents
for the treatment of HIV-1 infection in adults and
children;

SCHEDULE "A1"

the active ingredient is:

the brand name is:

the dosage form is:

the strength is:

the approved indication is: palliative treatment of adult and pediatric patients
(over 6 months of age) with advanced HIV-1
infection;

SCHEDULE "A2"

the active ingredient is:

the brand name is:

the dosage form is:

the strength is:

the approved indication is: use in combination with other antiretroviral agents
for the treatment of HIV-1 infection in adults and
children;

SCHEDULE "A3"

the active ingredient is:

the brand name is:

the dosage form is:

the strength is:

the approved indication is: use in combination with other antiretroviral agents
for the treatment of HIV-1 infection in adults;

SCHEDULE "B"

(1) Agreed Price:.....

SCHEDULE "B1"

(2) Agreed Price:.....

SCHEDULE "B2"

(3) Agreed Price:.....

SCHEDULE "B3"

(4) Agreed Price:.....