

2nd Global Fund and Global Drug facility Invitation to manufacturers of first, second and third-line anti-tuberculosis medicines to submit an Expression of Interest (Eoi) for product evaluation by Expert Review Panel (ERP)

JULY 2011

I. Purpose of this invitation for Eoi

The purpose of this Eoi is to invite submissions of first, second and third-line anti-tuberculosis product dossiers for review by the ERP for which there are less than 3 products¹ of the same formulations that are WHO-Prequalified or SRA-approved or ERP-reviewed are available in the global market.

The Global Fund and the Global Drug Facility (*GDF*) are using the same ERP process (in terms of products, questionnaire dossier, process mechanism hosted by WHO/QSM as described at <http://www.theglobalfund.org/en/procurement/pharmaceutical/> under “A, B and ERP-reviewed products”). The synchronization of the dossier review process for non-WHO prequalified or non-SRA authorized TB products has been accepted by the WHO, GDF and the Global Fund. This should minimise duplication of work for manufacturers and ERP members.

Therefore, information submitted to, and the information and advice provided by, the ERP in connection with this Eoi will be shared with, and used by GF and GDF² for procurement and supply management purposes.

II. Background

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the *Global Fund*) provides grants to support national and global efforts to increase access, care and treatment in approximately 140 countries.

The Global Fund Quality Assurance Policy defines uniform and stringent quality requirements apply to all antiretrovirals, anti-tuberculosis, and antimalarial pharmaceutical products purchased with Global Fund resources irrespective of the source (“QA Policy”³).

¹ INN, strength, dosage form, type of packaging (HPDE container or Alu/PvC foil blister or Alu/ALU foil strips)

² The Global Drug Facility (GDF) is an initiative of the Stop TB Partnership to increase access to quality-assured tuberculosis (TB) medicines for DOTS implementation, a TB control strategy. GDF is housed at the World Health Organization (WHO) headquarters in Geneva and managed by a small team in the Stop TB partnership secretariat. For further information on GDF's services and operations, please refer to: <http://www.stoptb.org/gdf/>.

³ http://www.theglobalfund.org/documents/psm/PSM_QAPharm_Policy_en.pdf

In principle, antiretrovirals, antituberculosis, and antimalarial pharmaceutical products can be funded using Global Fund resources if they are:

- (a) prequalified by the WHO Prequalification Programme; **and/or**
- (b) authorized for marketing in a country with a stringent drug regulatory authority (SRA)⁴ (registration "for export only" is not sufficient) or approved/subject to a positive opinion under one of the following schemes: Canada S.C. 2004, c. 23 (Bill C-9) procedure, or Art. 58 of European Union Regulation (EC9 No. 726/2004) or US-FDA tentative approval; **or**
- (c) products of which the dossiers were reviewed and permitted for use for a time limited period by an independent panel of technical experts (ERP-Expert Review Panel) . Information about the ERP Mechanism is found at <http://www.theglobalfund.org/en/procurement/pharmaceutical/> (under "A, B and ERP-reviewed products").

In order to assist the Global Fund Principle Recipients (PR) to identify the regulatory status of the antimalarials, Global Fund has developed a list of products classified according to the above QA requirements (a, b, c).

The current list can be viewed/downloaded from the following website:

http://www.theglobalfund.org/documents/psm/List_TB.pdf

In July 2010, GDF revised its Quality Assurance Policy and Procedures as part of a collaborative process to ensure harmonization with the policies of two major multi-lateral financing mechanisms (i.e. The Global Fund and UNITAID), and other organizations (i.e. The Union; UNICEF, Médecins Sans Frontières) involved in TB control and in particular to:

- ensure global consistency on quality standards set for procurement and supply of anti-TB medicines as well as medical items,
- avoid duplication of effort.

With the combined objectives to improve the safety, efficacy and quality of products procured by GDF, the GDF quality assurance system is based on:

- recommendations by WHO / Stop TB Strategy;
- authorization for use by recipient countries;
- recommendations by the relevant WHO Programmes, that is, Prequalification of Medicines Programme (PQP);
- authorization for marketing by a stringent national medicines regulatory authority (SRA) in the country;
- positive opinion for procurement purposes by an Expert Review Panel, for a specified time period where there are no WHO-prequalified or SRA-approved products available; and
- a quality monitoring programme for supplied products, including independent random quality control

⁴http://www.theglobalfund.org/documents/psm/List_of_Countries_SRA.pdf

III. Product Formulations included in this Eol

The recommended active ingredients, dosage forms and strengths ("Formulations") listed in this document have been identified by WHO's Department of Tuberculosis as vital to effective treatment for people suffering from tuberculosis. These formulations are included either in the WHO Model List of Essential Medicines⁵ and/or in the WHO standard treatment guidelines⁶ for treatment of TB and/or in National/institutional Guidelines.

In addition to the above, this Eol also invites submissions of dossiers of anti-tuberculosis drugs:

- a) to treat XDR-TB (extensively drug resistant tuberculosis) and
- b) first and second line anti-TB drugs produced and used solely in INDIA for review by the ERP

NOTE:

The Global Fund QA policy strongly recommends that PRs implement mechanisms to encourage adherence to treatment regimens (including but not limited to providing medicines in FDCs, once-a-day formulations and/or blister packs, and providing peer education and support), to monitor and contain resistance, and to monitor adverse drug reactions according to existing international guidelines (Ref: Point6:"Global Fund Quality Assurance Policy for Pharmaceutical Products (as amended and restated on 14 December 2010⁷).

Hence FDC is considered as the preferred option.

IV. Eligibility Criterion 1:

A) Requirements:

The following criteria are required to be fulfilled by the manufacturer if a product is to be accepted for ERP review under this *criterion*. This criterion has been in force from the beginning of the ERP process and was adopted by the Board in November 2008.

- 1.the manufacturer of the product has submitted an application for pre-qualification of the product by the WHO Prequalification Programme and it has been accepted by WHO for review; OR the manufacturer of the product has submitted an application for marketing authorization to any SRA, and it has been accepted for review by the SRA, and
- 2.the product is manufactured at a site that is compliant with all standards of Good Manufacturing Practice (GMP) that apply to the relevant product formulation, as verified after inspection by the WHO Prequalification Programme OR any SRA OR a

⁵ WHO Model List of Essential Medicines. Adult, March 2010
http://www.who.int/medicines/publications/essentialmedicines/Updated_sixteenth_adult_list_en.pdf
WHO Model List of Essential Medicines. For Children. March 2010
http://www.who.int/medicines/publications/essentialmedicines/Updated_second_children_list_en.pdf

⁶ WHO. Treatment of tuberculosis: guidelines for national programmes. 2009, 4th edition.
WHO/CDS/TB/2003.313.http://whqlibdoc.who.int/publications/2010/9789241547833_eng.pdf

⁷ http://www.theglobalfund.org/documents/psm/PSM_QA_Pharm_Policy_en.pdf

regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme (PIC/S)⁸.

B) Formulations included in this invitation for EoI under Eligibility Criterion-1

The formulations included in this category are:

- (B1) First Line anti TB medicines
 - a. Single ingredient first-line anti-tuberculosis medicines
 - b. Fixed-dose combinations of first-line anti-tuberculosis medicines
 - c. STOP TB Patient kits
- and
- (B2) Second Line anti TB medicines

B.1) First Line anti TB medicines

NOTE:

For all the products the preferred standard packaging specifications are:

For adult formulations:

- Blister of 28 tablets, 24 blisters in a box (i.e. 672 tablets in a box)
- 1000 loose tablets in HDPE container for specific use e.g. by hospital/clinics

For paediatric formulations:

- Blister of 28 tablets, PvdC/PVC/Alu blister, 3 blisters in a box (i.e. 84 tablets in a box) or Alu/Alu foil strip of 6 tablets, 14 strips in a box (i.e. 84 tablets in a box).

However this does not preclude the manufacturer from submitting dossiers for other pack sizes.

a. Single ingredient first-line anti-tuberculosis medicines

- Ethambutol, oral liquid 25mg/ml
- Ethambutol / dispersible scored 100 mg
- Ethambutol, film coated tablet/caps 200mg; 275mg
- Isoniazid, film coated tablet 50 mg; 150mg scored
- Isoniazid, tablet/caps 300 mg
- Pyrazinamide oral syrup 30mg/ml
- Pyrazinamide, film coated tablet/dispersible 150 mg scored tablet
- Pyrazinamide, film coated tablet/caps 250mg scored tablet
- Pyrazinamide, film coated tablet/caps 400mg
- Rifampicin tablet, Caps 150mg; 300mg;
- Streptomycin, powder for injection 0.75g as sulphate (vial)
- Streptomycin, powder for injection 1g as sulphate (vial)

b. Fixed-dose combinations of first-line anti-tuberculosis medicines

- Isoniazid + Rifampicin, film coated tablet/caps
 - Tablet/Caps 150 mg + 150 mg
 - Tablet/Caps 150 mg + 300 mg

⁸ <http://www.picscheme.org/members.php>

- Isoniazid 75mg+ Rifampicin 150mg, film coated tablet/caps
- Ethambutol tablet/caps 400mg + Isoniazid 150mg
- Ethambutol + Isoniazid + Rifampicin film coated tablet/caps 275 mg + 75 mg + 150 mg
- Isoniazid + Pyrazinamide + Rifampicin film coated tab/caps 150mg+500mg+150mg
- Ethambutol + Isoniazid + Pyrazinamide + Rifampicin scored tablet
275mg+75mg+400mg+150mg
- Isoniazid + Pyrazinamide+ Rifampicin 75mg+400mg+150mg scored Tablet

c. STOP TB Patient kits (GDF)

Eligibility to supply the patient kits will be determined based on the eligibility to supply the constituent products, that is, fixed-dose combination products of first-line anti-tuberculosis medicines, single ingredient first-line anti-tuberculosis medicines which have been WHO-prequalified, SRA-authorized or ERP-reviewed.

B.2) Second Line anti TB medicines

NOTE:

For all the products the preferred standard packaging specifications are:

For adult formulations:

- Blister of 10 tablets PvdC /PVC/Alu Blister pack or Alu/Alu strip/blister, foil of 10 tablets, 9 blisters in a box
- loose tablets in HDPE container for specific use e.g. by hospital/clinics
- 80 vials per box

However this does not preclude the manufacturer from submitting dossiers for other pack sizes.

Single ingredient second-line anti-tuberculosis medicines

- Amikacin, powder for solution * 1g/4ml , vial/ampoule
- Capreomycin, powder for injection 1g, vial/ampoule
- Cycloserine Caps 250mg
- Ethionamide, tablet 250 mg, tablet,
- Kanamycin, powder for injection 500 mg and 1g vial,
- Levofloxacin, tablet 250 mg, tablet 500 mg, tablet 750 mg,
- Moxifloxacin, tablet 400 mg
- Ofloxacin, tablet 200 mg and 400mg tablet,
- Prothionamide, tablet 250 mg
- Para-Aminosalicylic Acid (PAS) sachets, 4 g granules,
- Para-Aminosalicylic PAS Sodium jar; granules sachets; powder for oral solution in sachet.
- Terizidone, capsule/tablet, 250mg, 300 mg

* with/without water for injection

C) Submission process: [refer to the ANNEX-1 of this document](#)

V. Eligibility Criterion 2:

A) Requirements:

The following criteria are required to be fulfilled by the manufacturer for a product to be eligible for ERP review under *Eligibility Criterion 2* as per Global Fund QA policy amendment adopted by Global Fund Board in December 2010 and adopted by GDF 2010 in their QA policy.

The product is manufactured at a site that is compliant with all standards of Good Manufacturing Practice (GMP) that apply to the relevant product formulation, as verified after inspection by the WHO Prequalification Programme OR an SRA OR a regulatory authority participating to the Pharmaceutical Inspection Cooperation Scheme (PIC/S) and it is not listed in the WHO invitation to manufacturers to submit an expression of interest for product evaluation by the WHO Prequalification Programme.

(Ref: Point 13: "Global Fund Quality Assurance Policy for Pharmaceutical Products (as amended and restated on 14 December 2010"⁹)

B) Formulations included in this invitation for EoI under Eligibility Criterion 2

The formulations included in this category are as follows:

- (B1) First-line anti-tuberculosis medicines
 - a. Single ingredient first line anti-tuberculosis medicines
 - b. Fixed dose combinations of first-line anti-tuberculosis medicines
- (B2) First-line anti-tuberculosis medicines in the form of 'PRODUCT'¹⁰ used solely in India.
- (B3) Second-line anti-tuberculosis medicines used solely in India
- (B4) Third line anti-tuberculosis medicines used for the treatment of extensively drug resistant (XDR-TB)
- (B5) Water for injection (solvent)

B.1. First-line anti-tuberculosis medicines

NOTE:

For all the products the preferred standard packaging specifications are:

For adult formulations:

- Blister of 28 tablets, PvdC/PVC/Alu blister, 24 blisters in a box (i.e. 672 tablets in a box), or PvdC/PVC/Alu Blister 10 tablets and 9 blisters in a box
- 1000 loose tablets in HDPE container for specific use e.g. by hospital/clinics

For paediatric formulations:

- Blister of 28 tablets, PvdC/PVC/Alu blister, 3 blisters in a box (i.e. 84 tablets in a box) or Alu/Alu foil strip of 6 tablets, 14 strips in a box (i.e. 84 tablets in a box).

⁹ http://www.theglobalfund.org/documents/psm/PSM_QA_Pharm_Policy_en.pdf

¹⁰ PRODUCT is defined under b.3 on page 8.

However this does not preclude the manufacturer from submitting dossiers for other pack sizes.

* The Global Fund QA policy strongly recommends that PRs implement mechanisms to encourage adherence to treatment regimens (including but not limited to providing medicines in FDCs, once-a-day formulations and/or blister packs, and providing peer education and support), to monitor and contain resistance, and to monitor adverse drug reactions according to existing international guidelines.

a. Single ingredient first line anti-tuberculosis medicines

- Ethambutol film coated tablet 600mg, 800mg.
- Isoniazid , film coated tablet 75mg;
- Isoniazid oral syrup 50mg/5ml.
- Pyrazinamide film coated tablet 500mg, 750mg;
- Rifampicin oral syrup 20mg/ml.
- Rifampicin film coated tablets/capsules 75mg, 450mg

b. Fixed dose combinations of first-line anti-tuberculosis medicines

- Isoniazid + Pyrazinamide + Rifampicin 30mg+150mg+ 60mg film coated/ dispersible scored tablets
- Isoniazid + Rifampicin ; film coated tablet/ dispersible scored tablets
 - Tablet 30 mg + 60 mg
 - Tablet 60 mg + 60 mg

B.2. First-line anti-tuberculosis drugs in the form of ‘PRODUCT’¹¹ used solely in India.

The treatment of TB susceptible cases in India with first-line anti-tuberculosis medicines, in National/institutional TB guidelines in India involves procurement and the use of combi-packs or blisters of several formulations or one formulation (depending on the treatment box in question).

For the purpose of this Eol, Combi-pack is thus the primary packing placed in a pouch which is referred to as the secondary packing, which in turn is placed in a treatment box which is referred to as the tertiary packing. This whole pack, consisting of tertiary, secondary and primary units, is termed as ‘PRODUCT’. Where there is only one formulation, the ‘PRODUCT’ refers to the blister/foil primary packing placed in the secondary pack.

The ‘PRODUCTS’ listed in this document have been recommended for funding by the Technical Review Panel. Taking this into account, the third supplement Expression of Interest is posted to enable manufacturers to supply ‘PRODUCT’ that meet Global Fund Quality standards.

¹¹ PRODUCT is defined under b.3 on page 8.

| Product code | Product description and composition | |
|------------------|--|--|
| PRODUCT 1 | Treatment box for Cat I Patient. Each treatment box containing 24 combi-packs of Schedule-I in one pouch and 18 multi-blister calendar combi-packs of Schedule-2 in another pouch | |
| | Each combi-pack of Schedule-I containing 1 R Cap of 450mg 2 H Tabs of 300mg each 2 E Tabs of 600mg each 2 Z Tabs of 750mg each | Each multi-blister calendar combi-pack of Schedule-2 containing 3 R Caps of 450 mg each 6 H Tabs of 300mg each 4 Pyridoxine Tabs of 5mg each |
| PRODUCT 2 | Treatment box for Cat II Patient. Each treatment box containing 36 combi-packs of Schedule-I in one pouch and 22 multi-blister calendar combi-packs of Schedule-3 in another pouch | |
| | Each combi-pack of Schedule-I containing 1 R Cap of 450mg 2 H Tabs of 300mg each 2 E Tabs of 600mg each 2 Z Tabs of 750mg each | Each multi-blister calendar combi-pack of Schedule-3 containing 3 R Caps of 450 mg each 6 H Tabs of 300mg each 6 E Tabs of 600mg each 4 Pyridoxine Tabs of 5mg each |
| PRODUCT 3 | Treatment box for Cat III Patient. Each treatment box containing 24 combi-packs of Schedule-4 in one pouch and 18 multi-blister calendar combi-packs of Schedule-2 in another pouch | |
| | Each combi-pack of Schedule-4 containing 1 R Cap of 450mg 2 H Tabs of 300mg each 2 Z Tabs of 750mg each | Each multi-blister calendar combi-pack of Schedule-2 containing 3 R Caps of 450 mg each 6 H Tabs of 300mg each 4 Pyridoxine Tabs of 5mg each |
| PRODUCT 4 | Treatment box for prolongation of Intensive Phase of Cat-I & Cat. II. Each box containing 5 pouches and each pouch containing 12 blister combi-packs of Schedule-1 Each combi-pack of Schedule 1 containing 1 R Cap of 450mg 2 H Tabs of 300mg each 2 E Tabs of 600mg each 2 Z Tabs of 750mg each | |

| Product code | Product description and composition | |
|--------------|---|--|
| | | |
| PRODUCT 5 | <p align="center">Injection Streptomycin Kit</p> Streptomycin kit for injection containing Inj. Streptomycin 750 mg - Box of 24 vials Sterile water for injection IP 5 ml - Box of 24 ampoules Disposable syringe and needle - 24 each | |
| PRODUCT 6 | <p align="center">10 Blister or Foil pack containing</p> 10 capsule of Rifampicin 150mg each | |
| PRODUCT 7 | <p align="center">10 Blister or Foil pack containing</p> 10 Tablets of INH 100mg each | |
| PRODUCT 8 | <p align="center">10 Blister or Foil pack containing</p> 10 Tablets of Pyrazinamide 500mg each | |
| PRODUCT 9 | <p align="center">7 Blister combi-pack in one pouch containing</p> Each combi-pack of Schedule 1 containing 1 R Cap of 450mg 2 H Tabs of 300mg each 2 E Tabs of 600mg each 2 Z Tabs of 750mg each | |
| PRODUCT 10 | <p align="center">9 Blister or Foil pack containing</p> 10 Tablets of Ethambutol 800mg each | |
| PRODUCT 11 | <p align="center">10 Blister or Foil pack containing</p> 10 Tablets of INH 300mg each | |
| PRODUCT 12 | <p align="center">10 Blister or Foil pack containing</p> 10 Tablets of Rifampicin 450mg each | |
| PRODUCT 13 | <p align="center">Treatment box for paediatric category (6-10 Kg). Each treatment box containing 24 combi-packs of Schedule-5 in one pouch and 18 multi-blister calendar combi-packs of Schedule-6 in another pouch</p> | |
| | <p align="center">Each combi-pack of Schedule-5 containing 1 R Tab of 75mg</p> | <p align="center">Each multi-blister calendar combi-pack of Schedule-6 containing</p> |

| Product code | Product description and composition | |
|--------------|--|--|
| | 1 H Tab of 75mg 1 E Tab of 200mg 1 Z Tab of 250mg | 3 R Tabs of 75 mg each 3 H Tabs of 75mg each 4 Pyridoxine Tabs of 5mg each |
| PRODUCT 14 | Treatment box for pediatric category (11-17 Kg). Each treatment box containing 24 combi-packs of Schedule-7 in one pouch and 18 multi-blister calendar combi-packs of Schedule-8 in another pouch | |
| | Each combi-pack of Schedule 7 containing 1 R Tab of 150mg 1 H Tab. of 150mg 1 E Tab of 400mg 1 Z Tab of 500mg | Each multi-blister calendar combi-pack of Schedule-8 containing 3 R Tabs of 150 mg each 3 H Tabs of 150mg each 4 Pyridoxine Tabs of 5mg each |
| PRODUCT 15 | Treatment box for prolongation of Intensive Phase of Cat I & Cat II pediatric cases (weight bands 6-10 kg & 18-25 kg). Each box containing 5 pouches and each pouch containing 12 blister combipack of Schedule-5 Each combi-pack of Schedule - 5 containing 1 R Tab of 75mg 1 H Tab. of 75mg 1 E Tab of 200mg 1 Z Tab. of 250mg | |
| PRODUCT 16 | Treatment box for prolongation of Intensive Phase of Cat I & Cat II pediatric cases (weight bands 11-17 kg, 18-25 kg and 26-30 kg). Each box containing 5 pouches and each pouch containing 12 blister combipack of Schedule-7 Each combi-pack of Schedule 7 containing 1 R Tab.of 150mg 1 H Tab. of 150mg 1 E Tab of 400mg 1 Z Tab. of 500mg | |
| PRODUCT 21 | 10 Blister or Foil pack containing 10 Tablets of Ethambutol 200mg each | |
| PRODUCT 23 | 10 Blister or Foil pack containing 10 Tablets of Pyrazinamide 750mg each | |

| Product code | Product description and composition |
|--------------|---|
| PRODUCT 26 | 10 Blister or Foil pack containing 10 Tablets of Pyridoxine 100mg each |
| PRODUCT 31 | 10 Blister or Foil pack containing 10 Tablets of Pyridoxine 50mg each |

B.3 Second line anti-tuberculosis drugs used solely in India

NOTE:

For all the products the preferred standard packaging specifications are:

For adult formulations:

- Blister of 10 tablets PvdC /PVC/Alu Blister pack or Alu/Alu strip/blister, 9 blisters in a box
- loose tablets in HDPE container for specific use e.g. by hospital/clinics
- 80 vials per box

However this does not preclude the manufacturer from submitting dossiers for other pack sizes.

- Capreomycin, powder for injection 500 mg vial
- Capreomycin, powder for injection 750 mg, vial
- Kanamycin, powder for injection 750 mg, vial,
- Ethionamide, tablet 125 mg tablet
- Para-Aminosalicylic Sodium (PAS), sachets 10 g granules, preferably 100 sachets per box.

B.4 Third line anti-tuberculosis medicines used for the treatment of extensively drug resistant (XDR-TB)

NOTE:

For all the products the preferred standard packaging specifications are:

For adult formulations:

- Blister of 10 tablets PvdC /PVC/Alu Blister pack or Alu/Alu strip/blister, 9 strips/blisters in a box
- loose tablets in HDPE container for specific use e.g. by hospital/clinics

However this does not preclude the manufacturer from submitting dossiers for other pack sizes.

- Amoxicillin/Clavulanate 875/125mg and 500/125mg tablet,
- Clofazimine 50mg, 100mg tablet
- Clarithromycin 500mg tablet
- Linezolid 600 mg, tablet
- Thiacetazone 150mg tablet

B.5 Water for injection (solvent)

Water for injection (solvent) 5ml vials/amps

C) Submission process: **please refer to ANNEX-2 of this document**

VI. Additional informations/instructions to the applicant

1. Completeness of the documents submitted to Global Fund Secretariat for ERP review is screened by the QA officer. All documents indicated under section (c) submission (ANNEX-1 and ANNEX-2) must be sent by the applicant. Incomplete submission will not be forwarded to the ERP.
2. The eligibility of the submissions for the ERP review will not be considered by the Global Fund Secretariat. It is under the ERP's responsibility to review and to judge the eligibility as to whether to perform or not the risk benefit assessment of the submitted dossiers.
3. For any product not found to comply with the required standards during previous ERP review, all documentations requested should be re-submitted in full.
4. The applicant is requested to indicate clearly under which Eligibility Criterion (1, or 2) the product has been submitted for this ERP review.
5. It is highly recommended to send an undertaking with the shipment of sample that is sent along with the dossiers, indicating that the samples are sent for review purpose only, will not be used on humans or animals have no commercial value and will not be placed in the market. This would ensure smooth transit at the customs in the country of origin and in Switzerland as well.

Electronic documentation should be submitted on a CD. Files should be named to reflect their content as mentioned in this letter (e.g. "Covering Letter.pdf"). For ease of reference, electronically submitted annexes to the questionnaire should be named corresponding to the letters on the list of annexes on page 17 of the questionnaire (e.g. "A.pdf" for information on the formulation of the product).

The information provided with the submission will be received by the Global Fund and will be shared by the Global Fund with GDF and ERP members for the purposes of facilitating the ERP review of the submission and advice to the Global Fund (such advice will also be shared with GDF).

Submissions should be sent by surface mail to the following address:

Mr Abu Saleh
Program Officer
Pharmaceutical Management Unit
8, Chemin de Blandonnet
CH- 1214 Vernier, Geneva
Switzerland

The deadline for submission is **15 September 2011, 17:00 h** Geneva time.

Subsequent invitations for Eol will be published from time to time as necessary.

VII. Further informations and enquiries

Guidelines on the application process for ERP review is available on the Global Fund website. Kindly direct any enquiries to:

Dr Joelle Daviaud
The Global Fund Secretariat
Tel: +41-58 -791-1758
Fax: +41-58 -791-1701

Email: joelle.daviaud@theglobalfund.org

With a copy to **Paloma Marroquín Lerga**: lergap@who.int

Kindly direct any enquiries directly relating to GDF to:

Paloma Marroquín Lerga
The Global Drug Facility
Fax: +41 22 791 4886
Email: lergap@who.int

With a copy to:
Dr Joelle Daviaud
The Global Fund Secretariat
Fax: +41-58 -791-1701

Email: joelle.daviaud@theglobalfund.org

Geneva, 12 July 2011

ANNEX-1

Applications for review by the ERP under Eligibility Criterion 1

C. Submission process for Dossier

All manufacturers interested in submitting applications for review by the ERP under Eligibility Criterion 1 for products listed are requested to submit the following information and material for each product under consideration.

For each product awaiting WHO-prequalification:

- A covering letter expressing interest to submit the product to the ERP for review
- An acceptance letter from the WHO Prequalification Programme confirming that the submission for the product has been accepted for review, and stating the WHO reference number assigned by WHO specifically to the product.
- Certification issued by WHO Prequalification Medicine programme confirming that the site and production line where the product is manufactured comply with all aspects of Good Manufacturing Practice (GMP), or a letter describing arrangements made to obtain such certification and stating the date when it will be supplied
- A completed Pharmaceutical Product Questionnaire, as available at <http://www.theglobalfund.org/documents/psm/TechQuestionnaireFPP-ERP-review.doc>. In lieu of annexes, reference can be made to the dossier submitted for WHO prequalification. Annexes should be submitted in case of any changes or updates.
- A non-returnable product sample as requested in Section VIII of the questionnaire

For each product awaiting marketing authorization by a stringent drug regulatory authority:

- A covering letter expressing interest to submit the product to the ERP for review
- An acceptance letter from the SRA confirming that the submission for the product has been accepted for review.
- Certification, issued by a regulatory authority, which is a member, observer or associate of ICH or a member of PIC/S, confirming that the site and production line where the product is manufactured comply with all aspects of Good Manufacturing Practice (GMP), or a letter describing arrangements made to obtain such certification and stating the date when it will be supplied.
- A completed Pharmaceutical Product Questionnaire (attached), and all annexes as applicable
- A non-returnable product sample as requested in Section VIII of the questionnaire

Documentation should be submitted in hard copy (on paper) and electronically, except for annexes to the Pharmaceutical Product Questionnaire, which should be submitted electronically only.



Submissions should be sent by surface mail to the following address:

Mr Abu Saleh,
Program Officer, Pharmaceutical Management Unit
8, Chemin de Blandonnet
CH- 1214 Vernier, Geneva
Switzerland

The deadline for submission is **15 September 2011**, 17:00 h Geneva time

ANNEX-2

Applications for review by the ERP under Eligibility Criterion 2

C. Submission process for Dossier

All manufacturers interested in submitting applications for review by the ERP under *Eligibility Criterion 2* for products listed are requested to submit the following information and material for each product under consideration.

- A covering letter expressing interest to submit the product to the ERP for review;
- Certification, issued by WHO Prequalification Medicine programme confirming that the site and production line where the product is manufactured comply with all aspects of Good Manufacturing Practice (GMP), or a letter describing arrangements made to obtain such certification and stating the date when it will be supplied;

and/or

- Certification, issued by a regulatory authority which is a member, observer or associate of ICH or a member of PIC/S, confirming that the site and production line where the product is manufactured comply with all aspects of Good Manufacturing Practice (GMP), or a letter describing arrangements made to obtain such certification and stating the date when it will be supplied;
- A completed Pharmaceutical Product Questionnaire (attached);
- A non-returnable product sample as requested in Section VIII of the questionnaire.

Documentation should be submitted in hard copy (on paper) and electronically, except for annexes to the Pharmaceutical Product Questionnaire, which should be submitted electronically only.

Submissions should be sent by surface mail to the following address:

Mr Abu Saleh,
Program Officer, Pharmaceutical Management Unit
8, Chemin de Blandonnet
CH- 1214 Vernier, Geneva
Switzerland

The deadline for submission is **15 September 2011, 17:00 h** Geneva time