

LIST OF TUBERCULOSIS PHARMACEUTICAL PRODUCTS classified according to the Global Fund Quality Assurance Policy

The list is an overview of pharmaceutical products subject to the Global Fund Quality Assurance Policy that are listed in National and/or WHO standard treatment guidelines and classified according to the various options (A, B, and ERP reviewed) defined in the Global Fund Quality Assurance Policy (July, 2009). The list is developed as a tool to assist Principal Recipients (PR) of Global Fund grants to identify the status of finished pharmaceutical products according to the Global Fund Quality Assurance Policy.

The pharmaceutical products are listed based on the following information

A classified product - Listed on WHO prequalification list;

B classified product - Stringent NDRA Registration letter/Marketing Authorisation;

ERP reviewed product- **Permitted for time limited use** based on advice by the Expert Review Panel (ERP)

List of products selected for procurement by relevant UN agencies for **certain multi-source FPPs for malaria and first-line TB treatment (Interim Exception-validity until December 31, 2010)**

Please note that the list is not an exhaustive list. A PR can procure product(s) not listed in the current list as long as PR demonstrates that the product is compliant with the Global Fund Quality Assurance Policy.

The Global Fund list includes the following information:

- "Important Notes" for helpful information;
 - **A, B, and ERP** reviewed products;
 - Period **validity** of ERP reviewed products;
 - "+" means combination product, both fixed-dose combination (co-formulated) and co-packaged product (i.e. co-blister)
 - **[A+B]+C** means A and B are in fixed-dose formulation and C is co-packaged
 - **Yellow color** identifies new entries while **pink color** identifies modification of an existing entry.
- <http://www.theglobalfund.org/en/about/procurement/list/>

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Important Note: In November 2008, The Global Fund Board approved the revised Quality Assurance Policy to be effective from July 1, 2009

Expert Review Panel (ERP): Expert Review Panel is an independent technical body composed of external technical experts, hosted by WHO Department of Essential Medicines and Pharmaceutical Policies, to review the potential risks/benefits associated with the use of FPPs that are not yet WHO-prequalified or SRA-authorized and to advise the Global Fund in its decision on whether to allow grant funds to be used to procure FPP. ERP reviewed products can be procured for a limited time (maximum 12 months). However, under certain circumstances, it is possible to extend the recommendation period. Contracts to supplier/manufacturer for an ERP recommended products should not be longer than the validity period of the recommendation of that product. For detail information on ERP process and Quality Assurance information, please look at <http://www.theglobalfund.org/en/procurement/quality/?lang=en>

Procurement of ERP Reviewed Products: Principal Recipients (PRs) must inform the concerned Fund Portfolio Manager (FPM) at the Global Fund in writing by filling the "Notification Form" (available on website) if they intend to procure ERP-reviewed pharmaceutical product(s). The Global Fund Secretariat will review the notification request and upon issuing a " no objection" letter to the PR for the requested selection, procurement can only proceed.

Important Notes

This List may be used by Principal Recipients of Global Fund grants when considering options with respect to procurement of pharmaceutical products subject to the Global Fund Quality Assurance Policy. The list aims at providing countries with information that will assist them in their procurement options. Please note that the list is not designed to be a basis for countries to select products to be included in their National Treatment Guidelines or to replace any applicable and legally required procurement processes. The Global Fund requires its grant recipients to comply with applicable procurement laws and provides the list only for the identification of products/manufacturers that comply with the Global Fund's quality assurance policy. It is important to note that there is no strict requirement to procure according to the list, as long as the Principal Recipients can ensure that the procurement is conducted according to the Quality Assurance policy. Further more, the Principal Recipient should not rely solely on the information provided in the list but should obtain evidence of products compliance with the Quality Assurance policy. For the above reasons, we strongly encourage users to ensure they are using the most recent version on our website when conducting procurement.

The Lists are updated regularly based on evidence received by the Global Fund. Interested parties are invited to supply information and evidence of products meeting the policy criteria on an ongoing basis. For the above reasons, we strongly encourage users to ensure they are using the most recent version on our website when conducting procurement.

According to the Global Fund QA policy, if there are two or more A or B classified manufacturers available for any given product AND the product is available from these manufacturers, then such product must be procured from A or B classified product manufacturers.

The PR must notify by writing to the Global Fund Secretariat (Fund Portfolio Manager) and receive the "No Objection" letter from GF secretariat before procuring any products complying with option " ERP Reviewed".

For ease of reference, each "product" has been identified in this list with a unique "Product reference number" (Column A). Please see examples below.

Product Ref.No	International Non-proprietary name	Strength	Dosage form	Supplier/Manufacturer	Global Fund QA Standard	WHO Pre-qualified/ SRA/	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
16 XYZ		50mg	Tablet	*Pharma Company A*	A - B	Yes	--	*Pharmaville*	Country A	HDPE bottle	60
17		100mg	Tablet	*Pharma Company B*	A - B	Yes	--	*Pharmaville*	Country B	HDPE bottle	60

This example show 2 different variants of the same active ingredient. Because the strength is different it is considered 2 different products. If the strength had been the same but the dosage form had been different (i.e. tablet and liquid) it would also have been considered two different "products". Therefore the table shows two different "Product Reference numbers (16 and 17). As there is only one manufacturer of each "product" the PR has the opportunity to identify and contract with a Ci or Cil supplier.

Product Ref.No	International Non-proprietary name	Strength	Dosage form	Supplier/Manufacturer	Global Fund QA Standard	WHO Pre-qualified/ SRA/	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
25 ABC		150mg	Tablet	*Pharma Company A*	A - B	Yes	--	*Pharmaville*	Country A	Blister, HDPE bottle	10, 60
			Capsules	*Pharma Company B*	A - B	Yes	--	*Pharmaville*	Country B	HDPE Bottle, Blister	60, 10

In this example the product is considered to have two manufacturers because both manufacturers are supplying the same strength even though they do not have the same dosage form. Therefore the product is having the same "Product Reference number" (25).

For the application of this policy several different dosage forms may be grouped under the same Product Reference Number and will therefore be considered the same type of products when identifying the number of available manufacturers.

For example: Within solids the following dosage forms are grouped together: Tablets, Dispersable tablets, Hard capsules, Soft capsules, Chewable Tablets, Scored Tablets etc.
 Within liquids the following dosage forms are grouped together: Oral solution, Powder for solution, Suspension, etc.

Disclaimer:

The Global Fund does not endorse or warrant the fitness of any product on the List for a particular purpose, including in regard of its safety and/or efficacy in the treatment of HIV/AIDS, tuberculosis or malaria. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent confirmation that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund's quality assurance policy. The Global Fund does not warrant or represent that the products listed have obtained regulatory approval for use of treatment of any disease in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of any product included in the list.

“ The Global Fund requirement for 2nd line TB drugs procurement is that the procurement, using Global Fund grants, must be conducted through the Green Light Committee (GLC) of the Stop TB Initiative. Therefore, these products will no longer be listed in the Global Fund list of TB products. For more information on the GLC can be obtained from the WHO representative in the recipient country or from the enclosed website at www.who.int/tb/dots/dotsplus/management/en/index.html.”

List of A or B products for 1st line TB treatment:

If there are two or more ‘A’ or ‘B’ products available, then the product **must** be procured from one of the A or B products.

Ref. No	International Non-proprietary Name	Strength	Dosage form	Supplier/Manufacturer (s)	Global Fund QA Standard	WHO Prequalification/SRA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
1	Cycloserine	250 mg	Capsule	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman Himachal Pradesh	India	Al strip	10
	Cycloserine	250 mg	Capsule	Aspen Pharma	A	Yes	--	Port Elizabeth	South Africa	HDPE bottle	100
2	Ethambutol	100mg	Tablet	Labatec Pharma	B	Yes	--	Meyrin, Geneva	Switzerland	PVC/Alu Blister	10*1
3	Ethambutol	400 mg	Tablet	Cadila Pharmaceuticals Ltd	A	Yes	--	Dholka, Ahmedabad,	India	Blister ; HDPE bottle	10; 1000
	Ethambutol	400 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	Blister HDPE Bottle	10, 28; 1000
	Ethambutol	400 mg	Tablet	Labatec Pharma	B	Yes	--	Meyrin, Geneva	Switzerland	HDPE bottle	100
4	Ethambutol + Isoniazid	400 mg + 150 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	Blister HDPE Bottle	10, 28; 1000
5	Ethambutol + Isoniazid + Rifampicin	275mg+75mg+150mg	Tablets	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	HDPE container	1000
6	Ethambutol + Isoniazid + Pyrazinamide + Rifampicin	275 mg + 75 mg + 400 mg + 150 mg	Tablet	Lupin Ltd	A	Yes	--	Aurangabad	India	Blister; HDPE bottle	4; 100 500
	Ethambutol + Isoniazid + Pyrazinamide + Rifampicin	275 mg + 75 mg + 400 mg + 150 mg	Tablet	Sandoz Pty Ltd	A	Yes	--	Strides Arcolab, Bangalore Sandoz, Kolshet, Thane	India	Blister; PP Bottle	10; 1000
	Ethambutol + Isoniazid + Pyrazinamide + Rifampicin	275 mg + 75 mg + 400 mg + 150 mg	Tablet	Wyeth Pakistan Ltd	A	Yes	--	Karachi	Pakistan	Blister	80
	Ethambutol + Isoniazid + Pyrazinamide + Rifampicin	275 mg + 75 mg + 400 mg + 150 mg	Film coated Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	LDPE bag in sealed Alu sachet further	500, 1000
7	Ethionamide	250 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	Al/PET/LDPE triple lam	100; 10
8	Isoniazid	100 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	LDPE bag further packed in LDPE	1000; 10
9	Isoniazid	300 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	LDPE bag further packed in LDPE	1000; 10
10	Isoniazid + Rifampicin	30mg+ 60mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	HDPE container	1000
	Isoniazid + Rifampicin	60mg + 60mg	Dispersible Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	LDPE/PET/AL; HDPE container	1000

Ref. No	International Non-proprietary Name	Strength	Dosage form	Supplier/Manufacturer (s)	Global Fund QA Standard	WHO Prequalification/SRA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
11	Isoniazid + Rifampicin	75 mg + 150 mg	Tablet	Lupin Ltd	A	Yes	--	Aurangabad	India	Blister ; HDPE bottle	15; 100, 500, 1000
	Isoniazid + Rifampicin	75 mg + 150 mg	Tablet	Sandoz Pty Ltd	A	Yes	--	Strides Arcolab, Bangalore Sandoz Pty Ltd, Kolshet, Thane	India	Blister ; PP bottle	10; 1000
	Isoniazid + Rifampicin	75 mg + 150 mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	PET/Alu/LLDPE triple laminated	500, 1000
12	Isoniazid + Rifampicin	150 mg + 300 mg	Tablet	Sandoz Pty Ltd	A	Yes	--	Novartis, Kempton Park,	South Africa	Blister ; PP bottle	10; 20, 40, 60, 500
	Isoniazid + Rifampicin	150 mg + 300 mg	Tablet	Groupo Lepetit	B	Yes	--	Anagni	Italy	Blister	8, 24
13	Isoniazid + Rifampicin + Pyrazinamide	30mg+ 60mg+ 150mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman	India	HDPE container	1000
14	Pyrazinamide	400mg	Tablet	Cadila Pharmaceuticals Ltd	A	Yes	--	Dholka, Ahmedabad,		Blister ; HDPE bottle	10; 1000
	Pyrazinamide	400mg	Tablet	Macleods Pharmaceutical Ltd	A	Yes	--	Kachigam, Daman		HDPE bottle	1000
	Pyrazinamide	400mg	Tablet	Micro Labs Ltd	A	Yes	--	Hosur, Tamilnadu	India	HDPE container	1000
15	Pyrazinamide	500mg	Tablet	Micro Labs Ltd	A	Yes	--	Hosur, Tamilnadu	India	HDPE container	1000
	Pyrazinamide	500mg	Tablet	Labatec Pharma	B	Yes	--	Meyrin, Geneva	Switzerland	HDPE bottle	100, 1000
16	Rifampicin	150mg	Capsule	Labatec Pharma	B	Yes	--	Meyrin, Geneva	Switzerland	PVC/Alu Blister	10*8
17	Rifampicin	300mg	Capsule	Labatec Pharma	B	Yes	--	Meyrin, Geneva	Switzerland	PVC/Alu Blister	10*4

End of the TB products list

List of ERP (Expert Review Panel) Reviewed Products which are permitted for time limited use:

If there is no or only one A or B product available, grant funds may be used to procure a ERP reviewed product eligible for procurement for limited time (12 months) period. The PR must send the "notification form" (available at <http://www.theglobalfund.org/en/procurement/quality/?lang=en>) to the Global Fund and upon receiving the " No Objection" letter form the Global Fund, the procurement can proceed. Please note that the QC test of the selected ERP product will be performed by the Global Fund.

Ref. No	International Non-proprietary Name	Strength	Dosage form	Supplier/Manufacturer (s)	Global Fund QA Standard	WHO Prequalification/ SRA	Period Validity for ERP Review	Manufacturing site	Country	Material	Pack
1	Ethambutol	400 mg	Tablet	Svizera Labs	ERP Reviewed	--	30.06.2010	Turbhe, Navi Mumbai	India	HDPE;PVDC Blister	1000;24*28
	Ethambutol	400 mg	Tablet	Lupin Ltd	ERP Reviewed	--	30.10.2010	Aurangabad	India	Al/PVC/PVDC; blister; HDPE bottle	10*10 1000
2	Ethambutol + Isoniazid	400 mg + 150 mg	Tablet	Svizera Labs	ERP Reviewed	--	30.06.2010	Turbhe, Navi Mumbai	India	Blister HDPE Bottle	10, 28; 1000
	Ethambutol + Isoniazid	400 mg + 150 mg	Tablet	Cadila Pharmaceuticals Ltd	ERP Reviewed	--	30.06.2010	Dholka, Ahmedabad,	India	PVC/PVdC/ Alu Blister	28*24
3	Ethambutol + Isoniazid + Rifampicin	275mg+75mg+150mg	Tablets	Lupin Ltd	ERP Reviewed	--	30.06.2010	Aurangabad	India	HDPE bottle; PVC/PVC/Alu blister	1000; 24*28
4	Isoniazid	300 mg	Tablet	Svizera Labs	ERP Reviewed	--	30.06.2010	Turbhe, Navi Mumbai	India	HDPE; PVDC/Alu blister	1000; 24*28
5	Isoniazid + Rifampicin	30mg+ 60mg	Tablet	Lupin Ltd	ERP Reviewed	--	30.06.2010	Aurangabad	India	Al/Al strips	6*15
6	Isoniazid + Rifampicin	75 mg + 150 mg	Tablet	Svizera Labs	ERP Reviewed	--	30.06.2010	Turbhe, Navi Mumbai	India	HDPE; PVDC/Alu blister	24*28
7	Isoniazid + Rifampicin	150 mg + 150 mg	Tablet	Lupin Ltd	ERP Reviewed	--	30.06.2010	Aurangabad	India	HDPE bottle; PVDC/Alu blister	1000; 24*28
8	Isoniazid + Rifampicin + Pyrazinamide	30mg+ 60mg+ 150mg	Tablet	Lupin Ltd	ERP Reviewed	--	30.06.2010	Aurangabad	India	Al/Alu Strips	6*15

End of ERP Reviewed products list