



**РЕГИОНАЛЬНЫЙ СЕМИНАР ПО ВОПРОСУ УСКОРЕННОГО ВНЕДРЕНИЯ
РУКОВОДСТВА ВОЗ ПО ПРОФИЛАКТИКЕ И ДИАГНОСТИКЕ ТУБЕРКУЛЕЗА И ЛЕЧЕНИЮ
ТУБЕРКУЛЕЗА С ЛЕКАРСТВЕННОЙ УСТОЙЧИВОСТЬЮ (ЛУ-ТБ)**

**REGIONAL WORKSHOP ON ACCELERATED IMPLEMENTATION OF WHO GUIDELINES
ON TB PREVENTION, DIAGNOSIS, AND DRUG-RESISTANT TB (DR-TB) TREATMENT**

Access to diagnostics and medicines in the WHO EURO region

Day 2 – 29th April 2025

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Poor-quality anti-TB medicines: a neglected risk for global TB control and resistance

- . Substandard & falsified (SF) antibiotics, including TB medicines, increase the risk of adverse patient outcomes, cause economic harms and drive AntiMicrobial Resistance (2022)*
- . SF, especially substandard, anti-TB medicines are present worldwide (2023). However, TB medicine quality data are few and are therefore not generalizable that 15.2% of global anti-TB medicine supply is SF**

WHO survey in EECA countries (2011)***

- 11% of substandard TB medicine samples
- All WHO prequalified products complied with specifications as did all samples supplied by StopTB Global Drug Facility
- ☐ WHO recommendation: all TB medicine manufacturer should consider participating in the WHO Prequalification Programme
- ☐ USP PQM+ program active in 3 EECA countries & indirect support to a 4th one till recently (e.g., strengthening regulatory authorities, QC laboratories, manufacturing capacity)

* <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9394205/pdf/bmigh-2022-008587.pdf>

** <https://pubmed.ncbi.nlm.nih.gov/37433693/>

*** https://extranet.who.int/pqweb/sites/default/files/documents/TBQuality-Survey_Nov2011_1.pdf





How to ensure access to:

- quality-assured
- most affordable
- WHO-recommended TB treatments and prevention medical products to 100% of people in need?

Prices of DR-TB medicines with multiple generic manufacturers^o

Medicine	Current price per patient per month, US\$*	Estimated cost-based generic price (per month), US\$ +	% change in GDF price, 2020 to 2022	% change in GDF price, 2015 to 2022
linezolid (600mg)	5	5-13	-180%	-3,050%
levofloxacin (500mg)	3	7-17	+17%	-23%
moxifloxacin (400mg)	9	4-8	-13%	-181%
cycloserine (250mg)	22.50	23-36	+4%	+25%
clofazimine (100mg)	15	4-11	0%	-119%

* Lowest GDF price (multi-generic source drug)¹²

+ Target price ranges are based on the estimated costs of active and inactive pharmaceutical ingredients, formulation, packaging, and a cost-plus model, which includes a reasonable profit margin. Prices could reach these levels with adequate market competition and transparency.¹³

GDF: Global Drug Facility

^o <https://msfaccess.org/dr-tb-drugs-under-microscope-8th-edition>

Despite significant price decrease in the past 10 years for off-patent DR-TB medicines, unjustified high price for linezolid can be found in some WHO EURO countries (up to 60 times GDF price)

Prices of newer DR-TB medicines

Medicine	Purchasing mechanisms	Manufacturer	Prices, October 2024 (6-month course)	Cost-based target generic prices (6-month course)*
Bedaquiline 100mg tablet	GDF	Johnson & Johnson	\$130	\$48-102
	GDF	Lupin	\$90	
	GDF	Macleods	\$90	
	Government tender, Russian Federation	Pharmstandard	\$1650	
Pretomanid 200mg tablet	GDF	Viatis/Mytan	\$224	\$66-210
	GDF	Macleods	\$238	
	GDF	Lupin	\$169	
Delamanid 50mg tablet	GDF	Otsuka	\$1190	\$30-96
	GDF	Viatis / Mytan	\$800	
	Government tender, Russian Federation	R-Pharm	\$1488	

* <https://msfaccess.org/dr-tb-drugs-under-microscope-8th-edition>

** Lowest GDF price

*** Target price ranges are based on the estimated costs of active and inactive pharmaceutical ingredients, formulation, packaging, and a cost-plus model, which includes a reasonable profit margin. Prices could reach these levels with adequate market competition and transparency. <https://pubmed.ncbi.nlm.nih.gov/28073970/>

Despite significant price decrease for Pa (except in EU) and Bdq (except in RF, EU), still high price for Dlm but generic competition expected by Q1 2026

INN of the drug	Kyrgyz Republic	Republic of Moldova	Republic of Tajikistan	Ukraine
Amikacinum	green	green	red	green
Amoxicillinum + Acidum clavulanicum	green	green	red	green
Bedaquilinum	red	red	yellow	green
Clofaziminum	red	green	yellow	50 mg
Cycloserinum	green	green	red	green
Delamanidum	red	red	red	25 mg
Ethambutolum	green	green	green	green
Imipenemum+Cilastatinum	green	green	red	red
Isoniazidum	green	red	red	green
Levofloxacinum	green	green	yellow	green
Linezolidum	green	green	green	150 mg
Moxifloxacinum	green	green	yellow	green
Natrii para-aminosalicylas	green	green	red	red
Pretomanidum	green	green	green	green
Prothionamidum	green	red	red	red
Pyrazinamidum	green	green	yellow	green
Rifampicinum	green	red	green	green
Rifampicinum + Isoniazidum	green	green	green	green
Rifampicinum + Isoniazidum + Pyrazinamidum + Ethambutolum	green	green	green	green
Rifapentinum	red	red	green	red
Rifapentinum+Isoniazidum	red	red	green	red
Rifampicinum + Isoniazidum + Pyrazinamidum	red	red	green	green
Rifampicinum + Isoniazidum + Ethambutolum	red	red	green	red

green - registered, yellow - pending registration, red - no registration

List of registered medicines by country in 2022-2023

. Important progresses made in recent years for local registration of TB medicines

. WHO Collaborative Registration Procedure and alternative mechanisms enhanced WHO prequalified TB medicine registrations

. Still progress to be made, especially for rifapentine-based formulations for adults and children for TPT, also pediatric formulations for DS/DR-TB

SURVEY OF PAEDIATRIC TB POLICIES IN 14 COUNTRIES

Child-friendly DS-TB fixed-dose combinations

rifampicin/isoniazid 75mg/50mg dispersible tablet from Macleods (India), Lupin (India)
rifampicin/isoniazid/pyrazinamide 75mg/50mg/150mg dispersible tablet from Macleods, Lupin

Child-friendly single formulations for DS-TB, DR-TB and TPT

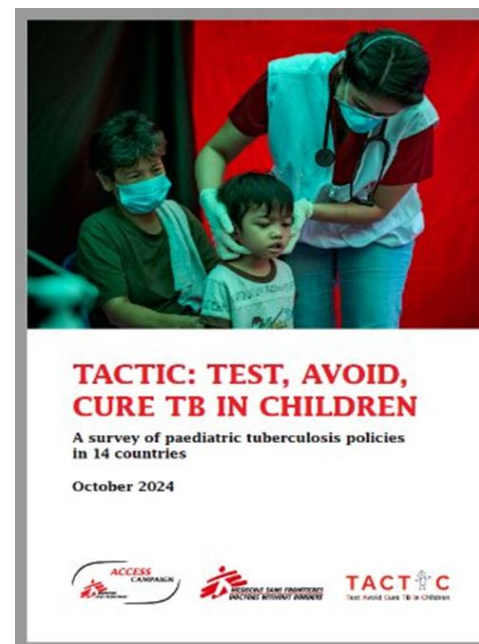
bedaquiline 20mg dispersible tablet from Johnson & Johnson (USA)
cycloserine 125mg capsule from Macleods
delamanid 25mg dispersible tablet from Otsuka (Japan)
ethambutol 50mg dispersible tablet from Micro Labs (India)
ethambutol 100mg dispersible tablet from Macleods, Micro Labs
ethionamide 125mg dispersible tablet from Macleods, Micro Labs
isoniazid 50mg dispersible tablet from Micro Labs
isoniazid 100mg dispersible tablet from Macleods, Micro Labs
levofloxacin 100mg dispersible tablet from Macleods, Micro Labs
linezolid 150mg dispersible tablet from Macleods, Micro Labs
pyrazinamide 150mg dispersible tablet from Macleods, Micro Labs
rifapentine, 150 mg, dispersible tablet from Lupin

Paediatric TB formulations that are not child-friendly

clofazimine 50mg soft capsule from Novartis (Switzerland)
clofazimine 50mg tablet from Macleods
moxifloxacin 100mg dispersible tablet from Macleods, Micro Labs

Note that there are some variations across suppliers, with some medicines being available in both child-friendly and paediatric-only formulations depending on the supplier.

TACT C
Test Avoid Cure TB in Children



<https://msfaccess.org/tactic-test-avoid-cure-tb-children>

SURVEY OF PAEDIATRIC TB POLICIES IN 14 COUNTRIES

Mapping policy and implementation gaps in countries to advocate for funding and resources

- **Policy survey in 15 countries**

Afghanistan, CAR, DRC, India, Mozambique, Niger, Nigeria, Pakistan, Philippines, Sierra Leone, Somalia, South Sudan, Uganda + Poland

- 8 policy questions and 11 implementation questions

- Chapters:

- Diagnosis of TB
- Prevention of TB
- Treatment of DS-TB and DR-TB
- Country factsheets

Dashboard

Survey indicator	Afghanistan	Central African Republic <i>*Guidelines are being updated</i>	Democratic Republic of the Congo	Guinea <i>*Guidelines are being updated</i>	India	Mozambique	Niger	Nigeria	Pakistan <i>*Guidelines are being updated</i>	The Philippines	Sierra Leone	Somalia	South Sudan	Uganda <i>*Guidelines are being updated</i>
DIAGNOSIS														
DS-TB treatment for children can be initiated without bacteriological confirmation or chest X-ray (ie, based on clinical evaluation only)														
WHO treatment decision algorithms are included in national policy documents														
Xpert MTB/RIF Ultra test on stool specimens is included in national guidelines						no data								
Operational research is undertaken to evaluate the use of Xpert MTB/RIF Ultra test on stool specimens						no data								
PREVENTION														
National guidelines recommend 3HR or 3HP as a short TPT regimen option for children below age 5 who are household contacts														
National policies recommend 3HR or 3HP as a short TPT regimen option for children and adolescents living with HIV														
TPT can be provided to PLHIV and children below age 5 without a test (TST and/or IGRA)														
TREATMENT OF DS-TB														
A 4-month treatment regimen for children and adolescents with non-severe DS-TB is included in national policies														
Paediatric formulations of HR, HRZ and ethambutol are procured														
National policies recommend the use of bedaquiline for children with DS-TB of all ages														
TREATMENT OF DR-TB														
National policies recommend the use of delamanid for children with DR-TB of all ages														
Injectables are not recommended for children with MDR/RR-TB														
Paediatric formulations of bedaquiline and delamanid are procured														
Paediatric formulations of other second-line TB drugs are procured														

Country Factsheets



	AFG	CAR	DRC	GNA	IND	MOZ	NIR	NRA	PAK	PHIL	SL	SOM	SS	UGA
DS-TB treatment can be initiated on clinical evaluation only														
WHO Treatment Decision Algorithm in the policy														
Xpert on stool is in the policy						no data								

KEY FINDINGS

- **9 out of 14 countries'** policies indicate that DS-TB treatment for children can be initiated without bacteriological confirmation or chest X-Ray.
- **5 out of 14 countries'** policies include treatment decision algorithms recommended by 2022 WHO guidelines, and **4 out of 5 of these countries** have materials available at the NTP to support the implementation of these.
- **10 out of 13 countries'** policies recommend the use of the Xpert MTB/RIF Ultra assay on stool specimens as a diagnostic tool for pulmonary TB and rifampicin resistance in children, and **8 out of 10 of these countries** have materials available at the NTP to support the implementation of this.ⁱ
- **1 out of 3 countries** that do not yet include stool-based testing for TB in children in national guidelines are conducting operational research on this.

THANK YOU!
СПАСИБО!

