

TECHNICAL BRIEFING NOTE

Technical step process to switch to new paediatric tuberculosis formulations

INADEQUATE PEDIATRIC TREATMENT

➔

NOW AVAILABLE



INCORRECT DOSES



BROKEN PILLS



CRUSHED PILLS



BAD TASTE



CORRECT DOSES, DISSOLVABLE IN WATER, TASTES GOOD



INADEQUATE PEDIATRIC TREATMENT



NOW RECOMMENDED

Weight bands	Numbers of tablets		
	Intensive Phase		Continuation Phase
	RHZ	E	RH
	60/30/150	100	60/30
4-6kg	1	1	1
7-10kg	2	2	2
11-14kg	3	2	3
15-19 kg	4	3	4
20-24kg	5	4	5
25 kg+	Go to adult dosages and preparations		

Weight bands	Numbers of tablets		
	Intensive Phase		Continuation Phase
	RHZ	E	RH
	75/50/150	100	75/50
4-7kg	1	1	1
8-11kg	2	2	2
12-15kg	3	3	3
16-24 kg	4	4	4
25 kg+	Go to adult dosages and preparations		

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Introduction

Tuberculosis (TB) is a major cause of illness and death among children. Each year, at least 1 million children get TB and another 140,000 die—that’s nearly 400 children that needlessly die each and every day from the disease.

For too long, there were no appropriately dosed TB medicines for children. The World Health Organization (WHO) revised their guidelines for childhood drug-sensitive TB treatment in 2010, recognizing that children are not just little adults—they need higher doses of the medicines relative to their body weight than an adult would need. Companies, however, did not produce any products conforming to the new guidelines, lacking incentives and reliable market information.

Since then, health providers and care givers around the world have had to improvise treatments for children with TB. To achieve a correct dose, they have to split or crush a number of bitter-tasting pills that children must then swallow or if pediatric FDCs exists to estimate correct doses by using combinations of it. This makes the six-month treatment for TB even more difficult and results in a guessing game of whether children receive the correct dose of medicines. Ultimately, this can make TB treatment ineffective and increase rates of drug resistant TB in children.

Over the past three years, TB Alliance and WHO have worked to bring quality-assured, affordable, child-friendly TB medicines in the correct internationally-recommended dosages to market.

Now, simple, child-friendly medicines for drug-sensitive TB are available. The tablets are fixed dose combinations (FDCs) that contain the proper doses for children of multiple drugs. These include rifampicin 75 mg + isoniazid 50 mg + pyrazinamide 150 mg, which is used for the first two months of treatment, followed by rifampicin 75 mg + isoniazid 50 mg for a remaining at least four months. They are available in a fruit flavour that is palatable for children. These medicines are not new treatments, but are improved dosage forms that are simpler for providers and parents to administer, and easy for children to take. They are made to dissolve in water in just a few seconds, allowing for easier consumption for children.

BOX 1 : MORE INFORMATION

Products	<ul style="list-style-type: none"> • Rifampicin 75 mg + Isoniazid 50 mg + Pyrazinamide 150 mg (2-month intensive phase) • Rifampicin 75 mg + Isoniazid 50 mg (4-month continuation phase)
Formulation	<ul style="list-style-type: none"> • Tablets come in palatable fruit flavors • Tablets are dispersible in 10 seconds. To be mixed in 50 ml water. • Once reconstituted, dispersion should be drunk within 10 minutes.
Training Needs	<ul style="list-style-type: none"> • Designed to be easy to use and to allow administration of WHO-recommended dose without crushing or chopping tablets. • Minimal training required for providers, including parents, to administer.
Administration	<ul style="list-style-type: none"> • Transition to new products can occur at any time during the treatment course. • FDCs to be dissolve in 50ml of water and child should consume the complete fluid within 10 min of dissolving. To be taken on an empty stomach
Safety Profile	<ul style="list-style-type: none"> • Products are not new drugs, but are new formulations of existing first-line drugs and have a comparable safety profile to FDCs currently on the market.
Packaging	<ul style="list-style-type: none"> • Similar to current FDCs but different color coding on package and foil for both FDCs • Aluminum foil blister pack; 28 per sheet (7x4), 3 sheets per pack → 84 total per box
Shelf Life/Storage	<ul style="list-style-type: none"> • Shelf life of 2 years • Cold chain not required
Additional products in pipeline	<ul style="list-style-type: none"> • Ethambutol 100 mg, dispersible • Isoniazid, 100 mg, dispersible • Pyrazinamide, 150 mg, dispersible

For detailed technical information refer to the WHO fact sheet describing the new FDC (http://www.who.int/tb/FDC_Factsheet.pdf?ua=1), for product information on MacLeod Product fact sheet (or visit tballiance.org/children, <http://www.who.int/tb/areas-of-work/children/en/>).

TB Alliance is working with WHO, Stop TB Partnership/GDF, UNICEF, Management Sciences for Health and other organizations to encourage uptake in countries with high TB burdens and to reach children affected by TB at all levels or sectors of healthcare. Initial roll-out of the new medicines is expected in early 2016.

Scope and purpose

The purpose of this document is to support TB program managers, treatment centres and facilities, procurement and supply chain specialists as well as technical assistance providers to plan and implement a transition to new paediatric dose forms.

Having a plan in place to transition to new medicines reduces and removes certain risks. When new products are introduced, it is important, for example, to manage a phasing-out of old medicines. Quantification, especially timing of procurement and delivery of new medicines, is also important to ensure that there are no shortages in the transition. National level quantification plans need to be aligned with implementation plans at the levels of treatment centres. New medicines must arrive in time to make it possible for new patients to be enrolled using the new medicines, but with enough notice where there are sufficient quantities of the previous medicines for current patients to finish their treatment courses. Medicines that arrive without training or formal notification can create questions and confusion at the health facility level, so a training component that is well timed with the arrival of new medicines is important.

These steps are useful to decision makers and managers across different technical areas in developing, facilitating and implementing a strategy for a smooth transition to the new paediatric dosage forms. Each of the steps described in the document will require adaptation to the context of national TB programs. If countries are using current treatment guidelines, the medicines do not represent a change in strength; however, for countries that have not adopted the new treatment guidelines, the FDC contains higher amounts of active pharmaceutical ingredients than previous products. Also, some countries may not have previously used dispersible tablets for treating paediatric TB. Some national TB programmes will find that they have sufficient technical capacity to develop and implement such a plan easily, while others may find value in requesting technical assistance. Technical assistance can be requested from WHO, the Global Drug Facility, Management Sciences for Health, or other development partners active in preventing and treating paediatric TB.

Political advocacy

Political will and high level consensus to support the process of transition is crucial in ensuring that decision makers and managers have sufficient technical support and approvals.

The technical steps to switch to the new TB paediatric formulation involve different national entities such as the national regulatory authority, the national TB program and TB health care centres and the central medical stores. In certain countries, finance ministries or others may need to be involved as well. The first step would be to identify the appropriate group of

stakeholders and facilitate consensus around the actions needed to support a transition to the new medicines.

This could be a single meeting or a series of discussions. The checklist and other documentation that would be useful in informing stakeholders are included in the annexes to this document. A coordination meeting at the beginning of the process is recommended to clearly define the roles and responsibilities of each entity. It is also important to review the timing of the activities, as they are generally inter-related.

Technical steps process

A: National Policy and regulation

1.1 Updating national TB guideline

- Countries should update their National TB guidelines to align with WHO 2014 TB treatment guideline recommendations (***Guidance for national tuberculosis programmes on the management of tuberculosis in children – 2nd ed. WHO 2014***).
- Countries could also take the opportunity to align and adapt their TB Strategic Plan accordingly.

BOX 2 : MORE INFORMATION

WHO Recommendations

Guidance for national tuberculosis programmes on the management of tuberculosis in children – 2nd ed. WHO 2014
(http://www.who.int/tb/publications/childtb_guidelines/en/)

Recommendation 8 (updated from the 2010 Rapid Advice with new range dosing for Isoniazid)

The following dosages of anti-TB medicines should be used daily for the treatment of TB in children:

- isoniazid (H) 10 mg/kg (range 7–15 mg/kg); maximum dose 300 mg/day
- rifampicin (R) 15 mg/kg (range 10–20 mg/kg); maximum dose 600 mg/day
- pyrazinamide (Z) 35 mg/kg (range 30–40 mg/kg)
- ethambutol (E) 20 mg/kg (range 15–25 mg/kg)

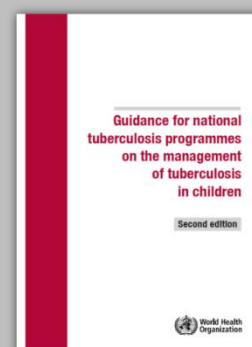
First line treatment of drug-sensitive TB consists of a **two-month** intensive phase with isoniazid, rifampicin, pyrazinamide (and, depending on national guidelines, Ethambutol), followed by a continuation phase with isoniazid and rifampicin for at **least four months**.

For the intensive phase of treatment:

rifampicin 75 mg + isoniazid 50 mg + pyrazinamide 150 mg

For the continuation phase of treatment:

rifampicin 75 mg + isoniazid 50 mg



1.2 Inclusion in nEML and/or National Formulary

- Countries need to integrate the new dosage formulation into the National Essential Medicines list and/or National Formulary. In some countries, procurement and import authorization is restricted to the medicines that are on these lists.
- The new FDC pediatric formulations are referenced as a recommendation in the WHO Model List 2015 (<http://www.who.int/medicines/publications/essentialmedicines/en/>) and the recent commercial availability of the two FDC will support inclusion of additional reference information on the WHO EML. However WHO EML can serve as a reference and the countries should not wait to update their own nEML .

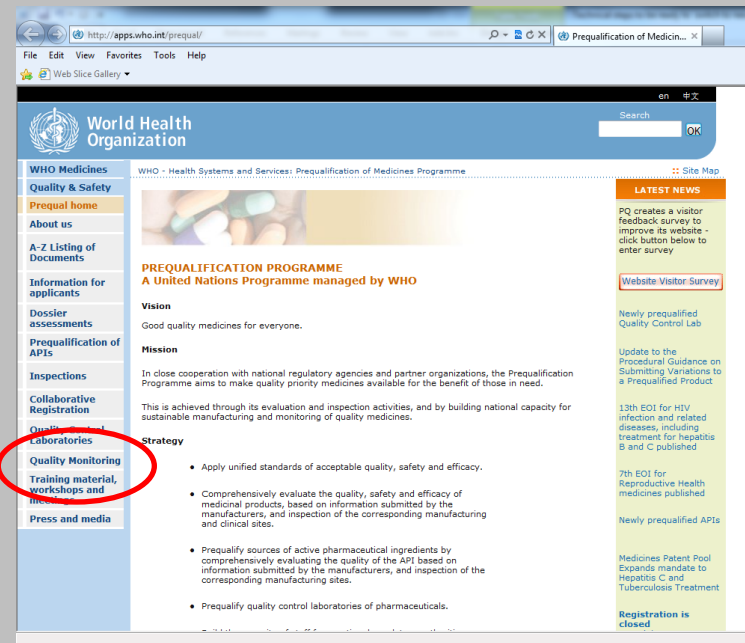
1.3 Registration through national medicines regulatory authority (NMRA):

- The paediatric FDCs have been approved for procurement through GDF after review and approval by the WHO Expert Review Panel (ERP). The WHO prequalification process is underway and full approval is expected in 2016. The WHO PQ website contains the WHO List of Prequalified Medicinal Products and the status of product dossiers under assessment by the WHO Prequalification Programme is available for public information.
- From a country perspective: the dossier registration for the new formulations should be initiated in advance to ensure the medicines can be properly and legally imported to the country. WHO encourages national market authorization or registration as well as post-marketing surveillance and pharmacovigilance process.
- In countries where registration is delayed, the use of regulatory waivers or short term authorizations could be temporarily facilitated to support initial procurement and availability of the child-friendly FDCs.
- As an option to facilitate the registration process, countries are invited to register to the WHO Collaborative Registration procedure. More information on Collaborative Registration can be found on <http://apps.who.int/prequal/>. This is especially recommended for countries that would like to avoid regulatory waivers for TB products in the past. Under the collaborative procedure, WHO will share prequalification assessment information on a specific product confidentially with NMRAs, based on an agreement they have with manufacturers. The NMRA will then issue their registration decision within 90 days of receiving access to the shared information, which could accelerate the registration.

BOX 3 : MORE INFORMATION

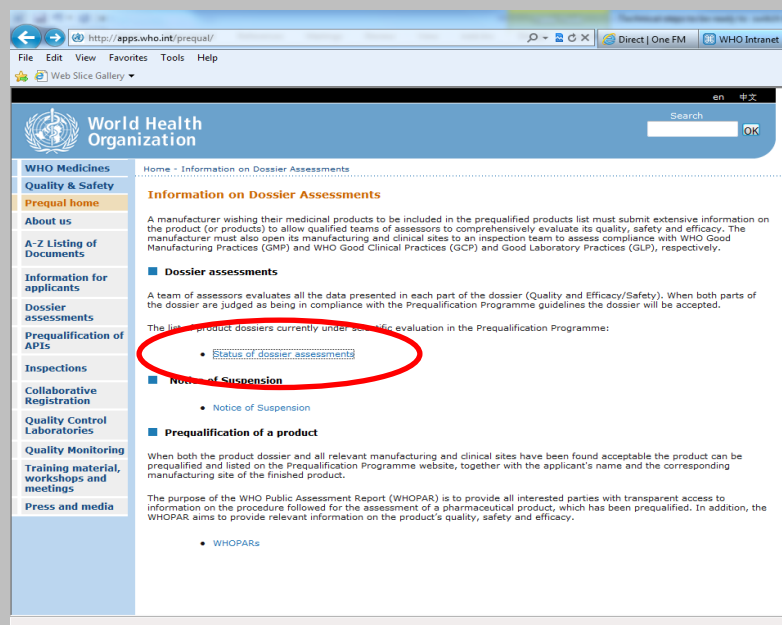
WHO collaborative registration

Lists of countries who have signed the collaborative registration are available on the website (<http://apps.who.int/prequal/>). To access to more information on countries, click on 'collaborative registration'.



WHO Prequalification website (<http://apps.who.int/prequal/>)

On the website, the WHO List of Prequalified Medicinal Products and the status of product dossiers under assessment in the WHO Prequalification Programme can also be consulted to track the prequalification process.



B: Forecasting, quantification and procurement

2.1 Forecasting and quantification

- Forecasting/quantification should be aligned with your procurement plan to make sure that there is minimum wastage and a smooth transition from use of old paediatric formulations to the new FDC.
- Decisions should be made based on most recent inventory data. It is highly recommended to perform a physical count of current stock at the beginning of the quantification process.
- The quantification should be done by using the most reliable, accurate and recent data and should include:
 - o Amounts for one year, including agreed buffer stocks according to national recommendations or the donor agreement (e.g. the Global Fund, the Global Drug Facility, or other bilateral donors)
 - o Information based on validated quantification methods such as morbidity, consumption analysis (using previous formulations as a proxy) or service-based methods. Any method should be adjusted to accommodate targets or other known activities that would impact the quantification.
 - o A starting average of 3 tablets per day per child for the initial quantification. If detailed information on the weight bands of children currently on treatment or other trends on weight bands are available, the average of 3 tablets could be replaced with the correct dose per weight band.
 - o An analysis of stock on hand **and** stock already in the procurement pipeline (e.g., stand by and in transit orders) – be aware of expiry date of current stock.
 - o Normal lead times for procurement, e.g., no changes in production lead time are expected from supplier to deliver the new FDC compared to the old formulation.
- Use a quantification tool that is familiar to the country systems, including the GDF drug calculation sheet (<http://www.stoptb.org/gdf/drugsupply/psmtools.asp>), QuantTB (V3) (<http://siapsprogram.org/tools-and-guidance/quanttb/>) or others. Note that Quant TB allows monitoring and early warning systems.

NB : For the Global Fund eligible countries, the “List of Health Products” and quantification should be updated when changing formulations and align with national and WHO therapeutic guidelines. **Update your list of health products – and quantification (LOHP)** (http://www.theglobalfund.org/documents/fundingmodel/FundingModel_HealthProductsQuantitiesAndRelatedCosts_Template_all/)

BOX 4 : MORE INFORMATION

Checklist of data needed for the quantification:

1. List of the first paediatric line TB medicines used in the country, including information of drug presentation (as listed above) + daily dose + weekly frequency + duration in months.
2. List the number of paediatric cases enrolled (started on treatment) above per month (i.e., total of cases that initiated treatment regimen in each month) in the last two years.
3. Rate or number of cases that stopped or discontinued treatment for any reason combined (i.e., “attrition rate”), such as loss to follow-up, defaulted, died, change to another regimen, etc. in the last 2 years. In QuantTB this information has to be registered by medicine.
4. Number of cases expected (future) to start on the treatment regimen described above. This information could be already available in NTP strategic plans, in documents required by the Global Fund or donors. However, it is important to review existing numbers in light of historical information about previous enrolment and trends for the future.

Children

Weight bands	Number of tablets		
	Intensive phase		Continuation phase
	RHE 75/50/150	E 100	RH 75/50
4-7 kg	1	1	1
8-11 kg	2	2	2
12-15 kg	3	3	3
16-24 kg	4	4	4
25kg +	Go to adult formulation		

Note that children above 25kg are taking adult formulation therefore are to be count with adults for the quantification.

Adults

Weight bands	Number of tablets	
	Intensive phase	Continuation phase
	RHZE150/75/400/275	RH150/75
26 - 29kg	2	2
30 - 39kg	2	2
40 - 54kg	3	3
55 - 70kg	4	4
70 kg +	5	5

5. Stocks of medicines at the central level or across the country. Also the date when the stock information has been collected (i.e., inventory date).
6. Calculate the consumption and month of stock available per product type.
7. Number of medicines in number of units (not package) already ordered (or procured), but not yet received (i.e., "Stock on order") and the expected date of receiving (expiry date is not mandatory, but important if available).
8. Lead time country tailored. How to determine the lead time for your country?
 - ☐ Take into account the in country process (meeting, validation, signature)
 - ☐ Take into account the validation process national or international (donors).
 - ☐ Take into account the response time when submitting your proposal to GDF/ donors/ and the approval time for the money transfer.
 - ☐ Take into account the GDF / manufacturer lead time
 - ☐ Take into account a green light procedure if your country is applying it (import permit for the manufacturer before shipping products)
 - ☐ Take into account the shipping time (transport air / sea freight or both sometime for landlocked countries)
 - ☐ Take into account the custom clearance process in your country
 - ☐ Take into account the transport from the port of entry to the storage site(s)
- 9) Buffer stock, minimum and maximum months of stock (at least at the central level).

For additional information on quantification basic data refers to QuantTB manual (<http://siapsprogram.org/wp-content/uploads/2015/12/QuantTB-Users-Guide-18-November-2015-format.pdf>) .

BOX 5: MORE INFORMATION

In order to do a proper quantification countries need to have reliable data. This requires standardized recording of individual patient data, including information on treatment outcomes, which are then used to compile quarterly treatment outcomes in cohorts of patients.

Basic data that needs to be captured for children to ensure adequate and reliable quantification for paediatric TB medicines are listed below (this list is not exhaustive).

- All different case types must be reported separately: pulmonary cases are distinguished from extrapulmonary cases – (e.g. sometimes the MIS reports only some case types – smear positive).

- Laboratory-confirmed cases must be distinguished from clinically diagnosed cases.
- New cases must be distinguished from previously treated cases.
- Data must be routinely collected for at least each of the following variables for all TB cases:
 - o Age or age group
 - o Weight
 - o Sex
 - o Year of registration
 - o Bacteriological results
 - o History of previous treatment
 - o Anatomical site of disease
 - o For case-based systems, a patient identifier

For additional information on TB data consult WHO monitoring and evaluation website (http://www.who.int/tb/dots/monitoring_evaluation/en/).

2.3 Transition plan

- A strong transition plan assumes that stocks of previous formulations have been managed in a manner that ensures both sufficient availability as well as minimal wastage.
- The first step to plan the transition is to determine the number of months of stock available in the total pipeline for the country, which is used to calculate how long the current stocks will last considering intensive and continuation phases of treatment and retain the shortest expiry date between the two products.
Note that you could choose to switch the intensive or continuation phase independently but it will be more complex.
- According to the number of months of stock on hand, a country would determine when to start and conclude the transition. The transition would occur before the current stocks would be consumed by current patients along with a limited number of new patients.
- Working in reverse from when facilities need the new medicines, the orders and arrival of the new products should be timed to accommodate normal distribution practices in the country e.g. if normal distribution takes 3 months, the product should arrive in country with 3 months prior to actual need.
- The time schedule for the transition should be long enough to allow adequate rolling out but not too long to prevent stock out in the regions/districts and non-moving stock at the central level (stock which is awaiting delivery).
- In many countries, the plan will also need to prioritize by geographic location of centers:
 - o Because it is difficult to shift dispensing at all sites at once, a phased approach that prioritizes particular locations might be helpful. The plan will need to identify which regions county/region/dispensing point should go first.
 - o The remaining stock of the old formulation at regional level should guide priorities for the roll out
 - o The storage capacity at central and regional level is an important factor for considering your procurement plans
 - o Once the transition starts, it will be important that the plan include precautions for managing two types of paediatric formulations in circulation at the same time in the country, as that could cause confusion for health care providers and patients.
 - o The seasonal factors are to be considered, for e.g. some countries have regions stockpiling for the rainy or winter season when transportation is difficult.

- The distribution cycle from central to peripheral is important – if based on a quarterly versus monthly distribution cycle it will take longer to shift all the dispensing sites. In such a case stock will remain at central level for longer, which shall alert you of the of the product shelf life.
- Careful monitoring of the stock on hand and consumption rates is important before and during transition. The scale-up of training or new childhood TB interventions could alter consumption rates in country.



NB : For the Global Fund countries no specific format/template is required for the transition plan but the transition plan should be submitted to the Global Fund with the updated list of health products.

2.4 Supply planning

- The supply plans should accommodate the transition plan in terms of time schedule/timelines.
- The new FDCs are available through the Global Drug Facility at the already agreed and negotiated price http://www.stoptb.org/gdf/drugsupply/drugs_available.asp. If a country is procuring through GDF, the procurement of the new FDC is done using the same GDF Direct Procurement Request Form, available in English and Spanish on the GDF website.
(http://www.stoptb.org/gdf/drugsupply/procurement_forms.asp. All countries with TB burden are encouraged to consolidate their orders through the GDF; however, as needed, the new FDCs can also be procured directly from the manufacturer (Macleods). Prices and other terms and conditions may be different.
- It is critical to allow for the procurement plan to be continuously adjusted and updated, especially during a transition. When procuring through GDF, an online tracking system (GDF Order Management System) allows country to track orders and delivery schedules. Countries could also develop their own excel spread sheet to follow their procurement processes.
- The GDF standard lead time is 4-6 months upon the receipt of payment and including production lead time.



NB : For the Global Fund countries no specific format/template is required for the transition plan but the transition plan should be submitted to the Global Fund with the updated list of health products.

2.2 Pricing

- Current Prices for the new FDCs (as of February 2016) are:
 - RH 75/50: US\$ 2.41 (Box of 84 tablets)
 - RHZ 75/50/150: US\$ 2.95 (Box of 84 tablets)

For additional information on price and product refer to the GDF online product list at: (http://www.stoptb.org/gdf/drugsupply/drugs_available.asp)

- Other manufacturers may enter the TB paediatric market in 2016, which is may affect long term price options; however, current prices are expected to remain stable through 2016.



NB: Global Fund countries should contact their Fund Portfolio Manager to discuss any implications that the transition might have on budgets or targets. If reprogramming is

needed, countries should work with their Global Fund country team to ensure that funds are available to support the transition process.

C: Quality monitoring activities for pharmaceuticals

3.1 Quality risk management in the supply chain:

- Manufacturer storage recommendations: *Do not store above 25°C , store in dry place and protected from light.*
- In many countries the storage requirements of under 25°C and the dry place recommendations would require close monitoring of the products' storage conditions (temperature and humidity) along the supply chain (at central and peripheral level) like for any other medicines according to Good Distribution and Storage Practices (WHO ref for GDP http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf and GSP http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf or national guidelines).
- Additional information on product sensitivity could be made available through the registration dossier or the manufacturer

3.2 Post marketing/pharmacovigilance:

- WHO advocates for the Active TB drug-safety monitoring and management, and pharmacovigilance remains very relevant today for the TB practitioner. The scaling up of treatment such as the introduction of new drugs/formulations among populations with varied demographic profile, nutritional status and background comorbidity (e.g., HIV-TB) may influence the form and frequency of adverse drug reactions (see: <http://www.who.int/tb/areas-of-work/drug-resistant-tb/treatment/pharmacovigilance/en/>).
- It is recommended that countries train health workers to report the adverse drug reactions using their own reporting form to National Pharmacovigilance Center or National Drug regulatory Authority. Monitoring adverse drug reactions is very important as it is a new dosage form. If countries are using current treatment guidelines, the medicines do not represent a change in strength; however, for countries that have not adopted the new treatment guidelines, the FDC contains higher amounts of active pharmaceutical ingredients than previous products. Also, some countries may not have previously used dispersible tablets for treating paediatric TB.
- The pharmacovigilance (PV) Toolkit website contains useful resources and information. (<http://pvtoolkit.org/>). On the PV toolkit website you will find how to join the WHO Programme for International Drug Monitoring. The drug alert system could be access on the WHO website (<http://www.who.int/medicines/about/en/>)

3.3 Quality Assurance system:

- WHO and partners have developed the MQAS guidelines for procurement and management of medical products. It includes guidance on the use of pre-/post shipment inspection, sampling, quality control, receipt of stock procedures as well as good storage practices. (WHO TRS-968- Annex 3: http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/ISBN9789241209861-TRS986.pdf)



NB : For countries operating under Global Fund guidance, in-country quality monitoring procedures for pharmaceutical products per requirements for the Global Fund principal recipients can be found on:

<http://www.theglobalfund.org/en/healthproducts/qualityassurance/pharmaceutical/>

D: Plan training and information

4.1 Cascade training

Past experience suggests that training should be implemented as part of a transition to a new product, even if the training is minimal. This reduces confusion and potential unintended misuse of the product.

- Once the new guidelines are updated and adopted, countries should organize training for the different clinical staff prescribing and/or dispensing TB paediatric formulations.
- New algorithms for planning and practical aids should be designed and put in place to support trainings.
- Central and peripheral medical stores personnel should also be included in trainings.
- To align training with timelines that make sense in terms of procurement cycles/programmatic needs and take opportunities such as the World TB Day to highlight complementary information on new paediatric TB formulations to medical staff and the general population.
- A tool kit that countries may find useful for adaptation, including a video can be found on http://www.who.int/tb/challenges/childtbtraining_manual/en/ . TB Alliance also developed a toolkit for educating children. (<http://www.tballiance.org/downloads/community/Childhood-TB-Toolkit.pdf>,)

4.2 Technical assistance

- Depending on the outcome of the self-assessment (annex 1) and the availability of in-country resources (human and financial), additional technical assistance may be requested from partners;
- It is recommended that the initial request for technical assistance to be made to agencies that are currently supporting the national TB program. The focal point to organize the technical assistance, if requested, will be the PR (SR) and/or the WHO TB focal person already assisting/supporting the national TB program.
- Coordinating the technical assistance is important to avoid over burdening the national program.
- GDF will continue its monitoring missions to the eligible countries and could also provide targeted technical assistance to support the uptake of new paediatric formulations.

E. List of Technical assistance focal points per organisation:

WHO/ HQ

Procurement supply chain

- Lisa HEDMAN, Technical officer, hedmanl@who.int
- Sophie LAROCHE, Technical officer, laroches@who.int

TB Technical support and coordination

- Annemieke BRANDS, Technical officer, brandsa@who.int
- Malgorzata GRZEMSKA, Technical Support Coordination, grzemska@who.int

Prequalification/ Collaborative registration

- Deusdedit MUBANGIZI, technical officer, mubangizid@who.int

MSH

- Maura Soucy Brown, Technical advisor, msoucy@msh.org
- Patricia Jodrey Paredes, Senior advisor, pparedes@msh.org
- Reem Ghoneim , Technical advisor , rghoneim@msh.org

Stop TB partnership / GDF

- Babale Magali, Country and Technical Support Team Leader and Acting Procurement Team Leader, magalib@stoptb.org
- Hye Lynn Choi, Technical Officer, hyelynn@stoptb.org
- Nigorsulton Muzafarova, product Quality Officer, nigorsultonm@stoptb.org

The Global Fund

- Angelica Perez, Senior Health Product Management Specialist, Angelica.Perez@theglobalfund.org

Global Alliance for TB Drug Development

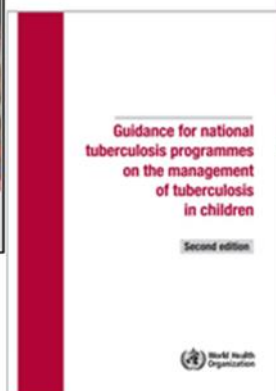
- Shelly Malhotra, Director, Market Access, shelly.malhotra@tballiance.org
- Cherise Scott, Director, Pediatric Programs, cherise.scott@tballiance.org

F: Resources for the new introduction

Tools and guidelines



Tools and guidelines



SUPPLEMENT
Improving access to better tuberculosis treatment for children



Additional resources:

<http://www.who.int/tb/en/>
http://www.who.int/tb/challenges/childtbtraining_manual/en/
<http://www.tballiance.org/child-survival/child-tb-resources>

Annex 1: self-assessment check list for the National TB programme

Should you identify any gaps or require technical assistance in any of the below mentioned areas, please contact the relevant technical agency focal person's as specified in the document for more information.

General coordination

- ☐ Official willing of all parties involved to shift medicines
- ☐ Set up monitoring committee
- ☐ Schedule support and technical assistance if needed
- ☐ Organize partners meeting to inform all TB stakeholders about the change
- ☐ Ensure regular supply chain monitoring

National Policy and Regulation

- ☐ Update your national guideline to align with WHO 2014 TB treatment guideline recommendations (***Guidance for national tuberculosis programmes on the management of tuberculosis in children – 2nd ed. WHO 2014***).
- ☐ Update your national TB strategic plan accordingly
- ☐ Support NRA to consider signing the MOU for the Collaborative Registration OR
- ☐ Inform GDF, the Central Medical Stores or appropriate authority of the intention to purchase the new formulations and facilitate the submission of a dossier
- ☐ Liaise with Medicines Regulatory Authority for registration process
- ☐ Set up or call for the committee in charge of the revision of the nEML to include the new TB pediatric formulation

Forecasting and quantification

- ☐ Set up the committee for the quantification of Tb medicines
 - ☐ Analyze past procurement to decide on overlapping time between new formulations and old formulations
 - ☐ Gather all the requested information to perform quantification exercise (refers box 4 on page 7)
 - ☐ Set up a strategy for the transition plan with all parties involved in TB medicines procurement, distribution and use (central warehouse, transit warehouse, hospital, DOTs centers)
- ☐ Monitor TB medicines availability in country to reevaluate constantly the quantification (Quant TB early warning system or any other inventory monitoring tool)

Procurement & Supply planning

- ☐ Engage procurement procedure (through GDF or directly with manufacturer)
- ☐ Develop a supply planning to closely follow the transition period process

Quality monitoring activities

- ☐ Include new TB formulations in the national safety drug monitoring and management programs (post marketing surveillance and pharmacovigilance)

Trainings

- ☐ Develop national training tool for the different health staff involved (refer to WHO/TB Alliance training tool) – do not forget to inform and train warehouse staff
- ☐ Share information with all staff involved in the procurement and supply chain management before arrival of medicines in the country.
- ☐ Schedule staff training, if necessary, before the arrival of medicines in the country (refer to the transition plan period dates)

Assessment completed
by

Name : _____

Position : _____

Date : _____

Finding verified by

Name: _____

Position : National TB program manager

Date : _____