

# Ensuring Sustainable Access to TB Medicines through Inclusion in the Philippine National Formulary

Using a systems strengthening approach, the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is building the capacity of the pharmaceutical system at all levels to reduce the country's tuberculosis (TB) burden through increased access to pharmaceutical and laboratory services. Specifically, program objectives are to:

- Ensure the availability of effective, quality, and safe pediatric fixed-dose medicine combinations (FDC) for TB
- Ensure the availability of effective, quality, and safe anti-TB medicines for multi-drug resistant (MDR) TB
- Build the capacity of the National Tuberculosis Program in registering existing and new TB medicines in the Philippine National Formulary.

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## BACKGROUND

TB caused an estimated 14,000 deaths in the country in 2015, according to the World Health Organization's (WHO) Global Tuberculosis Report for that year, which classifies the Philippines as a high TB-burden country. The National TB Control Program (NTP) of the Department of Health (DOH) leads the effort to ensure access to anti-TB medicines. The DOH's Pharmaceutical Division (PD) and Food and Drug Administration (FDA) also help ensure access through regulating in-country registration, quality, safety, and affordability.

## Seeking Sustainable Access to New Drugs

The DOH requires medicines to be included in the Philippine National Formulary (PNF), the country's essential medicines list, before government funds can be used to acquire them.

Pediatric anti-TB medicines, which are commonly kept in bottles, present storage and distribution problems for the NTP and health facilities because of their bulky size. Further, administering them is time consuming and imprecise. New pediatric fixed-dose combination TB medicines recommended by the WHO have several advantages. However, they were not included in the PNF, so therefore could not be purchased with government funds.

Further, the program wanted the PNF to include the anti-TB for MDR-TB medicines it currently uses. These are acquired through the Global Drug Facility (GDF) under a grant from the Global Fund, and are exempted from PNF inclusion. However, depending solely on the inclusion exemption as well as external funding for these medicines is not sustainable.

Therefore, the NTP plans to transition to government funding for these medicines, and including them in the PNF was a prerequisite step. The NTP also sought to build its capacity to acquire needed drugs in the future and to help ensure sustainable access to them.

## APPROACH

SIAPS helps countries adopt new medicines and regimens by using a systems strengthening approach that engages stakeholders, builds on existing systems or establishes new ones where appropriate, strengthens human resources via trainings, improves the distribution chain for new TB medicines, and records and reports information for decision making in relevant areas.

SIAPS promotes stewardship and pharmaceutical governance by working with NTPs to coordinate all in-country partners and to define roles and responsibilities for implementation of these new medicines and regimens. The overall goal is to promote sustainability among all parts of a health system.

## INTERVENTION

To begin the project, SIAPS helped coordinate regular planning meetings and discussions with the NTP's Drugs and Supplies Management (DSM) sub-technical working group. SIAPS then facilitated collaboration among the NTP, the PD, WHO, and the GDF.

The NTP then finalized the list of anti-TB for MDR-TB medicines to be acquired through the

GDF. Assisted by SIAPS, the DSM prepared the required rationale, references, and guidelines used as basis for presentation to the Formulary Executive Committee (FEC) of the PD. The DSM then circulated the prepared documents and presentation for review by the NTP manager and DSM sub-technical working group members and revised the materials accordingly. Finally, the DSM coordinated with the PD to finalize the NTP manager's presentation to the FEC.

## RESULTS

In October 2015, three new pediatric fixed-dose formulations were approved for inclusion in the PNF, two of which are dispersible flavored tablets. This ensures that the program will be able to acquire these medicines by using government funds. In addition to being easier to administer to children, the tablets are easier to store, take up less storage space in warehouses and health facilities, and are easier to distribute, thereby drastically reducing the logistics management burden and costs.

Further, five anti-TB medicines for MDR-TB were included in the PNF in September 2016. This will ensure that these medicines are consistently available to patients whether procured using government or external funds.

**Table 1. New anti-TB medicines included in the PNF**

<b>MDR drugs</b>	Capreomycin 1 g powder for injection
	Para-amino salicylic acid 4 g sachet
	Moxifloxacin 400 mg film-coated tablet
	Prothionamide 250 mg film-coated tablet
	Cycloserine 250 mg capsule
<b>Pediatric drugs (new formulations)</b>	Rifampicin 75 mg + isoniazid 50 mg + pyrazinamide 150 mg dispersible fixed-dose combination tablets
	Rifampicin 75 mg + isoniazid 50 mg dispersible fixed-dose combination tablets
	Ethambutol 100 mg tablet

With this experience, the DSM can take the lead on completing the approval documents and process to acquire new drugs the program needs. The DSM now regularly meets with its sub-technical working group to compile a list of needed medicines and coordinate completing requirements for inclusion approval.

## WAY FORWARD

The DSM needs close coordination to agree upon and finalize medicines that should be included in the formulary. Further, the program should be able to clearly justify inclusion of these products, together with

reference guidelines and recommendations. Lastly, the FEC should set up a meeting schedule that is coordinated and finalized with the appropriate NTP manager.

The NTP is already planning to include other medicines in the formulary such as *bedaquiline*, a powerful new drug for the management of MDR-TB, and rifapentine to manage latent TB. Faced with evolving global recommendations and guidelines, the NTP is now in a better position to adapt and keep up with progress in managing TB and ensure that the Philippines has access to the best possible medicines and treatment.

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**ABOUT SIAPS** | The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program works to assure access to quality pharmaceutical products and effective pharmaceutical services through systems-strengthening approaches to achieve positive and lasting health outcomes. SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health.

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