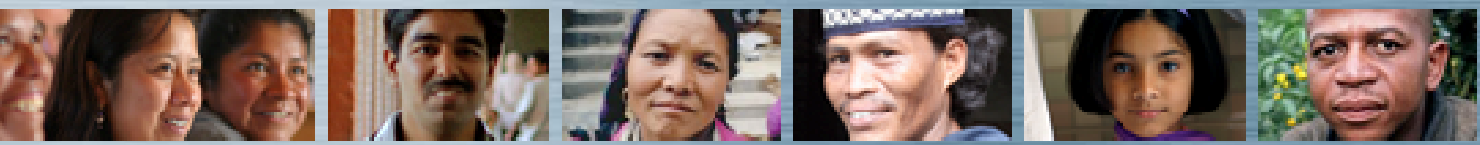
TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

Analysis of the Global TB Drug Market and Country-Specific Case Studies of TB Drug Distribution Channels

Philippines Case Study



Prepared with IMS Consulting

November 2006

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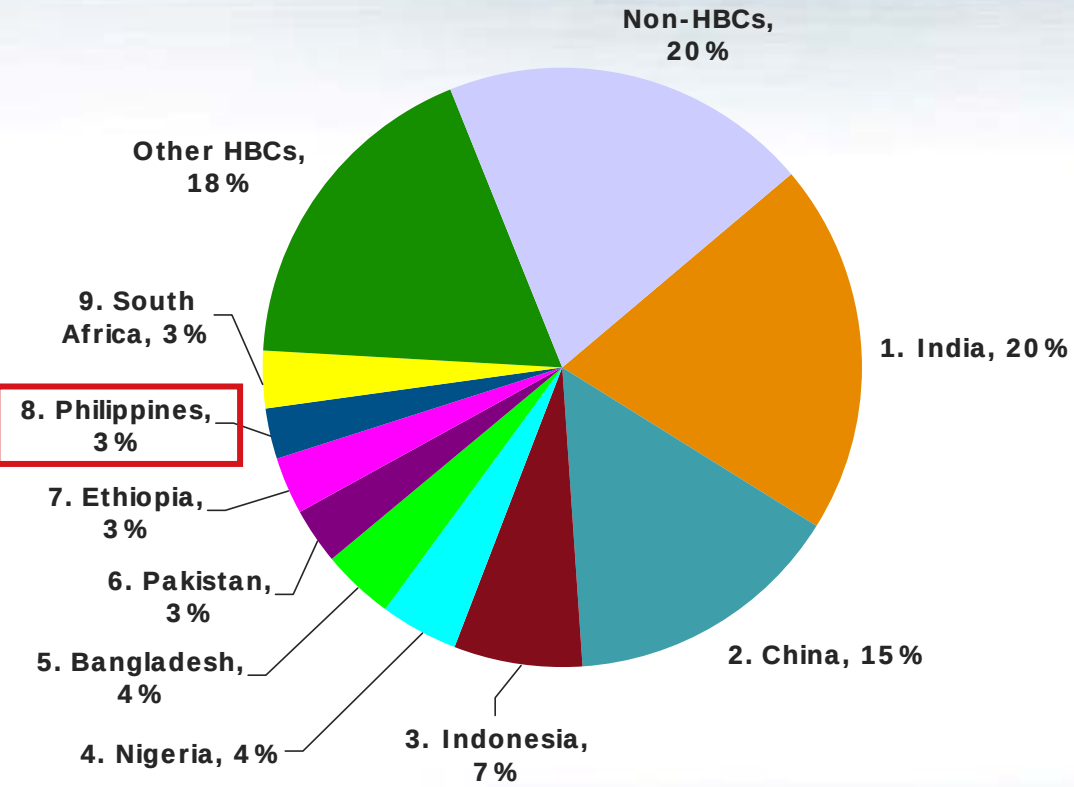
Philippines rank 9th out of all high burden countries in terms of prevalence of tuberculosis

Share of worldwide incidence of TB (total= 8.8 M new cases per year)



- **According to the WHO and the NTP (2004 estimates):**
  - **Incidence: 293 cases per 100,000 (about 132/ 100,000 smear +)**
    - **Highest incidence among working males and the urban poor**
  - **Prevalence: 563 per 100,000**
  - **Total treated cases in public sector estimated at 135,000**
  - **Mortality: 40 per 100,000**
  - **New MDR-TB cases: 1.5%**
  - **Less than 1% are HIV +**

Source: WHO Geneva; WHO Report 2006: Global Tuberculosis Control; Surveillance, Planning, and Financing
Source2:PMDI MAT Dec-2005;
Source3: Tupasi et al, Tuberculosis in the urban poor settlement and 1997 Tuberculosis Prevalence Survey in the Philippines

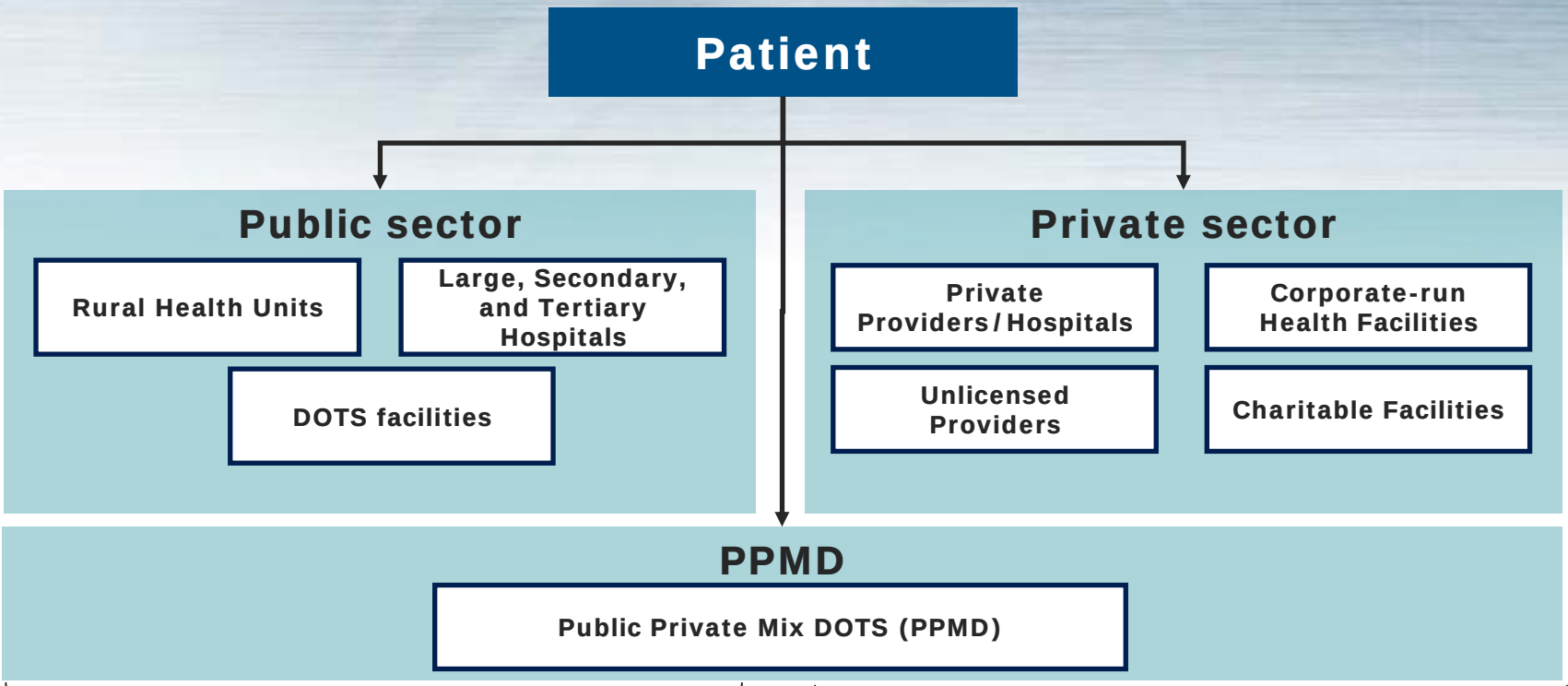
This high TB rate has left many patients out of work and significantly impacted the annual income of families

The loss of a day's wage due to TB infection has resulted in an estimated 150 M USD of lost wages annually

1Phil Peso = .01877 USD
1 USD = 53.37 Phil Pesos

Source: Philippine TIPS Study, 2003

TB patients have a range of choices of where they can receive treatment in the public and private sector



The general public can utilize public facilities for free TB drugs and obtain diagnosis and treatment coverage

However, the social stigma associated with TB, the anonymity, and the recognition of higher quality has led many patients to utilize the private sector for TB treatment

Public sector coverage for TB was initiated in 1910 through the Philippines Tuberculosis Society

1910-1930

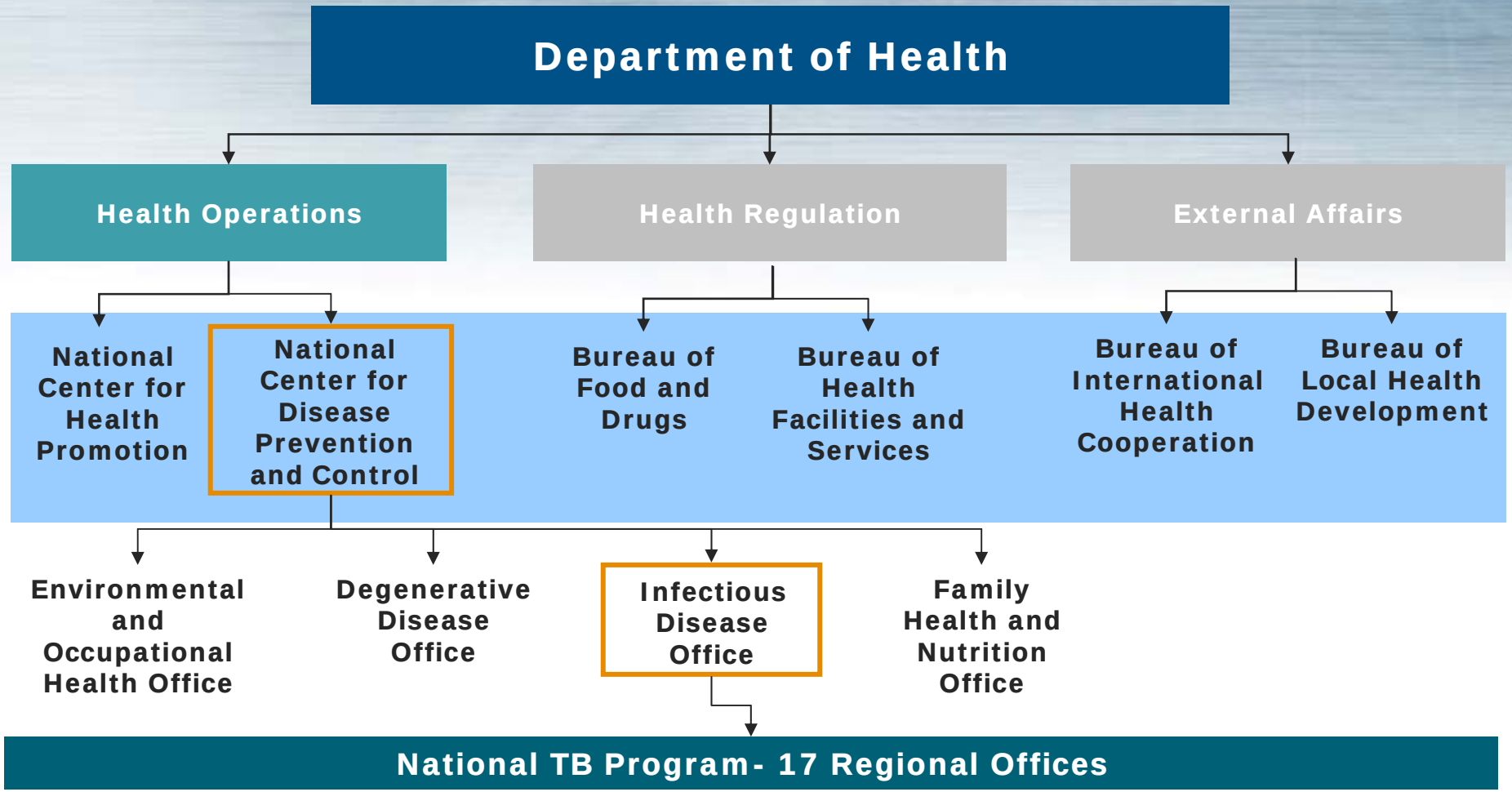
- TB control efforts were initiated by the Philippine Islands Anti-Tuberculosis, now called the Philippine Tuberculosis Society, Inc. (PTSI)
- Main efforts included case-finding and in-patient services
- Head office located in Quezon City at Quezon Institute

1930-1953

- Increasing incidence rates led to creation of a TB commission in 1932
- In 1933, the power of TB commission were transferred to Bureau of Health
  - Funded through the Philippines Charity Sweepstakes which started in 1934
- In 1950, TB Commission finally emerged under the DOH as the Division of TB
  - Division of Tuberculosis established a TB Center at the DOH compound
  - This center provided TB diagnostic and treatment services

Source: Comprehensive and Unified Policy for TB Control in the Philippines -2004

In 2000, the Philippines' National TB Program (NTP) was established under the Infectious Disease Office



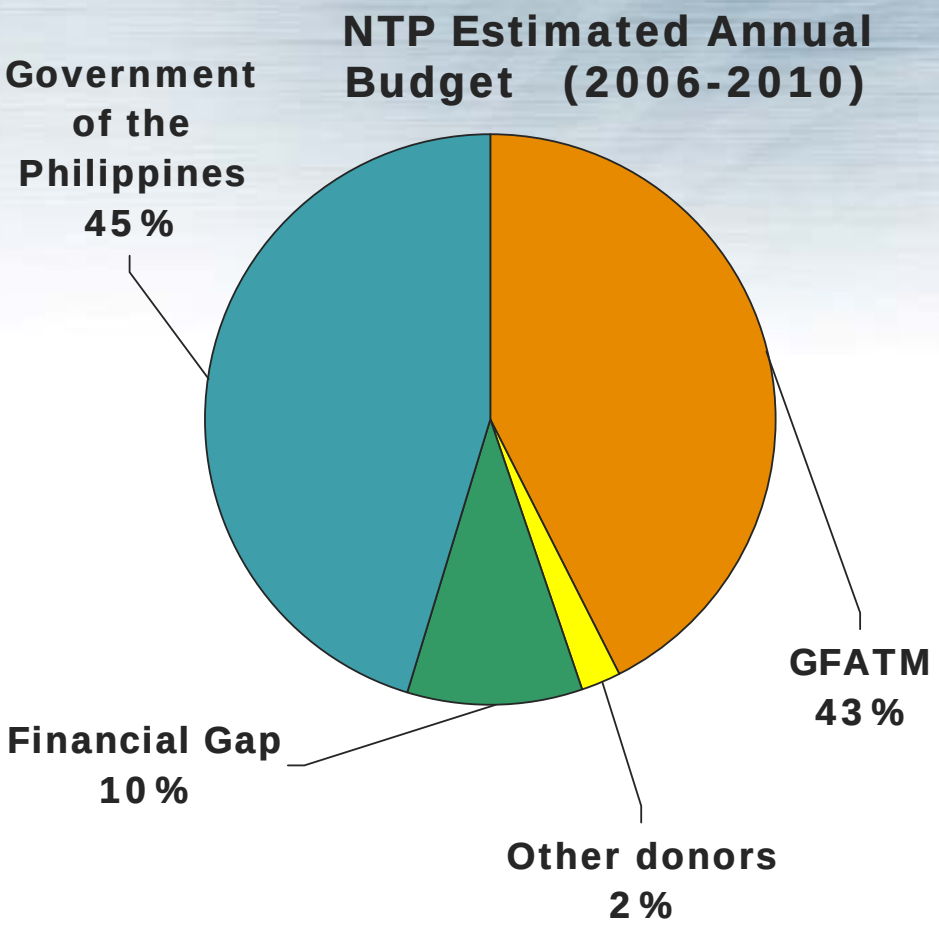
Source: Philippine DOH website;

With the decentralization of the healthcare system, regional heads are now in charge of NTP implementation

Level of NTP	Description of Responsibilities
DOH Central	• *Policy-making* • *Ensuring adequate supplies for the NTP* • *Collecting and analyzing data of Quarterly NTP reports for future planning and policy development*
DOH Regional: Central Health Departments	• *Coordinate with all stakeholders of the region with the DOH* • *Ensure adequate TB supplies*
Local / Provincial Government Unit	• *Procurement and distribution of drugs, particularly Cat III drugs* • *Ensure adequate funding at the local level* • *Monitor and supervise implementation of NTP*
Municipal / City Health Office	• *Coordinate all NTP activities* • *Procurement and distribution of drugs, particularly Cat III drugs* • *Conduct training, monitoring and evaluation of NTP program at municipal / city level* • *Perform Quality Assessment*
Barangay / Rural Health Units	• *Provide diagnosis and treatment provisions to patients as well as case finding activities*

Source: Cambridge Interviews

45% of the national TB program's budget is funded through internal sources



External Funding includes:

- GFATM Round 2: $11.4M USD (581M PP) for TB for 2003-2007- Providing drug funds for PPMD and MDR-TB
- GFATM Round 5: $46.9K USD (2,392M PP) for 6 years (2006-2011)- Includes additional activities beyond drugs i.e. TB/HIV treatment, electronic TB registration/reporting, advocacy, public awareness
- SEMP 2 Loan (World Bank): Good for TB drugs in FDCs for 150,000 cases per year from 2004-2006 (procured through GDF)
- USAID: $2.5M USD towards enhancing LGU capacity with increased units
- Also includes funding from JICA, CIDA (ending in the next year), GDF and WHO

Funding Gap

- Planning to fill the budget through USAID and other grants within the next year

1Phil Peso = .01877 USD
1 USD = 53.37 Phil Pesos

Source: Cambridge interviews with NTP and Dr Thelma Tupasi

PhilCAT, a leading organization for DOTS implementation and TB control, works in collaboration with the DOH

What it is

- Founded by DOH, leading specialty societies, and pharmaceutical industry representatives in 1994
- Made up of 67 member organizations from government, professional societies, NGO's, business groups, local coalitions, and individuals

Vision and Mission

- **Vision:** A TB-Free Philippines
- **Mission:** Broad based coalition committed to prevent, control, and eliminate TB

Role

- Acts as directing and coordinating body for a significant number of organizations with anti-TB interests, serving as the convergence point
- Adopt DOTS as a national policy and standard practice in both the government and private sectors
- Increase the number of DOTS accredited centers
- Research and Development of effective models to adopt for effective community based programs against TB
- Advocating the use of DOTS to private practitioners in rural areas
- Continued education and training for TB specialists
- Acquisition and dissemination of drugs through the DOH and GDF
- Mobilize the necessary funding and people resources

Source: Synthesis of the PhilCAT Strategic and Organizational Development and Sustainability Planning Technical Assistance

Together, with the assistance of several other organizations, PhilCat and the DOH created a Comprehensive and Unified Policy Manual for TB Control

Roles of the NTP

- Description of the NTP
- Values, Mission and Goals
- Key Targets
- NTP strategies including political commitment, standardized treatment, drug supply, program management, data and information systems, and case detection methodology
- Role of Collaborating Agencies
- Functions of NTP health workers at various levels

NTP Policies and Procedures

- For all NTP Core facilities they provide detailed objective policies and procedures for:
  - Case finding (diagnosis)
  - Case holding (treatment)
  - Recording and reporting
  - Logistics Management
  - Monitoring, supervision, and evaluation
  - Quality assurance

Guidelines for NTP implementation

- This provided a set of guidelines for a variety of non NTP facilities including:
  - Private physicians and health care facilities
  - National and local government organizations
- Enables more consistent and accurate case finding, case holding, and recording and reporting

Source: Comprehensive and Unified Policy for TB Control in the Philippines (2004)

The regimen recommended and used by the NTP is a daily, weight adjusted regimen using fixed-dose combinations

Treatment Category	Patients	Treatment Regimens*	
		Intensive Phase	Continuation Phase
Category I	New smear-positive PTB New smear-negative PTB w/ severe x-ray lesion New severe extrapulmonary TB	**2HRZE (Type I blister pack + E tablet)**	**4HR (Type II blister pack)**
Category II	Relapse Treatment failure "Others"	**2HRZES/ 1HRZE (Type I blister pack + E tablet + S vial)**	**5HRE (Type II blister pack + E tablet)**
Category III	New smear-negative PTB w/ mild x-ray lesion	**2HRZ (Type I blister pack)**	**4HR (Type II blister pack)**

*H- INH, R-Rifampicin, Z- PZA, E- Ethambutol, S- Streptomycin; numbers refer to length of therapy (months)

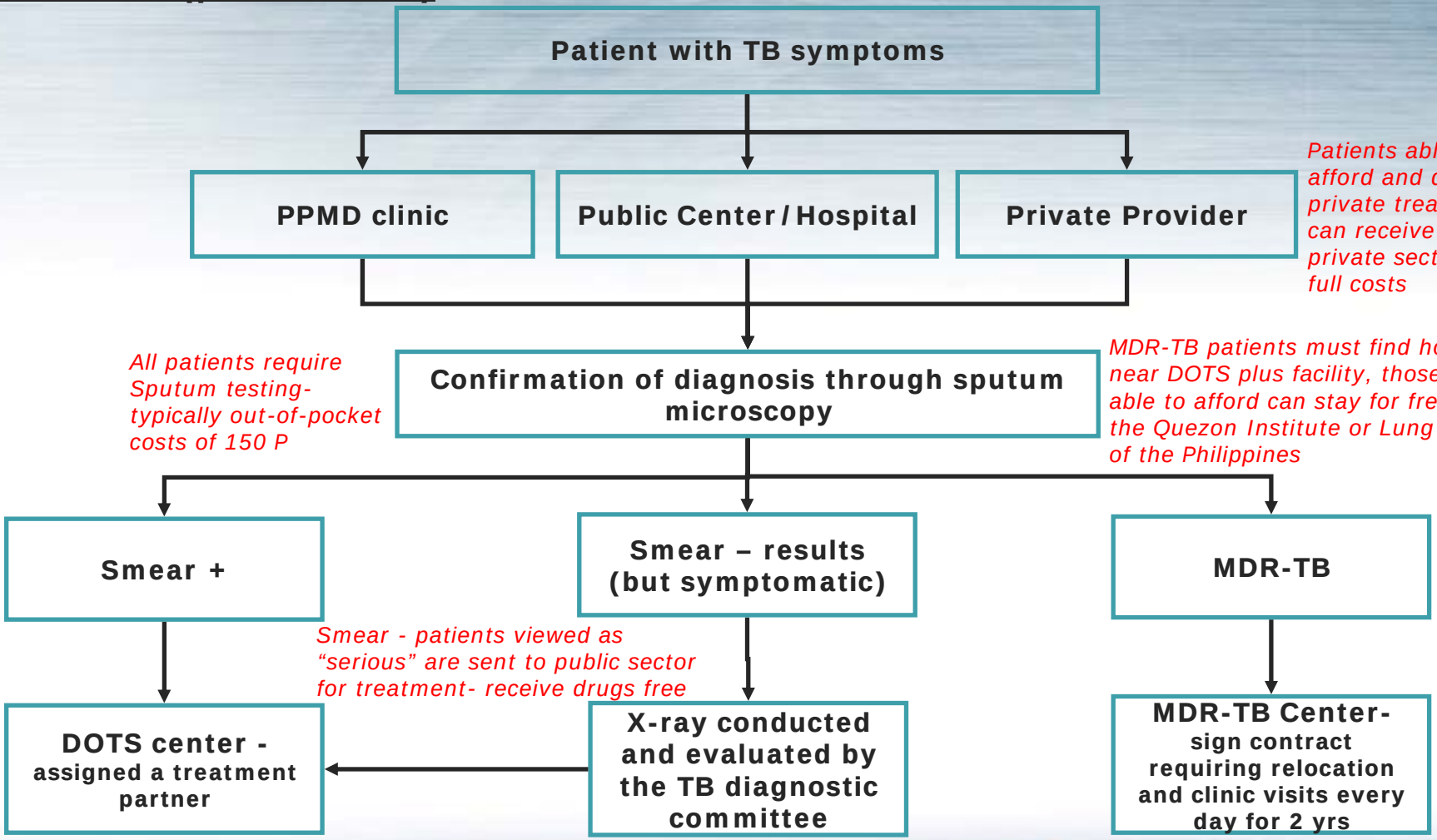
Details on the 1st line Regimen

6-8 month treatment regimen. Recommended treatment is DOT 7 days a week for the first 6 months to limit defaulting. Some facilities require patients to come in every day for first two weeks and then every other day from then on. At home DOTS with a treatment partner is allowed 1 week prescription at a time. If patient is cavitary, may extend continuation phase to 3 months for a total of 9 month treatment

Source: USAID-PhilTIPS; The Philippine Private Sector TB Drug Facility: A Need and Supply Situation Analysis

Ideally, all patients in both the public and private sector will be treated based on NTP guidelines

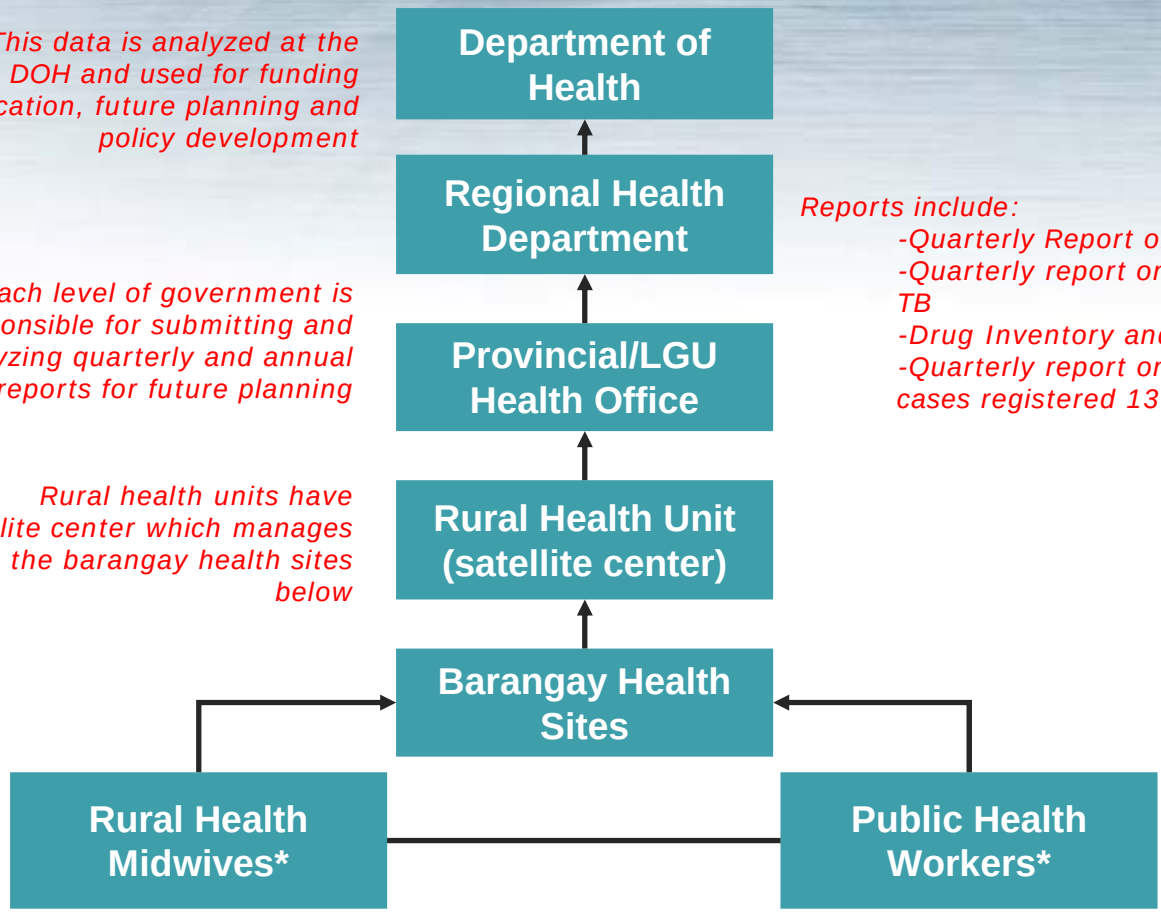
Patient flow (public sector)



Source: Cambridge interviews; Who http://www.wpro.who.int/internet/files/stb/hangzhou/Day_1/05_privately_initiated_ppmd_phl.pdf

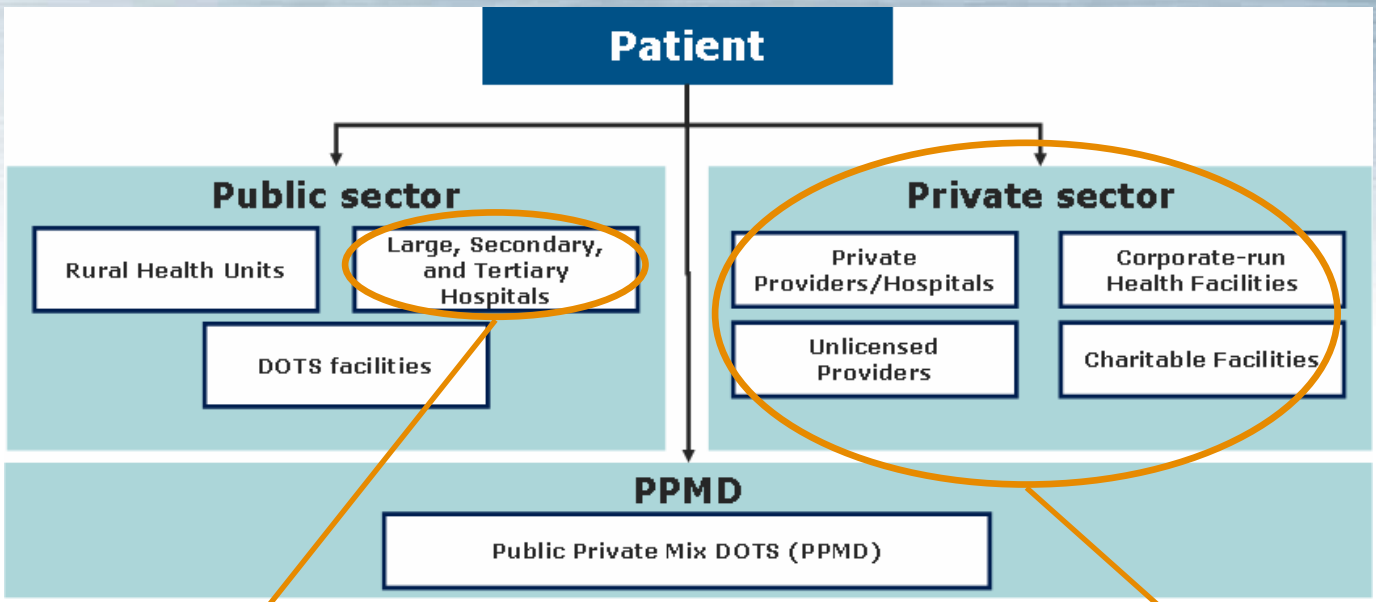
To track all patients and forecast supply, a bottoms up reporting system is used

Flow of reporting



**Assigned as treatment partners*
Source: Comprehensive and Unified Policy for TB Control in the Philippines; March 2003

A number of public sector facilities and many private providers do not practice DOTS

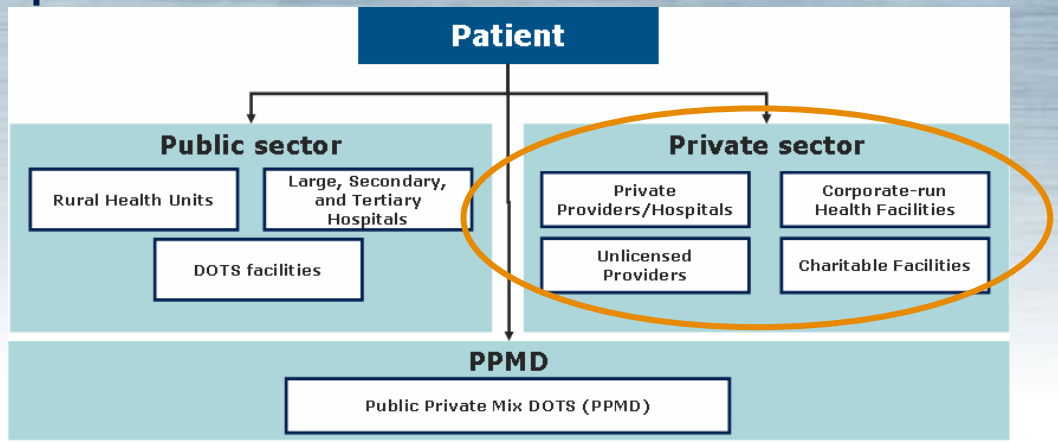


- These facilities include non-DOTS certified public health facilities including large, secondary and tertiary facilities
- Although providing free drugs to patients, these facilities may not participate in DOTS and are not currently reimbursed by PhilHealth

- A highly fragmented sector that accounts for a large percentage of total TB patients
- Oversight of this sector is difficult and practices in TB treatment vary widely

Source: Cambridge interviews

Many patients today still prefer to self-medicate or be treated in the private sector



- Many patients may seek treatment in the private sector, self-medicate (go directly to pharmacy) or not seek treatment at all because of:
  - Lack of access to health services and facilities
  - The social stigma attached to TB being the "poor man's disease"
  - Fear of isolation from the community or family
  - Lack of knowledge regarding severity and dangers of disease

Source: Cambridge interviews; USAID- Toward an Enabling TB Policy Environment; A policy Analysis of Private Sector Participants in TB DOTS;

In the private sector, TB drugs are currently the 15th top selling TA category in the Philippines reaching $23M or 2% of total drug market

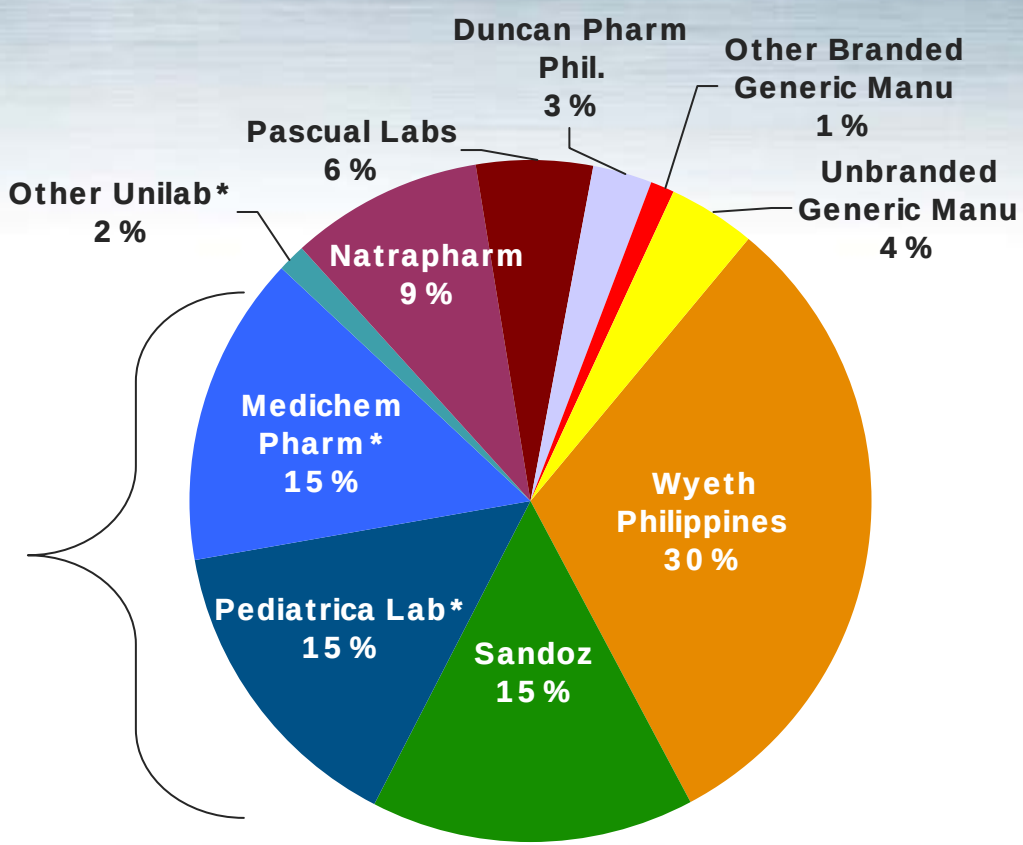
Top 10 Brands	Manufacturer	Generic	Sales (USD)	% Total Sales
MYRIN P	Wyeth	HRZE	$4,953,585	21.55
MYRIN	Wyeth	HRE	$2,228,786	9.69
RIMAPED	Pediatrica	R	$1,638,272	7.13
QUADTAB	Medichem	HRZE	$1,539,000	6.69
RIMACTAZID	Sandoz	HR	$1,347,105	5.86
KIDZ KIT 2	Natrapharm	HR	$1,080,956	4.70
COMPRILEX	Pediatrica	H+pyridozine	$935,723	4.07
KIDZ KIT 3	Natrapharm	HR+pyridozine	$934,770	4.07
TRES	Sandoz	HRE	$850,201	3.70
TRITAB	Medichem	HRE	$763,025	3.32
TOTAL			$16,271,423	**70.78**

Source: IMS MAT- Mar 06

Over half the value of the private TB market is supplied through local manufacturers, particularly Unilab

- **The top 5 companies make 88% of all TB drugs available**
  - **Unilab affilitiates together capture 32% of the TB market**
- **Growth of the top 2 MNCs, Wyeth and Sandoz, has slowed down**
- **Market growth drivers are <u>Unilab affiliates*</u> (branded generics) with Medichem and Pediatrica posting the highest growth rates**

<u>TB Manufacturers 2005 (Value)</u>



Note: Unilab affiliates are all noted with an asterisk on chart

Source: IMS MAT- Dec 2005

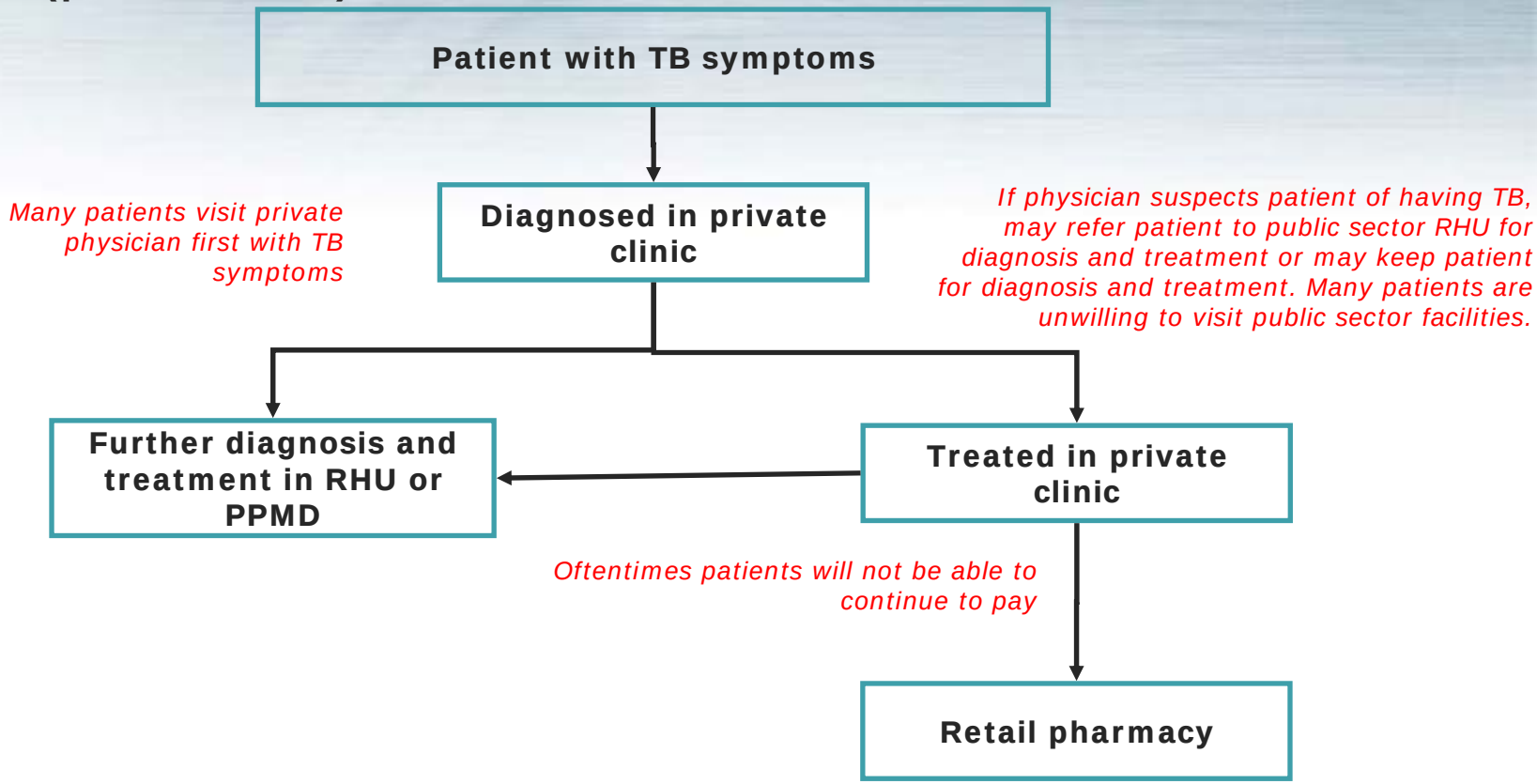
As the private sector is unregulated, patients may receive different regimens or incomplete treatment

	Retail Pharmacy	Non-DOTS facility
Prescription inconsistency	• No prescriptions required • Estimated that 70-90% may enter pharmacy without prescription • Buy medicines because “Vitamins for the Lungs”	• Lack of knowledge regarding the TB problem or resistance • No follow-up with patients to ensure compliance • Tend not to follow NTP guidelines or any guidelines
High cost and inadequate regimens	• Typically provide branded agents a few days at a time • Do not question prescribed regimen • Tend to mark up costs up to 30% • 60%-80% of patient have requested pharmacists to modify their prescription due mainly to price	• Tend to prescribe high cost branded agents • Regimens many times inadequate • Treatment lacks structure or flexibility around patient needs

Source: Cambridge interviews

Patients initiating treatment in the private sector may remain or be referred to a public sector DOTS center/ PPPMD

Patient flow (private sector)



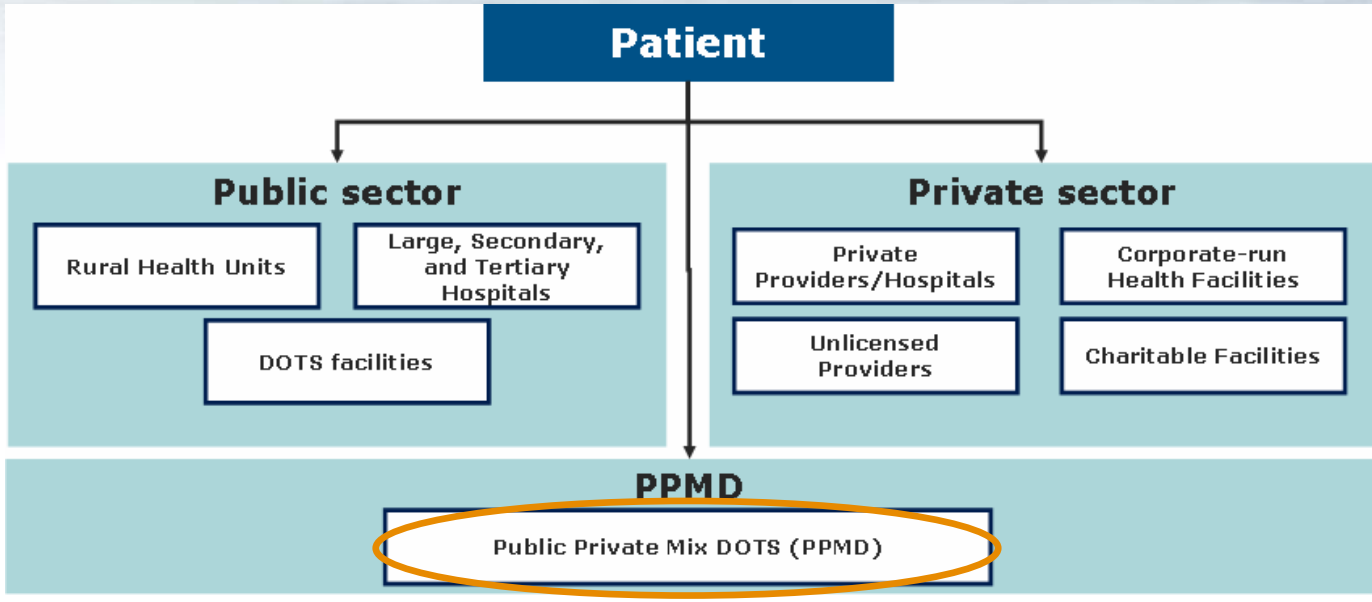
Source: Cambridge interviews

Prices obtained in through local or multinational suppliers are more expensive than those through the GDF

Treatment Category	Drug regimen	Cost of Therapy Using Local Products (USD)	Cost of Therapy Using GDF Products (USD)	Ratio of Mean Local to GDF price
Category I	2HRZE/4HR	$135.36	$17.89	7.6
Category II	2HRZES/5HR	$315.84	$32.50	9.7
Category III	2HRZ/4HR	$135.36	$17.89	7.6

Source: Cambridge Interviews

In an effort to extend the NTP's capacity and scope of influence in the private sector, the Public-Private Mix DOTD (PPMD) Program was launched in 2003



Source: Cambridge Interviews

PhilTIPS, a partner of PhilCAT, has been a major factor in implementing PPMD initiatives

What it is

- USAID funded project working in partnership with PhilCATS through increasing private sector influence in TB control
- PhilTIPS 1 project ends 2006, PhilTIPS 2 will look into recommendations of study results and feasibility of implementation

Goal

- Increase the successful diagnosis and treatment of TB patients
- Achieve a success rate of at least 85% through the commercial private sector services in selected sites
- Obtained through implementation of DOTS services

Services

- Support of TB policy reform and financing
- Support of operations research
- Improving private provider access to DOTS drugs and DOTS provider reimbursement under the national health insurance
- Designing provider incentives to increase TB detection and DOTS completion rates
- TB services expansion in the private sector through grants and technical assistance to health facilities
- Training of physicians and those in allied health professions
- Certification of facilities
- Increased teaching and communications of TB control and DOTS to support informed decision making

Source: USAID Philippines- Population, Health, and Nutrition. Philippine Tuberculosis Initiatives for the Private Sector

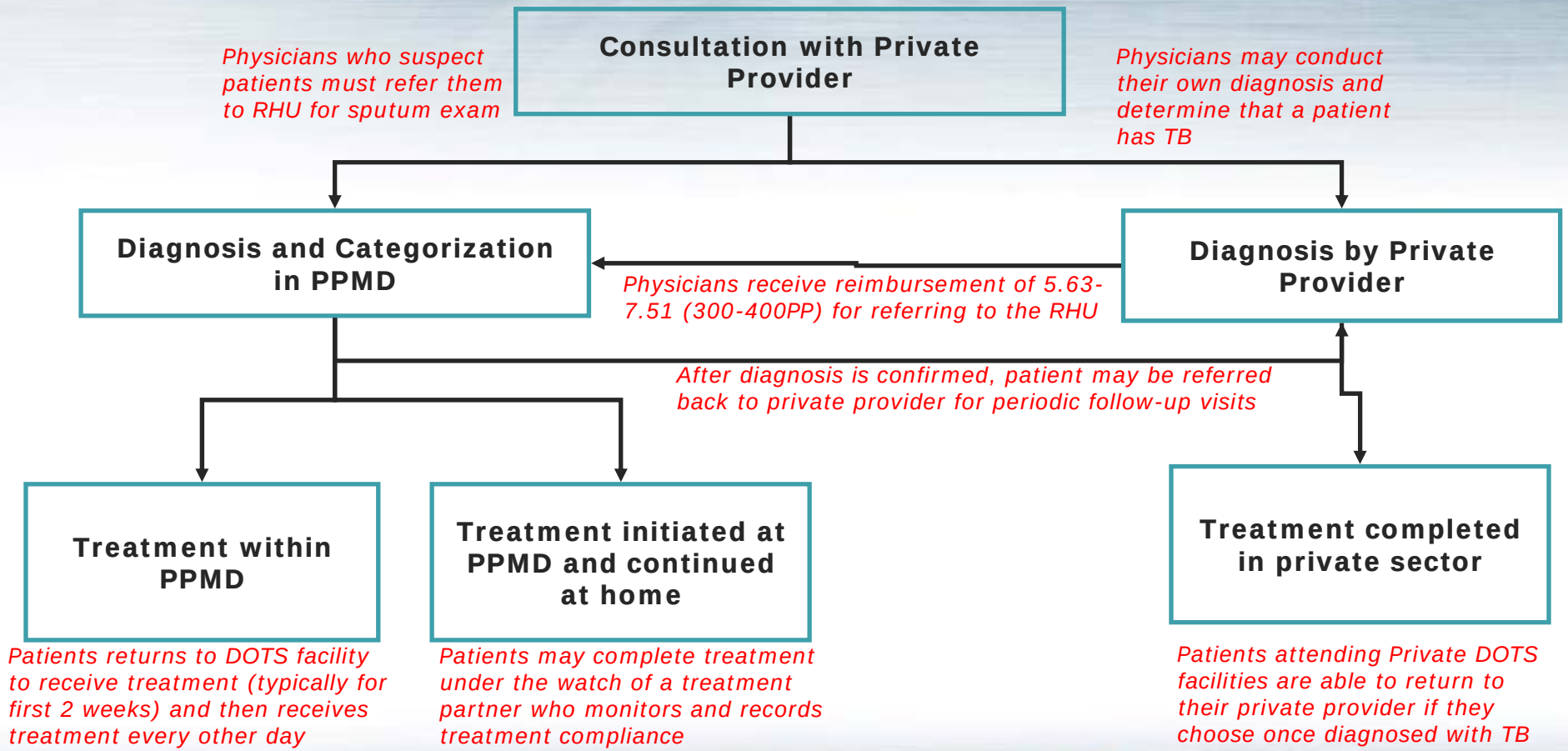
Currently a total of ~100 PPMD facilities have been established with an additional ~100 planned for 2006

- Impetus for the PPMD was the large number of patients preferring treatment in the private sector
- 100 facilities have now been certified by the National Coordinating Committee for PPM-DOTS, including 20 units establish by PhilTips
- 70 units established through GF R2 support to date, with an additional 100 planned for 2006
- Over 2000 private physicians have been trained on NTP and DOTS strategy
  - All private practicing physicians are required to pass training provided by the province, DOH, and PhilCat
- Over 2/3's of the medical schools have become involved in DOTS activities to promote physician education

Source: WHO Philippines Country Report 2005; PhilCat; Cambridge interviews

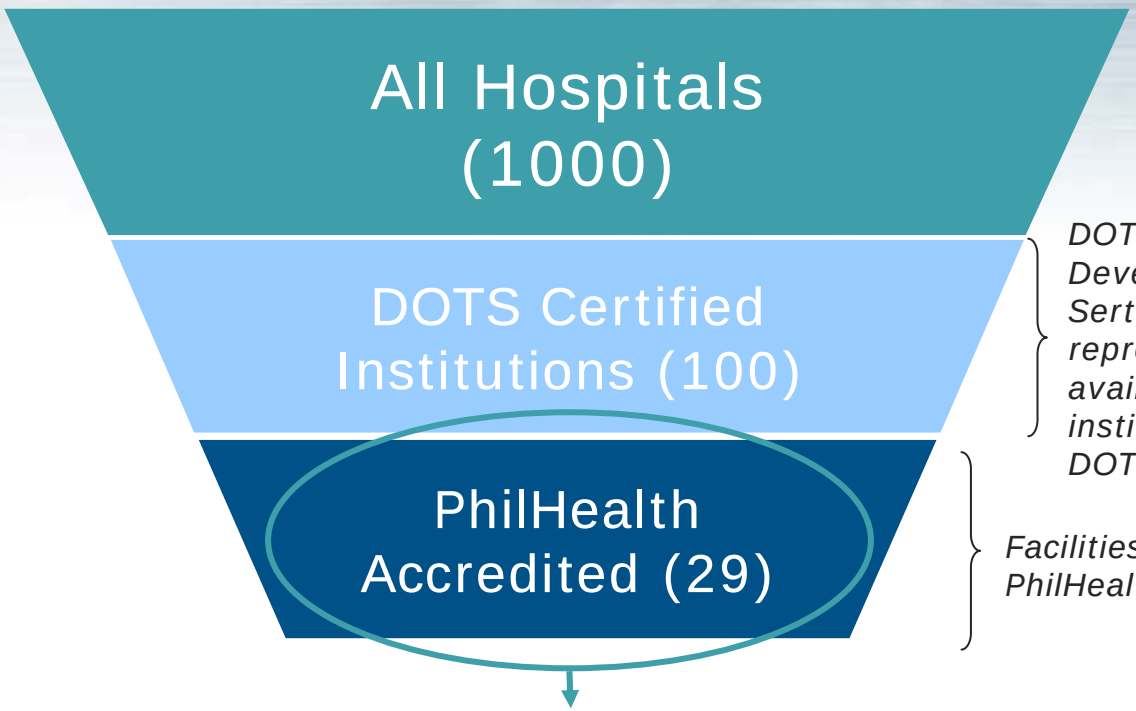
Under the PPMD model, private physicians affiliated with the PPMD are supposed to refer TB patients to the PPMD

Patient flow through PPMD



Source: Cambridge interviews

DOTS-certified, PhilHealth accredited centers (public and private PPMDs) receive reimbursement for PhilHealth patients as incentive



DOTS Certification by Center for Health Development of the DOH, jointly with the Sertrong Sigla Team and with private representatives of local coalitions, if available. This is the first hurdle before institutions can receive PhilHealth TB DOTS outpatient reimbursement

Facilities must receive accreditation from PhilHealth

Only 29 facilities Qualified for TB Outpatient Reimbursement

Source: PhilHealth Stats and Charts 2004
Source 2: PhilCAT List of Certified DOTS Facilities
www.philcat.org

Reimbursement is ideally allocated according to the PhilCAT recommended benefit allocation

Amount participating physician receives for referring to PPMD

Amount participating physician receives for patients for follow-up visits

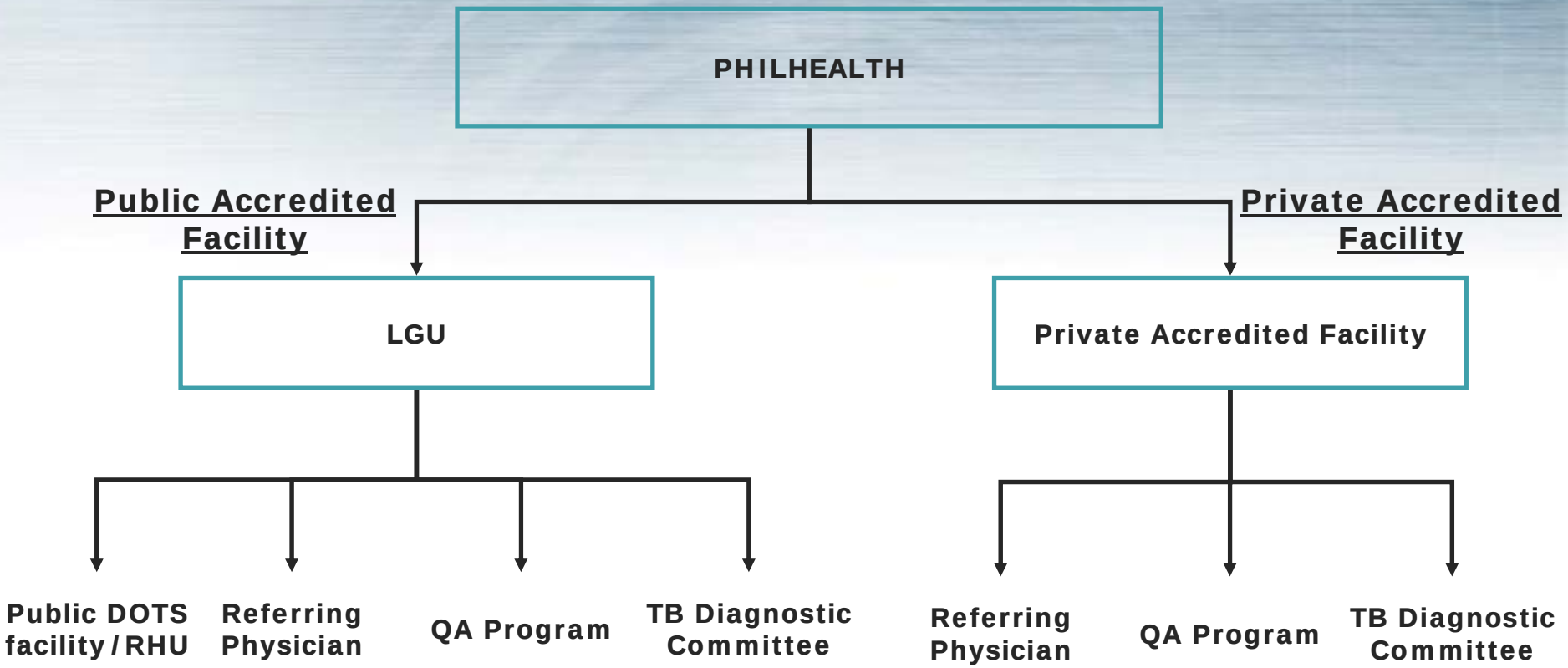
All DOTS certified centers receive reimbursement for each Phil Health patient treated

Recommended Benefit Allocation		
Activity	**Allocation (USD)**	**Recipient**
Referral of an active TB case	$1.87	DOTS referring physician, Barangay Health Worker
Clinical consultation with DOTS referring physician (following schedule of the follow-up sputum exam)	$6.57/ month for 3 months =$19.71	DOTS referring physician
QA for Sputum Microscopy	$3.75	Provincial or City Health Office QA program
TB Diagnostic Committee	$13.14	TB Diagnostic Committee
Pool for Contingency (drugs)	$23.46	RHU/HC/PPMD Unit
Recording and reporting sessions with certified DOTS referring physicians	$3.75	RHU/HC/PPMD Unit
Production of NTP- PPMD forms	$3.75	RHU/HC/PPMD Unit
Advocacy activities-meetings with DOTS referring physicians	$5.63	RHU/HC/PPMD Unit

Total = 4,000 P or 78 USD

Source: Operational Guidelines for PPMD in the Philippines; DOH and PhilCAT -2004

This distribution mechanism relies on LGUs and private accredited facilities to distribute the money



All referring physicians, public DOTS facilities, RHUs, QA Programs, and TB Diagnostic Committees ultimately rely on the Local Government Unit or the Private facility to provide them with their allotted payment; however many never receive the reimbursement

Source: Interviews; Operational Guidelines for PPMD in the Philippines; DOH and PhilCAT -2004

Another effort to join the public and private sectors is the introduction of the Pharmacy DOTS initiative (PDI)

Pharmacy DOTS Initiative (PDI)

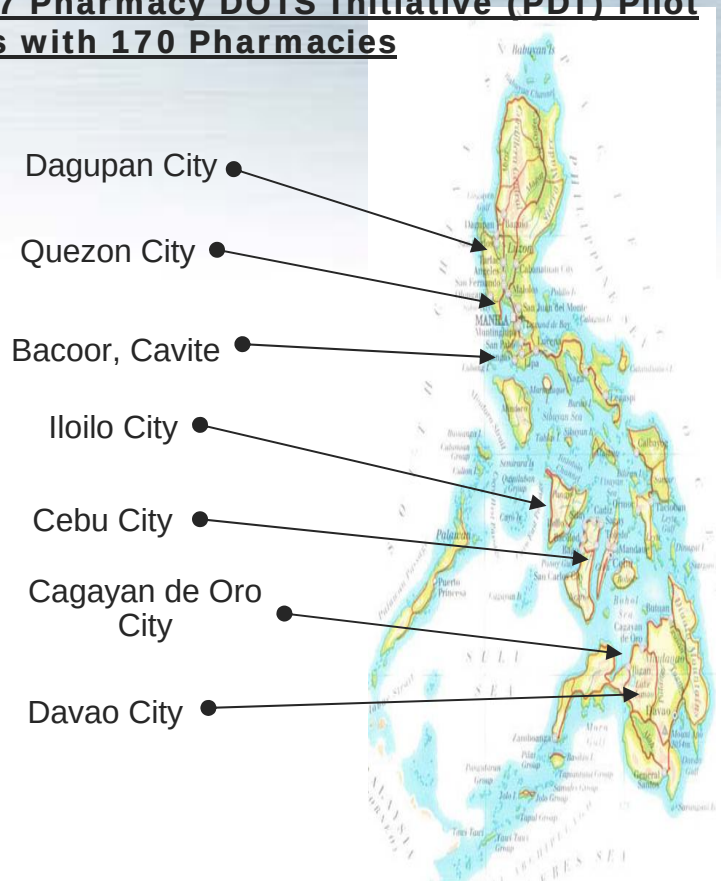
The need for this initiative was based on a number of factors:

- About 85% of all patients seeking treatment in the private sector directly approach drug stores for their medical needs with less than 20% compliant
- 22% do not initially seek advice from a health care professional and just seek advice from local pharmacists
- More than half of the non-PDI pharmacists sell TB drugs to customers without a prescription

Source: USAID PhilTIPS- Discouragng TB Self-Medication- Philippine Drug Stores as Private Sector Partners

To date, 7 Pilot PDI sites have been initiated across the country to ensure TB medicines are dispensed with prescriptions

The 7 Pharmacy DOTS Initiative (PDI) Pilot Sites with 170 Pharmacies



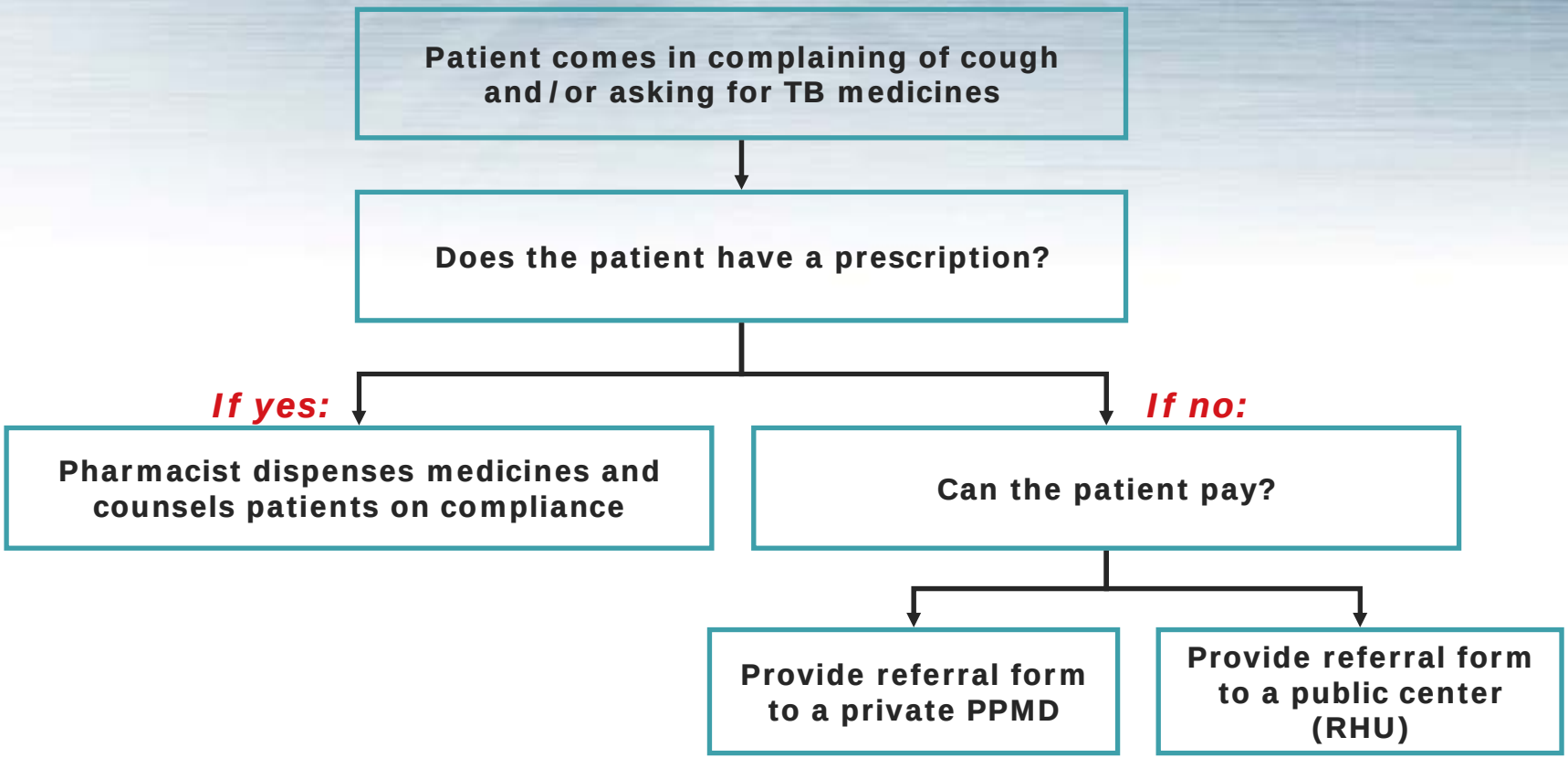
- Formally launched in April of 2004
- 7 sites covering 509 drug stores including several large pharmacy chains
- As of April 1 2006, there were 23,520 drugstores
- Pharmacies are trained:
  - **Not** to prescribe anti-TB medicines without prescription
  - **To identify** potential TB patients by the drugs they try to buy (w/o prescription) or by their symptoms
  - **To counsel patients** and refer to public institutions for diagnosis
  - To advise patients on importance of continuing full treatment regimen

"Most suspects and patients go to drugstores without prior diagnosis…. Sometimes people ask for vitamins for the lungs"
(Drugstore Owner involved in PDI)

Source: Cambridge Interviews; USAID PhilTIPS- Discouraging TB Self-Medication- Philippine Drug Stores as Private Sector Partners

The objective of the PDI is to ensure that TB suspects are referred to the public sector for proper diagnosis

Example: Dispensing pathway at PDI participating pharmacies



TB suspect contact information recorded at pharmacy and provided to BFAD on monthly basis. No further follow-up from pharmacy to ensure patients seek diagnosis at the referred center.

Source: Cambridge Interviews with PDI participating pharmacies

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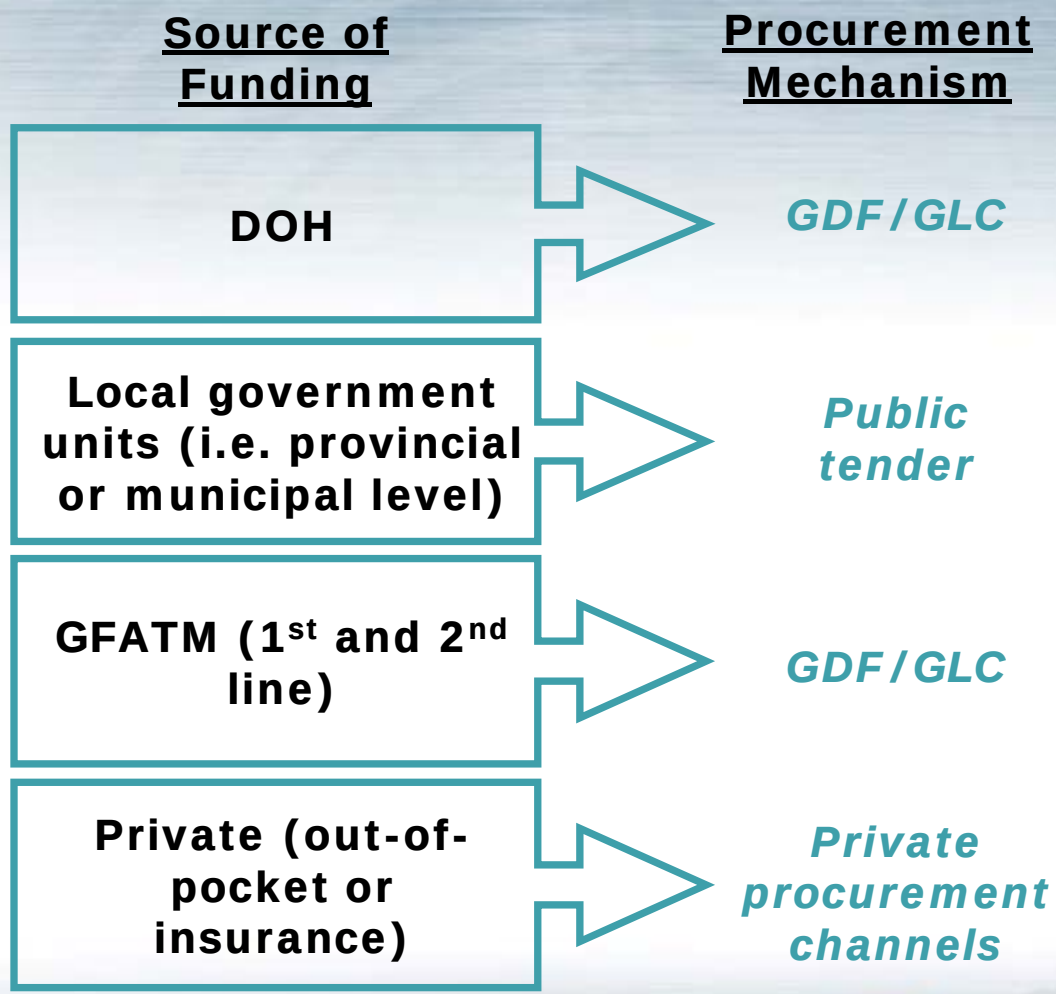
In the Philippines, funding drives the procurement mechanism through which TB drugs are purchased



Source: Cambridge Interviews

*Started in 2006

TB medicines for Category I and II patients are centrally procured by the Department of Health (NTP) from the GDF

Public Sector (GDF)

1. GDF drugs delivered twice a year to the DOH (port of entry)
2. Drugs delivered to central warehouse in Manila

GDF

DOH

Regional DOH (CHD)

3. Air 21 (local FedEx) distributes to 17 regional warehouses

4. Distributed from Regional DOH to the 1,712 provincial warehouses or to major cities through a contracted freight service

   Ideally distributed on a quarterly basis when possible; however often distributed more frequently, i.e., monthly

Provincial Health Office (PHO)

City / Municipal Health Office (CHO / MHO)

5. Drugs subsequently distributed to public facilities (BHO/RHU), and public and private initiated PPMDs on a quarterly to monthly basis

PPMD

Public Hospitals/ Clinics

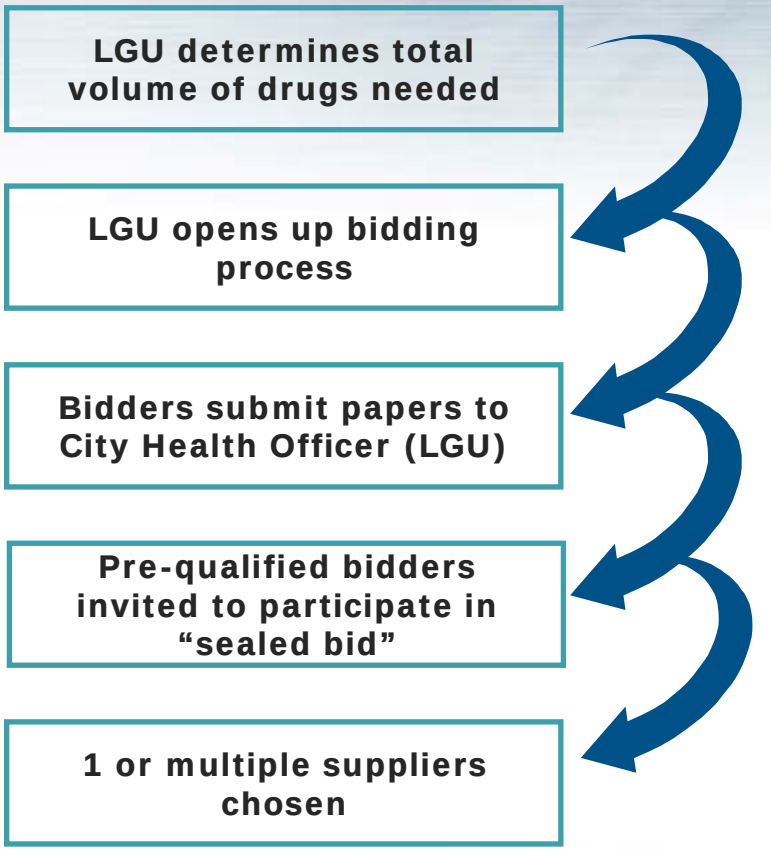
Bangaray Health Office (BHO)/ Rural Health Unit (RHU)

Bangaray Health Station (BHS)

6. Mid-wives provide to treatment partner (weekly) or patient on a daily basis

Source: Cambridge Interviews

LGU's generally procure TB medicines for Category III patients through local budgets



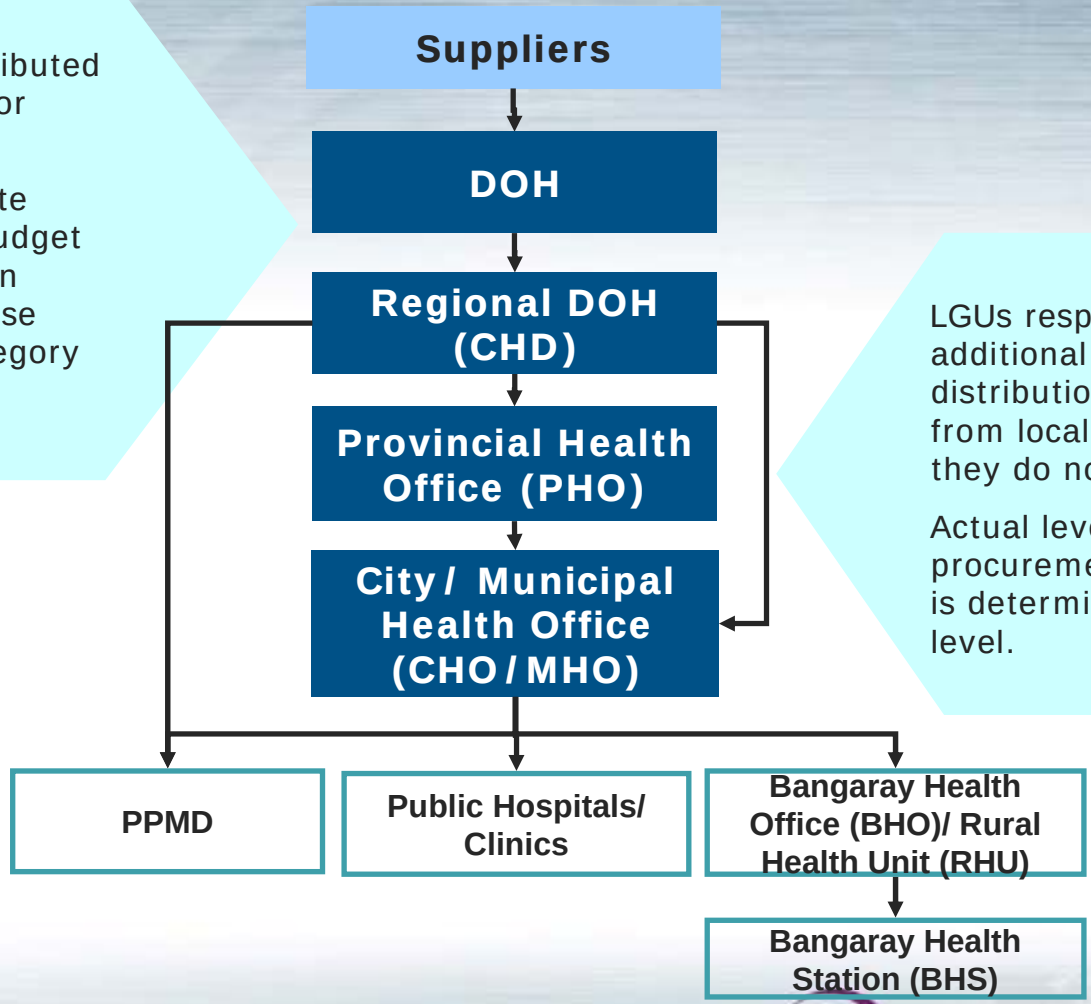
- **Process:**
- Local Government Unit (LGU) determines the number of drugs needed and total funds they will allocate
- Eligible bidders are invited to participate
- Bidders must submit:
  - Bioavailability studies
  - Product registration
  - Clinical Studies
  - Batch sample
- Once pre-qualified, accepted to participate in a "sealed bid" (typically 3-4 suppliers)
- Supplier(s) win the bid based on:
  - Track record (i.e. good delivery and supply)
  - Batch certificate
  - Price

Cat III drugs are purchased from local suppliers, not the GDF, and are delivered direct from the supplier to the LGU

Public Sector (LGUs)

GDF sourced drugs are distributed from the DOH to the LGUs for Category I and II patients.

LGUs are expected to allocate resources from their local budget to procuring Cat III drugs. In some instances, they may use national supply to treat Category III patients



LGUs responsible for additional procurement & distribution of Cat III drugs from local manufacturers- they do not procure from GDF.

Actual level of funding for procurement of Cat III drugs is determined at the local level.

Source: Cambridge Interviews

To track case detection and supply at each level, each unit reports patient cases and supply to the unit above

Flow of Reporting (Public Sector)

- **Department of Health**
- **Regional (Center for Health Development)**
- **Provincial / City**
- **Municipal / RHU**
- **Health Facility (e.g. BHS, PPMD unit)**

CHD consolidates and analyzes data prior to submission to DOH

Provinces / Cities then report quarterly to the regional level

Municipal level / RHU submits monthly report to provincial level

Smallest units (BHS) submit to RHU; larger units submit directly to provincial or city level.

Forecast is used to:

- ***Determine national budget for TB drug procurement***
- ***Place orders with suppliers—whether GDF or public tender winners***

Source: Comprehensive and Unified Policy for TB Control in the Philippines (2004)

A buffer stock should be kept at each level though the actual amount varies based on available resources

An adequate reserve should be maintained at each site	
DOH level	3 months
Regional Level	3 months
Provincial Level	3 months
Municipal Level / Pharmacy	2 months

CALCULATED BY:

1. Number of blister packs / tablets needed based on the number of patients registered in the previous quarter
2. Multiplied by two (include the buffer stock).
3. Deducting the drugs left from the past quarter.

_____

Total Order

Source: Comprehensive and Unified Policy for TB Control in the Philippines (2004), Interviews

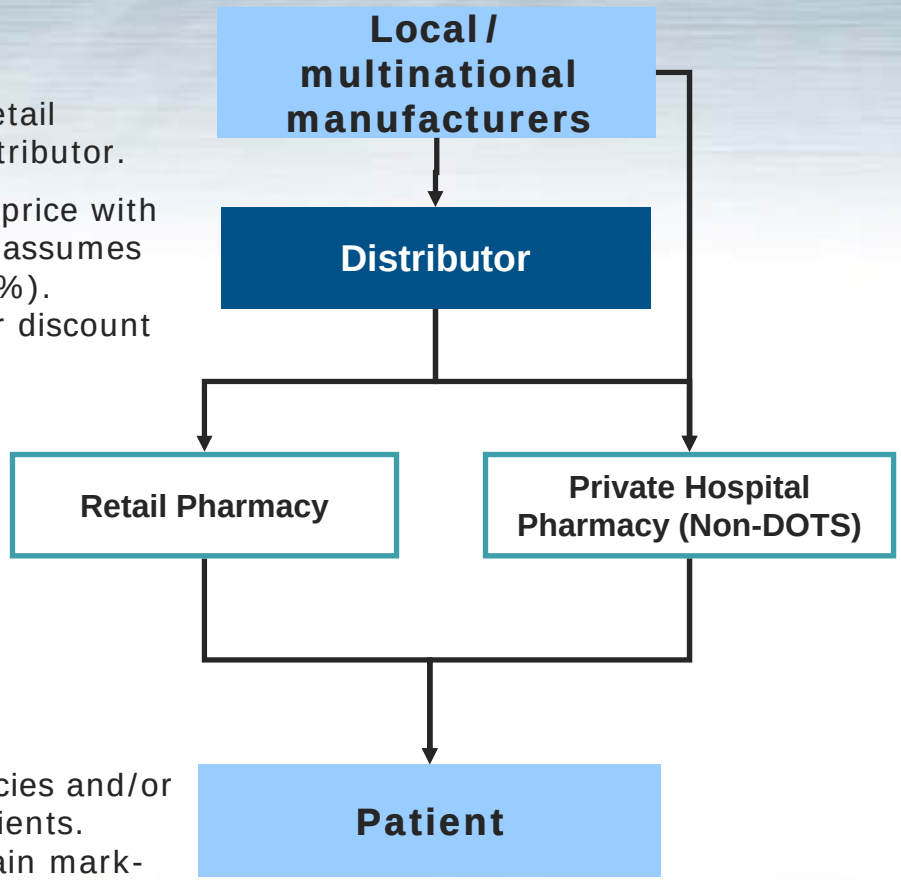
In the private sector, TB medicines flow through the same commercial channels as other medicines

Private Sector (Retail Pharmacy and Non-DOTS Hospital Pharmacy)

1st / 2nd point of sale:

Manufacturer sells directly to retail pharmacy or via a 3rd party distributor.

Manufacturer usually has a list price with a suggested retail price (which assumes a mark-up at retail level, i.e. 7%). Pharmacy can negotiate further discount (5-20%) beyond that.

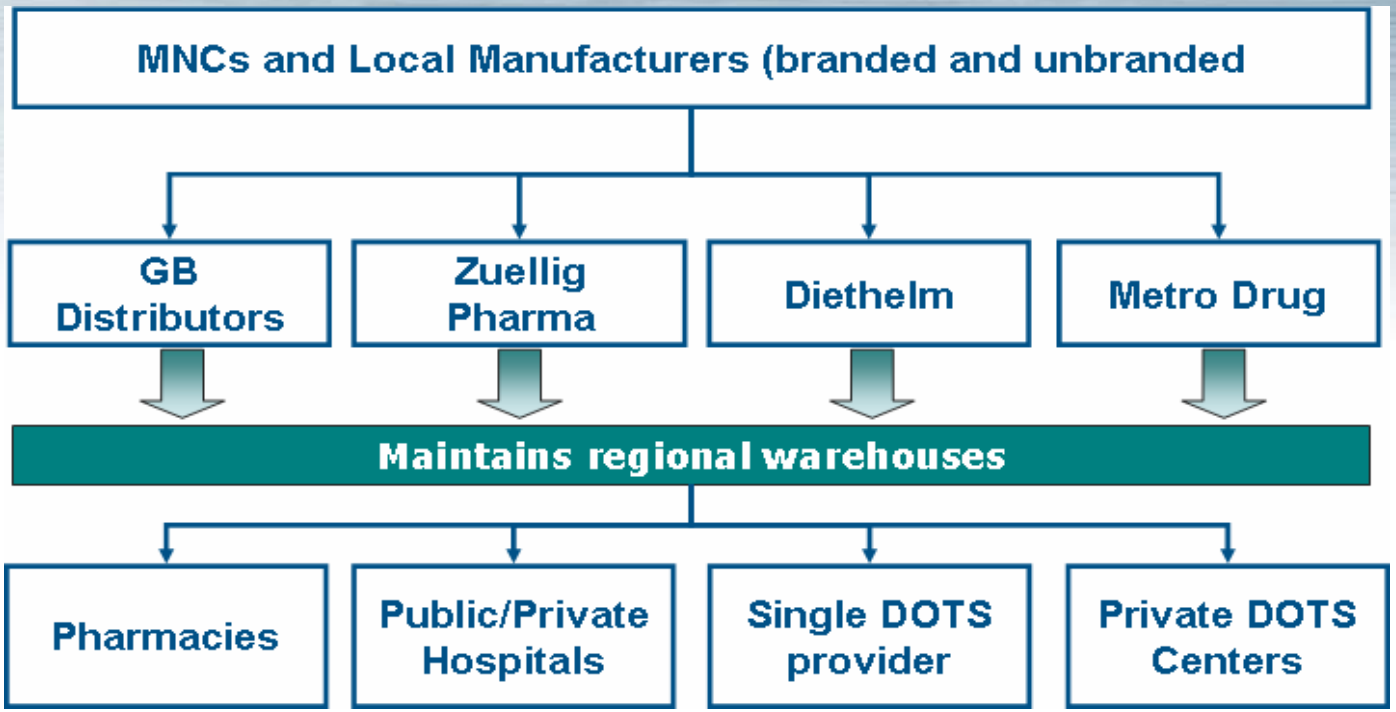


Some private hospitals/ physicians may keep stock within pharmacy at facility, depending on size of the facility.

3rd point of sale: Retail pharmacies and/or providers then sell drugs to patients. Retail pharmacies sell at a certain mark-up from the ex-manufacturer's price.

Source: Cambridge Interviews

TB medicines are typically delivered from manufacturer to the facility via 3rd party distributors



1. **Zuellig Pharma** - largest drug distributor. Through its information infrastructure, it is able to effectively and efficiently deliver appropriate level of supply
2. **Diethelm, GB and Metro/Marsman** - also well-known drug distributors with technological facility and warehousing capability.
3. **Self distribution** – some companies have their own distribution system
4. **Freight Forwarders** – used by DOH in its Contract Distribution System (CDS) nationwide.

Source: USAID-PhilTIPS; The Philippine Private Sector TB Drug Facility: A Need and Supply Situation Analysis

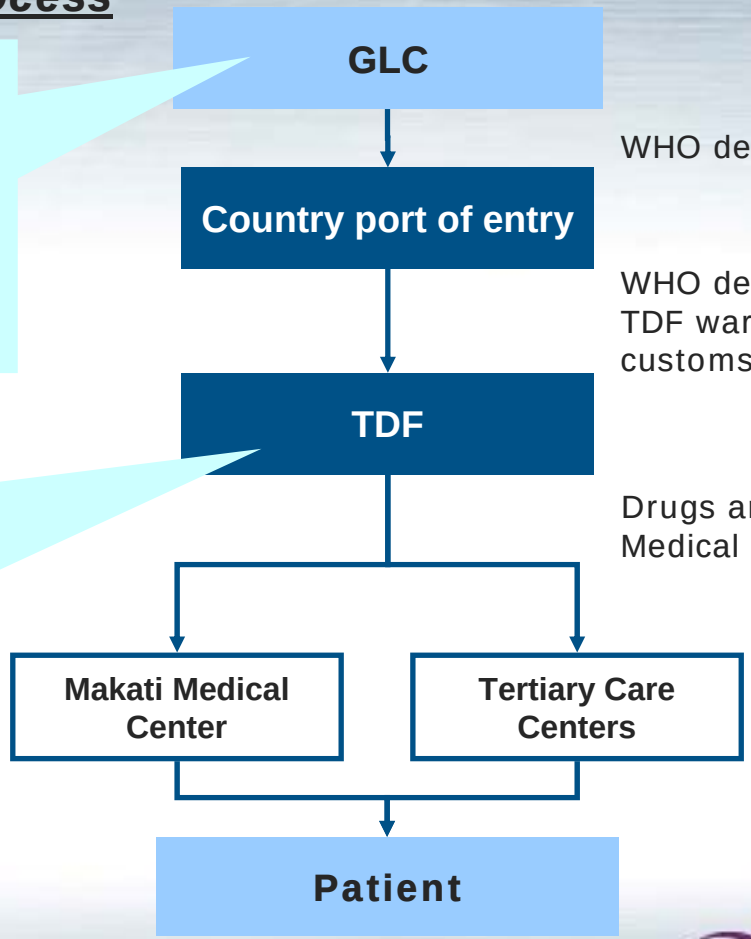
Most 2nd line products are procured through the GLC/GDF and dispensed by GLC approved DOTS-Plus Project at the Tropical Disease Foundation

Approval / Ordering Process

1. GLC approves cohort number of patients treated
   - 2003: 50 patients to be treated w GFATM 2 grant
   - 2006: 2,500 patients planned to be treated with GFATMS 5 grant

2. Once approved by GLC. drugs are ordered through the WHO procurement office by Tropical Disease Foundation (TDF) on an intermittent basis (subtracts this number from the total grant

Flow of drugs



WHO delivers 2nd line drugs to port of entry

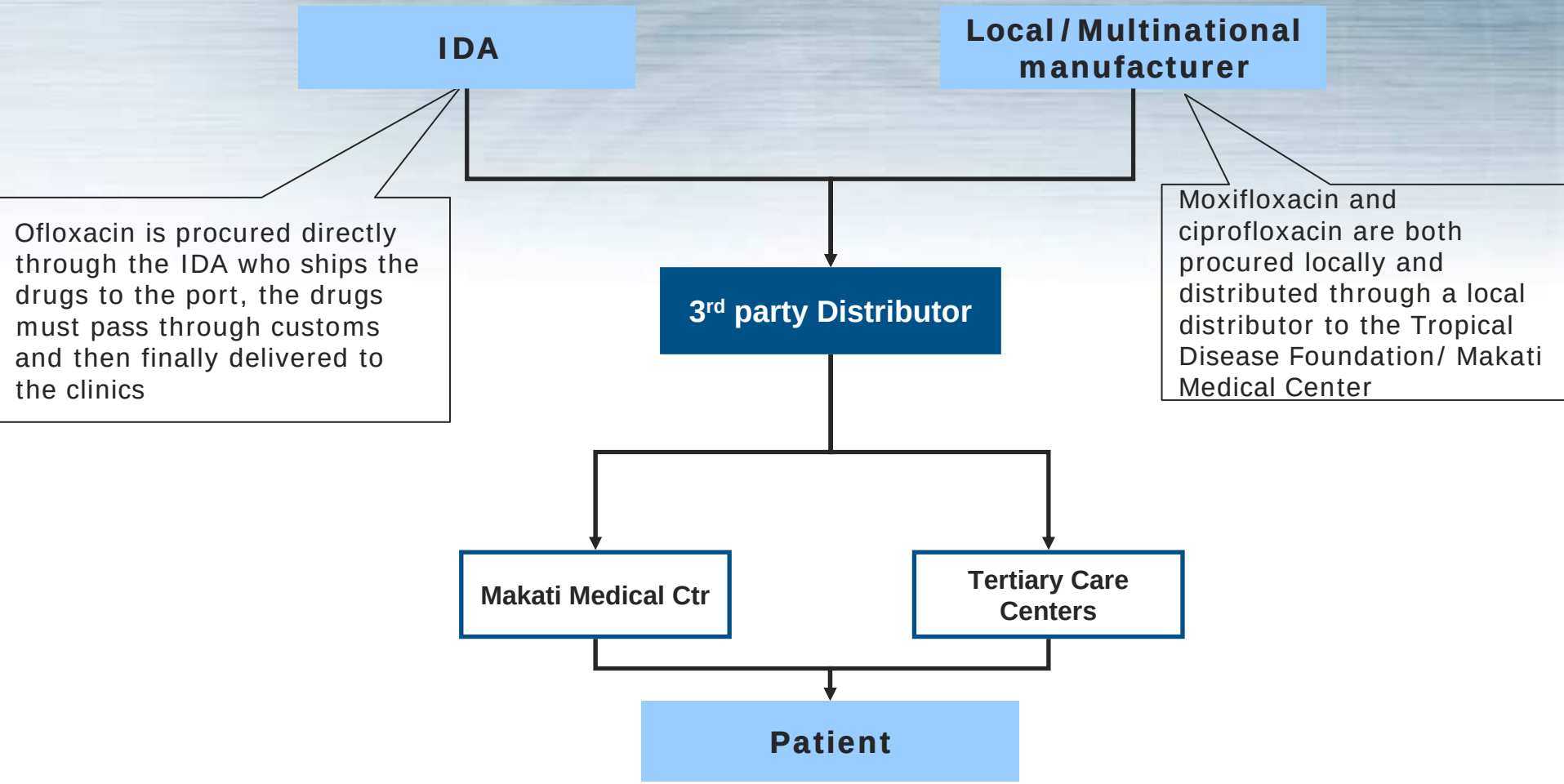
WHO delivers drugs from port to the TDF warehouse via a 3rd party customs broker

Drugs are typically provided at Makati Medical Center DOTS+ Clinic (daily)

Drugs also delivered to mid-wife for patients at Quezon Institute or Lung Center of the Philippines on a monthly per-patient basis

Source: Cambridge Interviews

However some of the fluoroquinolones are procured through other mechanisms



Source: Cambridge Interviews

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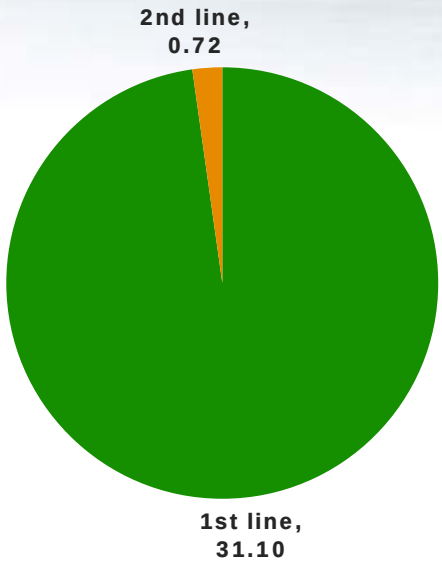
The Philippines TB drug market is valued at 31.2M USD

Total TB Market Value 2005 (Approximately 31.2M USD)



A predominantly 1st Line market:

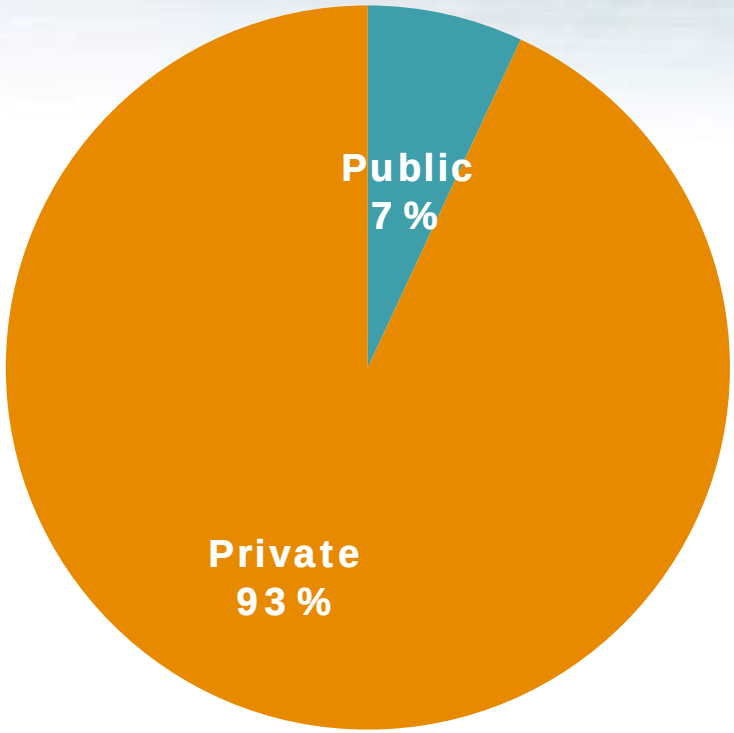
- **1st line market makes up almost 100% of the total market**
- **1st line is driven by sales of FDCs through both the GDF and local manufacturers**
- **Majority of use of 2nd line products are used for indications other than TB, with fluoroquinolones most predominantly used**

**This is based on IMS panel survey data which indicates TB use vs other indications for each product. Qualitative data only based on physician poll.*

Source: MIDAS-IMS retail data; Cambridge analysis; GDF; GLC Report; Interviews

The 1st line market is a total of 31.1 M USD

Total 1st line TB Market Value by Sector 2005 (Approximately 31.1M USD)



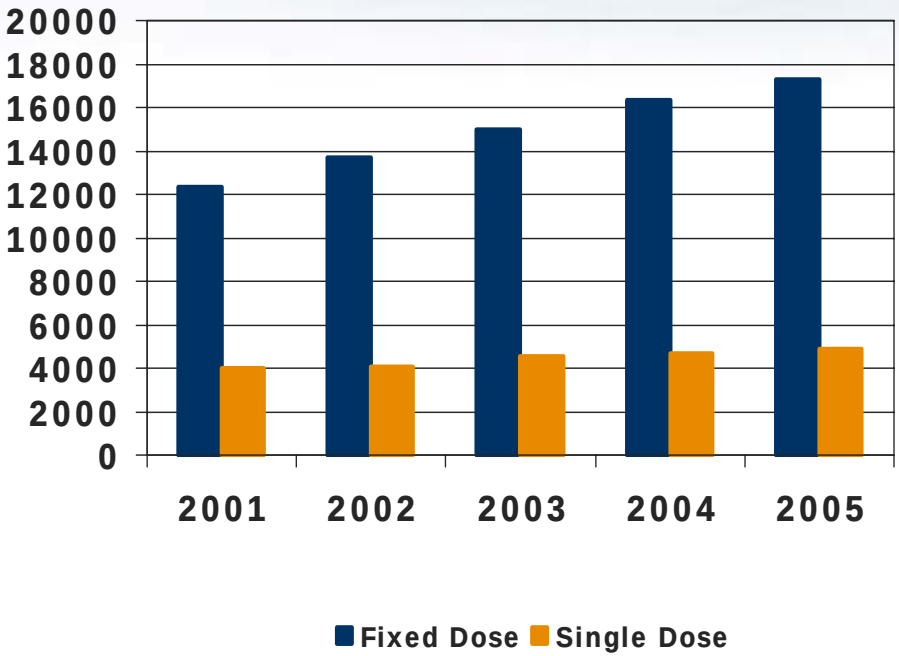
A predominantly private market:

- **Public sales comprise minority of spend at 2.16 M USD**
- **Public spend is primarily for Cat I and II patients as LGUs expected to purchase Cat III drugs; some may be used for Cat III**
- **All 1st line drugs procured by the NTP through the GDF**
- **Private market is highly fragmented and accounts for majority of spend at 28.9 M USD**

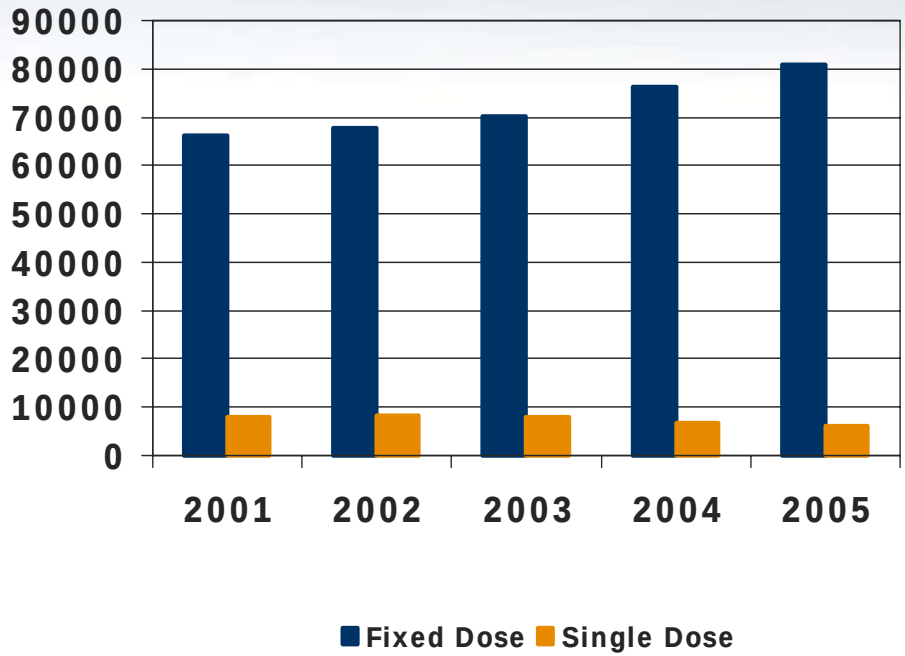
Source: MIDAS-IMS retail data; Cambridge analysis; GDF; GLC Report; Interviews

For the 1st line market, top-line sales figures from IMS indicate local branded manufacturers are driving the 1st line market toward FDCs

Value of 1st line TB Drugs USD (Thousands), FDC vs Single Agent



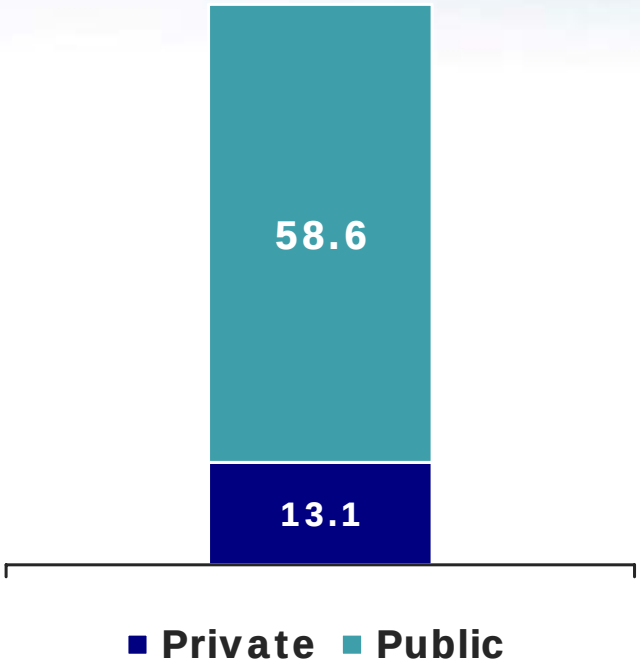
Volume of 1st line TB Drugs Total Units (Thousands), FDC vs Single Agent



Source: MAT-IMS retail data; Cambridge analysis

The 2nd line market is fairly limited, funded through GFATM grants or paid for out-of-pocket

Value of 2nd Line TB Market: Private vs. Public Sector (total approximately 72 thousand USD)



Public Sector

- GFATM R2 grant provides for treatment for 50 patients/ year
- Program expected to expand significantly in 2006 through GFATM R 5 grant (expected to treat 2,500 patients total between 2006 and 2010)

Private Sector

- Unknown number of patients consulting with and receiving treatment for TB each year
- Treatment practices vary considerably from physician to physician
- Many are treated initially with 1st line Cat II regimen

Source: MIDAS-IMS retail data; Cambridge analysis; GLC Report; Interviews

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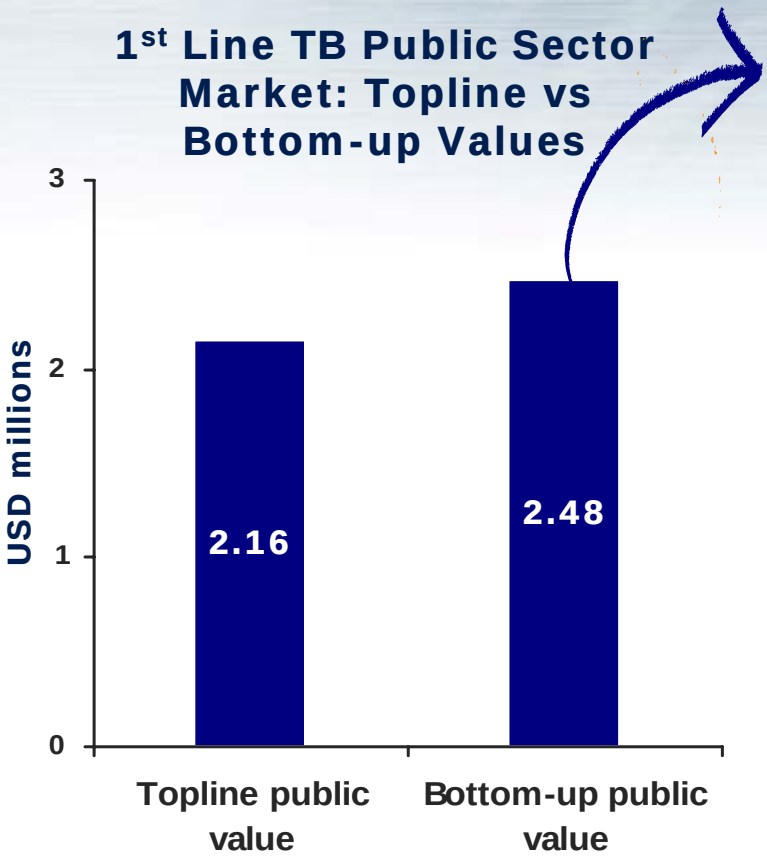
Appendix: Interviewed Stakeholders

Individual	Organization	Position
Dr Rosalind Vianzon	DOH, Office of Infectious Diseases	National TB Program Manager
Dr. Mariano Banzon	PhilHealth	
Dr. Asuncion Anden	DOH Center for Health Development, Metro Manila	Director
Dr. Amelia Medina	DOH Regional Office, Metro Manila	Regional Coordinator for TB Program, National Capital Region (Metro Manila)
Mr. Sergio Villahermosa	Provincial TB Program, Cebu	Supply Officer
Dory C Loquias	Provincial TB Program, Cebu	Provincial Coordinator for TB Program
Dr. Fulgencia Ricero	DOH, Batangas City	
Ms. Leticia Rivera	Provincial TB Program, Batangas City	Provincial Coordinator for TB Program
Dr. Nereza S. Javier, MD., MPH	Provincial TB Program, Cavite	Provincial Coordinator for TB Program
Dr Jubert Benedicto, MD	PhilCat	Chairman
Dr Charles Y Yu, MD MSC	PhilTIPS	Senior Advisor
Dr. Marilyn Noval-Gorra	PhilTIPS	Policy and Finance Advisor
Dr. Marilou Costello	PhilTIPS	Health Systems Advisor
Dr. Andre Daniel Villanueva	PhilTIPS	Pharmacy DOTS Initiative- Program Mgr
Jose Hesron D Morfe, MD	PhilTIPS; University of St Thomas Hospital (Private DOTS program)	Physician and DOTS program mgr

Appendix: Interviewed Stakeholders (continued)

Individual	Organization	Position
Dr. John Wong	PhilTIPS; Asian Development Bank Health Sector Development Program	Specialist for Drug Management and Finance
Arlene	University of St Thomas Hospital (Private DOTS program)	DOTS Nurse Coordinator
Dr. Victoria Basa-Dalay	DeLaSalle University (Private DOTS Program)	Chairman TB Research Unit
Dr Ruben Escarda	Visaya Community Medical Center (Private Hospital)	Physician and Dept Chairman of Internal Medicine
	Philippines General Hospital (Public Hospital)	
Michael Arabit	Makati Medical Center	Pharmacist
n/a	National Pharmacy Chain (PDI)	Pharmacist; purchasing manager
n/a	Supplier	Marketing coordinator; general manager
Ms. Marilyn Tiu	Med Express	Purchasing Manager
Mr. Earl Stanley Perez	Watsons Personal Care Stores	Comptroller - Merchandizing Division
Ms. Erlinda Pascual	Drugstores Association of the Philippines	President

Appendix: Our estimates of public sector 1st line drug spending of 2.16M USD are confirmed by both a top down and bottom up calculation



	Cat I	Cat II	Cat III
Total patients treated in the public sector	135,488		
%age per category**	60%	3%	37%
Patients per category	80,639	4,046	50,803
Price of treatment per patient (USD)*	17.89	32.50	17.89
Cost per category	1,442,632	131,495	908,865
Public Sector Value (USD)	**2,482,992**		

*See appendix for calculations of prices
**Based on figures indicated in NTP reports to and Interviews

Note: Includes 1st line drugs that may be used in 2nd line treatment of patient

Source: MIDAS-IMS stockist and retail data; Cambridge analysis; GDF; GLC Report; Interviews

Appendix: Starting in 2004, fixed dose combinations became an integral part of the recommended regimen

Drug	FDC-A 4-Drug FDC (HRZE)	FDC-B 2-drug (HR)
Rifampicin (R)	150 mg	150 mg
INH (H)	75 mg	75 mg
PZA (Z)	400 mg	
Ethambutol (E)	275 mg	

Drug	Dose per kg body weight and maximum dose
Rifampicin (R)	5 (4-6) mg/kg, and **not** to exceed 400 mg daily
INH (H)	10 (8-12) mg/kg, and **not** to exceed 600 mg daily
PZA (Z)	25 (20-30) mg/kg, and **not** to exceed 2 g daily
Ethambutol (E)	15 (15-20) mg/kg, and **not** to exceed 1.2 g daily
Streptomycin (S)	15 (12-18) mg/kg, and **not** to exceed 1 g daily

All staff are required to undergo training on the use of FDC before distributing the medications

NTP provides training workshops for all DOTS staff interested

Source: Comprehensive and Unified Policy for TB Control in the Philippines; March 2003

Appendix: Price per Patient Calculations, Public 1st line

Public Sector 1st Line Calculations – Bottom Up Approach using GDF Values

Patient Type	# of patients	%		
			$17.89	$1,442,631.71
Relapse	4,046.00	3%	$32.5	$131,495.00
Smear -	50,803.00	37%	$17.89	$908,865.67
Total	**135,488.00**	**100%**		**$ 2,482,992.38**

*Cat 1: Myrin- 12.15P per pill
Cat 2: Typically twice the cost of Cat 1
Cat 3: Same as Cat 1

Source: Cambridge interviews, MOH data

Appendix: Price per Patient Calculations, Private 1st line

Private Sector 1st Line Calculations – Bottom-Up Approach using Myrin and Myrin P*

Intensive	Cost per pill Pesos (Myrin)*	Pills per day	Days per week	Weeks per month	# of months	Pesos-Intensive Phase
Cat I	12.15	5	7	4	2	3402
Cat II	24.3	5	7	4	2	6804
Cat III	12.15	5	7	4	2	3402

Continuation	Cost per pill Pesos (Myrin)	Pills per day	Days per week	Weeks per month	# of months	Pesos-Continuation Phase	Total cost per Patient (Pesos)	Total cost per patient (USD)	Total Value
Cat I	8	5	7	4	4	4480	7882	$148	$5,353,821
Cat II	16	5	7	4	5	11200	18004	$338	$9,171,866
Cat III	8	5	7	4	4	4480	7882	$148	$4,015,366
								Total	**$18,541,052**

*Cat 1: Myrin- 12.15P per pill
Cat 2: Typically twice the cost of Cat 1
Cat 3: Same as Cat 1

Source: Cambridge interviews, MOH data

Appendix: Public Sector 2nd Line through GLC

	Quantity Delivered	Total Cost USD
Cycloserine	185,100	21208.04
Kanamycin	12350	3648.19
Ofloxacin	59900	1779.03
PAS	14550	17256.3
Protionamide	145900	14677.54
		58569.1

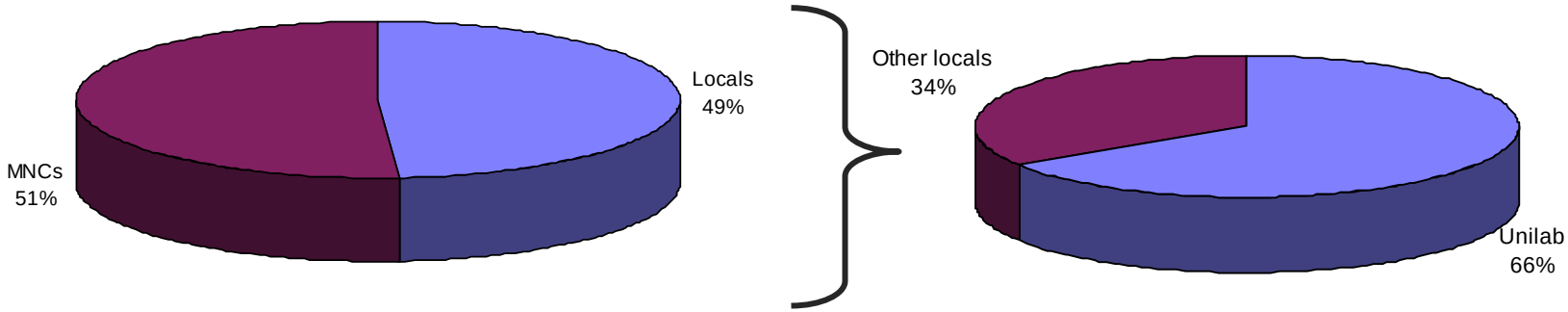
Source: GLC

Appendix: Private Sector 2nd Line

Drug	% of market share used for TB	Total value of market for all indications	Actual value of drug for TB
CIPROFLOXACIN	0.052%	10,692,184	$5,560
OFLOXACIN	0.023%	8,545,398	$1,965
CLARITHROMYCIN	0.043%	7,233,548	$3,110
LEVOFLOXACIN	0.023%	5,184,967	$1,193
AMIKACIN	0.023%	1,777,234	$409
MOXIFLOXACIN	0.023%	2,247,750	$517
GATIFLOXACIN	0.023%	1,243,952	$286
STREPTOMYCIN	0.043%	115,460	$50
		$37,040,493	$13,090

Source: IMS MIDAS retail data

Appendix: Private market players for TB (local vs MNCs)



- The branded segment is evenly split between the local manufacturers and MNCs
- Local companies have enough leverage in regulating prices
- Yet, market still allows a wide price band between MNC and local branded pricing.

- Unilab, is the biggest local manufacturer of branded generics.
- Own almost three quarters of the local TB branded business with 5 companies marketing various anti-TB drugs.
- Unilab's pricing is generally 40%-50% lower than MNCs.

Source: IMS MIDAS retail data

Appendix: The cost of TB products in the private sector

	Drug	Manufacturer	Dose	Cost per pill (USD)
1st Line	Myrin P	Wyeth	HRZE	0.23
	Myrin	Wyeth	HRE	0.18
	Tritab	Unilab	HRE	0.20
	Quadtab	Unilab	HRZE	0.18
2nd Line	Ciprofloxacin	Local	300 mg	0.34-1.50
	Clarithromycin	Local	300 mg	1.88

Source: IMS MIDAS retail data

Appendix: Wide variations in TB prescribing in private sector

- Private physicians adhering to the WHO recommended guidelines in TB management is alarmingly low.
- Lack of enablers and incentive to mandate adherence contributes to physicians individualized TB management.
- Effect on MDR due to inadequate and erroneous disease management has yet to be determined.

Disease Category	%Private Physicians Compliant with WHO Guidelines	No. of Regimen Variants
I	**16**	
New Smear positive case of TB	21	21
Seriously ill TB Case	14	25
Smear (-) but w / extensive parenchymal involvement on XR	12	27
Extra Pulmonary TC	17	27
II	**10**	**37**
Failure Case	0	27
Relapse Case	16	22
Smear + after 5 mos. of treatment	17	
III		
Smear (-) but with minimal PTB on CXR	30	21
MDR TB Case		17

Source: IMS MIDAS retail data

Appendix: 12 leading branded manufacturers account for 96% of the TB market, only 3 of which are MNCs

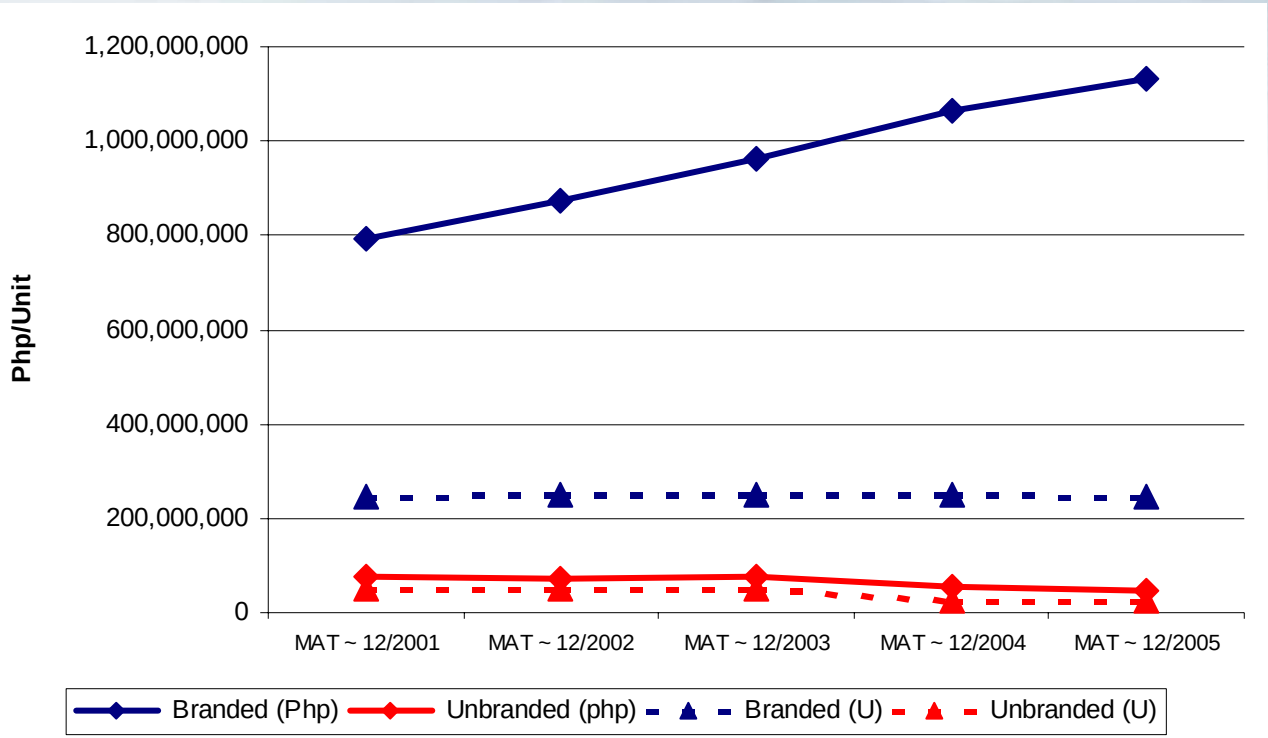
Top 12 TB Manufacturers (MAT Dec-05)				
Rank		PESOS	% Share	Growth vs. LY
	TB MARKET	1,179,200,484	100.00	5.52
	Branded	1,130,615,988	95.88	6.43
1	WYETH PHILIPPINES	366,300,914	32.40	0.48
2	SANDOZ	181,164,551	16.02	5.80
3	MEDICHEM PHARM *	174,202,500	15.41	88.98
4	PEDIATRICA LAB *	171,140,702	15.14	41.04
5	NATRAPHARM	108,042,795	9.56	24.13
6	PASCUAL LABS	65,430,577	5.79	-22.87
7	DUNCAN PHARM PHIL	30,013,128	2.65	-66.88
8	WESTMONT *	13,916,628	1.23	-27.97
9	TERRAMEDIC INC	12,515,743	1.11	2.76
10	BIOMEDIS *	3,145,863	0.28	22.06
11	PATRIOT PHARMA	2,550,311	0.23	2.60
12	UNITED AMERICAN *	1,210,320	0.11	-89.57

Branded generics from local manufacturers drive market growth.

- Market growth drivers are Unilab affiliates (branded generics) with Medichem and Pediatrica posting the highest growth rates.
- Growth of the top 2 MNCs, Wyeth and Sandoz, has slowed down – they posted below market growth and is extremely challenged by Unilab.

Source: IMS MIDAS retail data
* in red, Unilab group of companies

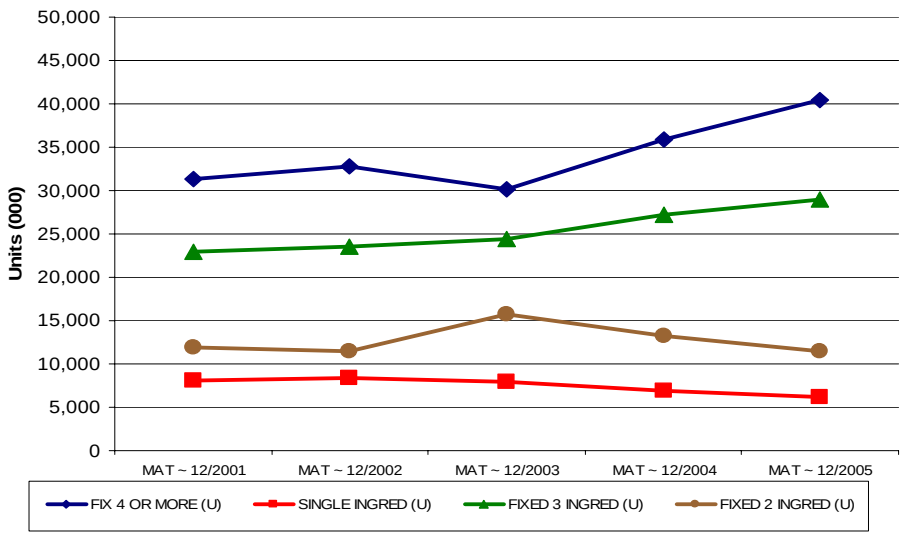
Appendix: Branded drugs dominate the TB market (private or LGU procured)



- The TB market posted a modest growth of 5.5% MAT Dec-05 and a 5-Yr. CAGR of 6.3%
- Driving the growth are branded drugs which comprise almost 96% of TB medication
- Unbranded Generics declined in both value and unit performance

Source: IMS MIDAS retail data

Appendix: MNCs and local branded generic manufacturers have successfully driven the trend towards FDCs



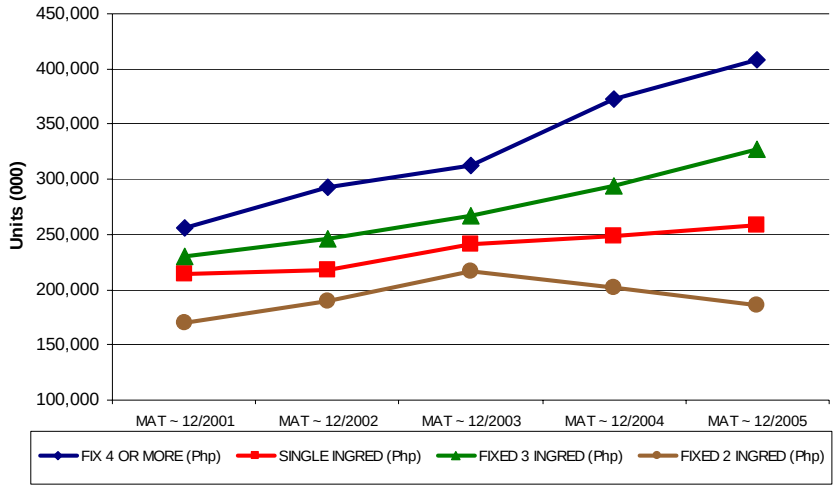
- 4-drug regimen has grown steadily in both in units and value in the last 5 years.

The 3-drug regimen posted modest but consistent growth in value and units over the last 5 years.

- Inspite of numerous players, there is an absence of unbranded generics in the 3-drug regimen.
- With 33% of the market, the 3 and 4 drug regimen account for almost 80% of the TB market

- While the single drug regimen posted a growth in value, it declined in units.

- The 2-drug therapy has declined in both value and units in the last couple of years.
- Similar to the single drug regimen, decline may be influenced by the government's treatment recommendation and manufactures efforts towards combination therapy (3 or more drugs).



Source: IMS MIDAS retail data

TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

Appendix: Health care workers involved in DOTS implementation

Title	Role
Public Health Nurses	Train health workers; maintain and update NTP register; supervise RHMs and ensure proper implementation of DOTS; assign and supervise treatment partners; manage case-finding and facilitate requisition and distribution of drugs/supplies; prepare, analyze, and submit Quarterly Reports to PHO/CHO
Rural Health Midwives	Important roles in implementing case finding activities; referrals of TB symptomatics; maintaining and updating treatment cards; implementing DOTS; providing continuous education; report and retrieve defaulters; and supervising BHW's to ensure proper implementation of DOTS
Medical Technologists/ NTP Microscopists	Perform sputum smear exams diagnosis and follow-up; submit results to MHO, PHN, and RHM; prepare Quarterly Report on Laboratory activities; and maintain NTP register
Barangay Health Workers	Voluntary workers who are integral to implementation of DOTS as treatment partners, including referrals, treatment, and reporting and retrieving defaulters; maintaining up to date NTP ID cards; and educating patient, family members, and community

Source: Comprehensive and Unified Policy for TB Control in the Philippines

Appendix: Types of hospital settings

	Financial obligations	Public/ Private Association	Drugs available on formulary	Comments
University Hospital	Fiscally autonomous	Private - Required to devote 10% of their capacity to public sector patients	Allowed to expand beyond PNDF	NA
Public Hospital/ Health Center	Any additional revenue earned through private out-of-pocket must be returned to national treasury	Many large public facilities provide private wards as supplemental income sources- treatment quality higher and drugs are branded	Generally restricted to essential drug list on PNDF and generics (larger hospitals tend to expand)	Tend to face shortages of equipment, drugs, and medical personnel Drug dispensing for public patients is typically from retail pharmacy
Tertiary Care Center	Any additional revenue earned through private out-of-pocket must be returned to national treasury	Public- provides specialty services	Allowed to expand beyond PNDF	Some have established private pharmacies on premise to expand formulary and increase income
DOH Hospital	DOH retains financial and administrative responsibility	Public, but tends to have higher standards and quality of care than regular public facilities	Restricted to essential drug list on PNDF	Currently receive parallel import drugs of 80 essential meds through the Philippine Intl. Trading Co.
Private Facility	Fiscally autonomous ~ 2/3rds of revenue is generated by out-of-pocket	Private - Required to devote 10% of their capacity to public sector patients	Expands beyond PDNF however these tend to markup prices up to 30%	Although treating public patients, these wards tend to be overcrowded, poor quality service, and distributing generic forms of drugs

Source: IMS Philippine Market Profile

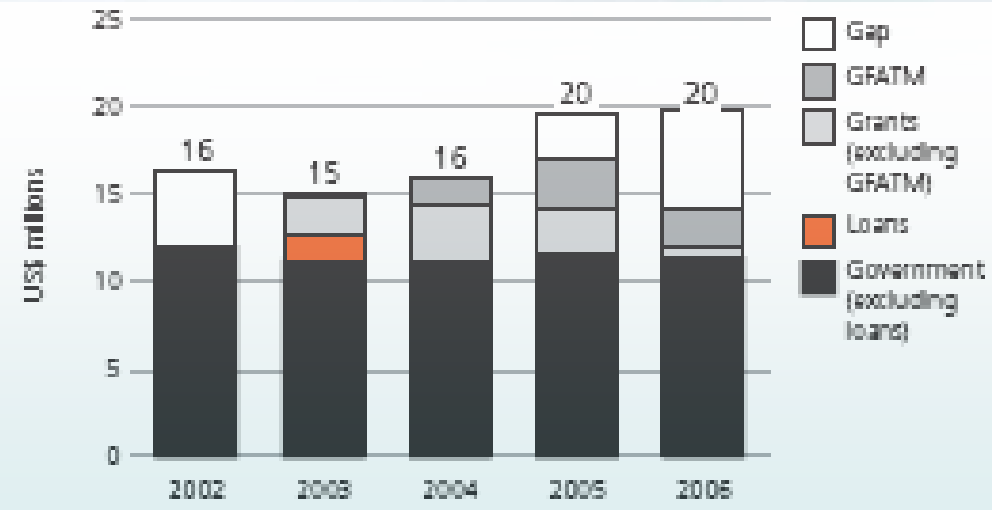
Appendix: Funding

Year	Loans (cases)			Total
	GFATM	GDF	SEMP 2 (World Bank)	
2003	NA	5,000	NA	5,000
2004	NA	16,000	150,000	166,000
2005	NA	50,000	300,000	350,000
2006	50,000	NA	NA	50,000
2007	50,000	NA	NA	50,000
Total	**100,000**	**71,000**	**450,000**	**621,000**

Source: USAID- Toward an Enabling TB Policy Environment; A policy Analysis of Private Sector Participants in TB DOTS

Appendix: DOH Budget and funding

NTP Budget by line item 2002-2006



- Philippine Government finances its NTP through the annual budgeting process under the General Appropriations Act (GAA)
- TB drugs are sourced as a budget line item from the Office of Secretary, DOH National TB Program
- NTP annual budget for 2005 was US $20 MM and did not increase for the year 2006
- Without additional contribution from government funding and with a lack of additional grants established, the Philippines are facing a huge funding gap for 2006 and beyond

Source: Global TB Control: WHO Report 2006

Appendix: There are multiple funding sources for local facilities and health departments including NGOS

NGOs

- Wide range of NGO's provide non-for-profit services
- Monetary resources are sourced through donor organizations, fundraising, or internally generated funds
- NGO's roles of TB treatment and control vary including:
  - Funding
  - Provision of treatment facilities/treatment capability
  - Provision training for other health practitioners
  - Provision of drug access and equipment for TB treatment

Partner Funds

- Mother hospitals provide funding and assistance to small clinics unable to support themselves
- Private PPMDs have issues sustaining facility with limited reimbursement
- These PPMD facilities supported by variety of sources:
  - Corporate responsibility funds
  - Major universities who provide additional resources
  - Private donor funds

Source: Synthesis of the PhilCAT Strategic and Organizational Development and Sustainability Planning Technical Assistance

Appendix: Insurance benefit expansion for TB patients

Benefit Policy	Implemented	Provisions for TB Patients
Disability and Sickness-Income Benefit for Government Workers (GSIS)	**1997**	Provides Initial Temporary Total TB Disability (TB Sickness) Benefit of 30 days to qualified members diagnosed with TB disease
Disability and Sickness-Income Benefit for Workers in the Private Sector (SSS)	**1997**	Provides Initial Temporary Total TB Disability (TB Sickness) Benefit of 30 days to qualified members diagnosed with TB disease
Employees' Compensation program (SSS-ECC)	**1998**	Provides Benefit to be given in the form of income benefit and reimbursement of medical expenses to qualified GSIS/SSS members diagnosed with work-connected TB disease
PhilHealth TB Out-patient Benefit Package (PHIC)	**2003**	Expansion of the basic health insurance to include an out-patient benefit package to eligible members with TB

Source: USAID- Toward an Enabling TB Policy Environment; A policy Analysis of Private Sector Participants in TB DOTS