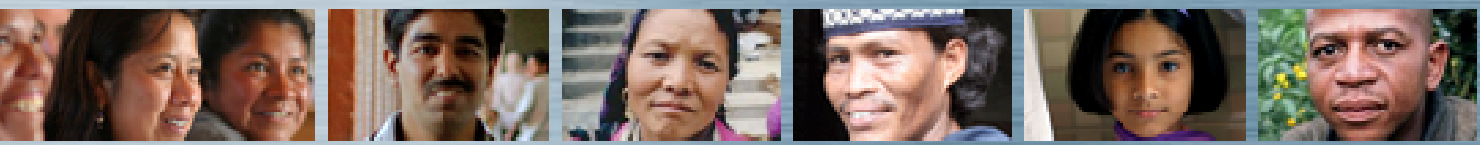
TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

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

India Case Study



Prepared with IMS Consulting

November 2006

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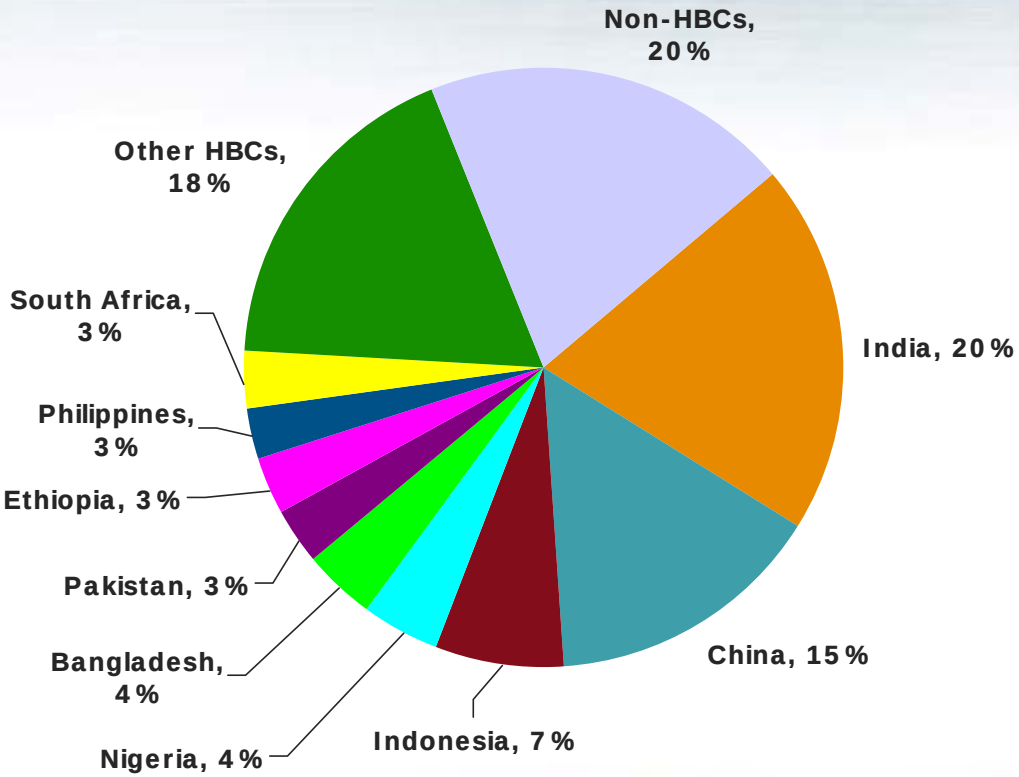
As the country with the highest TB burden, India accounts for approximately one-fifth of the new global TB cases

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



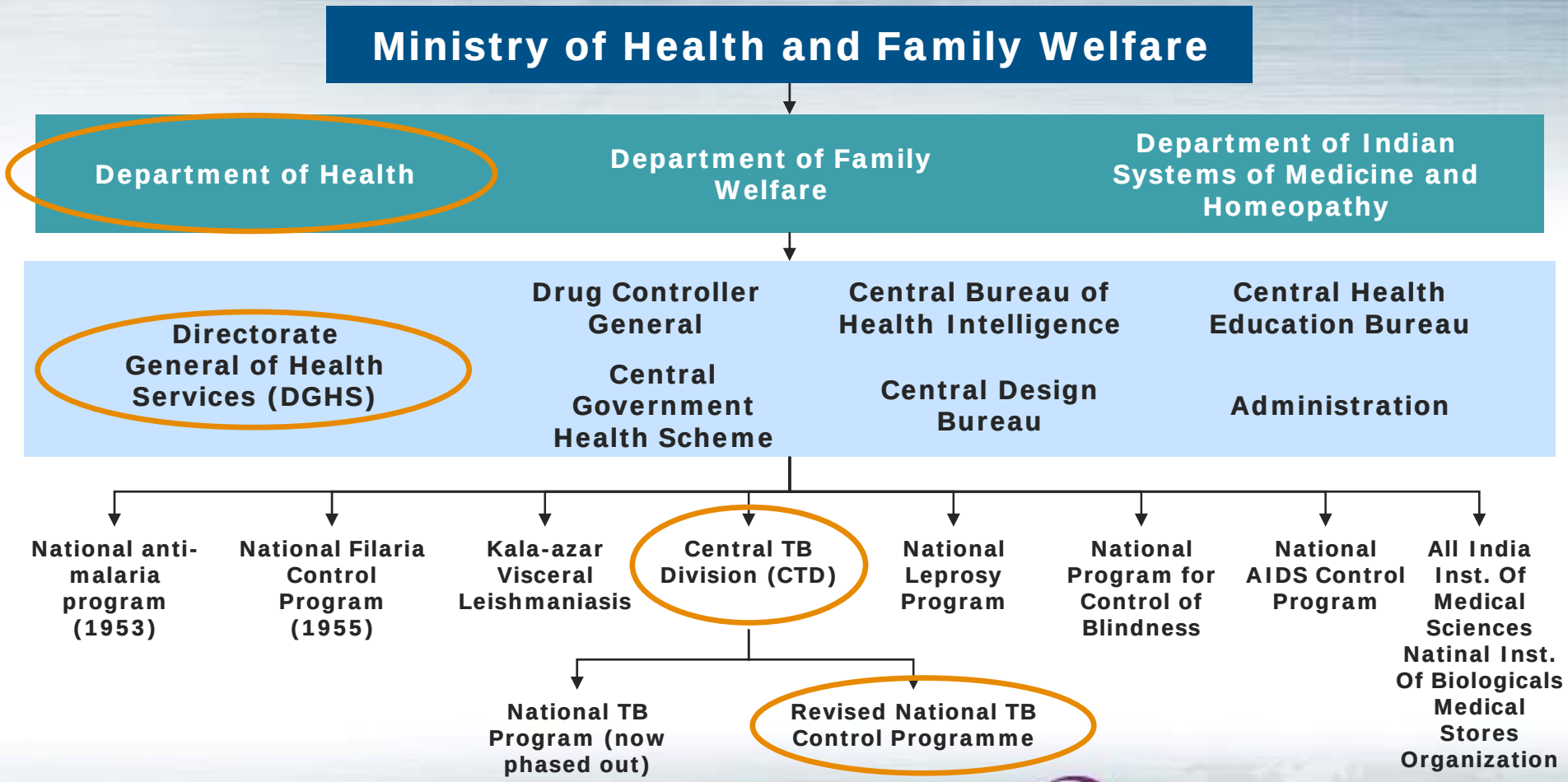
- **According to the WHO and RNTCP:**
- ~40% of adult population infected with *M.tb,* 10% of which will develop TB disease
- 1.8M new cases per year, ~0.8M of which are infectious
- Large impact on families
  - ~70% TB patients between 15-44yrs
  - 3-4 months work time/annual income lost
  - >300,000 children leave school because of parents with TB
- Kills more women than all causes of maternal mortality combined
- Great social stigma particularly for women

Source: WHO Geneva; WHO Report 2005: Global Tuberculosis Control; Surveillance, Planning, and Financing

The Revised National TB Control Program (RNTCP) is the keystone of the Government of India's efforts to control TB through the public sector

- **Formally launched in 1997 by the Central Government, using a loan from the World Bank**
- **Precursor is the National TB Program, which was started decades ago and is now phased out**
- **Implements and expands DOTS strategy across India utilizing**
  - **A network of laboratories designated to perform sputum smear microscopy**
  - **Public healthcare facilities**
  - **Partnerships with private healthcare providers**

The RNTCP falls under the responsibility of the Department of Health and the Directorate of General Health Services of India



Source: TB Drug Markets: India; Interviews

The program is administered via five different levels

Level of RNTCP	Description of Responsibilities
Central TB Division	• *Sets strategies and guidelines* • *Allocates funding* • *Procures drugs*
State TB Office	• *Responsible for planning, training, supervising, and monitoring program in respective states*
District TB Office	• *Overall responsibility of physical and financial management* • *Approximately 630 districts in the whole of India*
Sub-district / TB Unit (TU)	• *Approximately one per 500,000 population (250,000 in tribal or difficult areas)* • *Staffed by of one senior treatment supervisor (STS) and one senior TB laboratory supervisor (STLS)*
Peripheral Health Institution (PHI)*	• *Diagnose and deliver treatment to patients*

Responsible for decisions around drug procurement

*Majority of PHIs delivering RNTCP services are general health service facilities

Source: WHO-India website; RNTCP website

It is also supported by WHO technical consultants who work with the RNTCP in a variety of roles

	Number of WHO staff and types of support offered
Strategy	• Two national level staff • Assist in the development of strategic initiatives, revision of technical guidelines and training modules for RNTCP staff
Public-Private Mix (PPM) DOTS activities	• One national staff and 14 field consultants dedicated exclusively to RNTCP PPM DOTS activities • Help to recruit, train, and oversee PPM providers
Technical assistance *(including surveillance of drugs and logistics management)*	• 121 field consultants • Provide technical assistance to district and state TB officers • Report to CTD monthly on activities of states and districts • Alert CTD of potential drug shortages

Source: Interviews; WHO-India website

The RNTCP program is now in transition from Phase I to Phase II of implementation

Phase I (1993 to 2005)

- **Phasing out of NTP**
- **Initial pilot of DOTS programme through RNTCP**
- **Work towards achieving 100% DOTS coverage**

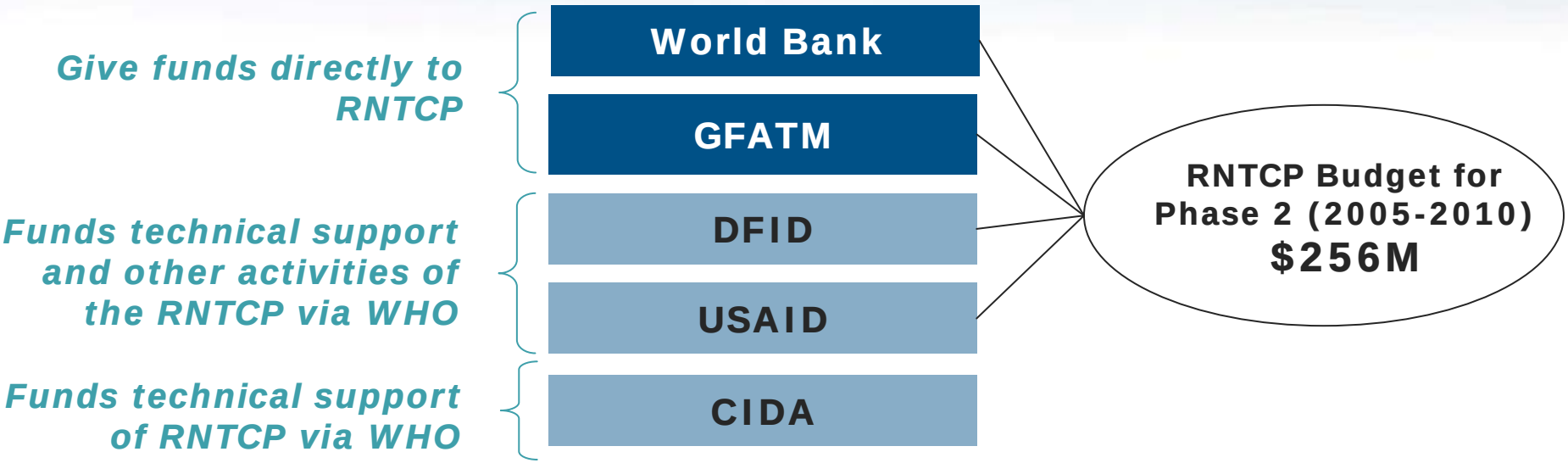
Phase II (October 1 2005 and beyond)

- Continued expansion of DOTS
- DOTS-Plus for MDR-TB
  - Treatment to follow DOTS-Plus guidelines
  - Will only be conducted in limited sites authorized by RNTCP
  - 100 cases will be enrolled in 2007 in two states: Gujarat and Maharashtra
- Paediatric TB
  - Treatment will be supplied in patient-wise boxes
  - Based on child's body weight: four weight bands
    - 6-10 kg; 11-17 kg; 18-25 kg and 26-30kg
    - Children weighing less than 6 kg will be treated with loose anti-TB drugs

Source: RNTCP 2006 Status Report

Its budget is approximately $256M over five years, the funding for which comes from a variety of sources

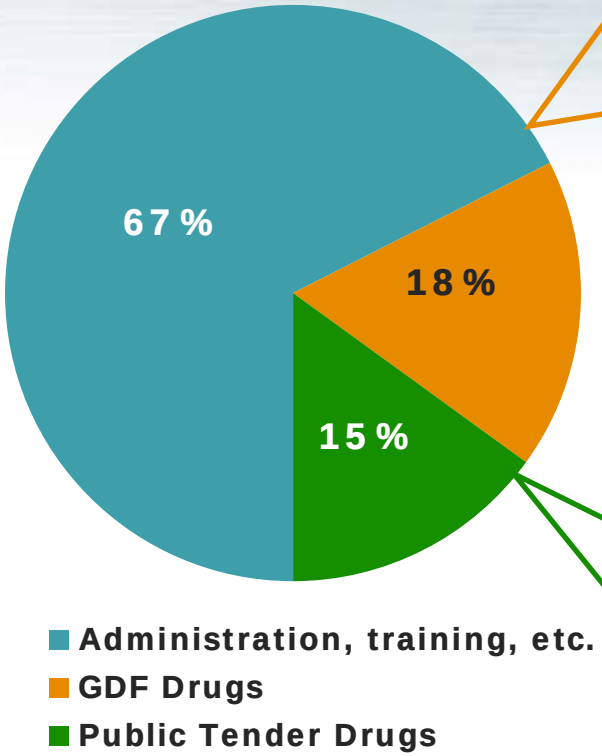
Key Funders of RNTCP (Phase II)



Source: Interviews; RNTCP 2006 Annual Report

Approximately a third of the budget for 2006/7 will be spent on TB drugs

RNTCP Annual Budget (Approx 76M USD)



GDF Drugs:

- **DFID Grant: $63.7M for 2005-2010 (RNTCP Progress Report) all of which is to be used for drug procurement for 500M population**
- **USAID Grant: $6.58M over five years (until 2007) a portion of which used for drugs for 23M population**

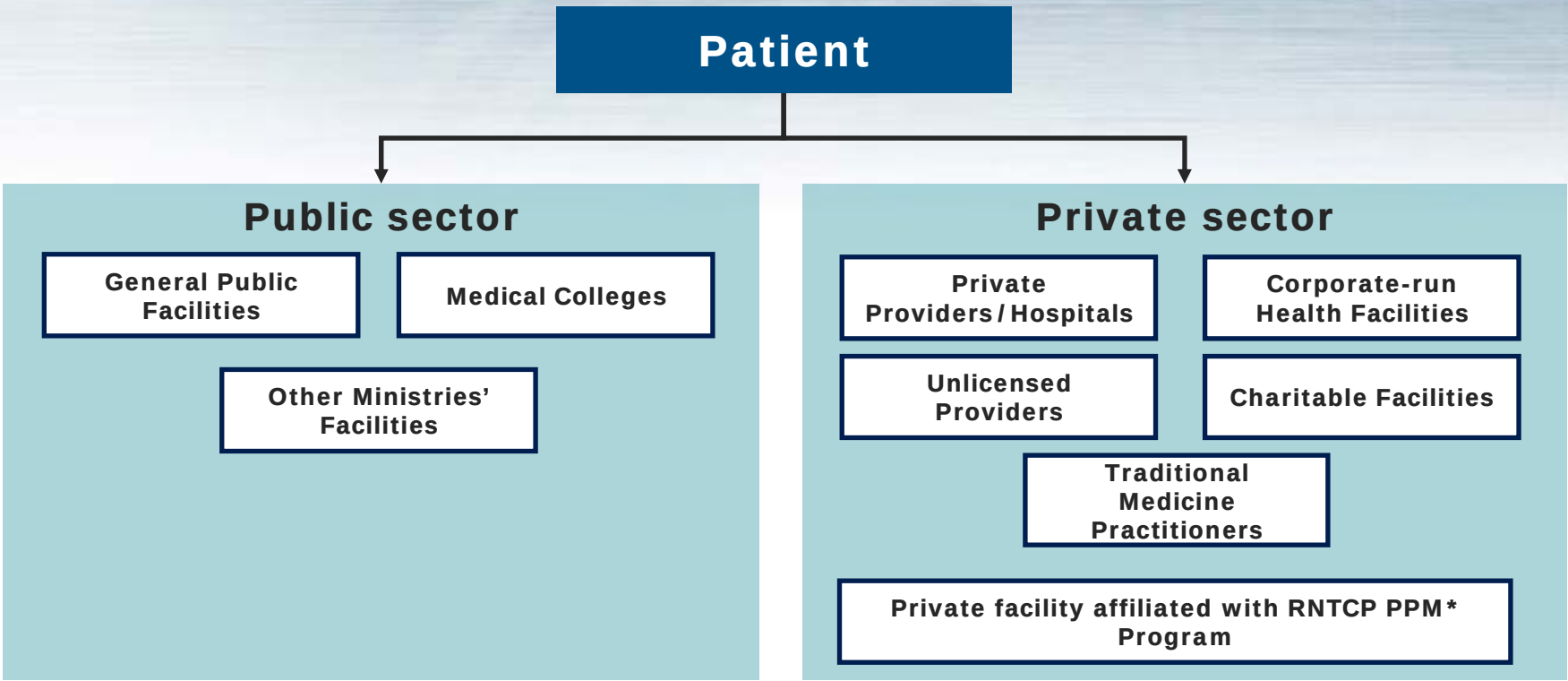
Public Tender Drugs:

- **Funded by GFATM and the Government of India***
- **Estimated by RITES to be 50M Rs= ~$11M per year**

**GoI funds include WB loans; contributions of each source pending outcomes of GFATM application process and final agreement with World Bank*

Source: Interviews; revised overall budget figure for 2006/7 from Katherine Floyd, WHO

TB patients in India have a range of choices of where they can receive treatment



*Public Private Mix

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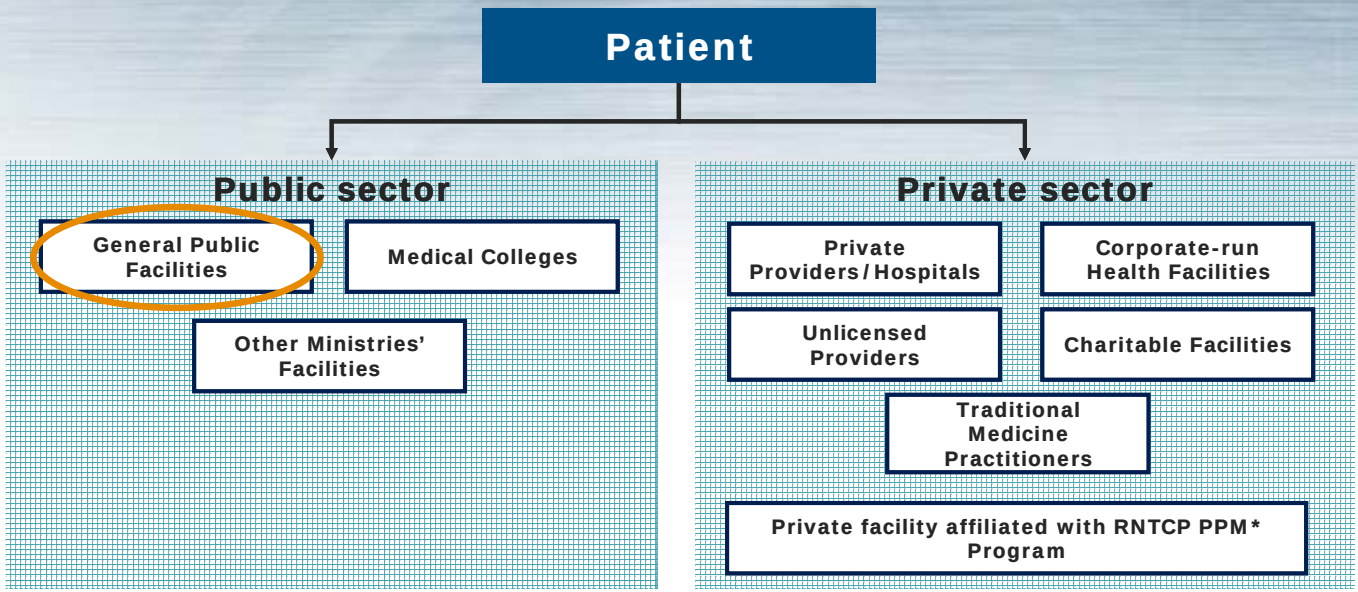
Those that approach the general public sector facilities receive free treatment



- The RNTCP is not a healthcare provider per se—rather its services are provided by the general public health facilities that are open to all of the population
- Facilities includes:
  - General clinics and hospitals
  - Specialized facilities that cater to patients with respiratory ailments or TB specifically

When they approach public sector facility, patients are diagnosed, categorized, and treated according to the RNTCP's guidelines

Consultation

- Patient approaches public health facility for consultation

Diagnosis and Categorization

- Patients who are suspected of having TB are then sent to be tested at one of the RNTCP's Designated Microscopy Centers (DMCs)
- Patients confirmed as having TB are then categorized into one of three categories, according to the sputum test results and their symptoms

Treatment

- Once categorization has been completed, a patient identity and treatment card is filled out
- A TB health visitor makes an initial visit to the patient's home to discuss the treatment program
- The patient begins treatment at the original site of diagnosis
- If the patient lives far from the site of diagnosis, he/she is referred for treatment at their nearest facility providing RNTCP DOT services

Source: TB Drug Markets: India; Interviews

The regimen recommended and used by the RNTCP is a thrice weekly regimen that does not use fixed-dose combinations

RNTCP TB Drug Treatment Regimen

Category	Definition	RNTCP Treatment Regimen	Method of administration
Category I	New smear-positive; seriously ill smear negative; seriously ill extrapulmonary	2 $H_3R_3Z_3E_3$ / 4 H_3R_3	• **No FDCs** • Patient-wise boxes (PWBs) with co-blistered strips of loose drugs*
Category II	Previously treated smear-positive (relapse, failure, treatment after default)	2 $H_3R_3Z_3E_3S_3$ / 1 $H_3R_3Z_3E_3$ / 5 $H_3R_3E_3$	
Category III	New smear-negative; and extrapulmonary, not seriously ill	2 $H_3R_3Z_3$ / 4 H_3R_3	

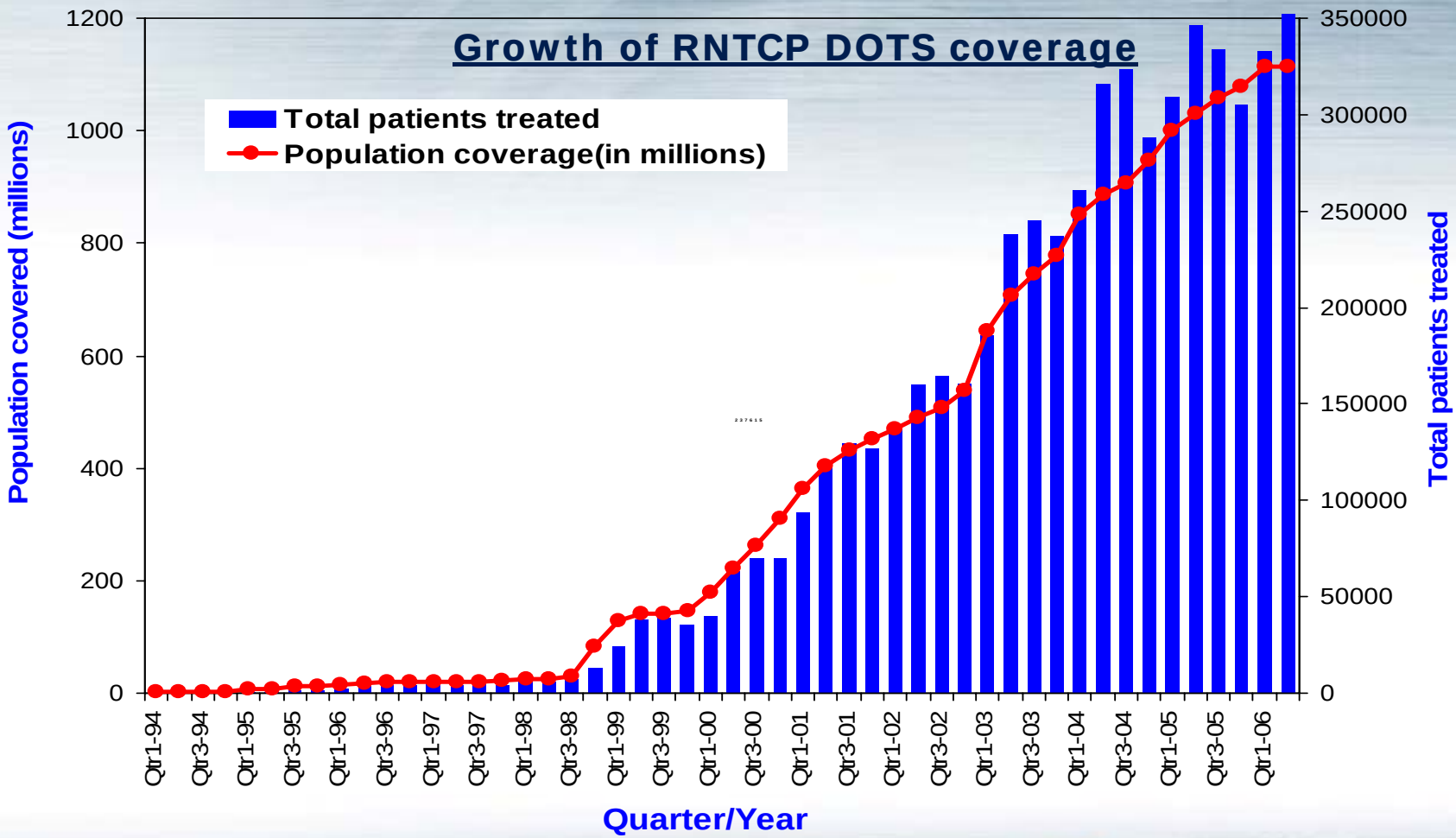
Details on the 1st line Regimen

6-8 month treatment regimen. All treatment thrice weekly. All doses in intensive phase are observed; at least the first dose of each week in the continuation phase is observed. Cat I and Cat II extended one month if smear+ at end of intensive phase.

**Each patient-wise box is manufactured by one supplier*

Source: RNTCP website

In 2005, RNTCP initiated 1.3 million patients on treatment



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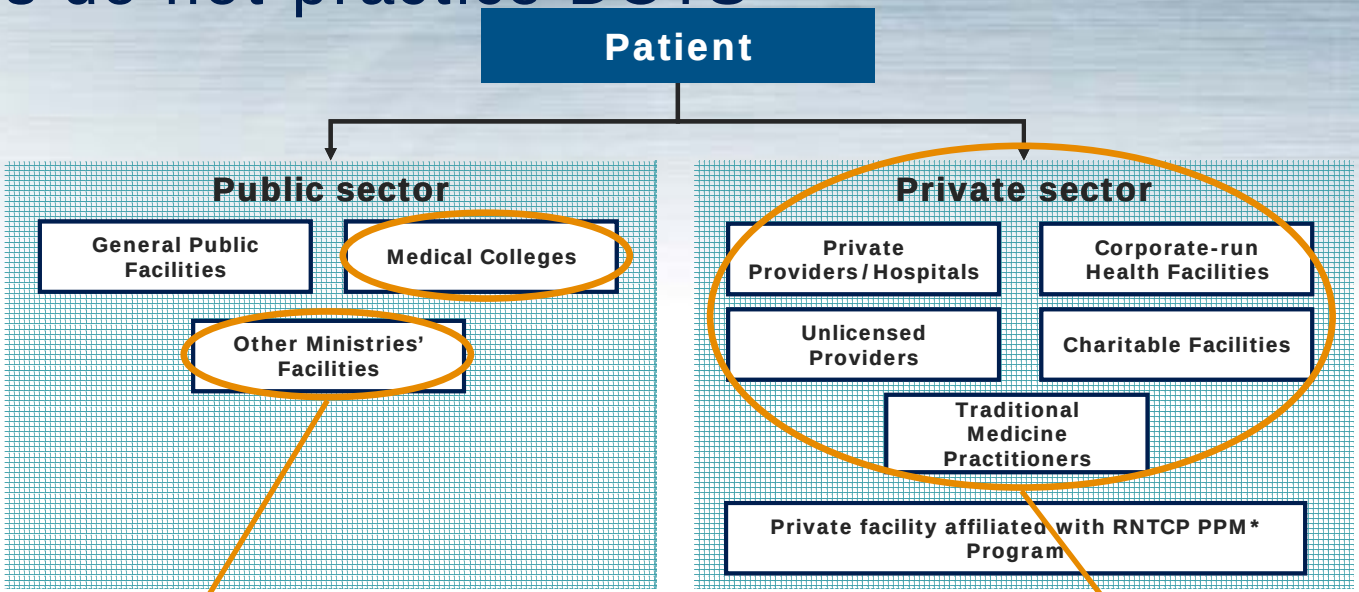
Though efforts are being made to involve them, a number of public sector facilities and many private providers do not practice DOTS

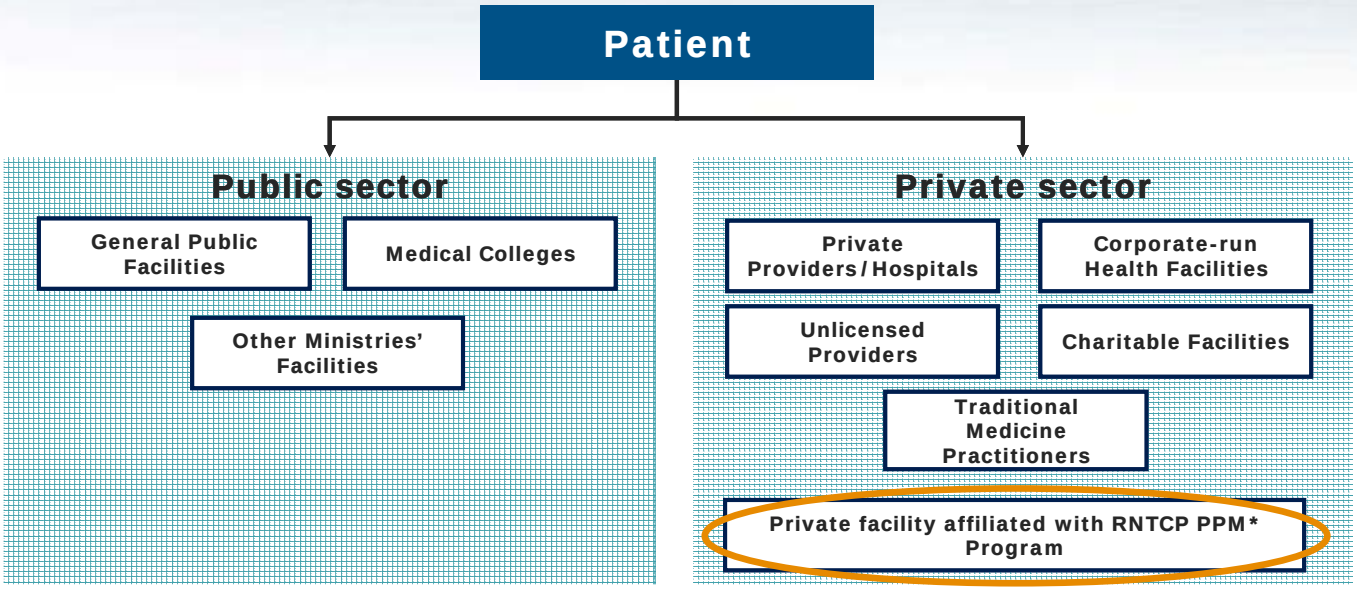


- These facilities include medical colleges and Other Ministries' facilities (for Railway, Defense, etc. employees only)
- Have historically run independently of the public sector's general health services and did not practice DOTS

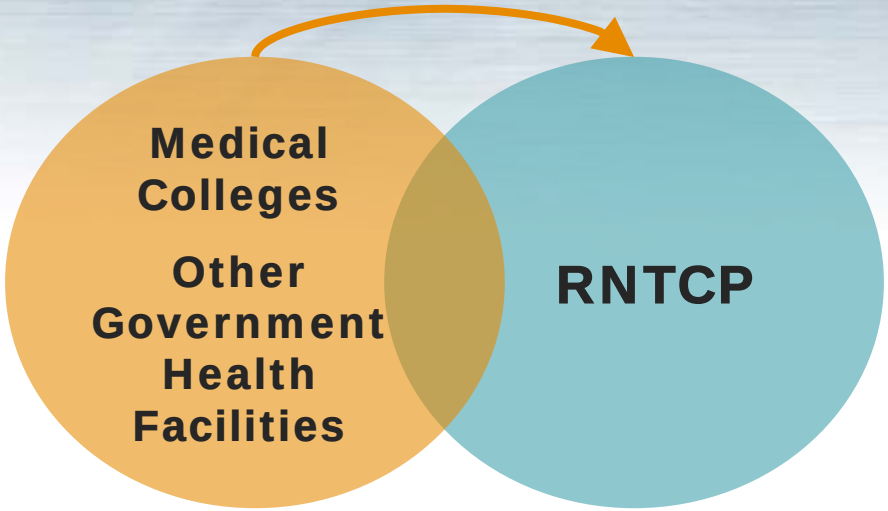
- A highly fragmented sector that accounts for the vast majority of the 500,000 licensed physicians in India and an estimated 1M unlicensed providers
- Oversight of this sector is difficult and practices in TB treatment vary widely

Source: RNTCP 2006 Annual Report; Interviews

In an effort to extend the RNTCP's capacity and scope of influence in the private sector, RNTCP Public-Private Mix (PPM) DOTS activities were launched in 1995



Part of this initiative has focused on unifying the public sector's efforts against TB

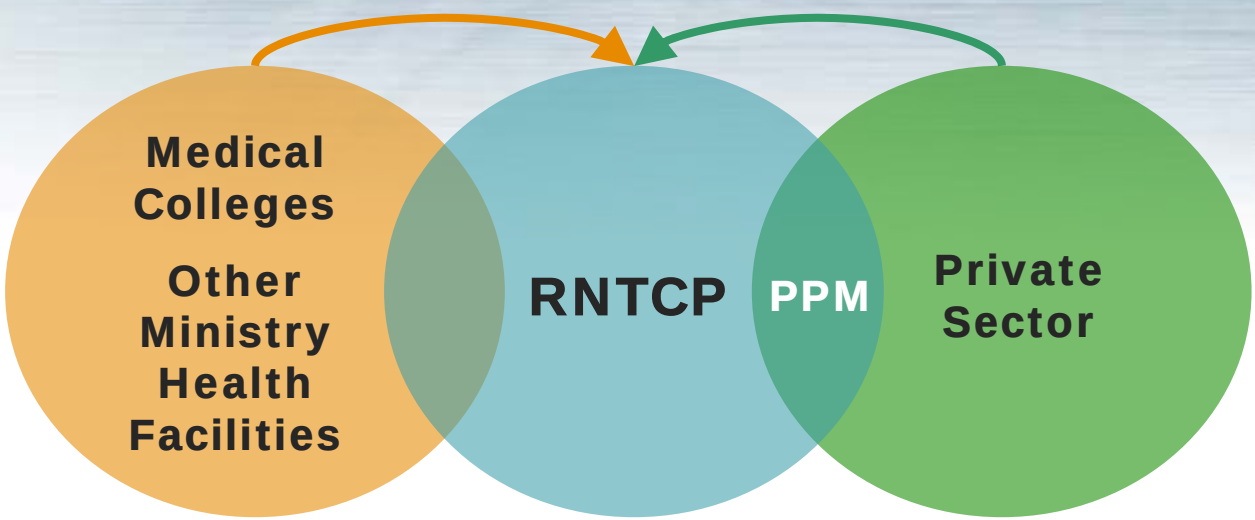


Other public sector facilities

- In recent years, RNTCP task forces have been established to merge treatment of TB in medical colleges with the RNTCP's DOTS programme
- 230 medical colleges are now participating in RNTCP
- Most other government health facilities (non-Ministry of Health) have now begun the process of converting to DOTS and merging their TB treatment practices with those of the RNTCP

Source: WHO-India website; RNTCP 2006 Annual Report; Interviews

The program also creates partnerships with providers in the private sector



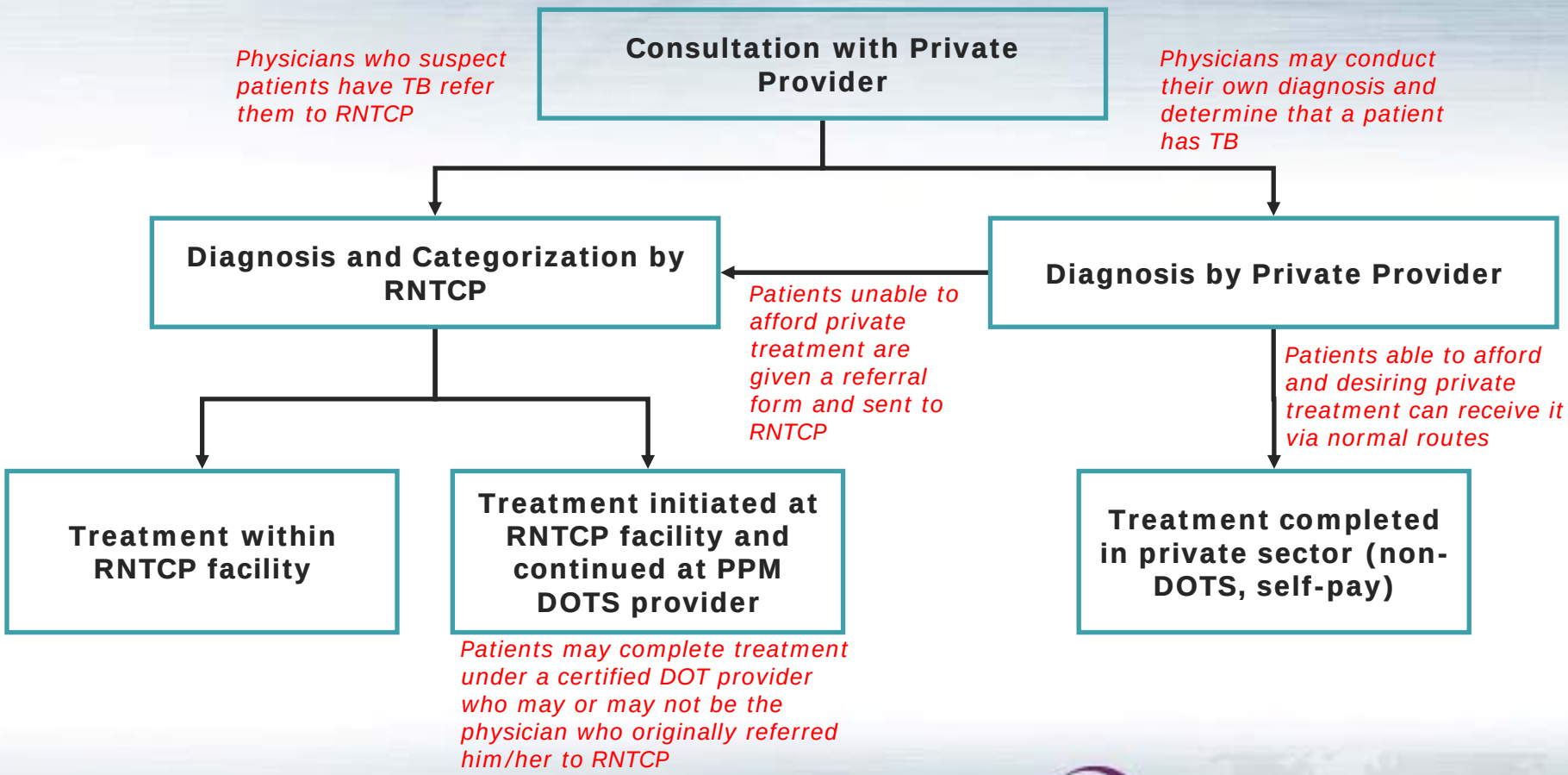
RNTCP PPM DOTS activities

- "Intensified PPM-DOTS" activities was initiated in 14 cities and a modified version is now rolled out in 70 districts
- RNTCP program-wide PPM-DOTS activities currently involve >10,000 private providers, >100 corporate run facilities, and >2000 NGOs—a small fraction of the total healthcare universe in India

Source: WHO-India website; RNTCP 2006 Annual Report; Interviews

Through the partnerships, patients can initially consult with a private provider and yet still be eligible for free DOTS treatment

Patient flow through RNTCP PPM-DOTS



Source: TB Drug Markets: India; RNTCP 2006 Annual Report; Interviews

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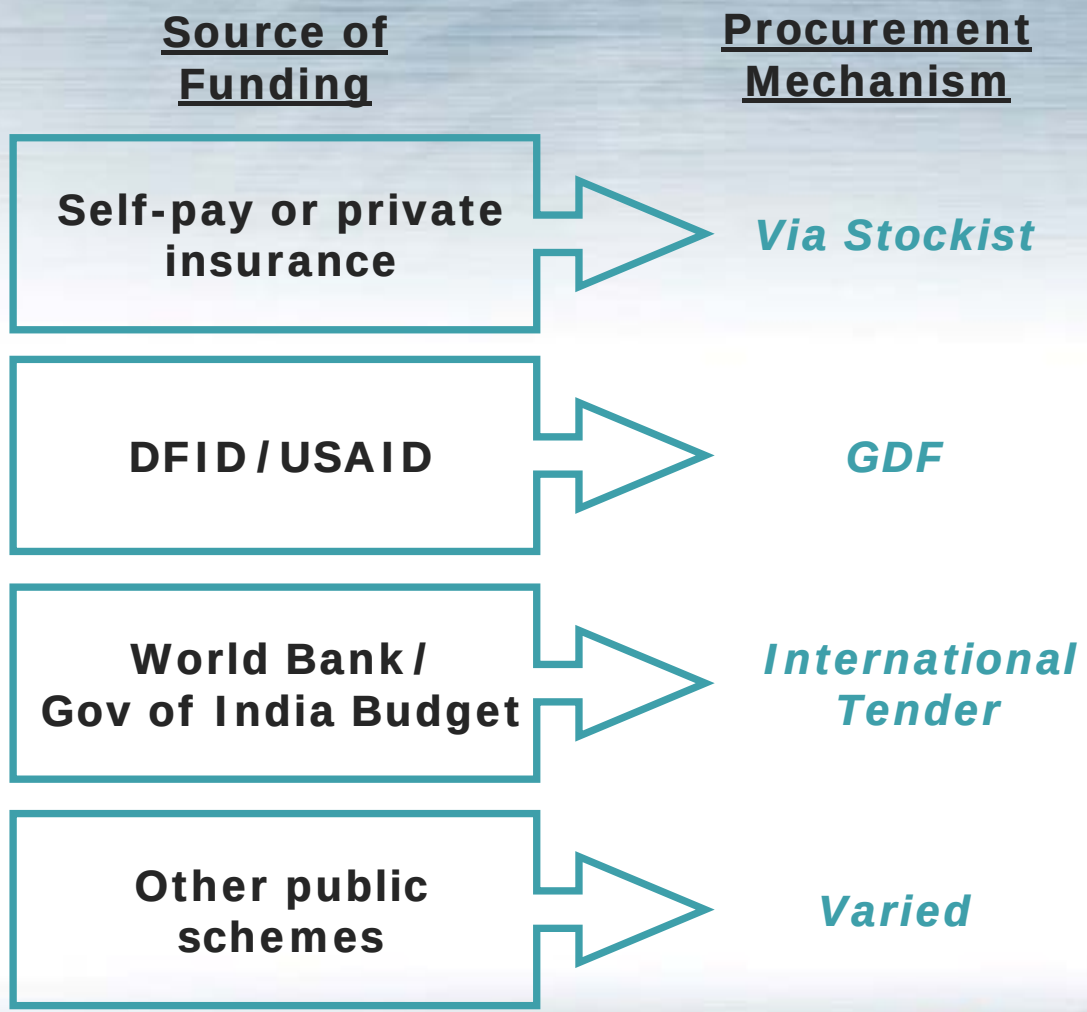
There are four main mechanisms through which TB drugs are supplied in India

Procurement mechanisms

	International Tender	GDF	Direct Negotiations	Via Stockist
Recipients of Drugs procured via mechanism	***Conducted by the RNTCP on behalf of:*** • ***General Public Facilities*** • ***Medical Colleges*** • ***Other Ministries' Facilities*** • ***PPM Partners***		• ***Other public facilities***	• ***Private facilities*** • ***Retail Pharmacies*** • ***Other public facilities***

Source: IMS Pharma PQ Systems; Interviews

Funding drives the procurement mechanism through which TB drugs are purchased



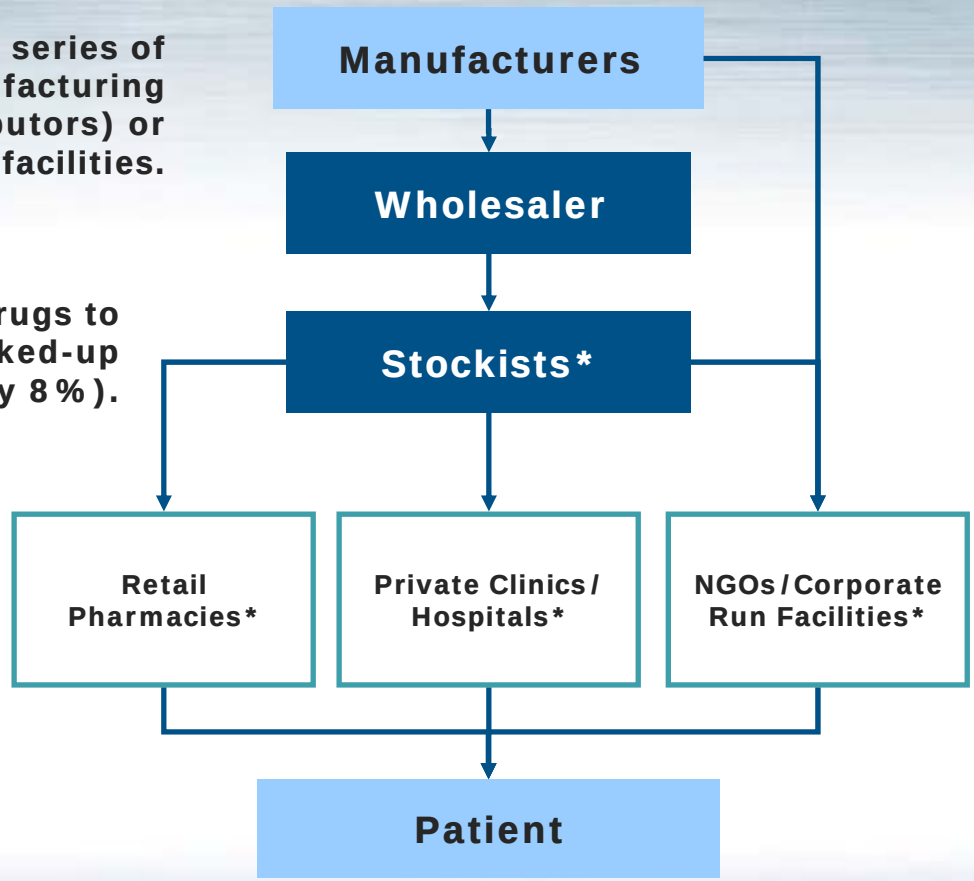
Private sector TB drugs flow through the same routes as do other pharmaceuticals

1st point of sale: Manufacturers work with a series of wholesalers who sell drugs at the ex-manufacturing price to private secondary stockists (distributors) or directly to certain healthcare facilities.

Secondary stockist sale: Stockists sell drugs to retail pharmacies, clinics, etc. at a marked-up price that has been predetermined (usually 8%).

Retail sale: Retail pharmacies and/or providers then sell drugs to patients—again at a marked-up price thas has been predetermined (usually 16%). This price to the patient is known as the max retail price (MRP).

Drug Flow: Private Sector Channels



*Bears the risk-burden of procurement

Source: ORG-IMS expertise

Lupin, Macleods, and Sandoz are the private market leaders, but a large number of smaller companies also participate

Private Sector Sales by Market Leaders (1st and 2nd line drugs, MAT 2005)

Company	Sales (in Million USD)	% Value Share
Lupin	31.3	44.9%
Macleods	12.4	17.9%
Sandoz-Novartis	5.6	8.1%
Shreya Life Science	3.3	4.8%
Cadila Pharma	3.2	4.7%
Concept Pharma	3.0	4.3%
Wockhardt	2.2	3.2%
Overseas Healthcare	1.9	2.7%
Themis Medicare	1.6	2.3%
Other Players	4.9	7.1%
Total	**69.4**	**100%**

Source: ORG-IMS data

The private sector relies on a highly fragmented pool of distributors and retailers to deliver drugs to patients

- The private sector consists of:
  - 18,000 stockists
  - 400-500K physicians
  - 237,000 chemists
  - 15,000 hospitals and institutions

- Development of relationships with these many players is a critical component to driving access and utilization in the private sector

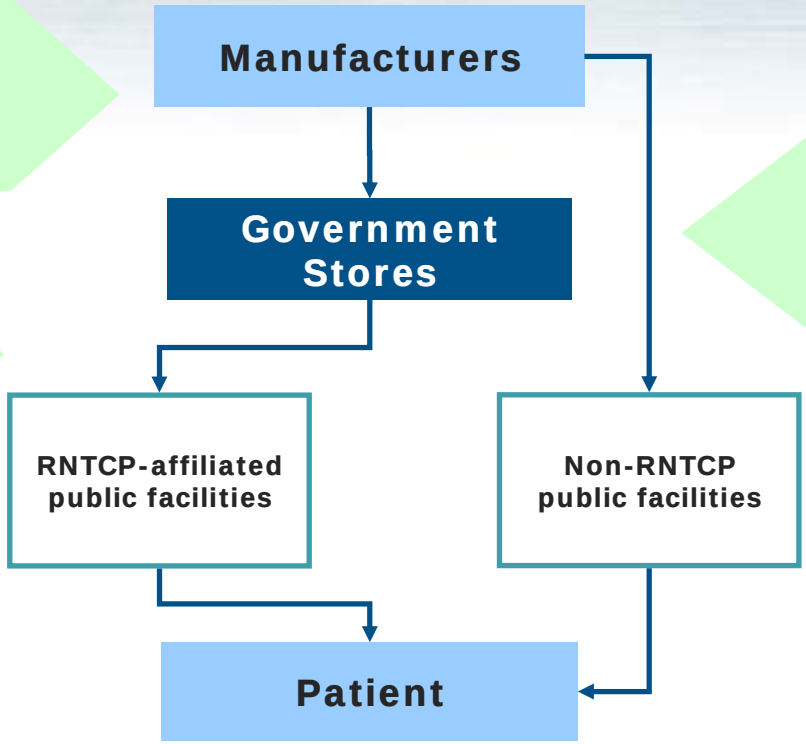
Source: IBEF Healthcare Report

TB drugs in the public sector flow through one of two major pathways: the RNTCP and non-RNTCP procurement mechanisms

Drug Flow: Public Sector Channels

Manufacturers are selected via a centrally-run bid and tender process and ship drugs to government stores

Government stores then distribute the drugs to RNTCP-affiliated facilities where they are administered to patients



Non-RNTCP public facilities buy directly from manufacturers (using either direct negotiations or a bid and tender process)

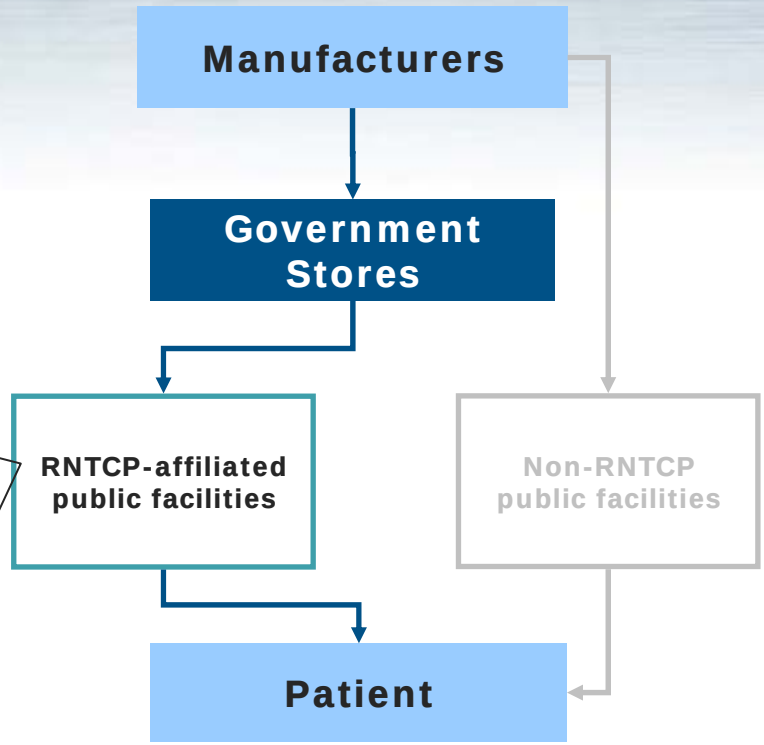
Source: Interviews

Most TB drugs in the public sector, flow through the RNTCP, which uses two procurement mechanisms

The RNTCP* purchases its drugs through one of two procurement mechanisms:

1. **International tender:**
   - **Administered by RITES (a private procurement agency) on behalf of the RNTCP**
   - **Covers over half of population**
2. **GDF:**
   - **Required route for TB drugs procured using DFID or USAID funding**
   - **Covers approximately 525 million population**

Drug Flow: RNTCP Public Sector Channels

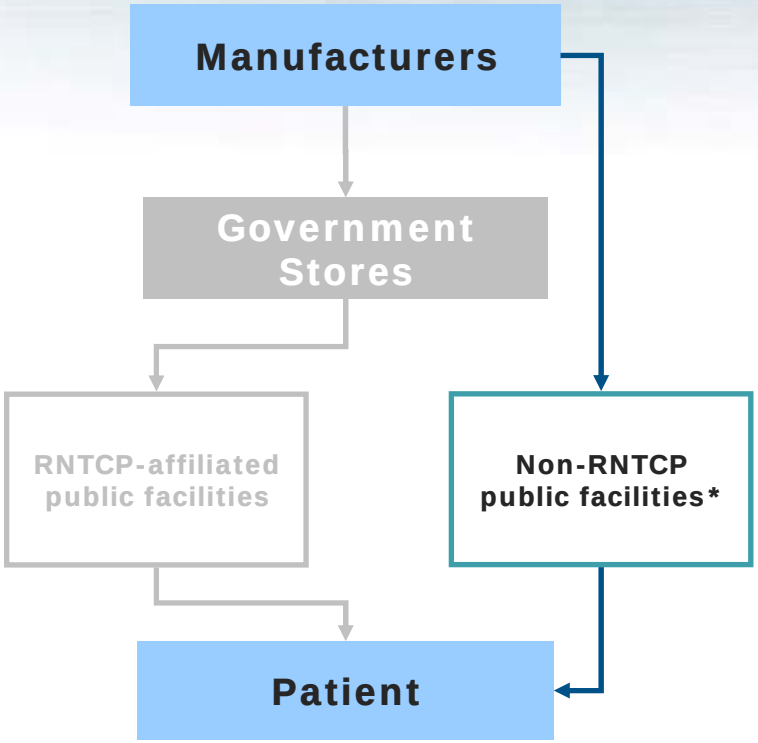


Source: RNTCP Annual Report 2006; Interviews

**Bears the risk-burden of procurement*

Facilities that are not participating in RNTCP procure directly from manufacturers, though this practice is becoming less common

Drug Flow: Non RNTCP Public Sector Channels

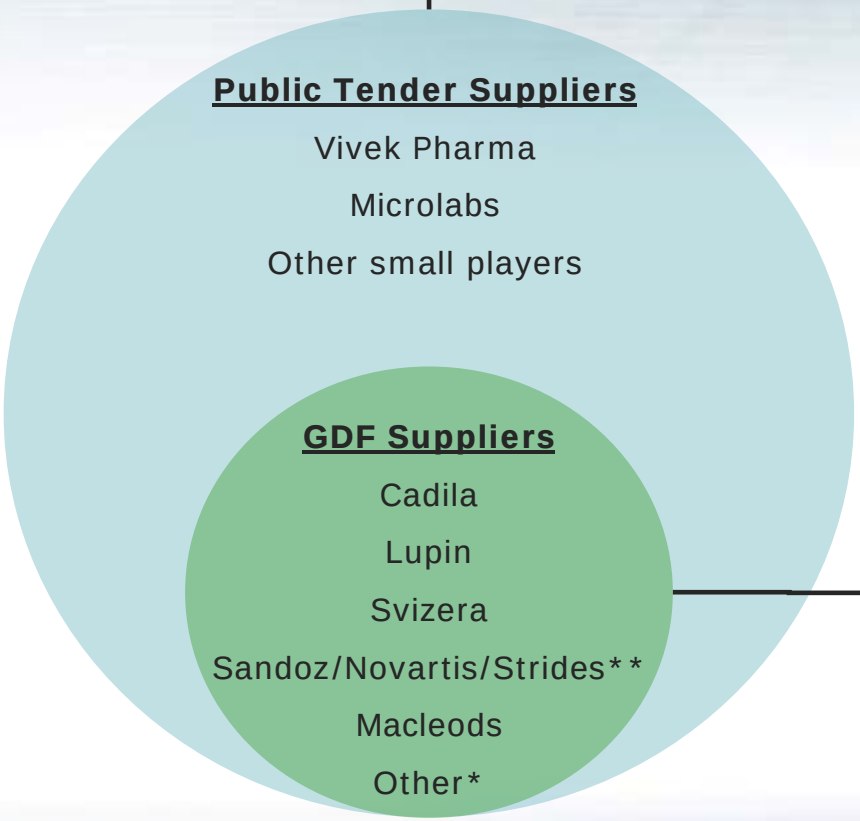


- **Certain public sector facilities—i.e., those run by other Ministries—do not procure their drugs via the RNTCP**
- **Instead, these facilities procure directly from manufacturers**
- **According to manufacturers, however, this procurement route is small and shrinking as more facilities leverage the RNTCP mechanisms**

**Bears the risk-burden of procurement*

Source: Interviews

The two procurement mechanisms leveraged by the RNTCP draw from an overlapping set of manufacturers



Public Tender Suppliers:

- WHO-GMP certified for each drug for the last two years
- Experience with the specified product for the last 2 years or experience with a similar product for the last 5 years
- Annual turnover (average over 5 years) must be 5 times what is supplied to GoI
- Annual production rate (in any one of the last 5 years) must be 3 times what is supplied to GoI
- Before contract can be signed, names are sent to World Bank for no-objection requirement (between RITES and suppliers)

GDF Suppliers:

- WHO-GMP approval at a minimum
- Assessed via the WHO/PSM TB Prequalification Project

**See appendix for full list of GDF suppliers*
***Strides and Sandoz partnership in this area will be ending soon*

Source: RNTCP Procurement Manual; GDF; Interviews

The suppliers are selected via bid and tender process run either by RITES for the public tender or UNDP-IAPSO for GDF

	Public Tender	GDF
Who administers the tender?	• RITES	• UNDP-IAPSO*
International or national tender?	• National unless procurement costs are estimated to be greater than $1M USD*	• International
Pre-qualification required?	• Yes	• Yes
How often is tender floated?	• Annually • Contract is good for one year	• Annually • Contract is good for one year
How is tender awarded?	• Once pre-qualified, suppliers are chosen mostly on the basis of price • Tender can be split among several suppliers	• Preference given to suppliers whose sites and products are pre-certified • Tender is split between a primary supplier and a secondary supplier

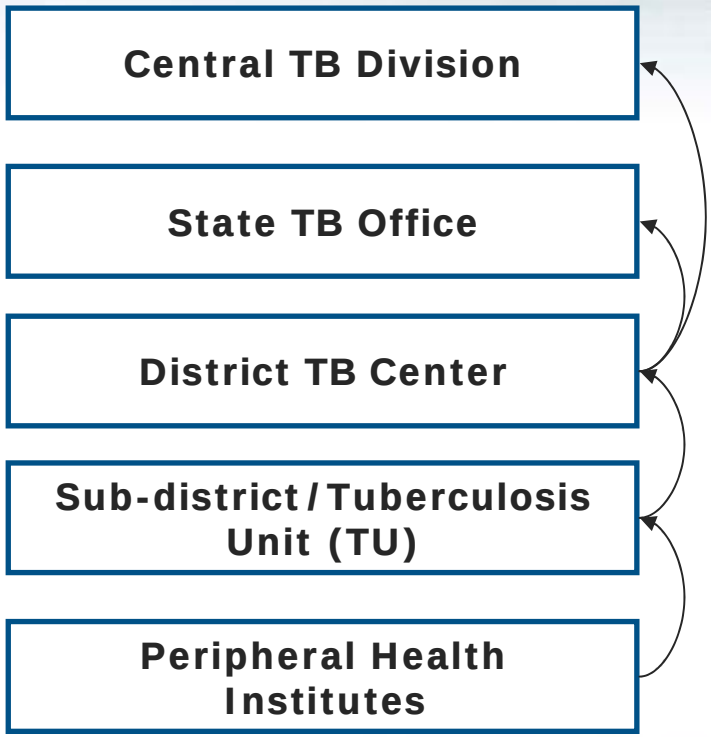
**Most drug procurements are over $1M and hence international*

Source: RNTCP Procurement Manual; GDF; Interviews

* Scheduled to shift to GTZ

The quantities ordered by the RNTCP are determined at the national level by the Central TB Division assisted by a private agency known as Strategic Alliance

Flow of Reporting



Districts report quarterly to both State and Central TB Division

TUs report quarterly to Districts

PHIs report monthly to Sub-district / TU

Central TB Division uses reports to generate a demand forecast

Forecast is used to:

- ***Write up the public tender***
- ***Place orders with suppliers—whether GDF or public tender winners***
- ***Determine quarterly supply allocations to government stores***

Source: RNTCP 2006 Annual Report; Interviews

All TB drugs are regularly tested for quality at various levels in the supply chain

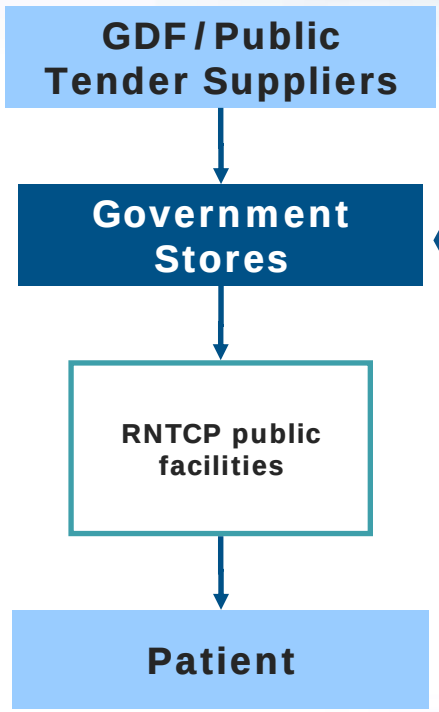
Quality Control of RNTCP TB Drugs

	GDF	Public Tender
Pre-dispatch	GDF contractual partner QCbatch tests all orders	RITES contractual partner QC batch tests all orders
Central level	CTD contractual partner QC batch tests select Government Medical Stores Depot supplies each quarter and also at random	
State / District / PHI level	Inspectors may also QC batch test samples of State Drug Stores, District Drug Stores, and/or PHI supplies (optional)	

Source: GDF; Interviews

Regardless of the mechanism used to purchase them, all TB drugs purchased by the RNTCP flow through the same hierarchy of government stores

Flow of Drugs: RNTCP Public Channels



- Government Medicines Stores Depot (GMSDs)--7 across the country
- State Government Stores--25 in 19 states
- District Government Stores
- Sub-district / TUs*

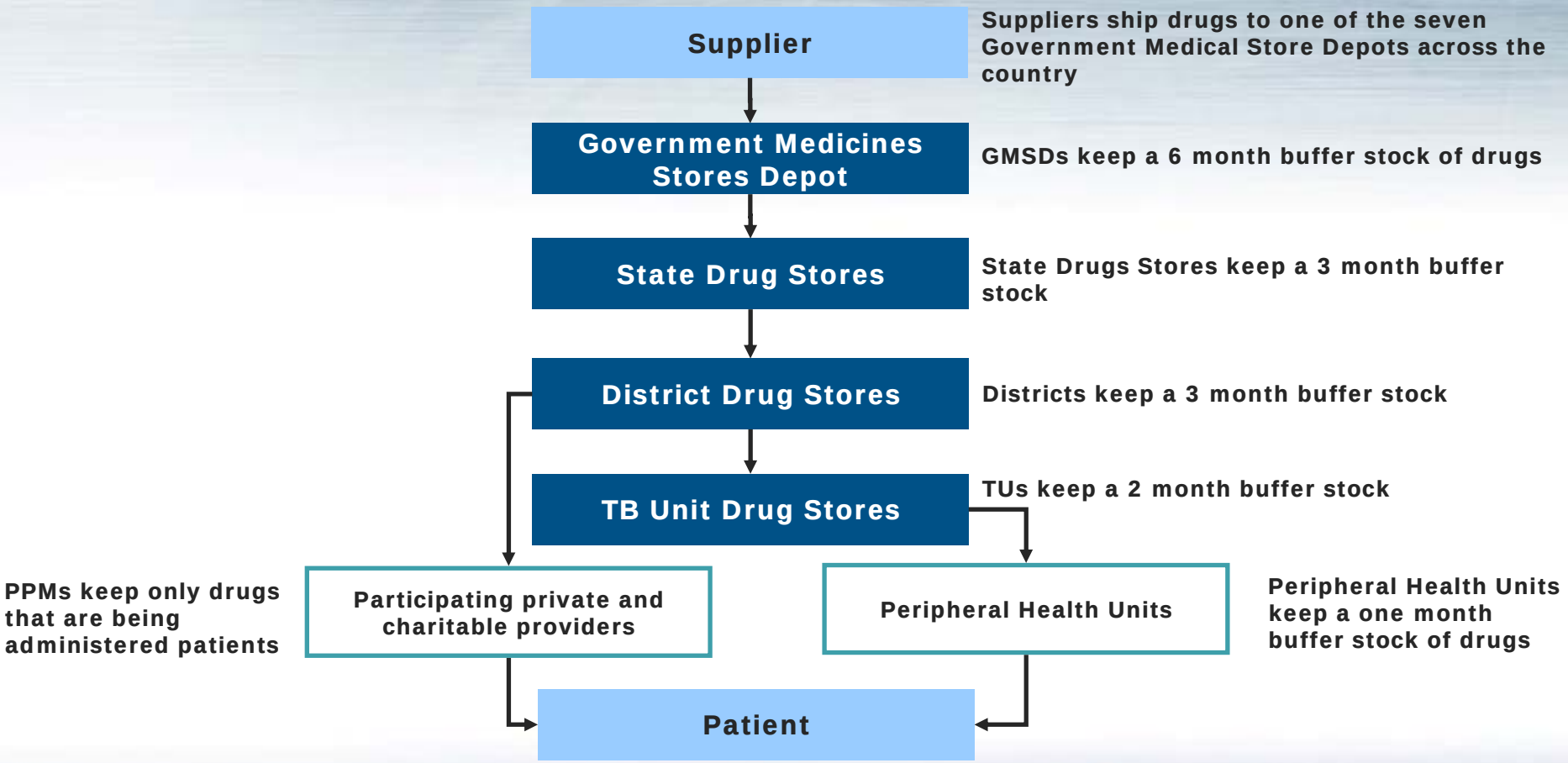
Point of delivery for all suppliers

**May serve as storage and treatment site*

Source: Interviews; RNTCP 2006 Annual Report

Every 6 months, the suppliers disburse orders to the GMSDs which serve as the starting point of distribution

Flow of Drugs through RNTCP



Source: TB Drug Markets: India

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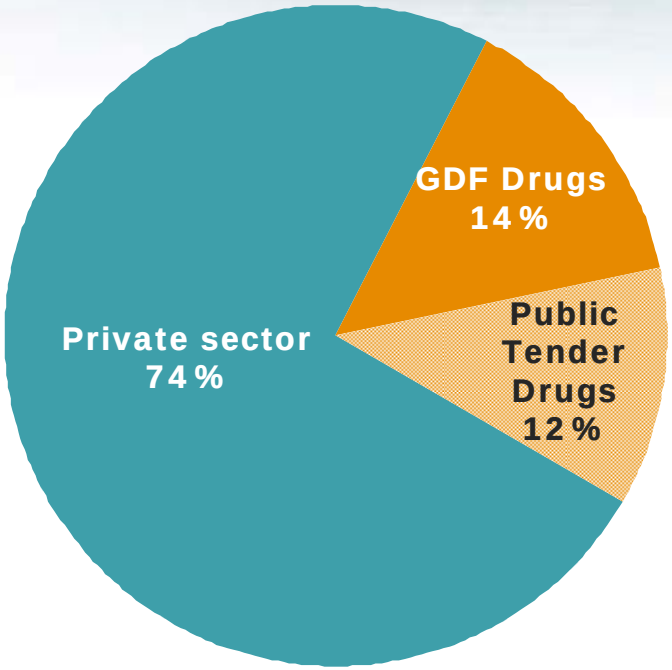
The total Indian TB drug market is valued at approximately 94M USD*, the vast majority of which is funded by private sector

Total TB Market Value by Sector (Approximately 94M USD)



A predominantly private market:

- **Private sector estimated at 69.7M USD or 74% of the total TB drug market in India**
- **Remaining quarter of the market is in the public sector**
  - **GDF procured drugs: 13.3M USD****
  - **Public tender drugs: 11M USD*****

**All figures, unless noted otherwise are based on the 1st point of sale*
***Distribution/administration costs included*
****Currently excludes paediatric and 2nd line drugs, which will be introduced sometime in 2006 and 2007 respectively*

Source: ORG-IMS stockist and retail data; IMS analysis; GDF; RNTCP 2006 Annual Report; GFATM website; Interviews

1st line drugs represent the vast majority (91%) of the total market value today

Total TB Market

Almost entirely a 1st line market

- **1st line drugs account for 86M USD or 91% of the total market**
- **GDF is exclusively 1st line drugs**
- **Shifting towards public sector as price controls lessen the commercial viability of this area**

Niched 2nd line market

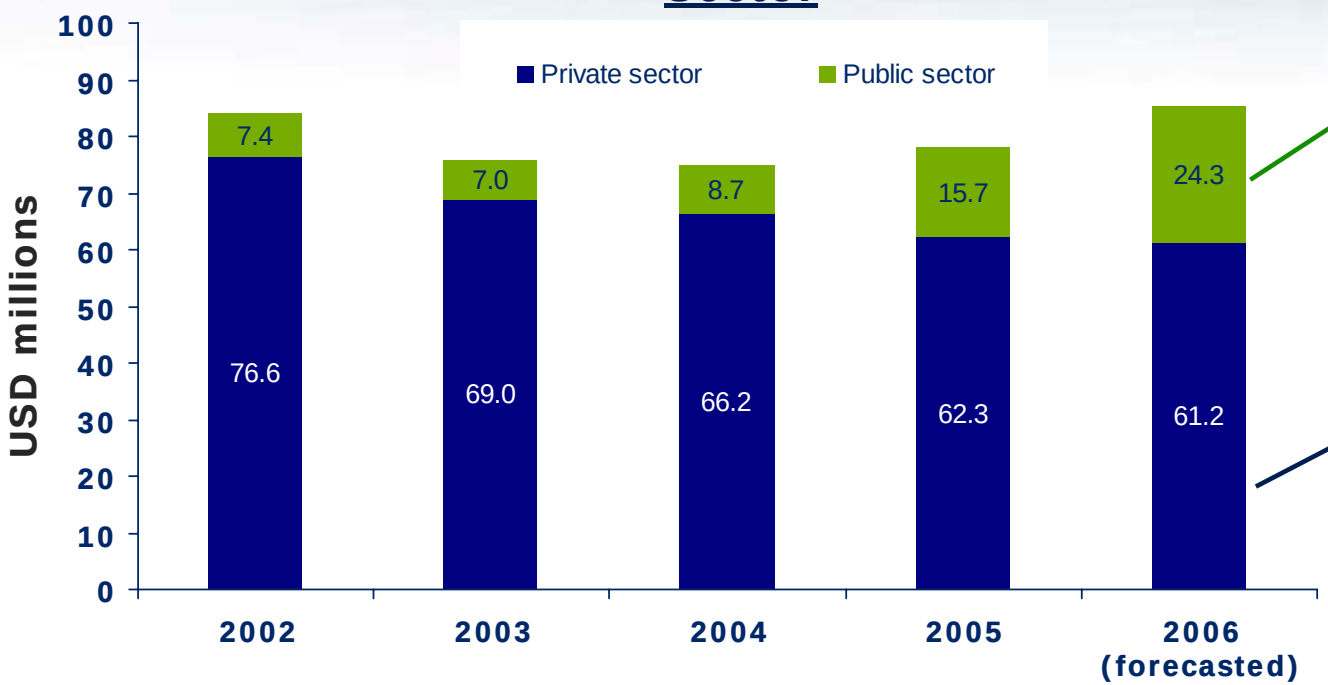
- **2nd line drugs account for 8M USD or 9%**
- **Public tender will only include MDR-TB drugs for 400 patients for 2007**
- **Will grow as RNTCP's MDR-TB treatment services scale up**
- **No price controls so far**

Note: Segmentation is by product—does not account for use of 1st line products in 2nd line treatment and vice versa

Source: ORG-IMS stockist and retail data; IMS analysis; GDF; RNTCP 2006 Annual Report; GFATM website; Interviews

The public sector has assumed a growing role in the funding of 1st line TB drugs, more than tripling its spending since 2003

Sales of 1st line TB Drugs, Public vs Private Sector



Budgets for 1st line TB drug expenditures have increased as the DOTS Program has expanded

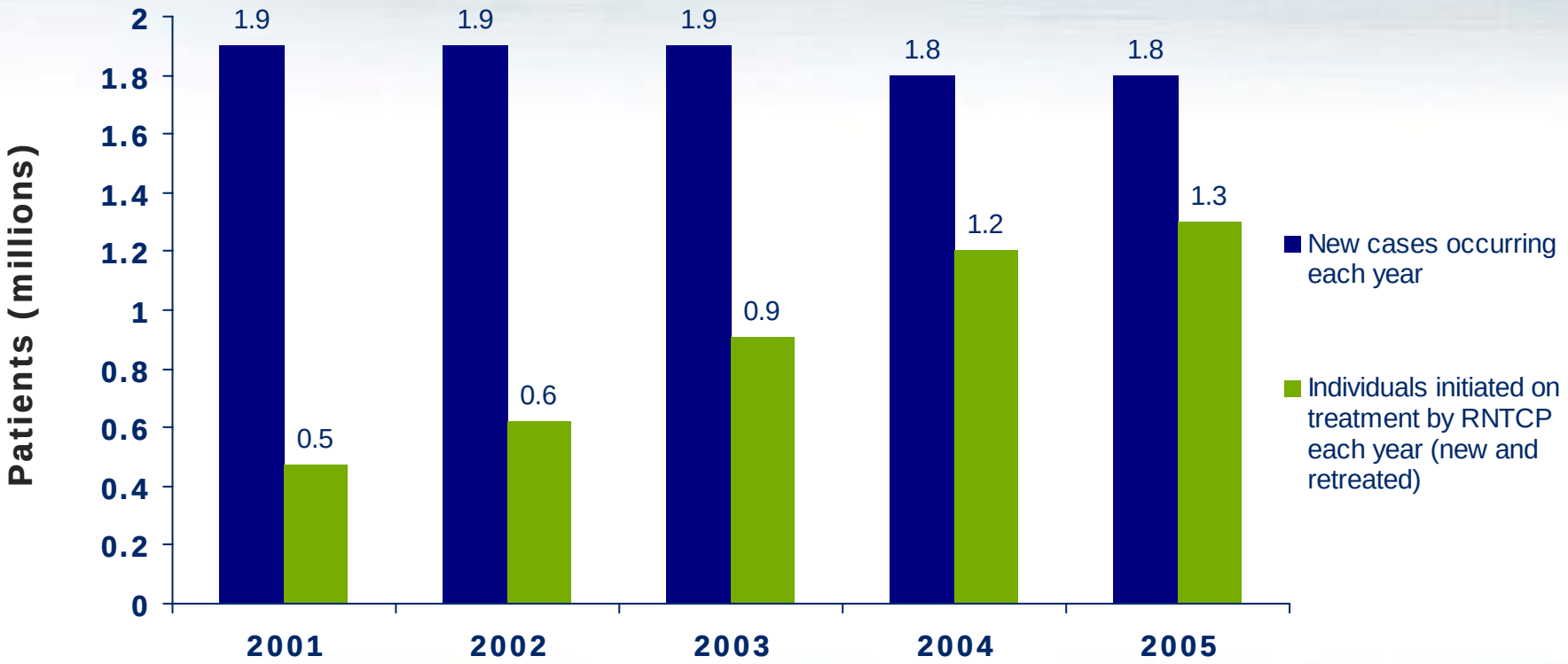
Price controls and increasing reach of the public sector have created some downward pressure on this market

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

Source: ORG-IMS stockist and retail data; IMS analysis; GDF; RNTCP 2006 Annual Report; GFATM website; Interviews

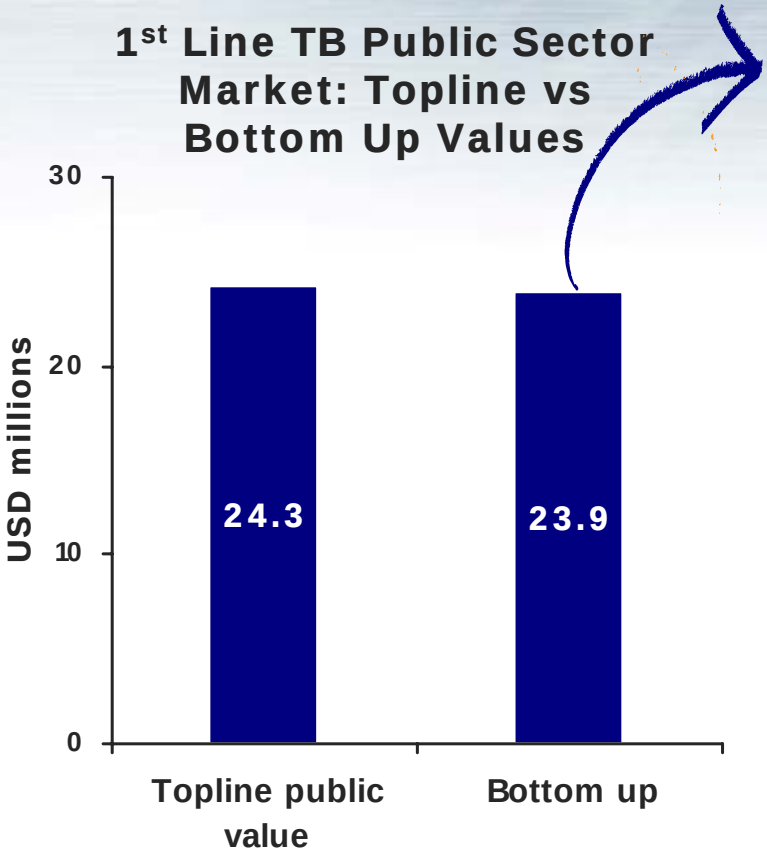
Growth in public sector spending on 1st line drugs is consistent with the increase in the number of treated cases within the public sector

Patients Treated in Public Sector vs Total Incidence



Source: WHO Report 2005: Global Tuberculosis Control; Surveillance, Planning, and Financing; RNTCP Annual Reports for 2006, 2005, 2004, 2003

Our estimate of public sector 1st line drug spending of 24.3M USD is confirmed by a bottom up calculation



	Cat I	Cat II	Cat III
Total patients treated in the public sector	1.3 million		
%age per category**	39%	17%	44%
Patients per category	507,000	221,000	572,000
Price of treatment per patient (USD)*	9.76	17.50	8.44
Cost per category	4,948,320	3,867,500	4,827,680
Cost per category, including buffer stock (factor of 1.75)**	8,659,560	6,768,125	8,448,440
Public Sector Value (USD)	**23,876,125**		

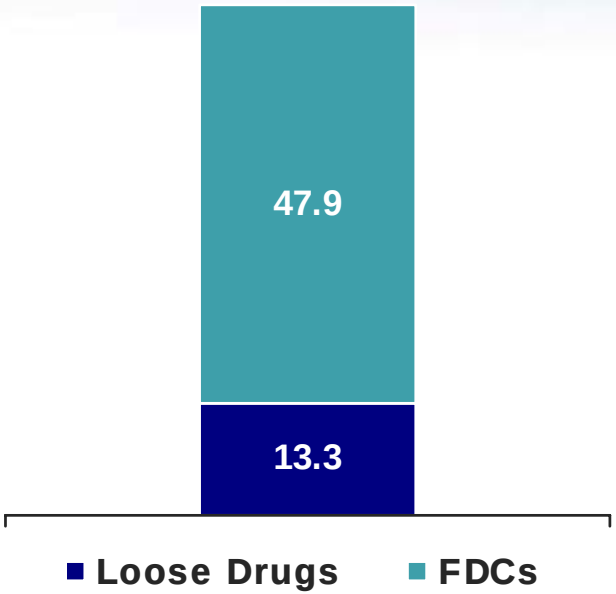
*See appendix for calculations of prices
**Based on figures indicated in RNTCP reports to GDF

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

Source: ORG-IMS stockist and retail data; IMS analysis; GDF; RNTCP 2006 Annual Report; GFATM website; Interviews

Topline sales figures from IMS indicate the private sector is accounting for $61M in 1st line TB drug spending

1st Line TB Private Sector Market: FDCs vs Loose Drugs (USD millions)



Private Sector

- **Led by Lupin (#1) and Macleods (#2)**
- **Value driven by FDCs: 78% of the market's value ($47.9M) is accounted for by FDCs, while only 22% ($13.3M) is found in loose drugs**
- **Unknown number of patients consulting with and receiving treatment for TB each year**
- **Treatment practices vary considerably from physician to physician**
- **Overlaps with the public sector—e.g., improperly treated patients seek re-treatment in the public sector and vice versa**

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

Source: ORG-IMS stockist and retail data; IMS analysis; Interviews

Patient volume estimates in the private sector will vary widely, depending upon the assumptions about treatment practices—making such estimates unreliable

Scenario 1: Assume compliance with WHO guidelines

	FDCs	Treatment with loose drugs
Value sales per Category (USD)	47.9 million	13.3 million
Price of treatment per patient (USD)*	26-30	30-38
Estimated # patients treated per category	1.6-1.8 million	346,000-451,000
Estimated Total # patients treated	1.95 to 2.25 million	

Scenario 2: WHO India rough estimate

	FDCs	Treatment with loose drugs
Value sales per Category (USD)	47.9 million	13.3 million
Price of treatment per patient (USD)*	40-50	
Estimated Total # patients treated	1.2 to 1.5 million	

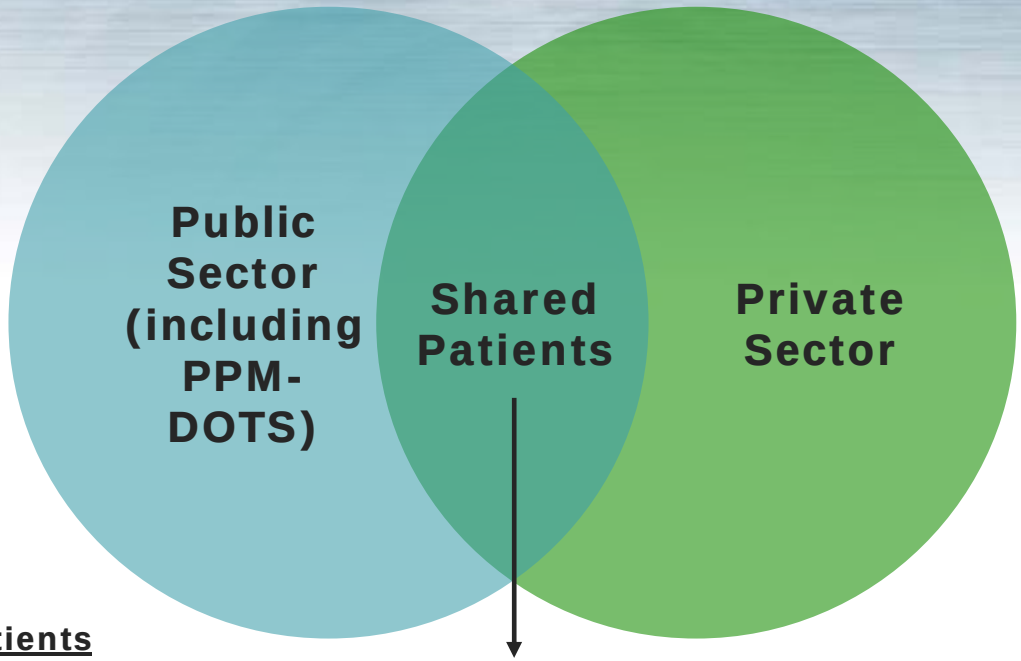
Hypothetical situations only

**See appendix for calculations of prices*

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

Source: ORG-IMS stockist and retail data; MedCLICK website; IMS analysis; Interviews

Estimating the volume or percentage of patients shared between private and public is difficult



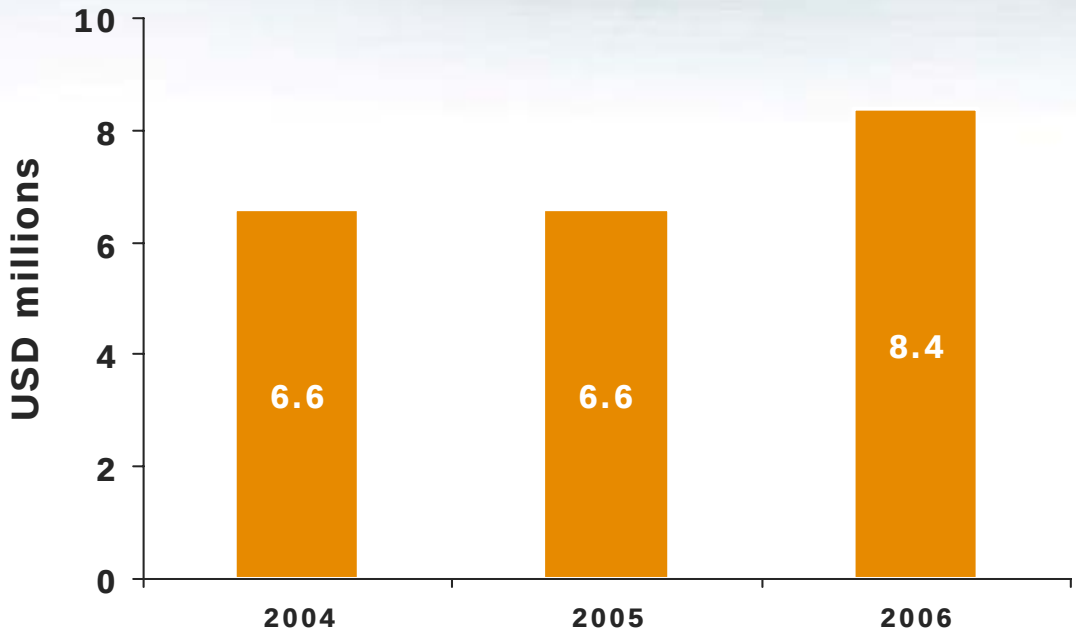
Examples of shared patients

- **Patient first consults in the private sector, is referred for diagnosis in public sector, and treated in either public or private sector (PPM-DOTS)**
- **Relapse or failed patients who split 1st and 2nd attempts between sectors**
- **Patients start but are unable to afford a complete course of therapy in the private sector and moving to the public sector**
- **Patients who start on DOTS but choose to go to self-medication in the private sector**
- **Etc.**

Source: WHO-India website; RNTCP 2006 Annual Report; Interviews

We estimate the 2nd line market to be 8M USD, mostly funded through the private sector

Value Sales of 2nd line TB Drugs*



2nd line drugs

- Led by Macleods (#1) and Lupin (#2)
- Entirely a private sector market
- Growth between 2005 and 2006 driven by an increased use of fluroquinilones
- Will include a growing public sector component starting in 2007 and beyond

**2nd line drugs adjusted to screen out use in other indications*

Note: Does not include 1st line drugs that may be used in 2nd line treatment of patients

Source: ORG-IMS stockist data; RNTCP 2006 Annual Report; Interviews

There is little reliable data available to accurately estimate the number of patients the $8M represents

- Epidemiological data from the WHO indicates that there approximately 44,653 new MDR-TB patients in India per year
- 2nd line treatment of these patients according to the WHO/RNTCP DOTS-Plus Guidelines would cost approximately $2200 to $2600 per patient (ex-manufacturing price, over two years in the private sector)
  - 6-9 months of daily doses of kanamycin, ofloxacin, ethionamide, cycloserine, pyrazinamide, and ethambutol
  - 18 months of ofloxacin, ethionamide, cycloserine, ethambutol
  - Price to the end-user (including stockist and retail mark-ups) would be $2800 to 3300 per patient
- The WHO India estimates that the cost of treatment would be approximately $1750

Source: ORG-IMS stockist data; MedCLICK website; WHO-India website; Global Incidence of Multidrug-Resistant Tuberculosis; Interviews

Country table of contents

Appendix: Interviewed Stakeholders

Individual	Organization	Position
Dr. VS Salhotra	Central TB Division	Chief Medical Officer
Dr. Pradeep Saxena	Central TB Division	Chief Medical Officer
Dr. Tarak Shah	WHO India (posted in Central TB Division)	WHO-RNCTP Medical Consultant
Dr. RP Vashist	State TB Division	State TB Officer for Delhi
Dr. Chaudury	State TB Division	State TB Officer for Maharashtra
Dr Suvanand Sahu	WHO India	National Professional Officer, TB
Dr. D. Fraser Wares	WHO India	Medical Officer, TB
Dr. Dhiman	WHO India	WHO-RNTCP PPM Medical Consultant, Dellhi
RK Pradham	Drug Controller Office	Representative
2 Directors	RK Mission Clinic and GTB Chest Clinic	NA
3 PPM Providers	NA	NA

Appendix: Interviewed Stakeholders (continued)

Individual	Organization	Position
Preetish Toraskar	Lupin	General Manager, Sales and Marketing
Alok Malik	Macleods	Sr. General Manager, Marketing
Rajesh Kabu	Macleods	Vice President, Sales and Marketing
Dr. Rajiv Alex	Sandoz	General Manager, Global TB Business and Exports
Mandar Deo	Sandoz	Marketing Manager, Global TB
Vinay Sapte	Maneesh Pharma-Svizera	Managiing Director
Ritu Khushu	Strategic Alliance (based in the Central TB Division)	Project Leader
Harish Gupta	RITES	Additional General Manager
Jayanti Patel	Maheshwar Distributors Private Ltd.	Chairman, Managing Director

Appendix: States and Union Territories

States

Andhra Pradesh
Arunachal Pradesh
Assam
Bihar
Chhattisgarh
Goa
Gujarat
Haryana
Himachal Pradesh
Jammu and Kashmir
Jharkhand
Karnataka
Kerala
Madhya Pradesh
Maharashtra
Manipur
Meghalaya
Mizoram
Nagaland
Orissa
Punjab
Rajasthan
Sikkim
Tamil Nadu
Tripura
Uttaranchal
Uttar Pradesh
West Bengal

Union Territories

Andaman and Nicobar Islands
Chandigarh
Dadra and Nagar Haveli
Daman and Diu
Delhi
Lakshadweep
Pondicherry

Complete list of GDF-ICB eligible manufacturers

Company	Location	Conditions
Aventis Pharma	Gazipur, Bangladesh	N/A
Cadila Pharmaceuticals Limited	Ahmedabad, Gujarat State, India	Non-rifampicin containing products only)
MacLeods Pharmaceuticals Limited	Kachigam Daman India	N/A
Lupin Laboratories Limited	Aurangabad, India	Rifampicin containing products only)
Sandoz Pty Limited	Kempton Park, South Africa	N/A
Strides Arcolab Limited	Bangalore, India	N/A
Svizera Private Labs Limited	Mumbai, India	N/A
Wyeth Pakistan Limited,	Karachi, Pakistan	N/A

Source: GDF

Appendix: External Funders of RNTCP

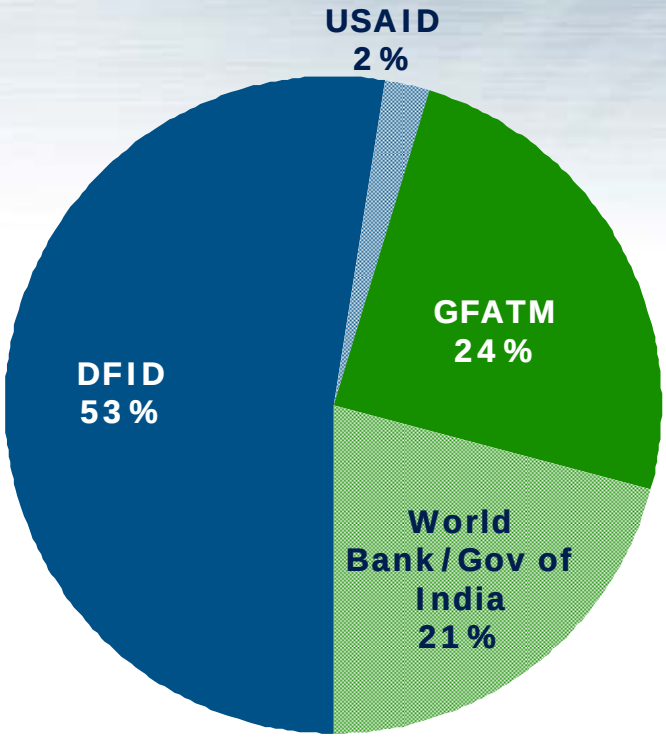
Group	Amount committed (USD millions)	# Years	Population	Expenses covered	Geographies covered
DFID	63.7	5 years	500M	Drugs	all
USAID	6.58	5 years	~25M	All	Haryana
GFATM R1	8.6	3 years	60M	All	3 states
GFATM R2	29	3 years	110M	All	2 states
GFATM R4	26	3 years	110M	All	2 states
GFATM R6 (pending)	Pending	Pending	60M	All	States covered in R1
World Bank	Pending (at least $170M)	5 years	Remainder	All	All

Highlighted boxes: years of commitment based on conversations—not confirmed

Source: RNCTP 2006 Annual Report; Interviews; GFATM website

Appendix: Public Sector 1st Line Market Value by Donor

Public Sector Market Share by Donor (2006 value Projections)

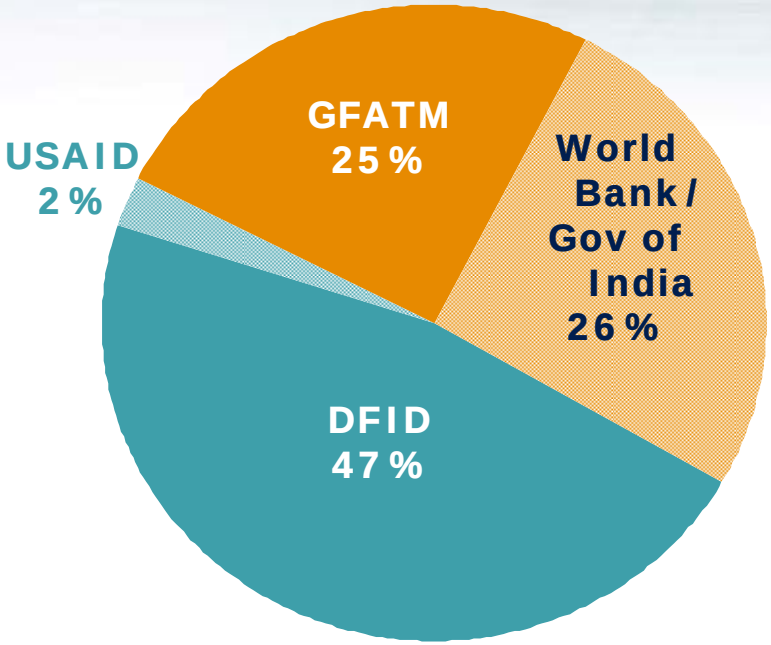


Category	Value (M USD)
DFID	12.74
USAID	0.54
GFATM	5.93
World Bank/Gov of India	5.04
Total	24.25

Source: RNCTP 2006 Annual Report; Interviews

Appendix: Public Sector 1st Line Market Volume by Donor

Public Sector Market Share by Donor (2006 volume projections)



Category	Population served (millions)
DFID	500
USAID	25
GFATM	270
World Bank/Gov of India	275

Source: RNCTP 2006 Annual Report; Interviews

Appendix: Dosing Assumptions

1st Line Regimen

Drug	Low Dose	High Dose
R	440	660
H	220	330
E	825	1100
Z	1100	1650

Based on recommended dosing in WHO Treatment of Tuberculosis: Guidelines for National Programs

Assumes daily dosing for 55kg patient

2nd Line Regimen

Drug	Dose
K	750
O	800
Eth	750
Cyclo	750
Z	1500
E	1000

Based on recommended dosing in WHO Treatment of Tuberculosis: Guidelines for National Programs

Assumes daily dosing 55kg patient over 24-27 months

Appendix: Private sector pricing assumptions

First Line Drugs

Drugs	Price per pack (INR)	Tabs per pack	MRP (USD)	Ex-manufacturer price (USD)
RHEZ	242.80	60	0.09	$0.07
RH	21.44	3	0.16	$0.13
R	53.47	10	0.12	$0.09
H	4.98	10	0.01	$0.01
E (low dose)	41.6	10	0.09	$0.07
Z (low dose)	84	10	0.18	$0.15
E (high dose)	34.5	10	0.08	$0.06
Z (high dose)	66.2	10	0.15	$0.12

Second Line Drugs

Drugs	Price per pack (INR)	Tabs per pack	MRP (USD)	Ex-manufacturer price (USD)
K	25.35	1	$0.56	$0.44
O	110	10	$0.24	$0.19
Eth	124.6	10	$0.27	$0.22
Cyclo	237.49	6	$0.87	$0.69
Z	66.2	10	$0.15	$0.12
E	34.5	10	$0.08	$0.06

Source: MedCLICK website

Appendix: Private sector price per 55kg Patient Calculations, 1st line FDCs

Low Dose

Phase	Drugs used	Tabs per day	Days per week	Total weeks	Total tabs	Total cost
IP	RHEZ	3	7	8	168	$11.91
CP	RH	1	7	16	112	$14.02
					Total cost of treatment	**$25.93**

High Dose

Phase	Drugs used	Tabs per day	Days per week	Total weeks	Total tabs	Total cost
IP	RHEZ	4	7	8	224	$15.88
CP	RH	1	7	16	112	$14.02
					Total cost of treatment	**$29.90**

Appendix: Private sector price per 55kg Patient Calculations, 1st line loose drugs

Low Dose

Phase	Drugs used	tabs per day	Days per week	Total weeks	Total tabs	Total cost
IP	R	1	7	8	56	$5.25
IP	H	1	7	8	56	$0.49
IP	E	1	7	8	56	$4.08
IP	Z	1	7	8	56	$8.24
CP	R	1	7	16	112	$10.49
CP	H	1	7	16	112	$0.98
					Total cost of treatment	**$29.53**

High Dose

Phase	Drugs used	tabs per day	Days per week	Total weeks	Total tabs	Total cost
IP	R	1	7	8	56	$6.88
IP	H	1	7	8	56	$0.49
IP	E	1	7	8	56	$3.38
IP	Z	2	7	8	112	$12.99
CP	R	1	7	16	112	$13.76
CP	H	1	7	16	112	$0.98
					Total cost of treatment	**$38.48**

Appendix: Private sector price per 55kg Patient Calculations, 2nd line drugs (24 months)

24 month regimen

Phase	Drugs used	tabs per day	Days per week	Total weeks	Total tabs	Total cost
IP	Km	1	7	24	168	$74.61
IP	Ofx	2	7	24	336	$64.75
IP	Eto	3	7	24	504	$110.02
IP	Cs	3	7	24	504	$349.51
IP	Z	2	7	24	336	$38.97
IP	E	1	7	24	168	$10.15
CP	Ofx	2	7	72	1,008	$194.26
CP	Eto	3	7	72	1,512	$330.07
CP	Cs	3	7	72	1,512	$1,048.53
CP	E	1	7	72	504	$30.46
					Total cost of treatment	**$2,251.35**

Appendix: Private sector price per 55kg Patient Calculations, 2nd line drugs (27 months)

27 month regimen

Phase	Drugs used	tabs per day	Days per week	Total weeks	Total tabs	Total cost
IP	Km	1	7	36	252	$111.92
IP	Ofx	2	7	36	504	$97.13
IP	Eto	3	7	36	756	$165.03
IP	Cs	3	7	36	756	$524.26
IP	Z	2	7	36	504	$58.46
IP	E	1	7	36	252	$15.23
CP	Ofx	2	7	72	1,008	$194.26
CP	Eto	3	7	72	1,512	$330.07
CP	Cs	3	7	72	1,512	$1,048.53
CP	E	1	7	72	504	$30.46
					Total cost of treatment	**$2,575.36**