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

Brazil Case Study
Country table of contents

- TB Control in Brazil
- Procurement and Distribution of TB Drugs
- Value and Volume of the Brazil TB Market
- Appendix
Most recent estimates from the MOH project about 120,000 total cases of TB in 2004

- In 2004:
  - 107,000 patients with TB (treated under Scheme 1)
  - 8,186 patients with TB who were previously cured or abandoned treatment (Scheme 1R)
  - 573 patients with TB meningitis (Scheme 2)
  - 4,093 patients who are resistant to RIF+INH (Scheme 3)
  - 1,070 who are resistant to RIF+INH+ at least one other drug used in Scheme 1 or 3 (classified as TB MR in Brazil and treated under Scheme 4)

- 45% of TB burden in Sao Paulo and Rio de Janeiro states

- In São Paulo State . . .
  - 21K total cases in state (17K within city)
  - 3K with TB/ HIV
  - 100 cases who are resistant to RIF+INH
  - 60% DOTS coverage and 30% in city (mostly south)

Source: IMS interviews
## TB Control in Brazil

The MOH has defined TB based on several schemes and has developed treatment guidelines for each category.

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scheme 1: “Esquema basico”</td>
<td>New cases of pulmonary and extra-pulmonary TB</td>
<td>2RHZ/ 4RH</td>
</tr>
<tr>
<td>Scheme 1R: “Esquema basico + Etambutol”</td>
<td>Previously treated cases that were cured or abandoned basic treatment*</td>
<td>2RHZE/ 4RHE</td>
</tr>
<tr>
<td>Scheme 2: “Esquema para tuberculose meningoencefalica”</td>
<td>Cases of TB meningitis</td>
<td>2RHZ/ 7RH</td>
</tr>
<tr>
<td>Scheme 3: “Esquema para falencia de tratamento aos outros esquemas”</td>
<td>Patient who failed scheme 1R, or who is resistant to rifampicin and isoniazid</td>
<td>3ZSEEt/ 9 EEt</td>
</tr>
<tr>
<td>Scheme 4: “TB MR”</td>
<td>Patient who is resistant to rifampicin, isoniazid ad at least one other medicine from Scheme 1 or 3</td>
<td>Amicacin/ Ofloxacin/ Terizidone/ Ethambutol Clofazimine (until March 2006) Pyrazinamide (from March 2006) (4 oral drugs + 1 injectable for first 12 months; 4 orals for remaining 6 months)</td>
</tr>
</tbody>
</table>

*Source: IMS interviews*

*Within the past five years; otherwise considered scheme 1 or new patients*
The National TB program sets the strategy, with implementation at the state and municipal level.

**Level of PNCT**

- **Central TB Division**
  - Sets priorities, strategies and guidelines for National TB program
  - Allocates funding to states
  - Procures drugs for states and municipalities
  - Monitors states

- **State TB Program**
  - Develop public awareness programs
  - Train healthcare workers
  - Monitoring and evaluation of municipalities
  - Reports annual forecasts to central TB division

- **Municipal TB Program**
  - Implementation and delivery of healthcare
  - Logistical delivery of medications to facilities
  - Monitoring and evaluation of healthcare facilities
  - Reports annual forecasts to state TB program

Source: IMS interviews
The MOH is responsible for purchasing 100% of TB medicines and provides them free of charge for all patients.

- TB patients are always treated in the public sector through the nation’s TB program (PNCT).
- Since patients are guaranteed free access to such medications under government-sponsored programs, all sales are prohibited in the private sector.
- Brazil offers a broad spectrum of 1st and 2nd line treatments.

Source: IMS interviews
The state is responsible for supervising health regions and municipalities and ensuring access to care

- Main role in coordinating the TB program
- Other than funding for drugs, most funds for TB program comes from federal government
- Responsible for ensuring healthcare workers are trained, for ensuring that patients have access to medicines and for developing public awareness campaigns
- Also responsible for supervising health regions and municipalities within their states
  - Some states provide financial incentives to ensure municipalities implement DOTS within their region
- May also be responsible for purchasing diagnostic equipment

Source: IMS interviews
Implementation of the TB program, including adherence to DOTS, is determined largely by municipalities.

- The “implementation” function that is responsible for diagnosing and treating patients.
- Municipalities determine how their budget is allocated, including for implementation of DOTS, of family health programs or of other efforts.
- Those municipalities with budget to do so will provide incentive to patients for DOTS; for example they may offer food and/or reimbursement for public transport.

*Source: IMS interviews*
The WHO recommends a 4-drug regimen for patients

**Recommended TBCTA dose regimen for previously untreated patients**

<table>
<thead>
<tr>
<th>Category</th>
<th>Daily</th>
<th>3 times a week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rifampicin</td>
<td>10 mg/kg (8-12; max of 600 mg)</td>
<td>10 mg/kg (8-12; max of 600 mg)</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>5 mg/kg (4-6; max of 300 mg)</td>
<td>10 mg/kg (4-6; max of 300 mg)</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>25 mg/kg* (20–30)</td>
<td>35 mg/kg* (30–40)</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>Children 20 (15-25)* Adults 15 (15-20)</td>
<td>30 (25-35)*</td>
</tr>
</tbody>
</table>

For 55 kg person, 1650 RIF, 1650 INH, 5775 PYR, 4950 EMB weekly.

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Initial phase</th>
<th>Continuation phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred</td>
<td>INH, RIF, PZA, EMB daily, 2 months</td>
<td>INH, RIF daily, 4 months</td>
</tr>
<tr>
<td></td>
<td>INH, RIF, PZA, EMB 3x/week, 2 months</td>
<td>INH, RIF 3x/week, 4 months</td>
</tr>
<tr>
<td>Optional</td>
<td>INH, RIF, PZA, EMB2 daily, 2 months</td>
<td>INH, EMB daily, 6 months</td>
</tr>
</tbody>
</table>

*Not in continuation phase

However, the treatment regimen for utilized by the PNCT differs from the WHO recommended regimen in that ethambutol is not included in the basic regimen.

### PNCT TB Drug Treatment Regimen for Scheme 1

<table>
<thead>
<tr>
<th>Category</th>
<th>PNCT Regimen (mg/day) for patient over 45 kg</th>
<th>WHO recommended for 45kg</th>
<th>WHO recommended for 70kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rifampicin</td>
<td>600 mg</td>
<td>450 mg</td>
<td>600 mg (because of max)</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>400 mg</td>
<td>225 mg</td>
<td>350 mg</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>2,000 mg*</td>
<td>1125 mg*</td>
<td>1750 mg*</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>not used for previously untreated patients</td>
<td>675 mg*</td>
<td>1050 mg*</td>
</tr>
</tbody>
</table>

**Details on the 1st line Regimen**

Initial phase is 2 months. Continuation phase is 4 months. Pyrazinamide (and ethambutol) not used in continuation phase.

TB patients typically present and remain treated at a public ambulatory clinic /or hospital

Most patients present to a GP or specialist at an ambulatory clinic

Some patients will go directly to the emergency room or general hospital

Patients suspected of TB are screened in the pulmonology department

Most TB patients receive treatment in the ambulatory clinic

Some high risk patients may be referred to a reference center or hospitalized for treatment

Source: IMS interviews
Patients can receive TB treatment at a community health center or a Family Health Program (FHP) rather than the hospital out-patient department from rural areas

- Efforts to improve the availability and quality of primary care have been under way for some time with the development of the Family Health Program (FHP), which was launched in 1994, mainly in rural areas
- The Family Health Team includes a GP, 1 dentist, 2 nurses and 2 community agents with responsibility for between 600 and 1000 families in specific municipalities
- Priority areas include diabetes, women’s health, pediatrics, hypertension, TB and leprosy
- More than 11000 teams are now working in rural communities and small towns, and the program has reached ~ 60 million people
- No pharmacy capacities exist at the FHP, and therefore, nurse will receive a month’s supply of TB medicines at a time to administer to the patient
- A new push to expand the program is now underway including expanding among urban areas, where there 30%-50% patients are initially attended in hospitals

Source: IMS interviews; IMS Health Market Prognosis
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Procurement and Distribution of TB Drugs

On an annual basis, the MOH projects the supply of drugs it must procure for TB and for multi-drug resistant TB.

**Estimate of supply for 2006**

<table>
<thead>
<tr>
<th>TB</th>
<th>Planned</th>
<th>Buffer stock</th>
<th>Total</th>
<th>Multi-drug resistant</th>
<th>Planned</th>
<th>Buffer stock</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid 100 mg</td>
<td>8,291,000</td>
<td>4,145,500</td>
<td>7,495</td>
<td>Isoniazid 100 mg</td>
<td>64,800</td>
<td>16,200</td>
<td>81,000</td>
</tr>
<tr>
<td>Isoniazid 100 mg + Rifampicin 150 mg</td>
<td>6,104,000</td>
<td>1,221,000</td>
<td>7,325,000</td>
<td>Isoniazid 100 mg + Rifampicin 150 mg</td>
<td>4,000</td>
<td>1,000</td>
<td>5,000</td>
</tr>
<tr>
<td>Isoniazid 200 mg + Rifampicin 300 mg</td>
<td>32,875,000</td>
<td>6,575,000</td>
<td>39,450,000</td>
<td>Isoniazid 200 mg + Rifampicin 300 mg</td>
<td>6,400</td>
<td>1,600</td>
<td>8,000</td>
</tr>
<tr>
<td>Pyrazinamide 500 mg</td>
<td>22,130,500</td>
<td>4,426,000</td>
<td>26,556,500</td>
<td>Pyrazinamide 500 mg</td>
<td>129,600</td>
<td>32,400</td>
<td>162,000</td>
</tr>
<tr>
<td>Pyrazinamide oral 3%</td>
<td>57,806</td>
<td>11,544</td>
<td>69,350</td>
<td>Rifampicin 300 mg</td>
<td>58,400</td>
<td>13,900</td>
<td>69,500</td>
</tr>
<tr>
<td>Pyrazinamide oral 2%</td>
<td>209,300</td>
<td>41,850</td>
<td>251,150</td>
<td>Streptomycin 1g</td>
<td>12,000</td>
<td>3,000</td>
<td>15,000</td>
</tr>
<tr>
<td>Rifampicin 300 mg</td>
<td>6,575,000</td>
<td>1,315,000</td>
<td>7,890,000</td>
<td>Etambutol 400 mg</td>
<td>836,794</td>
<td>209,200</td>
<td>1,046,000</td>
</tr>
<tr>
<td>Streptomycin 1g</td>
<td>149,300</td>
<td>59,050</td>
<td>208,350</td>
<td>Amicacina 500mg/2ml</td>
<td>62,400</td>
<td>15,600</td>
<td>78,000</td>
</tr>
<tr>
<td>Etambutol 400 mg</td>
<td>6,341,450</td>
<td>1,154,050</td>
<td>7,495,500</td>
<td>Amicacina 1g/ 4 ml</td>
<td>31,200</td>
<td>7,800</td>
<td>39,000</td>
</tr>
<tr>
<td>Etionamide 250 mg</td>
<td>916,050</td>
<td>182,950</td>
<td>1,099,000</td>
<td>Claritromicina 500 mg</td>
<td>29,200</td>
<td>7,300</td>
<td>36,500</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Offloxacino 400 mg</td>
<td>581,868</td>
<td>145,600</td>
<td>728,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Terizidona 250 mg</td>
<td>19,040</td>
<td>4,760</td>
<td>23,800</td>
</tr>
</tbody>
</table>

Source: MOH Estimates 2006
Procurement and Distribution of TB Drugs

It accounts for a planned level of stock and a reserve stock which it stores at a central warehouse in Brasilia.

- Each year the MOH projects need for upcoming year
- Estimates are built from the bottom up
  - Each municipality reports forecasts and stock to state
  - State reports to national MOH
- Supply delivered directly to state
- The MOH allocates an extra 25% buffer stock on top of the planned level of supply
- This reserve is kept at the MOH warehouse as a reserve supply

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<td>7,495,500</td>
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<tr>
<td>Etionamide 250 mg</td>
<td>916,050</td>
<td>182,950</td>
<td>1,099,000</td>
</tr>
</tbody>
</table>

Source: MOH estimates 2006
The MOH then negotiates directly with national and state laboratories to produce 1st and many 2nd line drugs

### Estimates for 2006

<table>
<thead>
<tr>
<th>Drug Description</th>
<th>Price per unit</th>
<th>Supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid 100 mg</td>
<td>.0164</td>
<td>LAFEPE/LQFAE/LFM</td>
</tr>
<tr>
<td>Isoniazid 100 mg + Rifampicin 150 mg</td>
<td>.0992</td>
<td>LAFEPE/LQFEX</td>
</tr>
<tr>
<td>Isoniazid 200 mg + Rifampicin 300 mg</td>
<td>.1654</td>
<td>LQFEX</td>
</tr>
<tr>
<td>Pyrazinamide 500 mg</td>
<td>.1213</td>
<td>FURP/LAFEPE/LQFAE/LQFEX/LFM</td>
</tr>
<tr>
<td>Pyrazinamide oral 3%</td>
<td>1.9500</td>
<td>LFM</td>
</tr>
<tr>
<td>Pyrazinamide oral 2%</td>
<td>.8299</td>
<td>FURP</td>
</tr>
<tr>
<td>Rifampicin 300 mg</td>
<td>.1415</td>
<td>LAFEPE/NUPLAN/LQFEX</td>
</tr>
<tr>
<td>Streptomycin 1g</td>
<td>.9630</td>
<td>FURP</td>
</tr>
<tr>
<td>Ethambutol 250 mg</td>
<td>.1014</td>
<td>FIOCRUZ/FURP/IQUEGO</td>
</tr>
<tr>
<td>Etionamide 250 mg</td>
<td>.2948</td>
<td>LQFEX</td>
</tr>
<tr>
<td>Ofloxacin 400 mg</td>
<td>.3899</td>
<td>LFM</td>
</tr>
<tr>
<td>Terizidona 250 mg</td>
<td>4.6060</td>
<td>FLOMED</td>
</tr>
</tbody>
</table>

Majority of products are produced by national and state labs including:

1. Farmanguinhos (national lab under Fiocruz)
2. Military labs include army (LQFEX), navy (LFM) and air-force (LQFAE)
3. State labs include
   - FURP (Sao Paulo)
   - LAFEPE (Pernambuco)
   - Nuplan (Rio Grande de Norte)
   - Iquego (Goias)

Source: MOH estimates 2006
The MOH uses a bid and tender process with labs to secure supply on an annual basis

**The MOH issues a bid...**
- After building the annual forecast, the MOH issues a bid to state and military labs to fill next year’s supply
- The MOH bases expectations on each lab’s production capabilities from the previous year’s production levels

**Conduct negotiations...**
- The MOH then reviews accepts bids directly with the state, military and national labs on the production level and timing of delivery
- Price is not a part of the negotiation process, rather the MOH determines the price they are willing to pay primarily based off of the previous year
- State labs have some ability to “turn down” the MOH if they do not have capacity, and have done so in recent years due to the price of raw materials

**Finalizes order**
- Once the MOH finalizes the negotiation with the lab, orders are sent directly from lab to the state/national warehouse
- The MOH determines to which destination each lab’s supply will go

*Source: IMS interviews*
Procurement and Distribution of TB Drugs

State labs negotiate with external suppliers for raw materials through a bid and tender process

**Process today:**

1. **State labs issue bids to suppliers annually for raw materials**
   
   Two major standards considered:
   
   1. Strength in accordance with Brazilian treatment regimens
   2. Quality compliant with Brazilian Pharmacopeia*

2. **State labs review and accept proposals from suppliers for a negotiated supply**

3. **If more raw materials are needed within the year, a lab can go directly to supplier for more if within 25% of the agreed range**

   • If needed supply exceeds this range, lab must issue a new bid

**2006 and Beyond**

• MOH starting to create a network of labs through the MOH to act as a pooled procurement mechanism and assist in price negotiations with suppliers of raw materials

* USP or European or British Pharmacopoeia would be used if data is unavailable in Brazilian pharmacopoeia

*Source: IMS Health Interviews*
Procurement and Distribution of TB Drugs

If there is a gap in supply between what the state labs can produce and the annual forecast, the PNCT will look into other options internally and then externally.

Description of process:

1. National TB Drug Producer Public Labs Networks
   - First option for TB drug production is the National Public Labs Network
   - Farmanguinhos is the lab with the highest capacity and is leading a process of development of FDCs, but bids are open to the public labs network

2. National private manufacturers
   - If Farmanguinhos cannot provide adequate supply, then the MOH would issue a bid for private manufacturers in Brazil
   - Manufacturers have to be pre-qualified by the Brazilian regulatory agency, ANVISA

3. International manufacturers
   - The last option would be to look for external suppliers
   - Some 2nd line drugs including amicacin and terizidone, are procured regularly from external suppliers
   - Most recently, FDC’s of rifampicin and isoniazid were procured through external suppliers in India

Source: IMS interviews
1st line drugs produced by state labs are distributed directly to state warehouses.

- Lab sends supply to state warehouses at pre-specified time.
- Majority of supply is sent directly to the state from the labs.
- States distribute to health regions.
- DRS distribute to municipalities within their region.
- Municipalities are generally responsible for delivering to the clinic, though variances exist. In Rio de Janeiro, for example, some clinics pick up supply of TB drugs from the municipal warehouse whereas other clinics receive delivery directly from municipality’s transport system.

Source: IMS interviews
Procurement and Distribution of TB Drugs

Though some variations exist in timing, TB medicines are generally released to the state who is then responsible for distributing within to the municipalities.

- **Drugs procured by the MOH government are initially shipped to state warehouses every 3 months**

- **Drugs are shipped the health region warehouse on a regular basis (usually every 2-3 months)**

- **Drugs are shipped directly to municipal every month**

- **Drugs are shipped directly to clinic or hospital on a monthly basis**

  **State Warehouse**

  **Health Region (DRS) Warehouse**

  **Municipal Warehouse**

  **Clinic or hospital**

  - Reports stock and need every three months to the MOH
  - Report stock and needs every 1-3 months* to state
  - Report stock and needs each month to municipal warehouse

** A larger state like Sao Paulo is divided into 24 health regions, so drugs are shipped direct to supplier to the regions rather than a central state warehouse.

*For example, in Sao Paulo municipality orders on a monthly basis and Rio de Janeiro orders every two months.

Source: IMS interviews
For MDR-TB, Helio Fraga is the main reference center that stocks and distributes drugs to supervised facilities.

**Distribution**

1. Lab distributes directly to National Reference Lab, who stocks all TB MR drugs.
2. Upon notification from TB reference center, Helio Fraga directly distributes drug to reference center or to health unit where patient has been identified. Drugs are ear-marked for a specific patient.
3. In some instances where a local health unit is authorized to treat the TB MR patient, Helio Fraga will distribute directly to the unit.

**Flow of Reporting and supervision**

1. If a TB MR case emerges, health unit must report case to reference center.
2. In many instances patients are referred to the reference center for further diagnosis and treatment. In instances where a patient will remain at the health unit, in which case, the reference center is responsible for supervising the health unit.
3. Reference center reports cases directly to National Reference Lab and remains under their supervision for patient care.

Source: IMS interviews
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The Brazilian TB market is valued at almost $10 M USD

New TB Cases - 44%

Resistant to INH+RIF - 11%

Resistant to INH+RIF+ at least one other drug from Scheme 1 or 3 - 39%

TB Meningitis - (<1%)

Re-treated - (6%)

Public market only:

- All distribution of 1\textsuperscript{st} and 2\textsuperscript{nd} line medicines is through the MOH
- Private sector (retail pharmacies) prohibited from selling TB medicines
- About half of the market value is for drug resistant patients

Source: MOH Estimates, 2004
1st line drugs represent half of the total market value today

1st line market
- 1st line drugs account for ~4.9M USD or 50% of the total market
- Public sector only
- Drugs traditionally produced internally through state, military or national laboratories

2nd line market
- 2nd line drugs account for ~5M USD or 50% of total market
- Some 2nd line drugs procured from international manufacturers through public tender; remainder produced internally

Source: MOH Estimates, 2004
For the 1st line market, about half of the value and volume is for FDCs of isoniazid and rifampicin.

**Total 1st Line TB Market Value by Drug in 2005 (5 M USD)***

- **RIF+INH**: 46%
- **Pyrazinamide**: 26%
- **Isoniazid 200 mg + Rifampicin 300 mg**: 12%
- **Isoniazid 100 mg**: 7%
- **Pyrazinamide 500 mg**: 26%
- **Rifampicin 300 mg**: 8%
- **Streptomycin 1g**: 0%
- **Etambutol 400 mg**: 7%
- **Etionamide 250 mg**: 1%

**Total 1st Line TB Market Volume by Drug in 2005 (102.8 M units)**

- **RIF+INH**: 54%
- **Pyrazinamide**: 24%
- **Isoniazid 200 mg + Rifampicin 300 mg**: 49%
- **Isoniazid 100 mg**: 10%
- **Pyrazinamide 500 mg**: 24%
- **Rifampicin 300 mg**: 8%
- **Streptomycin 1g**: 1%
- **Etambutol 400 mg**: 6%
- **Etionamide 250 mg**: 2%
- **Isoniazid 100 mg**: 2%
- **Isoniazid 100 mg + Rifampicin 150 mg**: 5%

*6 Million including buffer stock

Source: MOH Estimates, 2004
Cost per regimen is significantly higher for 2nd line regimens

<table>
<thead>
<tr>
<th>Scheme</th>
<th># of patients</th>
<th>Cost per patient ($)</th>
<th>Total value ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scheme 1* (New TB Cases)</td>
<td>107,000</td>
<td>$41</td>
<td>$4,387,000</td>
</tr>
<tr>
<td>Scheme 1R (Re-treated)</td>
<td>8,186</td>
<td>$69</td>
<td>$567,454</td>
</tr>
<tr>
<td>Scheme 2 (TB Meningitis)</td>
<td>573</td>
<td>$62</td>
<td>$35,492</td>
</tr>
<tr>
<td>Scheme 3 (Resistant to RIF+INH)</td>
<td>4,093</td>
<td>$270</td>
<td>$1,105,110</td>
</tr>
<tr>
<td>Scheme 4 (Resistant to RIF+INH + at least one other drug from scheme 1 or 3)</td>
<td>1,070</td>
<td>$3,625</td>
<td>$3,879,007</td>
</tr>
</tbody>
</table>

*Daily regimen used

Source: MOH Estimates, 2004
As such, despite representing about half of the value, the 2nd line regimen represent only about 4% of the volume (Schemes 3 and 4).

Out of total of 120,000 patients, 4% (or about 5,163 patients) were either resistant to RIF+INH only or + another drug:

- 4,093 are resistant to RIF+INH (Scheme 3)
- 1,070 are resistant to RIF+INH+ one other drug used in Schemes 1 or 3 (Scheme 4)

Source: MOH Estimates 2004
Country table of contents

- TB Control in Brazil
- Procurement and Distribution of TB Drugs
- Value and Volume of the Brazil TB Market
- Appendix
### Appendix: Interviewed Stakeholders

<table>
<thead>
<tr>
<th>Individual</th>
<th>Organization</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Joseney dos Santos</td>
<td>National TB Program</td>
<td>National TB Program Mgr</td>
</tr>
<tr>
<td>Dr. Waldir Silva</td>
<td>National TB Program</td>
<td>TB Program Advisor, MOH</td>
</tr>
<tr>
<td>Dr. Joao Batista Oliveira</td>
<td>Farmanguinhos</td>
<td>MOH consultant to Farmanguinhos</td>
</tr>
<tr>
<td>Dr. Miguel Hijjar</td>
<td>National Reference Lab (Helio Fraga)</td>
<td>Director of National Reference Lab</td>
</tr>
<tr>
<td>Andrea Sousa De Ataide</td>
<td>MOH/ National TB Program</td>
<td>Pharmacy services</td>
</tr>
<tr>
<td>Dr. Joel Keravec</td>
<td>Projeto MSH – Rational Pharmaceutical Management Program – Management Sciences for Health</td>
<td>Director MSH Office- Brazil/ former Anvisa</td>
</tr>
<tr>
<td>Dr. Vera Galesi</td>
<td>Sao Paulo State TB Program</td>
<td>State TB Program Manager</td>
</tr>
<tr>
<td>Marilene Vinhas</td>
<td></td>
<td>Pharmacist at warehouse</td>
</tr>
<tr>
<td>Dr. Naomi Komatsu</td>
<td>Sao Paulo Municipal TB program</td>
<td>Municipal TB Program Mgr</td>
</tr>
<tr>
<td>Dr. Lisia Freitas</td>
<td>Rio de Janeiro State TB Program</td>
<td>State TB Program Manager</td>
</tr>
<tr>
<td>Dr. Betina Durovsky</td>
<td>Rio de Janeiro Municipal TB Program</td>
<td>Municipal TB Program Manager</td>
</tr>
<tr>
<td>Dr. Solange Cavalcante</td>
<td>Rio de Janeiro Municipal TB Program</td>
<td></td>
</tr>
<tr>
<td>Dr. Rosangela</td>
<td>Bahia State TB Program</td>
<td>State TB Program Manager</td>
</tr>
<tr>
<td>Dr. Edilson</td>
<td>Minas Gerais State TB Program</td>
<td>State TB Program Manager</td>
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</table>
### Appendix: Interviewed Stakeholders (continued)

<table>
<thead>
<tr>
<th>Individual</th>
<th>Organization</th>
<th>Position</th>
</tr>
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<tbody>
<tr>
<td>Dr Luis Gustavo Bastos</td>
<td>Project MSH/ RPM Plus - Brazil</td>
<td>MSH consultant/ practicing physician</td>
</tr>
<tr>
<td>Dr Jorge Rocha</td>
<td>Project MSH/ RPM Plus - Brazil</td>
<td>MSH consultant/ practicing physician</td>
</tr>
<tr>
<td>Dr. Fernando Fiuzza</td>
<td>Instituto Clemente Ferreira TB Reference Center</td>
<td>Physician</td>
</tr>
<tr>
<td></td>
<td>São Paulo TB Reference Center</td>
<td></td>
</tr>
<tr>
<td>Dr. Ana Regina</td>
<td>Centro Municipal de Saúde Píndaro de Carvalho Rodrigues (DOTS)</td>
<td>Physician</td>
</tr>
<tr>
<td>Dr. Paulo Alburquerque</td>
<td>Policlinica Amaral Peixoto (Non-DOTS clinic)</td>
<td>Physician</td>
</tr>
<tr>
<td>Dr Afranio Kritski</td>
<td>Universidade Federal do Rio de Janeiro</td>
<td>Director of Academic TB Program</td>
</tr>
<tr>
<td>Dr German Filho</td>
<td>Fundação Ataulfo de Paiva - RJ</td>
<td>Director and former PNCT program mgr</td>
</tr>
<tr>
<td>Dr Marcio Thome</td>
<td>BEMFAM (NGO)</td>
<td>Director of logistics and supply</td>
</tr>
</tbody>
</table>
Appendix: Brazil Dosing Guidelines

**PNCT TB Drug Treatment Regimen for Scheme 1**

<table>
<thead>
<tr>
<th>Category</th>
<th>PNCT Regimen (mg/day) for patient over 45 kg</th>
<th>WHO recommended for 45kg</th>
<th>WHO recommended for 70 kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rifampicin</td>
<td>600 mg</td>
<td>450 mg</td>
<td>600 mg (because of max)</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>400 mg</td>
<td>225 mg</td>
<td>350 mg</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>2,000 mg*</td>
<td>1125 mg*</td>
<td>1750 mg*</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>not used for previously untreated patients</td>
<td>675 mg*</td>
<td>1050 mg*</td>
</tr>
</tbody>
</table>

*Details on the 1st line Regimen*

Initial phase is 2 month. Continuation phase is 4 months. Pyrazinamide (and ethambutol) not used in continuation phase.

Source: Brazil MOH; Tuberculosis Coalition for Technical Assistance.