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

South Africa Case Study

Prepared with IMS Consulting
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- TB Control in South Africa
- Procurement and Distribution of TB Drugs in South Africa
- Value and Volume of the South African TB Market
- Appendix
South Africa’s TB burden is national, with each region suffering from high incidence of TB

- South Africa is ranked 5th among countries with the highest TB burden (recently moved from 8th)
- There were approx 118,000 new smear positive TB cases in 2004 of which 60% were co-infected with HIV/AIDS
- Case notifications on the rise—partially due to start of NTP and prevalence of HIV
- Nearly all provinces have an incidence rate at or above 200 per 100K population

The National TB Program is under the Ministry of Health, within a section called “strategic health programs”
The program is staffed by a national program manager and 9 technical staff as well as a WHO national professional officer (NPO).

**National Level TB Staff and Flow of Reporting**

- **National TB Control Program Manager**
  - Reporting & Recording—2 staff
  - DOTS—1 staff
  - Advocacy and Social Mobilization—2 staff
  - Inpatient Care—2 staff
  - Training—2 staff
  - 4 Support Staff

- **WHO TB NPO**
  - Appointed by and reports to the MoH
  - Paid by WHO

Source: Interviews
Although policy is governed at the central level, like other health care issues, most decision making about services are decentralized to the provincial level.

### Level of NTP

<table>
<thead>
<tr>
<th>National</th>
<th>Provincial</th>
<th>District/Sub-district</th>
<th>Facilities</th>
</tr>
</thead>
</table>

### Description of Responsibilities

- **National**
  - Advising and formulating policies
  - Compiling data from provinces
  - Monitoring and evaluation

- **Provincial**
  - Advising and formulating policies
  - Compiling data from districts/sub-districts
  - Negotiating budgets for TB control and drug procurement

- **District/Sub-district**
  - Implementation of program
  - Supervision and evaluation of facilities
  - Compiling data from facilities

- **Facilities**
  - Administering treatment

Source: Interviews
South Africa’s annual TB expenses are estimated to be 250-300M USD

- **South Africa’s TB control program receives technical assistance from a range of NGOs and multilateral agencies:**
  - International Union Against TB and Lung Disease
  - World Health Organization (WHO)
  - Management Sciences for Health (MSH)

- **HIV/TB is one area in which grant money is used to a significant extent**
  - South Africa has received three GFATM grants for HIV/TB, totalling approximately 91M USD (most of which has been disbursed as of last year)
  - The Provincial Health Department of the Western Cape is also the recipient of a GFATM grant of approximately 15M USD

- **However, the program derives the vast majority of its funding from national and provincial healthcare budgets**

Source: The Stop TB Partnership in South Africa; Global TB Control, Surveillance, Planning, Financing – WHO (2006); Interviews
Provinces are allocated an “equitable share” of resources from the National Treasury, which is distributed to the districts and facilities.
Expenditures for TB are found within the category of primary health care.

- When the National Treasury allocates a province’s “equitable share” of funds, it provides some guidance as to how those funds are spent.
- However, provinces make the final decision as to how much to set aside for healthcare vs. education, social services, etc.
- Within healthcare, a certain budget is set aside for Primary Health, under which TB is folded.
- In rare instances (e.g., North West Program), the Provincial TB Coordinator may secure a budget for the TB program and TB drugs.
TB control in South Africa leverages the primary healthcare system.

**Patient Flow Through TB Settings of Care**

1. **Public sector**
   - General Public Clinics
   - General Public Hospitals
   - Military Facilities
   - Correctional Facilities

2. **Public-Private**
   - TB Program Partners

3. **Private sector**
   - Private Providers/Hospitals
   - Industry/Corporate Facilities
   - Traditional Medicine Practitioners
   - Charitable Facilities
The government of South Africa considers TB control the mandate of the public sector.

- TB control is primarily administered through public healthcare facilities—including those that cater to the general public, the military, and prisoners within correctional facilities.
- Guidelines for TB diagnosis and treatment authored at the national level.
- Funding is derived from provincial budgets.
Patients are typically diagnosed and treated by a public health facility—most commonly in a clinic setting

- Patient approaches public health facility for consultation
- Clinics are usually the first point at which patients present—hospitals are generally far between and require travel time

- Patients who are suspected of having TB are given a sputum smear test
- Sample is sent to microscopy lab for diagnosis
- Results are returned to the facility within 24-48 hours, though delays in the actual communication of those results to the patients are common

Source: Interviews
Patients who are confirmed as having TB may either be started on DOTS or referred to a specialist clinic.

Patient diagnosed with TB

TB

Severe symptoms and/or suspected of having MDR-TB

Patient referred to begin DOTS

- DOTS can take place in several settings:
  - Clinic
  - Community under supervision of a DOTS supporter
  - Workplace under supervision of DOTS supporter (employer)

- Under special circumstances, patient may be allowed to self-administer treatment

Patient referred to specialist clinic

- Patients receive care from a specialist clinic located in a district or regional hospital (e.g., Brooklyn Chest Hospital in the Western Cape)
- DST commences for patients suspected of having MDR-TB
- Patients receive inpatient care until cured or well enough to leave facility

Patient referred to ARV treatment site

- Patients receive TB and HIV treatment under care of a specially trained healthcare worker

Source: TB Control Programme [www.capegateway.gov.za](http://www.capegateway.gov.za); Interviews
TB Control in South Africa: Public Sector

TB smear positive patients are given an FDC treatment regimen that is administered five times per week.

### NTP 1st Line Drug Treatment Regimen

<table>
<thead>
<tr>
<th>Patient Category</th>
<th>NTP Treatment Regimen</th>
<th>Method of administration</th>
</tr>
</thead>
</table>
| Regimen 1: new smear positive, new smear negative, and extrapulmonary TB | 2 (HRZE)$_5$ / 4 (HR)$_5$ or 4(HR)$_3$ | **Use of FDCs**  
Patients directly observed once per week by healthcare worker  
Remaining doses in week are given to DOTS supporter who observes the patient |
| Regimen 2: previously treated TB patients after cure, after completion, interruption, and failure | 2(HRZE)$_5$S$_5$ / 1(HRZE)$_5$ / 5(HRE)$_5$ or 5(HR)$_3$ |  |
| Pediatric (for patients below 8 years) | 2(HRZ)$_5$/4(HR)$_5$ or 4(HR)$_3$ |  |

**Details on the 1st line Regimen**

6-8 month treatment regimen. All treatment five times weekly unless patient resides far from health facilities and have no DOTS supporter.

Those who are confirmed as having MDR-TB are treated with a standardized 2nd line treatment regimen

<table>
<thead>
<tr>
<th>Patient Category</th>
<th>Initial Phase</th>
<th>Continuation Phase</th>
<th>Method of administration</th>
</tr>
</thead>
</table>
| MDR-TB Patient   | 4 months (5 or 7 times per week)  
• Kanamycin  
• Ethionamide  
• Cycloserine  
• Pyrazinamide  
• Ofloxacin  
• Ethambutol or terizidone | 12-18(5 or 7 times per week)  
• Ethionamide  
• Cycloserine  
• Ofloxacin  
• Ethambutol or terizidone | • Patients are referred to special facility for inpatient treatment  
• 16-22 month personalized drug regimen based on DST |

**Details on the 2nd line Regimen**
Terizidone used in patients who are resistant to ethambutol. In exceptional circumstances, amikacin can be used in place of kanamycin and ciprofloxacin can be used in place of ofloxacin.

TB Control in South Africa: Public Sector

Since the inception of the national program in 1996, DOTS notification rates have grown rapidly.


Growth of DOTS in South Africa

DOTS notification Rate (new and relapse, per 100K pop)

DOTS Coverage %
Some provinces have chosen to incorporate private facilities into their TB programs

- Private providers—such as industry/corporate sponsored health facilities or charitable facilities—can be enlisted to provide TB treatment to patients
- These providers may receive funding from the government on a per patient basis to diagnose, categorize, and treat patients
- Some provinces have also recruited practitioners of traditional medicine—providing them with financial incentives to refer TB patients to the public sector and/or serve as DOTS supporters
These partners play various roles within the TB control program of any given province

**Initial Diagnosis and Referral**

- Some charitable facilities operating in regions in which the public sector resources are sparse may be enlisted to identify suspected TB patients and refer them to the public sector.
- Traditional medicine practitioners may also be trained to recognize patients who have TB and refer them to the public sector.

**DOTS Supporters**

- Because the direct-observation of all TB patients is often beyond the capacity of the public sector, it often relies on the help of other parties (i.e., DOTS supporters) to carry out observation once treatment has commenced.
- Charitable facilities may either serve as DOTS supporters themselves or help to recruit, train, and supervise DOTS supporters.
- Traditional medicine practitioners have also been enlisted to serve as DOTS supporters.

**Setting of Treatment**

- Some charitable facilities, such as those that used to be under SANTA, are used by the program to serve as a specialty clinic.
- In addition, industry/corporate-run facilities—e.g., large mining companies—may choose to partner with the government, receive funding on a per patient basis, and treat their employees with TB.

The private sector is not prohibited from prescribing and distributing TB drugs, but it is required to inform patients that they can receive free treatment in the public sector.

- Though most TB patients present to public facilities, TB diagnosis and treatment is possible in for-profit facilities and industry/corporate-run facilities.
- These private providers are required to report all cases of TB to the government and inform patients that free treatment is available in the public sector.
- In some cases, medical insurance will pay for TB drugs but will list it as “acute disease drug treatment” for which patients only receive a yearly allowance.
Although very uncommon, patients do have the option to receive treatment in the private sector.

**Patient Flow between Public and Private Sector**

- **Consults with private provider**
- If suspected of having TB, is informed that free public sector treatment is an option
  - Consults with public sector facility
  - Is diagnosed and receives treatment in public sector
    - Free of charge
  - Receives prescription from private provider
  - Picks-up prescription in retail pharmacy and initiates treatment on own
    - Self-pay or medical insurance, if plan covers TB

*Source: The Stop TB Partnership in South Africa, Interviews*
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There are three mechanisms through which TB drugs are procured in South Africa

**Procurement mechanisms**

- **National Tender**
- **Direct Negotiations**
- **Distributor/Wholesaler**

- **General Public Facilities**
- **Correctional and Military Facilities**
- **TB Program Partners**
- **Private facilities**
- **Retail Pharmacies**
- **Other**

Source: IMS Consulting PQ Systems, interviews
TB drugs are part of SA’s Essential Drug List (EDL) and thus are available through the public health system.

**Essential Drug List**
- Exists for non-TB as well as TB indications
- Exists in two forms: one for primary healthcare facilities and one for hospitals
- Published at regular intervals by the Ministry of Health’s National Essential Drug List Committee, with the assistance of an expert review committee
  - Primary Healthcare EDL last revised in 2003
  - Previous version released in 1998
- Criteria for EDL status are based on the WHO guidelines:
  - Proven safety and efficacy
  - Cost effectiveness
  - Meets the needs of a majority of the population

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**Key Influencers**

- Essential Drug List Committee
- Expert Review Panel
- NTP

*Not a member of the team but makes recommendations as to what drugs should be added for TB*

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Source: Ministry of Health (MoH) website, Interviews
TB and other drugs on the EDL are usually procured by Pharmaceutical Planning and Policy Cluster in conjunction with the National State Tender Board.

The Pharmaceutical Planning and Policy Cluster conducts the forecasts of drug needs based on reported used from provinces. It collaborates with the National State Tender Board—a government body that administers public tenders in all areas (not just pharmaceuticals)—to procure pharmaceutical products on behalf of the public healthcare system. In addition, the cluster negotiates with suppliers for pharmaceutical products that are not on tender.

Source: Ministry of Health website; Interviews
### Procurement and Distribution of TB Drugs in South Africa

Separate tenders for 1st and 2nd line drugs are floated once every two years

<table>
<thead>
<tr>
<th>Who administers the tender?</th>
<th>• National State Tendering Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>International or national tender?</td>
<td>• National</td>
</tr>
<tr>
<td></td>
<td>• Under exceptional circumstances, will issue and international bid</td>
</tr>
<tr>
<td>Pre-qualification required?</td>
<td>• Yes</td>
</tr>
<tr>
<td></td>
<td>• Companies and drugs must have marketing approval in South Africa</td>
</tr>
<tr>
<td>How often is tender floated?</td>
<td>• Once every two years</td>
</tr>
<tr>
<td></td>
<td>• When new treatment regimen introduced, contract can be shortened</td>
</tr>
<tr>
<td>How is tender awarded?</td>
<td>• 90% on price</td>
</tr>
<tr>
<td></td>
<td>• 10% on other factors (e.g., points accumulated under Preferential Procurement Policy Framework Act (2000)*)</td>
</tr>
</tbody>
</table>

*See appendix for full listing of pre-qualification requirements and more details on Preferential Policy Framework Act

Source: IMS Concise Guide; National Treasury of South Africa; General Conditions and Procedures of the State Tender Board; SABS Website
The tenders for 1st line TB drugs are currently held by Sandoz and Sanofi-Aventis, while the 2nd line tender includes a greater mix of suppliers

<table>
<thead>
<tr>
<th>1st Line Drug Suppliers</th>
<th>2nd Line Drugs Suppliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sandoz</td>
<td>• Be-tabs Pharmaceuticals</td>
</tr>
<tr>
<td>• Sanofi-Aventis</td>
<td>• Biotech Laboratories*</td>
</tr>
<tr>
<td></td>
<td>• Bizshelf Pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td>• Caps Pharmaceuticals*</td>
</tr>
<tr>
<td></td>
<td>• Pfizer Laboratories*</td>
</tr>
<tr>
<td></td>
<td>• Sandoz</td>
</tr>
<tr>
<td></td>
<td>• Sanofi-Aventis</td>
</tr>
<tr>
<td></td>
<td>• International suppliers</td>
</tr>
</tbody>
</table>

*Suppliers of streptomycin, which is also used in the 1st line treatment of relapse patients

Source: Interviews
Procurement and Distribution of TB Drugs in South Africa

Starting in the next one to two years, the two 2nd line drugs that are not currently on tender will be manufactured in South Africa by Aspen Pharmacare:

- A separate tender is run for 2nd line drugs that are manufactured by a local company and are needed in large enough quantities to run a tender.
- At this time, the public tender includes terizadone, ethambutol (loose), pyrazinamide (loose), streptomycin, and kanamycin are on tender.
- Capreomycin and cycloserine are procured via direct negotiations with international suppliers.

- Eli Lilly has agreed to a technological transfer of two second line drugs—capreomycin and cycloserine—to Aspen Pharmacare*

*Aspen is also in discussions with Lupin to receive a technological transfer for 1st line FDCs, though the agreement is still being finalized.

Source: Eli Lilly website; Interviews
Procurement and Distribution of TB Drugs in South Africa

In the public sector, TB drugs flow through a series of government depots before reaching the facilities and patients.

Drug Flow: Public Sector Channels

Contracted distributor picks up drugs from suppliers and ship them to the government depots.

Government depots then distribute the drugs to NTP affiliated facilities.

Facilities administer treatment to patients.

Source: Interviews
Procurement and Distribution of TB Drugs in South Africa

Provincial depots place orders with suppliers and serve as the starting point for drug distribution to the government depots and general public facilities.

**Flow of Ordering: General Public Facilities**

- **Provincial depots** place orders with the suppliers based on reported use.
- **District depots** place orders with the provincial depots.
- **Hospitals** place orders with the district depots.
- **Clinics** will place orders with either hospitals or with the district depot.

Ordering is done either by a general pharmacist or a healthcare worker and is largely independent of the TB Program.

Source: Interviews
They also serve as the sourcing point for other facilities working in cooperation with the NTP.

**Flow of Ordering: Other NTP-affiliated Facilities**

Orders with the provincial depots are placed either by warehouses acting on behalf of multiple facilities or a facility itself. In a few instances, the facilities may order directly from the suppliers at public tender prices.

*Source: Interviews*
In the private sector, TB drugs flow through the same routes as other pharmaceuticals and are subject to a set mark-up structure.

**Drug Flow: Private Sector Channels**

1. **1st point of sale:** Manufacturers sell their TB drugs to distributors

2. **2nd point of sale:** Distributors sell to distributors at a 2.5%* markup (no more than R1)

3. **3rd point of sale:** Wholesalers sell drugs to retail pharmacies and private clinics/hospitals at a 12.5%* markup (no more than R5)

Retail sale: Retail pharmacies then dispense drugs to patients at a 24%* mark-up (no more than R24 per pack). Dispensing doctors are limited to 16% (no more than R16)

*%age of SEP, refer to appendix for details on Single Exit Pricing

Source: IMS expertise
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The total TB market in South Africa is currently valued at approximately 21.8M USD, nearly all of which falls in the public sector.

**A publicly-driven market**
- The vast majority of the value of TB drugs flows through the public sector
  - The public sector is estimated to hold 92% (20.0 USD) market value share
  - The private sector accounts for the remaining 8% (1.8M USD)
- When segmenting the market from a volume (standard units) perspective, the market is also primarily in the public sector
  - 95.7% of the market volume lies in the public sector
  - 4.3% of the market volume is in the private sector

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

Source: Supplier figures, IMS database, IMS Consulting analysis
1st line drugs represent the vast majority of the total market value today

**Almost entirely a 1st line market**
- 1st line drugs account for 19.3M USD or 94% of the total market
- Predominantly public sector
- Heavy use of FDCs in both the private and public sector (where FDCs are recommended)

**Niched 2nd line market**
- Data suggest that 2nd line drugs account for 2.5M USD or 6% of the total market
- Public share of market value rapidly growing

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

Source: Supplier figures, IMS database, IMS Consulting analysis
In terms of value, 95 percent of the 1st line market is in the public sector.

### 2005 1st Line Value Sales

- **Private Sector**: 0.94 USD Millions
- **Public Sector**: 18.31 USD Millions

### 1st Line Drug Market

- 95% of the 19.25M USD 1st line market is in the public sector.
- Approximately 250-260K new patients initiated on treatment each year.
- Sanofi Aventis and Sandoz are the only players in the public sector:
  - Sanofi Aventis holds 49% volume share and 53% value share.
  - Sandoz holds 51% volume share and 47% value share.

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

Source: Supplier figures, IMS database, IMS Consulting analysis.
Expenditures on 1st line drugs vary considerably between provinces

2005 1st Line Public Value Sales by Province

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

Source: Supplier figures, IMS Consulting analysis
In the 2nd line market, the public sector holds the majority of the market value but by less of a margin than in the 1st line market.

**2005 2nd Line Value Sales***

- 2nd line drugs account for 2.5 M USD or 6% of total TB market
- Approximately 66% of the 2nd line market value is in the public sector
- Tenders issued and awarded by product and do not distinguish between use in TB or non-TB indications**
- Market as a whole is led by Sanofi Aventis, though shared by a larger number of players such as Betabs and Biotech

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

*Sales of cycloserine or capreomycin not available

**Figures presented adjusted for use in non-TB indications

Source: IMS database, IMS Consulting analysis
The public sector’s share of the 2nd line market has increased rapidly over the past five years.

**2001-2005 2nd Line Value Sales**

- **Public Sector**:
  - 2001: 113 USD Thousands
  - 2002: 118 USD Thousands
  - 2003: 544 USD Thousands
  - 2004: 1,215 USD Thousands
  - 2005: 1,715 USD Thousands

- **Private Sector**:
  - 2001: 654 USD Thousands
  - 2002: 774 USD Thousands
  - 2003: 888 USD Thousands
  - 2004: 888 USD Thousands
  - 2005: 854 USD Thousands

*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: IMS database, IMS Consulting analysis
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## Appendix: Interviewed Stakeholders

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<th>Individual</th>
<th>Organization</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Lindiwe Mvusi</td>
<td>National TB Control Program</td>
<td>NTP Director</td>
</tr>
<tr>
<td>Mandisa Helle</td>
<td>Pharmacy Planning and Policy</td>
<td>Dir of Pharmacy Services</td>
</tr>
<tr>
<td>Ms. Alvera Swartz</td>
<td>Provincial TB Control Program, West Cape</td>
<td>Provincial NTP Coordinator, Assistant Director, TB Control</td>
</tr>
<tr>
<td>Liezel Channing</td>
<td>Provincial TB Control Program, West Cape</td>
<td>Pharmacist ARV Program</td>
</tr>
<tr>
<td>Ann Preller</td>
<td>Provincial TB Control Program, North West</td>
<td>Provincial NTP Coordinator</td>
</tr>
<tr>
<td>James Kruger</td>
<td>District TB Control Program (Boland Overberg)</td>
<td>District NTP Director (Boland, Overberg)</td>
</tr>
<tr>
<td>Virginia de Azeveda</td>
<td>Sub-district TB Control Program (Kylitscha)</td>
<td>Sub-district NTP Director (Kylitscha)</td>
</tr>
<tr>
<td>Dr. M. Makhetha</td>
<td>WHO</td>
<td>TB Program Coordinator / NPO - TB</td>
</tr>
<tr>
<td>John Heinrich</td>
<td>SANTA</td>
<td>CEO</td>
</tr>
<tr>
<td>Ethel Makoena</td>
<td>SANTA</td>
<td>Chairman</td>
</tr>
<tr>
<td>Mrs Ria Grant</td>
<td>TB Care Association</td>
<td>Director</td>
</tr>
<tr>
<td>Prof. Gavin Churchyard</td>
<td>Aurum Institute</td>
<td>CEO</td>
</tr>
<tr>
<td>Dr. Penny Mkalipe</td>
<td>ESKOM</td>
<td>Medical Officer</td>
</tr>
<tr>
<td>Prof. Deon Du Plessis</td>
<td>Netcare</td>
<td>Medical Director</td>
</tr>
</tbody>
</table>
## Appendix: Interviewed Stakeholders (continued)

<table>
<thead>
<tr>
<th>Individual</th>
<th>Organization</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reuben Mawela</td>
<td>Sanofi Aventis</td>
<td>District Sales Manager, TB</td>
</tr>
<tr>
<td>Alan Beattie</td>
<td>Aspen Pharmacare</td>
<td>National Sales Manager (Public Sector)</td>
</tr>
<tr>
<td>Elaine Cross</td>
<td>Sandoz</td>
<td>Head of TB Supplies</td>
</tr>
<tr>
<td>Dr. Bernard Fourie</td>
<td>MRC</td>
<td>Research Associate/Clinical Trials Advisor to the MRC; Chief Scientific Officer/Dir of South African Operations of MEND</td>
</tr>
<tr>
<td>Jean-Pierre Sallet</td>
<td>MSH</td>
<td>Regional Technical Advisor</td>
</tr>
<tr>
<td>Tumi Molongoana</td>
<td>MSH</td>
<td>Senior Program Associate</td>
</tr>
<tr>
<td>Shabir Banoo</td>
<td>MSH</td>
<td>Senior Program Associate</td>
</tr>
<tr>
<td>Sipho Mthathi</td>
<td>TAC</td>
<td>CEO</td>
</tr>
</tbody>
</table>
Appendix: Other key stakeholders relevant to TB control

Cluster under which Medicines Control Council (MCC) sits:
- South African regulatory authority to whom new drug applications must be made
- Headed by Dr HZ Zokufa

National Health Laboratory Services (NHLS)

Source: Ministry of Health website, Interviews
Appendix: Medicines Control Council approvals process

1. **Company submits a dossier to the MCC**
   - Companies submit data on the drug they wish to gain approval for to the Medicines Control Council (MCC) in the form of a dossier.

2. **Evidence is considered by external experts**
   - Submissions are evaluated by external experts who evaluate drugs against standards laid down by the Medicines and Related Substances Control Act.

3. **Market access is granted**
   - Drugs meeting those standards are granted market access.

- **The MCC currently has a backlog of drugs to consider for market access and so drugs have faced delays of up to 3 years.**
- **Even drugs that are “fast-tracked” can expect timelines of 1 year from submission to approval.**
Appendix: Broad Based Black Economic Empowerment (BEE) Act

Details on the Broad Based Black Economic Empowerment Act

- Passed in 2004, designed to promote a more equitable distribution of wealth among all historically disadvantaged people (HDP)—i.e., women, disabled, black
- Operates via a scorecard with which a company’s progress in BEE is measured
- Required by any private company wishing to do business in the public sector
- Employed by all state-run bodies and the government when making decisions on procurement, licensing and concessions, and the sale of state-owned assets or businesses
- Feeds into the Preferential Procurement Policy Framework

BEE SCORECARD

<table>
<thead>
<tr>
<th>Direct empowerment through ownership and control of enterprises and assets</th>
<th>Management at a senior level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indirect empowerment: preferential procurement, enterprise development, corporate social investment</td>
<td></td>
</tr>
<tr>
<td>Human resource development and employment equity</td>
<td></td>
</tr>
</tbody>
</table>

Source: [www.southafrica.info](http://www.southafrica.info) – Black Economic Empowerment
Appendix: Preferential Procurement Policy Framework Act

**Key Factors of Framework**

<table>
<thead>
<tr>
<th>Factor</th>
<th>Details</th>
</tr>
</thead>
</table>
| **Price**       | • Established in 2000 to provide a framework for state procurement  \  
                   • Preferential points are awarded to companies for price, functionality and HDP involvement (see BEE Act)  \  
                   • For cases in which price and functionality are comparable, companies demonstrating economic empowerment of HDPs are preferred choices for tenders  \  
                   • Joint ventures with companies demonstrating high HDP involvement are common—e.g., Enaleni manufactures and supplies all Merck products for the government pharmaceutical tender market |
| **Functionality** |                                                                                                                                           |
| **HDP Involvement** |                                                                                                                                          |
| **Nationality** |                                                                                                                                           |

Appendix: Full treatment guidelines for Regimen 1 patients (new smear positive, new smear negative, extrapulmonary)

<table>
<thead>
<tr>
<th>Pretreatment body weight</th>
<th>Initial Phase (2 Months)</th>
<th>Continuous Phase (4 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>To be given 5 times per week</td>
<td>When given 5 times per week</td>
</tr>
<tr>
<td>RHZE (150/75/400/275)</td>
<td>RH (150/75)</td>
<td>RH (300/150)</td>
</tr>
<tr>
<td>30-37 kg</td>
<td>2 tabs</td>
<td>2 tabs</td>
</tr>
<tr>
<td>38-54 kg</td>
<td>3 tabs</td>
<td>3 tabs</td>
</tr>
<tr>
<td>55-70 kg</td>
<td>4 tabs</td>
<td>--</td>
</tr>
<tr>
<td>Greater than 71 kg</td>
<td>5 tabs</td>
<td>--</td>
</tr>
</tbody>
</table>

# Appendix: Full treatment guidelines for Regimen 2 patients (relapse)

## Initial Phase (1st 2 Months)

<table>
<thead>
<tr>
<th>Pretreatment body weight</th>
<th>To be given 5 times per week</th>
<th>When given 5 times per week</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RHZE (150/75/400/275)</td>
<td>Streptomycin (g)</td>
</tr>
<tr>
<td>30-37 kg</td>
<td>2 tabs</td>
<td>0.5</td>
</tr>
<tr>
<td>38-54 kg</td>
<td>3 tabs</td>
<td>0.75</td>
</tr>
<tr>
<td>55-70 kg</td>
<td>4 tabs</td>
<td>1.0</td>
</tr>
<tr>
<td>Greater than 71 kg</td>
<td>5 tabs</td>
<td>1.0</td>
</tr>
</tbody>
</table>

When given 3 times per week:

<table>
<thead>
<tr>
<th>RH (150/150)</th>
<th>E (400)</th>
<th>RH (150/150)</th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 tabs</td>
<td>2 tabs</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>3 tabs</td>
<td>3 tabs</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>--</td>
<td>--</td>
<td>3 tabs</td>
<td>4 tabs</td>
</tr>
<tr>
<td>--</td>
<td>--</td>
<td>3 tabs</td>
<td>4 tabs</td>
</tr>
</tbody>
</table>

Appendix; Full treatment guidelines for pediatric TB patients

<table>
<thead>
<tr>
<th>Pretreatment body weight</th>
<th>Initial Phase (2 Months)</th>
<th>Continuous Phase (4 months)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5 times per week</td>
<td>5 times per week</td>
</tr>
<tr>
<td></td>
<td>RHZ (60/30/150)</td>
<td>RH (60/30)</td>
</tr>
<tr>
<td>3-4 kg</td>
<td>0.5 tab</td>
<td>0.5 tab</td>
</tr>
<tr>
<td>5-7 kg</td>
<td>1 tab</td>
<td>1 tab</td>
</tr>
<tr>
<td>8-9 kg</td>
<td>1.5 tabs</td>
<td>1.5 tabs</td>
</tr>
<tr>
<td>10-14 kg</td>
<td>2 tabs</td>
<td>2 tabs</td>
</tr>
<tr>
<td>15-19 kg</td>
<td>3 tabs</td>
<td>3 tabs</td>
</tr>
<tr>
<td>20-24 kg</td>
<td>4 tabs</td>
<td>4 tabs</td>
</tr>
<tr>
<td>25-29 kg</td>
<td>5 tabs</td>
<td>5 tabs</td>
</tr>
<tr>
<td>30-35 kg</td>
<td>6 tabs</td>
<td>6 tabs</td>
</tr>
</tbody>
</table>

## Sandoz private sector prices (USD)

<table>
<thead>
<tr>
<th>Sandoz Trade Name</th>
<th>Pack Size</th>
<th>SEP Prices (VAT Excluded)</th>
<th>SEP Prices (VAT Included)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rimactane 150</td>
<td>100</td>
<td>16.50</td>
<td>18.81</td>
</tr>
<tr>
<td>Rimactane 300 Vials</td>
<td>1</td>
<td>17.29</td>
<td>19.71</td>
</tr>
<tr>
<td>Rimactane 450</td>
<td>100</td>
<td>29.03</td>
<td>33.09</td>
</tr>
<tr>
<td>Rimactane 600</td>
<td>100</td>
<td>54.15</td>
<td>61.73</td>
</tr>
<tr>
<td>Rimactazid 150/75</td>
<td>60</td>
<td>7.00</td>
<td>7.98</td>
</tr>
<tr>
<td>Rimactazid 300/150</td>
<td>40</td>
<td>6.20</td>
<td>7.07</td>
</tr>
<tr>
<td>Rimactazid 60/30</td>
<td>40</td>
<td>5.27</td>
<td>6.00</td>
</tr>
<tr>
<td>Rimactazid Paed 60/60</td>
<td>80</td>
<td>11.92</td>
<td>13.59</td>
</tr>
<tr>
<td>Rimactazid Paed 60/60</td>
<td>120</td>
<td>17.88</td>
<td>20.38</td>
</tr>
<tr>
<td>Rimcure Paed 3-FDC</td>
<td>80</td>
<td>15.93</td>
<td>18.16</td>
</tr>
<tr>
<td>Rimcure Paed 3-FDC</td>
<td>120</td>
<td>23.90</td>
<td>27.24</td>
</tr>
<tr>
<td>Rimcure Paed 3-FDC</td>
<td>500</td>
<td>99.57</td>
<td>113.51</td>
</tr>
<tr>
<td>Rimstar 4-FDC</td>
<td>40</td>
<td>4.60</td>
<td>5.24</td>
</tr>
<tr>
<td>Rimstar 4-FDC</td>
<td>60</td>
<td>6.90</td>
<td>7.87</td>
</tr>
</tbody>
</table>

*Source: Supplier figures*
## Sandoz private sector prices (USD) (continued)

<table>
<thead>
<tr>
<th>Sandoz Trade Name</th>
<th>Pack Size</th>
<th>SEP Prices (VAT Excluded)</th>
<th>SEP Prices (VAT Included)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rimstar 4-FDC</td>
<td>80</td>
<td>9.20</td>
<td>10.49</td>
</tr>
<tr>
<td>Rimstar 4-FDC</td>
<td>100</td>
<td>11.50</td>
<td>13.11</td>
</tr>
<tr>
<td>Rimstar 4-FDC</td>
<td>500</td>
<td>57.50</td>
<td>65.55</td>
</tr>
<tr>
<td>Sandoz Ethambutol HCl 400</td>
<td>100</td>
<td>12.67</td>
<td>14.44</td>
</tr>
<tr>
<td>Sandoz Pyrazinamide 500</td>
<td>100</td>
<td>14.72</td>
<td>16.78</td>
</tr>
</tbody>
</table>

Source: Supplier figures
### Appendix: Sanofi-Aventis private sector prices (USD)

<table>
<thead>
<tr>
<th>Sanofi-Aventis Trade Name</th>
<th>Pack Size</th>
<th>SEP Prices (VAT Excluded)</th>
<th>SEP Prices (VAT Included)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rifafour e-275</td>
<td>40</td>
<td>4.43</td>
<td>5.05</td>
</tr>
<tr>
<td>Rifafour e-275</td>
<td>60</td>
<td>6.64</td>
<td>7.57</td>
</tr>
<tr>
<td>Rifafour e-275</td>
<td>80</td>
<td>8.86</td>
<td>10.10</td>
</tr>
<tr>
<td>Rifafour e-275</td>
<td>100</td>
<td>11.65</td>
<td>13.29</td>
</tr>
<tr>
<td>Rifafour e-275</td>
<td>500</td>
<td>55.35</td>
<td>63.10</td>
</tr>
<tr>
<td>Rifinah 300 mg</td>
<td>40</td>
<td>5.83</td>
<td>6.65</td>
</tr>
<tr>
<td>Rifater Junior</td>
<td>40</td>
<td>7.00</td>
<td>7.98</td>
</tr>
<tr>
<td>Rifinah Junior</td>
<td>40</td>
<td>5.78</td>
<td>6.58</td>
</tr>
</tbody>
</table>

Source: Supplier figures