# MTHATHA AREA STOCK-OUTS UPDATE | MARCH 2013 – MAY 2013

# The chronic crisis - Essential drug stock-outs risk unnecessary death and drug resistance in South Africa.

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## *Patients on ARVs & TB drugs risk death & drug resistance as they continue to suffer treatment interruption*

A report by Doctors Without Borders (MSF), Treatment Action Campaign (TAC), the Rural Health Advocacy Project (RHAP), and SECTION27

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# EXECUTIVE SUMMARY

In this update on drug supply in the Eastern Cape and other provinces, Rural Health Advocacy Project (RHAP), Doctors Without Borders (MSF), the Treatment Action Campaign (TAC) and SECTION27 show that many thousands of patients on antiretroviral (ARV) and TB drugs in the Eastern Cape, as well as elsewhere, continue to experience stock-outs at health facilities.

On 10 October 2012, staff at Mthatha depot in the Eastern Cape staged a strike, following which 29 individuals were suspended, leaving the depot with only 10 working employees. Coupled with chronic supply chain issues, this precipitated widespread drug stock-outs in the region.

Because over 100,000 patients depend upon supplies of antiretroviral therapy (ART) from Mthatha depot, MSF, TAC, RHAP and SECTION27 were particularly concerned that this disruption would lead to a significant interruption to patients' critical drug supplies. This jeopardizes proper adherence and reduces the benefit of ARVs; leading to increased morbidity and mortality among patients as well as increasing drug resistance.

This concern was originally borne out by an MSF and TAC survey in January 2013 which found that 53% of facilities responding had experienced ARV and/or TB drug stock-outs, with 24% having to send patients home with no ARVS. A wide variety of other essential medicines were also affected.

The survey followed an intervention by MSF and TAC during December 2012 to respond to the burgeoning Mthatha depot crisis by supporting staffing, managing and ensuring drug delivery at the depot. This intervention helped to clear the backlog of drug orders and to bring the depot closer to normal levels of functioning.

In May 2013 MSF and TAC re-assessed the situation in the Mthatha depot. While some changes have been made, stock-outs for some drugs continue, and lack of adequate buffer stocks for others persist. Most importantly, 40% of facilities that contacted continue to suffer stock-outs of ARV and/or TB drugs, with a median duration for reported stock-outs of 45 days.

**It is both remarkable and saddening that disruption at this scale persists despite the clear identification of simple corrective measures in our January 2013 report; meaning that many thousands of patients continue to suffer.**

Continued staff shortages and lack of management at the depot appear to have contributed to this, as well as chronic supply dysfunctions producing initially reactive, and later erratic, ordering and supply at every level of the health system.

Any durable solution to the supply problems in the Mthatha region must make the Depot and health system as a whole more accountable to the patients that it serves.

**We call on both provincial and national health authorities to take urgent action both inside the depot itself and targeted at other breaks in the drug supply chain, so that patients can access an uninterrupted supply of the chronic medication they need in order to stay in good health. This is their constitutional right.**

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## Introduction

The maintenance of a functioning drug supply chain is essential to the proper clinical management of HIV and TB.

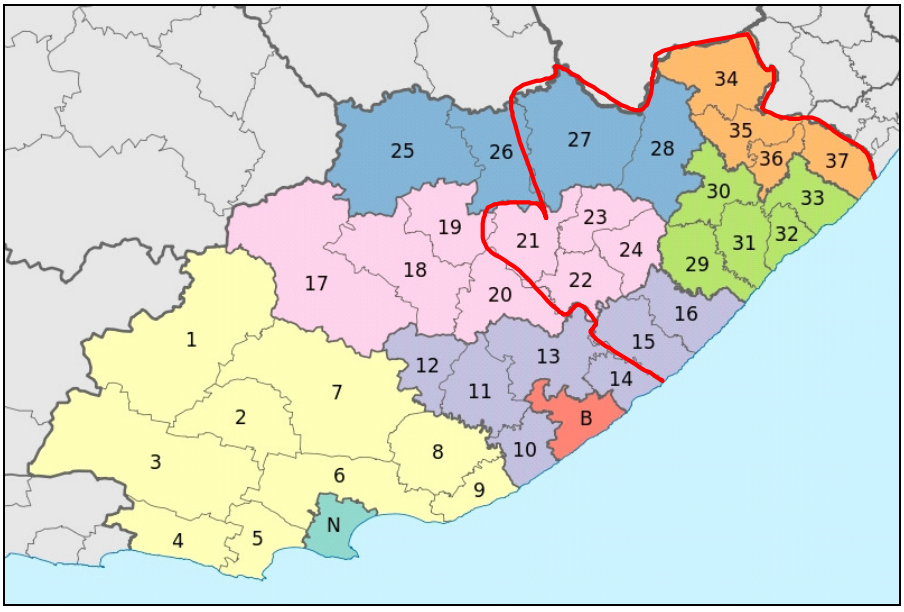
Stock-outs of antiretroviral and TB drugs cause huge damage to people's lives because subsequent interruption of patients' drug supply jeopardizes proper adherence, reducing the benefits of ARVs (1). Because of this, stock-outs of antiretroviral medicine can lead to increased drug resistance (2 -4) as well as to increased deaths among people living with HIV (5,6).

Mthatha in the Eastern Cape saw particularly severe drug supply chain disruption from late 2012 and early 2013, leading to an intervention by MSF and TAC to restore depot functioning. Now five months after this intervention concluded, we re-assess the situation and national context.

## *History of Intervention*

The Mthatha Depot serves over 300 medical facilities in the North-Eastern third of the Eastern Cape. Previously the depot employed 40 staff members, providing ARV therapy to over 100,000 patients.

Figure 1: Map of Area served by the Mthatha Depot (Area within the Red Line)




On 10 October 2012, staff members at Mthatha depot staged a strike, which lasted until 5 November 2012 following the strike the ECDOH suspended 29 staff, leaving the depot with only 10 working employees, mostly contract staff.

The shortage of staff, and limited management capacity, led to an unprecedented reduction of stocks in both the depot and the medical institutions it services, with supplies not received into the warehouse, orders not processed, items not issued to the medical facilities and, ultimately, drugs not being dispensed to patients in need.

In response, South African civil society organisations SECTION27 and the Rural Health Advocacy Project contacted MSF to help prevent massive treatment interruption of patients on ART.

In response, MSF sought approvals from the Eastern Cape authorities to intervene and ultimately began operations in Mthatha depot on 6 December 2012, working alongside TAC to implement the following support:

i. Two staff members to receive drug supplies at the depot
ii. Two data capturers for electronic entry of order requests from the medical facilities
iii. 24 staff to pack deliveries
iv. Increased management capacity, with one coordinator, one logistician and one senior pharmacist
v. MSF hired an additional pick-up vehicle to expedite deliveries

vi. MSF coordinated with the National and Provincial DoH to contact suppliers of the lacking ARV and TB items, in order to expedite their delivery to the depot.

vii) TAC managed a hotline allowing for patients and staff at affected facilities to report the duration and location of stockouts.

By 19 December 2012 the backlog of orders had been cleared and the depot was able to move to its regular functioning, with deliveries reverting to the planned rotation, rather than responding to the stock-out hotline priorities. This meant that facilities were once again being supplied with drugs and the risk of further excess morbidity and mortality was reduced. The MSF and TAC intervention at the depot was a short-term attempt to mitigate the adverse impact of depot disruption upon patients' health and well-being.

The intervention finished at the beginning of March 2013, after which time no MSF or TAC personnel have been present in the depot.

Clear recommendations were made at the time that MSF and TAC ceased their support in a joint report: Emergency Intervention at the Mthatha Depot: The Hidden Cost of Inaction (January 2013). Read the report online at http://www.msf.org.za/publication/emergency-intervention-mthatha-depot)

## Observations from the Mthatha Depot today (May 2013)

More than four months after our first report we have returned our attention to the Eastern Cape to assess drug supply chain adequacy and steps taken to address the late 2012/2013 drug supply crisis.

Partners have collected information, both from professionals and patients, which enabled us to assess the implementation of recommendations, as well as how well the supply chain functions.

### *Overall functioning*

The Mthatha depot is still not operating as a fully functioning depot, with the principal depot at Port Elizabeth continuing to handle many administrative functions centrally – including supporting the drug ordering process. There are ongoing issues with drug orders not being received by manufacturers and suppliers which lead to delays in dispatching items to the depot and then to the facilities it serves. Five months after the crisis the depot still does not have a full time manager in place, and this lack of management capacity on-site appears to contribute to a lack of follow-up, which means it will likely be months before the ongoing problems are resolved.

### *Ordering practices*

Some facilities report that the quantities of drugs that have been delivered to them are considerably smaller than the quantities ordered. In some cases, only 10% of the quantity of antiretroviral medicine requested has been received. Drug orders of HIV and TB drugs are usually only received after significant delay. In most cases it takes nearly two months between drug orders being placed and stock being received.

While facilities complain of under-supply by the depot, staff in the depot complain of over-ordering by facilities. Depot management report that some orders are far in excess of the perceived need of the ordering. This is reported to lead to subsequent downward adjustments, with the stated aim being to conserve stocks. . Some facilities explain that they over-order in an effort to ensure that their patients have access to life saving medication in anticipation of stock outs and undersupply from the depot.

Chronic dysfunctions in the supply system have led to initially reactive, and later erratic, ordering and supply behaviour at various levels of the health system.

As we noted in January, these problems appear to occur mainly at the secondary and primary healthcare levels, where individuals responsible for supply chain management often did not fully understand supply protocols; or how the system worked as a whole. The erratic nature of supply in the Mthatha region is not only wasteful and expensive, with drugs more likely to expire before they are dispensed, but the impact on individual patients who are forced to interrupt treatment, is also high and has potentially lead to excess mortality rates in the affected region of the Eastern Cape.

The disparity between the drug stocks volumes delivered to the depot and are drug stock volumes ordered, is caused by the fact that orders placed at the provincial level for some drugs must first be cleared at the national level before requested drugs can be supplied to depots. Effectively this means that the National Department of Health is reducing some of the orders

which depots make, in an attempt to preserve supplies of drugs stocks which are limited. This is a relatively new practice that has reportedly been put in place this year.

## *Staffing*

At the most recent visit there was a security presence at the depot (2 staff at main gate of depot and one inside depot), although the bags of TAC were not searched on our the most recent visit. The packing of medication was observed to be going on, although at a relatively slow pace.

The Mthatha depot remains extremely understaffed, with a critical shortage of packing staff and manual labourers, contributing to delays in processing and dispatching drug orders. The recruitment of a new depot manager is currently underway, but in the interim a senior depot manager has only been able to visit the site for one week every month.

Currently only 15 temporary staff continue to support the Mthatha depot's basic service, since the 29 staff who were suspended in a disciplinary process await the outcome of their disciplinary hearing while being on full pay, the case in still ongoing, with each individuals case needing to be heard separately. It is estimated that proceedings will be finished around the end of July.

Much of the staffing issues causing a delay are related to orders coming into the depot not being captured effectively on an electronic system by data capturers, which has a knock-on effect delaying the printing of pack orders. Most importantly the actual packing is heavily dependent on manual labour, carried out by teams of packers.

## Current stock of HIV and TB drugs at the Mthatha depot

The situation at the Mthatha depot has improved in terms of the proper ordering of stock as well as the persistence of stock levels since an MSF team was deployed to intervene at the depot last year. Whereas previously stock was not being stored in an organised manner, on the most recent visit it was noted that item storage was more organised; with specific medication we sought to check stock levels of correctly located in a marked position; this contrasts the situation before the intervention where medicine storage was extremely unorganised.

Nevertheless, since the end of the intervention a number of antiretroviral and TB drugs have been in short supply, with some drugs remaining completely out of stock at the depot. The following essential ARV drugs and TB drugs are in short supply:

- Efavirenz, 200mg
- Stavudine, 1mg/ml bottle
- Lamivudine, 150mg

Drugs that have been ordered by the depot, but which are still awaited by facilities or were incompletely delivered after four months or longer include Abacavir, Efavirenz, Lamivudine, Lopinavir, Nevirapine, Ritonavir, Stavudine, Tenofovir and Zidovudine. Orders by the depot for Lamivudine and Efavirenz appear to be particularly badly affected, with many orders placed by the depot still not received from suppliers after many months. As of the end of May 2013, some items remain completely out of stock, including:

- Lopinavir-Ritonavir-20mg/ml oral solution, 60ml bottle
- Ritonavir 80mg/ml solution, 90ml bottle
- Moxifloxacin

**Lopinavir-ritonavir oral solution is an essential part of first-line ART for infants. Stock-outs of this drug mean that the vital treatment of many infants is interrupted leading to a particularly high risk of death.**

For many other drugs, supplies are very limited. For example, Kanamycin Sulphate, a drug used to treat multi drug-resistant (MDR) TB, the stock quantity at the Mthatha depot is by far outstripped by the quantities ordered by facilities. Although the depot ordered additional stocks from the manufacturer in February, these stocks still have not arrived.

Other items that are out of stock at the depot include some antibiotics, some oral analgesics, and oral rehydration salts.

## Drug stock-outs at Mthatha depot: the situation then and now

### *January 2013*

**In January 2013**, we made contacted a total of 72 health facilities supplied by the Mthatha depot, to establish whether they had experienced stock-outs during the period September 2012 to January 2013.

**Of the 72 facilities surveyed, 24% reported that medical staff had to send some HIV or TB patients away without drugs.**

In total, we estimated that the disruption meant that approximately **5,494 adults** taking ARVs had to go least **one day without any ARV treatment** and many others for much longer. We also estimated that **561 children** were sent home without treatment.

The ability of clinics to provide patients with TB drugs, including standard first-line TB regimens (such as Rifafour) and paediatric TB formulations was also affected by the Mthatha supply disruption, with **22% of facilities reporting that they were completely unable to provide any medicine whatsoever to children with TB**.

We estimated that the disruption to patients' drug supply will contribute to tens of excess deaths over the course of the year.

### *May 2013*

**At the end of May 2013** we once again made contact with facilities served by the Mthatha depot to establish if they had experienced further drug stock-outs or shortages since the end of the MSF and TAC intervention.

Of the 107 facilities contacted, we obtained information from 70 facilities about drug stock-out. Of the responding facilities 24% reported a stock-out of one or more ARV drug, while 19% reported a stock-out of one or more TB drug, from March to May 2013.

Of the facilities contacted, 40% complained of having experienced a stock-out (of either a TB or HIV drugs from March to May 2013). 24% of facilities reported an ongoing stock-out of either a TB or ARV drugs, having lasted up until the time of the survey.

TAC visited all facilities with ongoing stock-outs and communicated details of the affected facility and type of drug stock-outs to the Mthatha depot staff, in order to facilitate rapid remedial action.

**The median duration of reported stock-outs in affected facilities was 45 days**. The implication of this is that facilities without buffer stocks of ARV drugs are likely to to send away large numbers of people whom they are responsible for managing treatment.

In **25%** of cases where stock-outs were reported, staff said they were forced to send patients home with no medication. In **64%** of cases, facilities report that they referred patients to other facilities to obtain medication, while in only in **7%** of cases, facilities report that they were able to switch patients to another available medication, or drug formulation.

In one case, a clinic had referred paediatric TB patients to be admitted to a hospital so that they could receive treatment on an inpatient basis, in order to avoid treatment interruption.

During the course of the last three months many thousands of people dependent on the service of the Mthatha depot will have been at risk of treatment interruption – based on the number of patients taking ART at the facilities we surveyed, the duration of stock-outs at these facilities and the number of affected individuals. **(See Table 1 below, for the full findings of the MSF and TAC May 2013 survey).**

**As we stressed in our January 2013, report the consequences of these drug stock-outs are that patients will stop gaining the benefits of ART; over time more deaths will occur as a result and the likelihood of the development of drug resistance also increases.**

**Table 1: Summary of results of telephone survey of health facilities within the Mthatha depot catchment area. Resulting percentages are based on information supplying information as the denominator.**

| | **RESULTS** |
|---|---|
| **CLINICS CALLED** | 107 |
| **CLINICS PROVIDING INFORMATION** | 70 |
| ***No Reporting ARV drug stockout (%)*** | 17 (*24.3%)* |
| ***No Reporting TB drug stockout (%)*** | *13 (18.6%)* |
| ***No. Reporting ARV or TB drug Stockout (%)*** | 28 (40%) |
| ***No Reporting ongoing stockout of ARV/TB drug (%)*** | *17 (24,3%)* |
| ***Median duration stockout (days)*** | 45 |
| ***No. report sending patients home without medication (% of those with stockouts)*** | 7 (25%) |
| ***No that report referring patients elsewhere (% of those with stockouts)*** | *18 (64,3%)* |
| ***No. that report switching regimen/medication(% of those with stockouts)*** | 2 (7.1%) |

***As of 30/05/2013. **For facilities which provided information on stock-out duration**

**Figure 2: Proportion of facilities with stock-outs of ARV and /or TBV drugs, results of surveys conducted before and after MSF and TAC intervention at Mthatha depot,**

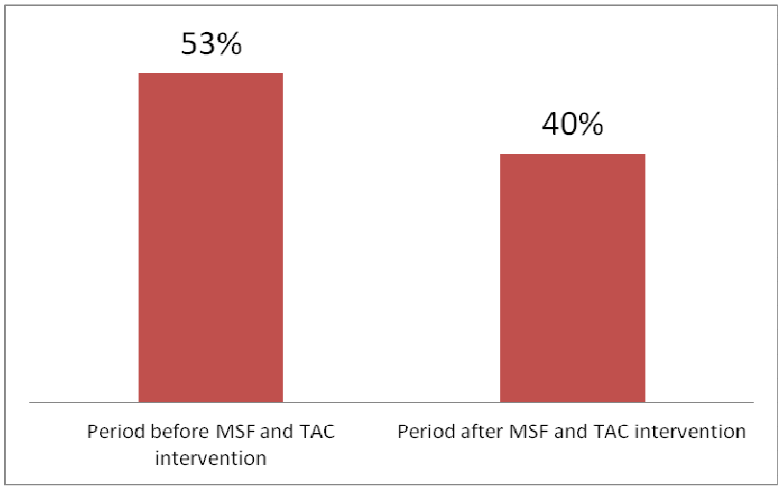



Figure2 indicates that the problems with stock-outs during March to May 2013 in health facilities served by the Mthatha depot were almost as common as they were during September 2012 to January 2012 the period prior to intervention by MSF and TAC.

**It is startling that so many people remain affected by interruption to ARV supplies now given that relatively simple measures could be taken to avert this. With thousands of regular patients currently affected, this situation continues to put patients at increased risk of developing resistance to antiretroviral and TB drugs, and spending time off treatment; as a result excess deaths will be expected to occur.**

Some of the ongoing stock-outs and shortages of ARV and TB drugs are attributable to continued disruption at the depot, others are the result of chronic problems with drug ordering and distribution in the affected area.

> **"Certain items are not stocked by the depot but rather they process the order, generate an order number and then submit it directly to the company who deliver the stock directly to us. This system is completely broken."**
>
> **"In March we discovered that less than a quarter of the items we had ordered from this list, which includes certain IV fluids and other critical items, had actually been captured at all at the depot (and most of those with errors!). Not even all of these (in fact again, fewer than half) had actually reached the company."** – Senior clinician from a health facility serve by Mthatha (May 2013)

The views of staff at affected facilities back up a picture emerging of a dysfunctional supply system. A senior clinician working in a facility supplied by the Mthatha depot describes the situation which illustrates that some orders which are placed by facilities are not captured by the depot, or subsequently registered at suppliers.

Patient reports underline the chronic nature of the problems in the region, which go beyond the current episode at the depot.

> **"I have been taking ARVs since 2008. Each year this {a stock-out} happens at least six times. I go to the clinic and they tell me there is no medication for me."** – 36 year-old unemployed man, Mantlaneni (January 2013)

## Drug supply and Stock-Outs in South Africa today

The ongoing Mthatha depot drug supply crisis represents an acute worsening of a chronic problem. But this is by no means a problem unique to the Eastern Cape. Today, there is a wide range of drugs that have been unavailable to patients all across South Africa..

Problems occur at multiple points in the procurement and supply process. And although we lack detailed information on drug stock-outs nationally, we have summarised below reported stock-outs and associated issues reported to MSF, TAC, RHPA and SECTION27 during the first six months of 2013.

The shortages of paediatric TB preparations seen in Mthatha is a reflection of stock-outs of these drugs across the country as a whole, with many preparations remaining in very short supply

## The National picture – Reports of stock-outs of antiretroviral drugs in 2013

Below we have summarized by time and location stock outs notified this year to MSF, TAC, RHPA and SECTION27.

### Eastern Cape

**May 2013:**

- RHAP received reports from Mooiplaas clinic of stock-outs of Fixed Dose Combination (FDC) ARVs during second week of May. All the surrounding clinics were reported to be experiencing the same problem.
- TAC received reports received from a health centre in Mantlaneni where patients were turned away without ARVs and advised to go elsewhere for medication.
- TAC received reports from Libode and Canzibe clinics, both of which had been without supplies of Tenofovir for one month.

**June 22, 2013**:

- TAC received a report from Jabavu clinic (not served by Mthatha) where patients were turned away from the clinic without ARVs.
- TAC also received reports from Philani, Buntingville, Ndonga, Lujizweni and St Elizabeth Gateway clinics that have experienced ARV stock outs, with St Elizabeth Gateway also experiencing stock outs of TB treatment

### Gauteng

- The Southern African HIV Clinicians Society reports that during 2013 there have been frequent reports of stock-outs from clinics in Johannesburg and the whole of Ekurhuleni. In most cases stock-outs affected Nevirapine, Efavirenz and D4T supplies (individually and in some cases, all at once). Many long-term, stable patients are reported to have been given dual, or mono therapy instead of the prescribed triple therapy

**March 2013:**

- TAC received reports that patients at Phenduka clinic in Thokoza in Ekurhuleni were given prescriptions to purchase their ARV's at Springbok Pharmacy in Alberton as there were stocks available.

**April 2013:**

- RHAP receives a report from a district hospital in OR Tambo District of stock-outs of Efavirenz as well as multiple other essential medicines.
- TAC organizes sit-ins and small pickets at a number of health facilities in the Ekurhuleni district. Shortages of medicines at health facilities are listed among reasons for the demonstrations.

**May 2013**:

- TAC received reports of two clinics in Ekurhuleni district with no Lamivudine, while a third clinic in the same region had no ARVs whatsoever.
- TAC received reports of wide spread treatment shortages across all clinics in the Thokoza district, as well as reports of Lamivudine stock-outs in clinics in Tsakane, Edenvale and Vosloorus.

### KwaZulu-Natal

**March 2013:**

- MSF in Eshowe reported low supplies of Tenofovir in the hospital pharmacy, as well as indications of stock mismanagement from the hospital to surrounding clinics. Patients at affected facilities report being provided with limited ARV supplies and they are requested to return for treatment refills at a later date.

**May 2013:**

- Eshowe-clinics supported by MSF reported shortages of FDC ARVs. Reportedly some patients who eligible for FDC were put on triple therapy. Many patients sent home with shortened ARV supplies that necessitates more frequent travel to clinics for refills. Stock-outs of paediatric ARVs are also reported.

### Limpopo

**June 2012 to June 2013:**

- MSF project in Musina reported shortage of Tenofovir at Messina hospital, resulting in patients only receiving adequate supply of ARVs for a short time.

**February 2013:**

- The SA HIV Clinicians Society received reports that TDF stock is being distributed to facilities in small quantities on a week-by-week basis leading to widespread shortages in clinics relying on that facility

**April 2013:**

- The SA HIV Clinicians Society reported that Lamivudine is out of stock in the main pharmaceutical depot in Limpopo, and consequently also in most institutions and clinics in the province.

**April 2013:**

- MSF staff reported Lamivudine shortage in Messina hospital. Patients are given a small quantity of medicine and told to return for further supplies at a later date.

**May 2013:**

- TAC receives reported from Limpopo of shortages of Lamivudine, and Stavudine from several health facilities.

## The national picture – in summary

Across most provinces frequent stock-out reports are received, but worryingly these shortages are not just of HIV and TB drugs, but also relating to a wide range of essential medicines.

Although we cannot establish the cause of all these individual stock-outs, some general impressions and insights can be drawn from these reports:

- Both large and small facilities are affected
- Smaller facilities are particularly vulnerable. They depend on bigger facilities for supplies downstream because they do not receive direct supplies from depots. When larger facilities are affected, they too are affected. Larger facilities may also withhold supplies when stock is scarce.
- Lamivudine and Tenofovir were the ARVs most frequently reported out of stock nationwide
- The frequency of individual stock-out reports in combined with the assessment of those on the ground suggest that Gauteng is badly affected in particular compared with other provinces.

It must be noted that in the Eastern Cape, prior to the May 2013 survey, there were only a handful of reports of stock-outs, but little indication of a ongoing wide-scale problem.

In retrospect we can see that in the Eastern Cape, reports reaching civil society organizations represented only the tip of the iceberg, as many more stock-outs and their impact go unreported. Given this preliminary overview of the problem, it is very likely that an active investigation in other provinces will uncover a nationwide problem of considerably greater magnitude than just merely the individual reports of stock-outs, summarized above.

## Issues relating to Fixed Dose Combination ART

The South African department of health (DoH) has, rightly been applauded for the April 2013 phasing in of a national roll-out of Fixed Dose Combination (FDC) drugs for people on ART. This is a simpler and improved treatment option, that significantly cuts down patients' daily pill burden and that may benefit treatment adherence. (8)

The DoH has stated that FDCs would contribute to a well functioning supply chain, by making the process of drug ordering and storage simpler. To meet national demand and to ensure the department did not put all its eggs in one basket the tenders to supply the FDCs were awarded to three different companies: Aspen Pharmacare, Cipla Medpro and Mylan pharmaceuticals. Health officials anticipated that FDC supply would not meet demand at April 2013 roll-out, there roll-out was phased by priority groups..

Priority group 1 includes all new patients starting ARVs for the first time, followed by Priority group 2, which includes HIV-positive pregnant women and breastfeeding mothers currently stable on 3TC, TDF and EFV, and subsequently followed by another five priority groups.

While stocks are currently insufficient to allow full roll out to all priority groups, even once full roll out is achieved, it should be stressed that an FDC version of TDF/FTC/EFV triple therapy does not represent a silver bullet to treating HIV in South Africa and it will never be the sole treatment regimen for all people living with HIV. Firstly, because some people (such as those with renal dysfunction) have contraindications to one or more of the drugs in this FDC and may need to take other ARVs. Secondly, because people who fail first-line ART will still need to be switched to second-line drugs. Consequently facilities will need to be able to manage single ARV drug stocks, and as these stocks are expected to become smaller over time, the management of

single drug stocks may become more difficult and stock-outs of these options may increase over time.

### Reports of FDC stock-outs

Despite optimism that FDC use would alleviate stock outs, just months into the national roll out, shortages are already being reported. Here, supply side problems seem to be a major problem. Manufacturers are reported to be at sub-optimal capacity because of lag time in updating machinery. As a result, drug availability has failed to meet expectations. TAC has also received reports that some health facilities have received only very small quantities of FDC, which are likely to be insufficient to meet the needs of all those in the first two priority groups. As more individuals become eligible to take FDC, vigilance will be needed to ensure that FDC supply can meet needs

## Stock outs and the law: the legal framework.

The state has an obligation under the Constitution to provide for access to healthcare services and not to reduce the level of healthcare provided as well as to promote the efficient, economic and effective use of resources. In addition legislation and other sources of law create further obligations including:

- Under the National Health Act 61 of 2003 to plan manage and control the cost of healthcare services
- Under the Public Finance Management Act 1 of 1999 to ensure the proper and efficient use of public funds, including proper stock control and to prevent fruitless and wasteful expenditure;
- Obligations under the Pharmacy Act 53 of 1974 to ensure the safe and effective storage of medicine

### Constitutional obligations on the ECDoH

Section 27(1)(a) of the Constitution affords everyone in South Africa "*the right to have access to health care services*". This right creates two forms of obligations on government. First, the Government must take steps toward the progressive realisation of the right to health. Second, the government may not take or permit any retrogressive measures that cut back on the health services it has already put in place. In the case of the Mthatha Depot, the ECDoH has violated both of these obligations.

Section 195 of the Constitution requires that public administration must be "[e]fficient, economic and effective use of resources must be promoted" (s 195(1)(b)). Moreover, public administration must be "accountable" and must respond to people's needs (s 195(1)(f,e)).

In addition to the right to health, the state is bound to respect, protect, promote and fulfil the rights to life (s 11) and dignity (s 10). This means that the state may not through bureaucratic inefficiency, inaction or mismanagement permit people to suffer and die because they cannot access life-saving medicines and medical supplies. A state that allows that to happen, as in the case of the Mthatha Depot, cannot be said to respect or protect the rights to life or dignity.

### Obligations under the NHA

The NHA sets out the foundations of the health care system. It places an obligation on the MEC to "ensure the implementation of national health policy, norms and standards in his province" (s 25(1)).

The NHA also places many obligations on the Superintendent General. He is responsible for planning and coordinating health services, developing public hospitals and other health establishments, managing the cost and finances for health, controlling the quality of health services and facilities and providing and maintaining equipment, vehicles and facilities. (s 25(2)(f,j,k,n,p).

The MEC and Superintendent General are, therefore, under obligations to ensure the adequate provision of services at Mthatha Depot through proper planning, coordination and oversight. Their failure to do so is a violation of these obligations.

### Obligations under the PFMA and Treasury Regulations

The PFMA is designed to regulate financial management to ensure that public money is spent effectively and to prevent or appropriately deal with fruitless and wasteful expenditure

The PFMA makes the Superintendent General the "accounting officer" of the ECDoH and places obligations on him. These include ensuring an appropriate, cost-effective procurement system, guarding against theft and fruitless and wasteful expenditure, ensuring the "effective, efficient, economical and transparent" use of resources for health and managing and safeguarding the ECDoH's assets, including medicines and equipment. (s 38(a)(iii), 38(b), 38(c)(ii) and 38(d)).

The lack of proper procurement systems and safety precautions at the Depot demonstrate the Superintendent General's failure to comply with these obligations.

Finally, regulation 10.1.1(b) of the PFMA Treasury Regulations requires the Superintendent General to ensure that the Depot's "stock levels are at an optimum and economical level". "Dues out" lists of phenomenal lengths demonstrate that he has roundly failed to meet this requirement.

### Obligations in terms of disciplinary procedures

The Public Service Coordinating Bargaining Council has coordinated agreement upon procedures to be followed in disciplinary actions against employees of the state. The Mthatha Depot employees were suspended with pay in December and remain on suspension. In this scenario, the procedures require that hearings be held "within a month or 60 days". (Section 7.2(c)) Disciplinary hearings have not yet taken place for the Depot employees. This is in contravention of the requirements of the procedures.

### Legal and other solutions

The Depot's dysfunction is an on-going violation of a number of legal rights and obligations. The state of the Depot cannot be allowed to continue at the cost of human lives. The ECDoH appears to be either unable or unwilling to address the problems despite knowing of them for several years and immense support from civil society. This raises the question as to whether the National Minister of Health must use his powers in terms of section 100 of the Constitution to intervene on an emergency basis to provide health services in line with national standards.

In addition, the TAC, RHAP, SECTION27 and several other partners have now formed and will soon expand the Eastern Cape Health Crisis Action Coalition. The Coalition seeks to mobilise a campaign and use the law to restore quality health care services in the Eastern Cape. Part of this effort will be focused on the serious problems at the Mthatha Medical Depot.

## Plans to address inadequacies in the national supply chain

### *SA national department of health response and plans*

#### Drug delivery

Nationally, there are plans for increased use of direct deliveries, bypassing depots, with ongoing pilot projects in Limpopo and Kwa Zulu Natal. This option is only likely to be practical for large deliveries. Direct deliveries of drugs to patient's homes, or for collection in stores, is also being considered for piloting in 2014. These offer a potential means of diversifying supply mechanisms, bypassing depots.

#### Drug supply

Increased use of split contracts (multiple suppliers) is proposed as a way of alleviating supply shortages; given that if one supplier cannot deliver then others may be able to pick up the shortfall. The current arrangements for the supply of FDCs are an example of this however the fact that supply remains below the level required for all patients to switch, highlights that even with multiple manufacturers supply may still not meet desired levels.

#### Legislative

Plans to establish a national office of health standards compliance, already under way. This would be an independent statutory body that would be able to receive and investigate stock out complaints.

### *A Civil Society Response: plans of the Stop Stock-Outs group*

In order to improve accountability to patients, RHAP, the Southern African HIV Clinicians' Society, SECTION27, TAC and MSF have set up a drug stock-out monitoring project to track stock-outs of essential drugs across South Africa. This will include monitoring on ARVs and and TB drugs in particular. Through the development and use of a online database the main objectives of the project are to:

- Monitor and report on drug stock-outs across the country
- Follow up on selected stock-outs to ensure that they are rapidly resolved
- Analyse collated data to assist the national department of health and other policy makers in understanding the root causes of stock-outs within the public health system.

## Conclusions

Serious ongoing and widespread stock-outs of life-saving drugs affecting patients on ARVs and TB drugs in the region served by Mthatha depot remain unresolved, even after an MSF and TAC intervention and clear recommendations.

Urgent action is required in order to ensure that patients do not face ongoing treatment disruption, risking drug resistance and death.

Many recommendations made in the January 2013 report by MSF and TAC regarding the disruption at the Mthatha depot have not been implemented (**see Appendix I**). If these recommendations were implanted there would have been done fewer stock-outs occurring at present.

The dysfunction of the Mthatha depot is a symptom of the ailing state of health care in the Eastern Cape more broadly. Doctor Trudy Thomas, the first MEC of Health in the Eastern Cape said: "*Over the last 15 years, I have witnessed the progressive deterioration of the EC DoH and the services it offers. This trend grew most acute over the last year and has culminated into a full-blown catastrophe*."

The problems to which Thomas refers, include, amongst others, the failure to properly budget; financial mismanagement; poor, or no systems for human resources; crumbling infrastructure; poor supply chain management; the lack of accountability and the lack of proper management generally.

The breakdown at the Mthatha depot is an example of these different elements combining to culminate in the desperate failure to deliver essential drugs and supplies in a timely and reliable fashion.

Not all the supply chain disruption in the Eastern Cape is attributable to issues at the depot level – some can also be attributed to chronic problems with drug ordering and stock keeping by facilities, as well as transport problems, or simply the failure of larger facilities to send drugs to smaller facilities at times of supply shortage.

At facility level there is a perception that any stock quantity ordered will be adjusted downward by national supply authorities. Consequently, this may lead to inflation of orders, thereby exacerbating a vicious cycle of inaccurate drug ordering.

Nationally, several civil society organisations have received reports of stock-outs from at least four different provinces around the country. Our experience in the Eastern Cape suggests that these reports from elsewhere are likely to represent only the tip of the iceberg, given that the vast majority of cases in the Eastern Cape were only identified after active efforts were made to identify affected clinics. While we have focussed here on HIV and TB dugs a wide range of other essential medicines have been affected.

As we noted in our January 2013 report, many of the failings outlined here are due more to ineffective governance rather than a single incident.

Pending the establishment of a robust monitoring system, the passive collection (waiting for, reports) of information on stock-outs does not appear to offer a sensitive monitoring mechanism.

Any durable solution to the supply problems in the Mthatha region must make the depot and health system as a whole more accountable to the patients that it serves. Without this fundamental change patients are likely to continue to suffer.

## Recommendations

**1) The Eastern Cape health department's disciplinary processes must be expedited and temporary replacement staff at the Mthatha depot must be hired immediately**
This recommendation was made in our January 2013 report. While the number of pharmacy staff in the depot has subsequently been increased, the depot remains understaffed in terms of packers and is still without senior management permanently in place. While the disciplinary process is ongoing, we reiterate our calls for the Eastern Cape DoH to ensure that temporary staff be appointed urgently.

**2) Active monitoring of drugs available in clinics in the Mthatha region must happen over the short term (next 6 months) .**
The current situation highlights that at present, reliance upon reports of stock-outs, which will lead to an underestimation of the problems facing clinics. We call on the national DoH to investigate supply levels at the clinics supplied by the Mthatha depot.

**3) When stock-outs are identified, the underlying reasons must be established for each and appropriate action undertaken. The individuals responsible for the stock-outs must be clearly identified.**
The issues in the Eastern Cape highlight that breaks at any point in the supply chain can cause stock-outs. There is no one solution. Individual cases will require individualized problem-solving

We call in the national / provincial DoH to establish a team with the remit to investigate the underlying contributory factors where stock-outs occur and ensure an emergency response. Considerations should also be given to joint visits (civil society and DoH) to affected facilities to ascertain causes for stock-outs.

**4) Improve stock-keeping and drug ordering at all levels of the supply chain**
In the immediate term, we recommend that facilities in the region receive a brief educational session by telephone. Further catch-up trainings and ongoing training must also be organised urgently.

Stock-keeping and drug ordering practices should be monitored through regular audits, linked to performance assessments.

Where the depot plans to supply a facility with less drugs that requested, we recommend that this be communicated to the responsible person at the facility concerned in order to allow for explanations, and to provide feedback.

We reiterate our January 2013 recommendation that the national and provincial DoH send additional experienced pharmacists to relevant clinics and sub-facilities to train staff at each site on monitoring stock levels, patient numbers and actual consumption figures.

Over the longer term, stakeholders should begin to design interventions to sustainably improve stock-keeping and ordering at all facilities.

**5) The national department of health should create an emergency team to respond to stock-outs – given the extent, importance, and frequency of essential drugs stock-outs nationwide**
The MSF/TAC emergency intervention in the Mthatha depot from December 2012 to March 2013 has shown that it is possible to correct a disastrous situation with limited resources, even if the impact remains short-lived without large systemic changes and action from the provincial

department of health. A roving team consisting of a few pharmacists with administrative support could prevent the majority of current treatment interruptions due to stock-outs.

**6) The national DoH should consider using the legal process to ensure accountability to patients**

Senior officials must be held accountable and the National DoH must consider the necessity of a section 100 intervention in the Eastern Cape.

# Appendix I

**Implementation of recommendations made in the report "Emergency intervention at the Mtatha Depot, the hidden cost of inaction, January 2013"**

| Recommendation | Action points | Implementation |
|---|---|---|
| **Additional Technical Support Required from EC DoH and National DoH** | One experienced Pharmacist is sent from National and the Province send at least one senior Depot Manager | Not fully implemented.<br><br>Following report extra pharmacist and 3 additional commserves were appointed to the depot.<br><br>Still no senior management continuously in place at the depot.<br><br>Still severely understaffed in terms of packers |
| **The HR disciplinary processes to be expedited and temporary replacements hired immediately** | Speedy resolution of the ongoing disciplinary process.<br><br>In parallel immediate substitution of affected staff by temporarily recruiting pickers and packers. | Not fully implemented. Staff remain suspended and current staffing levels well below pre strike levels. |
| **Immediate Supply of Ruptured Stock to the Depot** | The DoH must ensure the immediate supply of all ARVs and TB treatments that are still out of stock | Partially implemented, although stock-outs still occurring at the depot. |
| **Put in place capacity to monitor treatment ruptures at a local, Provincial and National level.** | | Not implemented. The current situation in Mthatha highlights the fact that treatment ruptures are often not detected at the provincial and national levels. |
| **Short term recommendation for community members and affected patients join the Provincial and National DoH on an Oversight Committee for the Mthatha Depot** | | No evidence of this recommendation being implemented. |

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