



Health

**Department of Health
Republic of South Africa**



Medicines Procurement Reform in the Public Sector

**Challenges and Opportunities for Improvement
of Medicines Procurement in South Africa's
Public Sector – March 2010**



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Document enquiries can be directed to:
Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS)
P.O. Box 1579, PRETORIA, 0001
SOUTH AFRICA
Attention: Mr. OMB Pharasi

Telephone: +27 12 326 4027

E-mail: bpharasi@msh.org

Authors

Name	Organization
Berger, Jonathan	AIDS Law Project
Hofmeester, Nashreen	Independent Consultant
Makhado, Mulatedzi	SPS/MSH
Miot, Jacqui	Independent Consultant
Moller, Helene	WHO
Pharasi, Bada, Chairman	SPS/MSH
Phillips, Dianne	SPS/MSH
Raubenheimer, Ticky	Independent Consultant
Sallet, Jean-Pierre	SPS/MSH
Suleman, Fatima	University of KwaZulu-Natal

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Abbreviations

ACAME	Association of Central Medical Stores for Generic Essential Medicines
ART	Anti-retroviral therapy
ARV	Anti-retroviral
CAM	Complementary and alternative medicines
CCMT	Continuous Care and Monitoring of Treatment
CDU	Chronic Dispensing Unit
CIB	Coordinated informed buying
COMED	Coordinating Committee for Medicines Procurement
CPPA	Central Pharmaceutical Purchasing Authority
CSP	Community Service Pharmacist
DST	Department of Science and Technology
DTI	Department of Trade and Industry
DUR	Medicine utilisation review
EML	Essential Medicines List
EMP	Essential Medicines Programme
EFT	Electronic funds transfer
EPI	Expanded Programme on Immunisation
FDC	Fixed dose combination
GCC	Gulf Cooperation Council
GDP	Good Dispensing Practice
HAS	HIV and AIDS / Sexually Transmitted Infection Unit
HAST	HIV and AIDS / Sexually Transmitted Infection / Tuberculosis Unit
HPCSA	Health Professions Council of South Africa
HDI	Historically disadvantaged individual
IP	Intellectual property
IPAP	Industrial Policy Action Plan
KPI	Key Performance Indicator
MCC	Medicines Control Council
MPTTT	Medical Products Technical Task Team
MRC	Medical Research Council
MSH	Management Sciences for Health
NDoH	National Department of Health
NDP	National Drug Policy (also National Medicines Policy)
NRF	National Research Foundation
NT	National Treasury
OECS	Organisation of East Caribbean States
PIASA	Pharmaceutical Industry Association of South Africa
POD	Proof of delivery
PPP	Pharmaceutical Policy and Planning
PPPs	Public/private partnerships
PPPFA	Preferential Procurement Policy Framework Act
RPL	Reference Price List
NIH	National Institutes for Health
NIPF	National Industrial Policy Framework

PAHO	Pan American Health Organisation
PFMA	Public Finance Management Act
PHC	Primary health care
PTC	Pharmaceutical and Therapeutics Committee
SADC	Southern African Development Community
SAMED	South African Medical Device Association
SAPC	South African Pharmacy Council
SCM	Supply Chain Management
SITA	State Information Technology Agency
SEP	Single exit price
STG	Standard Treatment Guideline
TCAM	Traditional, Complementary and Alternative Medicine
VEN (Classification)	Vital, essential, nonessential
WHO	World Health Organisation

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1. Executive Summary

INTRODUCTION

According to National Treasury (NT), healthcare expenditure, which includes goods and services, rose dramatically from R9.8 billion in 2002 to R30.7 billion in 2009. Tenders for pharmaceuticals awarded through the national tender system administered by NT amount to an estimated R10.5 billion for the current two-year tender period. This excludes expenditure on medical related items such as syringes, needles and dressings which are procured by most of the provinces on provincial tenders. These changes to the country's procurement system over the years, including the establishment of the 9 provincial tender boards, have resulted in a somewhat fragmented public procurement system for medicines.

Currently the medicines and medical devices procurement system is suffering from a lack of financial oversight, insufficient communication and liaison between stakeholders, poor procurement practices, outdated information systems and lack of human resources to support the current system.

BACKGROUND

The public sector healthcare facilities have been hard-hit by medicines shortages and, in the last few years, reports of stock-outs and budgets being exhausted have become more pronounced. The continued accrual of benefits to healthcare delivery from the current systems of medicines procurement has come under scrutiny. The vast amounts of money spent on the procurement of medicines are clearly not justified by the poor outcomes witnessed. It is against this background that the Minister of Health, Dr Aaron Motsoaledi, commissioned an in-depth assessment and review of the public sector's medicines procurement system.

OBJECTIVE

The objective was to conduct an in-depth assessment and review of the current procurement system of pharmaceuticals and medical devices in the country's public sector and to present recommendations to the Minister of Health for an improved medicines and medical devices procurement system for the public sector.

METHODOLOGY

The assessment involved a desk-top review and in-depth interviews with key informants in the provincial health departments, facilities and medicines depots, key officials in NDoH and NT and key pharmaceutical services providers in the private sector.

FINDINGS

These are among the key findings of the assessment:

Finance and Funding

- The Provincial pharmaceutical budget is not defined, which makes financial planning and monitoring impossible and the allocation of resources to pharmaceuticals is left to the discretion of the provinces.
- The amount allocated by NDOH for the provincial CCMT programme is almost always less than the amount requested for in the provincial business plan. This shortfall notwithstanding, it would seem that some of the funds have been spent on non-HIV items in at least one province, the Free State. Thus the expenditure on ARVs surpassed the budget in the 2008/09 financial year. This probably explains the funding gap carried into the 2009/10 financial year;
- There are a range of reasons why provinces are battling to maintain a constant supplies of ARVs. These include the budget shortfall, inadequate human resources, lack of liaison between Pharmaceutical Services and the CCMT directorate, and the poor quality of data which forms the basis for expenditure.
- The HIV and AIDS Directorate, in preparing for the new ARV tender which is expected to commence in the middle of the year, has made budget/expenditure projections which take into account an expected increase in the number of patients to be treated as a result of the decision to have some patients commenced on treatment at CD 4 count of 350.
- The Directorate has also decided to include fixed dose combinations in the new treatment protocols. This, coupled with the intention to navigate international pharmaceutical markets for cheaper ARV prices, should lead to a more cost-beneficial utilization of the scarce resources available for ARVs.

Procurement

- Tenders for medicines are arranged nationally by the Department of Health's Access to Affordable Medicines directorate, in collaboration with National Treasury, the contract manager for all contracts awarded. However, provinces are at liberty to procure medically related items on provincial tenders;
- Provinces have expressed dissatisfaction with NT's management of the tender process. Complaints range from the late awarding of tenders, a disregard for the requirements of safety and stability of products awarded (apparently linked to the lack of intimate knowledge of the clinical aspects of medicines on the part of senior tender adjudication officials), NT's electronic system "Procure's" seeming inability to interface with provincial depot systems, leading to delays in the capturing of prices and orders and NT's failure to apply punitive measures when suppliers do not perform accordingly. Although these complaints were heard in virtually all of the provinces, it has to be conceded that there was no focused attempt by the task team to verify these with NT;
- There is a discrepancy between the procurement policy and interpretation of the PFMA guidelines, which has given rise to variations in specifications for expensive medical devices and different prices in different provinces; The discrepancy in prices across provinces and within tender products is likely to be a reflection of a variance in the ability of the province to negotiate with the manufacturer. A centralized procurement agency would undoubtedly be in a better position to negotiate to the lowest price (or lower) for the whole country and to ensure improved consistency of pricing across the provinces;
- The envisaged national health insurance (NHI) authority will be faced with a serious challenge procuring services through such a diversity of procurement cultures, each having its own interpretation of the broad procurement principles of the Constitution;

Warehousing and Distribution

- There are too many depots that exist within the system. Every province has at least one medicines depot (The Eastern Cape and Western Cape have two each), with many having additional depots of a specialized nature, such as, for instance, a depot for the production of patient-ready packs,

an ARV depot, or a depot for the preparation and dispensing of chronic medicines. Some provinces have regional sub-depots which largely serve as transit points for the onward distribution of medicines to PHC clinics. The depots could, potentially, become an unnecessary, expensive and disruptive intermediary in the medicines supply chain. The private sector has also expressed a desire to assist with the role of warehousing and supplying on behalf of the public sector;

- Only the Gauteng provincial depot complies with the Medicines Control Act. Some of the major deficiencies leading to the non-compliance of the depots include the non-availability of Standard Operating Procedures, security issues, inadequate storage capacity, lack of temperature control and, crucially, the lack of pharmacy personnel for certain processes;
- Almost all depots use the services of private contractors for medicines delivery to the provincial facilities, applying varying mechanisms of paying for the services rendered. Three of the provinces have outsourced the services of procurement, warehousing and distribution. In the latter case, this does not appear to have led to improved medicines availability in the affected provinces, and in-depth investigations may confirm the view that the arrangements as currently administered do not provide value for money;
- Some provinces have come up with innovative mechanisms for improving patient satisfaction with medicine supply services. An example is the chronic dispensing unit (CDU) in the Western Cape. The benefits of establishing such a unit include the ability to generate various management reports regarding the use of medicines for chronic conditions, the commencement of efficient chronic disease management models for future healthcare modelling and planning and the enhancement of the provincial referral system. A significant proportion of chronic medicines in the private sector (including ARVs) are effectively distributed through “direct delivery” to patients’ homes or places of work. This system is cost-effective relative to the public sector distribution system. Also, the vast numbers of community/retail pharmacies, which far outnumber those in the public sector, offer a unique opportunity for provincial authorities to look to them as outlets for the dispensing of chronic medicines to State patients, thus reducing the burden on the crowded public sector hospitals. Such a role would be crucial in an NHI arrangement.

Information Technology

- There is no central location from where information across the country is accessible. The lack of integrated information systems and shared information also leads to inaccuracies in quantification. There is often a discrepancy between usage information obtained from suppliers and that obtained from the facilities and depots. The MEDSAS system that is in use at most of the depots has been in use since around 1994. This software is difficult to maintain and cumbersome to modify as a result of the technology limitations.
- Silos of information exist across the country and it is difficult to consolidate and compare this information across the country due to the lack of data management standards. The NDoH, in particular, struggles to obtain a holistic consolidated view of the national pharmaceutical supply chain.

Human Resources

- As indicated, the Directorate Affordable Medicines (DAM) is responsible for coordinating all national tenders for pharmaceuticals in collaboration with NT. DAM is located within the Pharmaceutical Policy and Planning (PPP) Cluster, which plays a key role in policy coordination, taking the lead in strategy formulation, influencing compliance with GPP and implementing a pharmaceutical monitoring and evaluation mechanism. For all of this co-ordination to happen, though, the PPP Cluster of the NDOH will need to be strengthened, firstly, by having the cluster manager position filled and, secondly, by putting in place incentives that will attract competent and experienced candidates to fill critical posts at the national level;
- The structure of pharmaceutical services among the provinces is not uniform, both in terms of the position occupied by the head of pharmaceutical services (HOPS) in the provincial hierarchy (i.e. level of post and direct participation in the provincial management structure), and the extent of oversight over key pharmaceutical functions such as the medicines depots. In those provinces where the HOPS is at the level of deputy director, they lack the necessary clout to exert meaningful authority or take full responsibility for pharmaceutical services delivery outcomes, and their level means posts at the lower levels are far less attractive than in other provinces. Where the medicines depot reports to a non-pharmacy position, this has led to the poor management of the medicines supply system, unless pharmacists have been put in charge of key functions in the chain;
- Vacancy rates in pharmaceutical services are generally high in most of the provinces.

RECOMMENDATIONS

Central Pharmaceutical Procurement Agency (CPPA)

- The establishment of a central authority within the NDOH, responsible for all issues related to medicines (including ARVs) selection, procurement, distribution and use, is hereby proposed.

The CPPA will have the following responsibilities:

- Manage financial allocations to the provinces for all pharmaceutical purchases, in close consultation with National Treasury;
- Manage procurement contracts on behalf of the province and have responsibility for the writing of product specifications for tender submissions. It will have oversight over the payment of suppliers of pharmaceutical and pharmaceutically related goods and services, which will be effected at the local level and put in place a support and accounting structure at the provincial level to ensure that service providers are paid timeously;
- Determine a national procurement list (in co-ordination with the Essential Medicines List) which will form the basis for all procurement in the public sector facilities;
- Have a sub-committee which will have oversight over pharmaceutical expenditure in tertiary institutions;
- Establish a unit responsible for price monitoring and risk analysis and which will also monitor corrupt and collusion practices;
- Coordinate and manage all donor funding and donations for pharmaceutical and medical items;
- It may, eventually, be the responsible body for the procurement of all pharmaceutical services and goods on behalf of the NHI authority.

A Cost-Benefit Analysis (CBA) is recommended to justify the viability of such an agency;

- It is recommended that the establishment of this entity be made possible through a conditional grant that will provide for the procurement of all pharmaceutical goods and services for the

public sector, including pharmaceuticals, pharmaceutical related items, vaccines and medical devices, and that the budget for the entire pharmaceutical expenditure be ring-fenced;

- Business plans presented to the NDOH have to be preceded by cooperation among the provincial units centrally involved in the HIV and AIDS arena. To this end, it is strongly recommended that Pharmaceutical Services, CCMT and HAST units in the provinces be urged to work together more closely;
- The procurement of certain high-cost items for the CCMT programme on the international markets for ARVs is supported for immediate implementation. However, a more detailed health economics analysis should be undertaken to determine the long-term sustainability of such international tendering;
- It is recommended that a feasibility study into the effects of the removal of VAT on medicines be undertaken;
- It is recommended that, in line with the recommendation for the establishment of the CPPA, all provincial tender boards cease the handling of tenders for pharmaceuticals and medical related items;
- It is recommended that more focused work be done on rationalising the procurement and control of medical devices and that this be seen as the beginning of a process leading to the adoption of a sound health technology policy for the country;

Industrial Policy and Medicines Supply

- The tensions between the desire to grow the local industry (Industrial Policy Framework) and the Constitutional mandate of the Health Minister to provide healthcare to the citizens of the country and do so cost-effectively, have to be resolved;
- It is imperative that a forum be established that will enable all the stakeholders involved in providing or supporting the provision of medicines an opportunity to engage Government on an on-going basis;
- The PPPFA and its regulations raise the difficult issue of a potential conflict between the State's industrial policy and its healthcare objectives. It is recommended that this conflict be addressed as a matter of urgency. To that end, the departments of Health, Trade and Industry, Science and

Technology and National Treasury need to convene a forum where conflicts between and among the different Government policies and objectives can be debated with a view to finding lasting solutions to the conflicts.

Warehousing and Distribution

- It is recommended that all outsourcing contracts for procurement, warehousing and distribution be reviewed before any extensions are considered, and that no new bids be invited for outsourcing until such time that the reviews have taken place and provinces are clearly in a position to satisfy the requirements for monitoring and assessment as specified in the Treasury guidelines/regulations for PPPs;
- It is recommended that an in-depth cost-benefit analysis be undertaken of currently outsourced services of procurement, warehousing and distribution. In particular, the mechanisms applied by the private warehousing contractors to charge for their services should be scrutinized to ensure that the State is not disadvantaged by such an arrangement;
- Central dispensing units, similar to the one in the Western Cape, should be given serious consideration by health authorities who want to improve service delivery;
- The above recommendations relating to improvement of the management of the depots notwithstanding, it is the view of the Task Team that the depots are costly and inconvenient intermediaries in the chain intended to ensure that medicines reach the facilities where patients receive treatment. The alternative recommendation, and certainly the one preferred by the Task Team, is for the gradual phasing out of the provincial depots while a solution is sought to service the PHC facilities and to strengthen the storage and logistics capacity of the hospitals. ;
- It is recommended that the national and provincial health departments investigate ways in which chronic medicines can be supplied to State patients. This would include consideration of community (retail) pharmacies and direct deliveries.

Information Technology

The following key recommendations are made to improve the information technology situation in the pharmaceutical supply chain:

- Development of national pharmaceutical data management standards to facilitate the ease with which information is exchanged across the entire supply chain ;
- Consolidation of the number of technologies used so as bring about a decrease in the total cost of ownership of the technologies that are used as enablers in the public sector supply chain;
- Improved software integration across the supply chain to facilitate the ease of information sharing and exchange and the resultant improvement in managing pharmaceutical availability;
- Introduction of innovative technology to facilitate product tracking and picking
- Should the depots remain, the outdated legacy systems at the MEDSAS depots should be replaced. The feasibility of the Oracle-based solution that has still not successfully been implemented should be reviewed for appropriateness;
- Introduction of a centralised management information warehouse, which would facilitate informed decision-making and increase visibility of problems along the supply chain;
- Development of a pharmaceutical supply chain information management framework will facilitate the exchange of information amongst the various stakeholders.

Human Resources

- It is recommended that the cluster manager post in the NDoH for pharmaceutical services be filled as a matter of urgency. Equally vital is the need to have vacant senior pharmaceutical management posts at the national level filled at market-related salaries so as to provide the necessary backing for the cluster manager;
- It is recommended that all the necessary legal and administrative steps be taken for the establishment of the pharmacy technician course and provision for the first intake of trainees by the beginning of 2011;
- The lack of comprehensive data on pharmaceutical personnel is a very significant gap in national human resource policies for the Health sector. The result is that national plans and budgets fail to provide adequately for the required investment in training, deployment and continuous development of pharmaceutical HR as a social and economic priority for the country. It will, therefore, be necessary to have a determination of the total human resources involved in providing pharmaceutical services in both the public and private sectors in South Africa, including

the Department of Health, Correctional Services, South African Military Health Services, municipalities, NGOs, the pharmaceutical manufacturing industry, wholesale, pharmacy schools, research institutions, the medicines regulatory authority and the Pharmacy Council, to extrapolate future pharmaceutical HR requirements and staffing norms and develop short- and long-term strategies to arrive as close to future requirements as possible, and

- It is recommended that provinces attempt to arrive at a uniform structure of pharmaceutical services in which the pharmacist is allowed to play the key role in the rendition of the services. The financial and logistics roles could be strengthened by deploying accountants and other supply chain functionaries in the depots or other key facilities.

2. Introduction

Historically South Africa has procured medicines and other pharmaceutical supplies for the public sector through the tender system. This process was aimed at achieving price advantages and the standardization of code lists in the public sector. The public (tender) market was estimated at R58m in 1982 when the decision was taken to introduce centralized procurement. The figure rose to R281m in 1993 and was measured at a staggering R3.7b in 2007 (this figure excludes ARVs). This is likely to increase as more people are put on treatment. The price advantages were possible due to the economies of scale achieved as a result of pooling the entire country's medicines procurement into one central mechanism. Over the years, a number of changes have been made that impact on the tender system. These include the establishment of the provincial tender boards, the replacement of the Department of Finance with the National Treasury and the subsequent attachment of secondary objectives to the tendering system such as preferential procurement for certain categories of population groups or persons (1).

No formal in-depth assessments have ever been conducted of the tender system since its inception in 1988 to establish whether government continued to derive efficiencies and price benefits following the amendments effected to the public procurement system over the years.

What has become clear is the fact that problems are encountered across all the spheres of the centralized procurement system, which has become increasingly fragmented as a result of the addition of the provincial tender boards. These include the actual tender system and its management at the National Treasury (NT), the coordinating functions at the level of the National Department of Health (NDoH), the increasing roles of the provincial tender boards, inefficiencies along the supply chain and generally poor depot management.

In the recent past the tender conditions have further changed, providing various types of concessions, for example as a result of the need to facilitate the participation of smaller companies, the increasing participation of foreign generic manufacturers, and the multinational companies significantly having reduced their local manufacturing capacity. As a result, the continued accrual of benefits to the State from the centralized procurement of medicines has come under scrutiny.

A study of tender prices compared to international procurement prices suggests that the current tender system does not achieve internationally competitive prices – the high tender prices for ARVs is a clear example of this(15). The current tender system requires review so that it achieves the better procurement prices which would allow government to treat more patients with the same budget.

The public sector healthcare facilities have been hard-hit by medicines shortages and in the recent past reports of shortages were more pronounced in certain provinces. Reasons provided have ranged from failure by provinces to pay suppliers, failure of suppliers to meet their tender quotas, lack of expertise to monitor activities along the supply chain, and most recently, the exhaustion of from the conditional grants for ARVs, as seen during 2008/09 in the Free State province.

3. Background

In February 2009, then Minister of Health, Barbara Hogan, appointed a task team, the Medical Products Technical Task Team (MPTTT) to investigate a wide-ranging list of issues affecting medicinal policy and the provision of pharmaceutical services in the country. The Task Team invited written and oral submissions from interested stakeholders, but was not, in the time allocated, able to conduct any comprehensive assessment of all the issues, particularly procurement. Some of the specific problems relating to medicines procurement that the MPTTT was able to discern in the short timeframe included the following:

- There does not seem to be a systematic mechanism for allocating provincial pharmaceuticals budgets; doubts have been expressed in some quarters that provincial budgets for pharmaceuticals are monitored, and the budgets are inevitably exhausted well before the end of the financial year. In the case of antiretrovirals, this has led to perennial shortages in many of the provinces, compromising the entire treatment strategy;
- Suppliers tend to withhold supplies as a result of prolonged non-payment by the provinces. When this happens, hospitals often resort to buy-outs, invariably at higher prices, albeit on credit, in order to alleviate the shortages;
- Provinces are at liberty to move the procurement of medical related products (these include

dressings, syringes, needles, sutures, test kits, reagent strips and other small devices) down to provincial level; this affects the whole purpose of achieving economies of scale gains through combined and centralized bargaining;

- Whereas the outsourcing of services such as warehousing, procurement and distribution is advocated where provinces lack the skills to carry out these services in-house, anecdotal evidence suggests that no benefits have been derived where these services have been outsourced. An additional complaint is that the performance of the private contractors is not being monitored and that the relevant service level agreements are not binding;
- The mechanism used by the private warehousing contractors to charge for their services may be inappropriate, resulting in increased expenditure and defeating achievement of the envisaged efficiency-gains of outsourcing;
- Specifications for medical devices are often out of date and not standardised as provinces each have their own specifications, methodologies, processes and procedures. This lack of uniformity in specifications seems to be also true for medical related items procured at the provincial level. Such a system is clearly open to abuse;
- Fixed period tenders for medical devices are extended beyond the expiry date or indefinitely, resulting in buyouts and increased costs to government. This also happened with the first tender for ARVs;
- South African generic manufacturers are said to be losing sales to imports from low-cost foreign generic companies who often have import tariffs protecting their home market, while in South Africa only raw materials carry customs duties, thereby disadvantaging local manufacturers;
- However, there is also the view that South African companies do not seem to be able to meet local demands, and that better prices could be sought and found on the international generics market. The question that arises is what impact this would have on the policy to support and strengthen the local industry;
- There is a view that much more could be done, both at the provincial level and at the level of

National Treasury, to monitor and evaluate suppliers' performance and their ability to ensure adequate and continuous supply of medicines of acceptable quality, thus minimizing the out-of-stock situations of essential medicines.

It was against this background, coupled with the fact that stock-outs of medicines, especially ARVs, continued to grip the country, that Barbara Hogan's successor as Minister of Health, Dr Aaron Motsoaledi, commissioned an in-depth assessment and review of the public sector's medicines procurement system which would include recommendations for an improved medicines procurement system for the public sector.

4. Objectives

4.1 General Objective

The objective was to conduct an in-depth assessment and review of the centralized procurement of pharmaceuticals and medical devices in the country's public sector and to present a number of options to the Minister of Health for an improved medicines procurement system for the public sector.

4.2 Specific Objectives

- To find answers to the following questions with regard to provincial procurement of medicines:
 - How are the provincial pharmaceutical budgets (including the budgets for ARVs) determined and how are they monitored? Which authority has the final say in the determination of pharmaceutical budgets? What criteria are applied in such determination?
 - What are the causes of systems failures leading to shortages, exhaustion of budgets and provinces not paying suppliers?
 - How can the organization of the procurement and payment systems be improved so as to avoid non-payment of suppliers and non-delivery of medicines and ensure a constant flow of supplies?
 - Could centralization of the authority for procurement organization and funding of pharmaceuticals and medical devices yield the most cost-effective procurement system? What would be the legal implications of such centralization of procurement authority?

- To identify challenges linked to the devolvement of procurement activities and powers to the provincial tender boards with respect to medical related items and medical devices, and identify associated public health risks;
- To determine how best specifications for medical devices should be standardized and in which authority this responsibility should be vested;
- To assess the role of the National Treasury at the operational level and in the day-to-day management of tenders for pharmaceuticals and medical devices and to consider whether the National Department of Health should not assume a more central position in the technical aspects of this role, especially with regard to overseeing procurement policies for pharmaceuticals.

5. Methodology

The methodology refers specifically to the work of the Task Team with regard to the procurement of medicines and does not include any assessment or collection of data with respect to medical devices. Chapter 9 briefly describes the current situation with regard to the use and regulatory status of medical devices.

The design of the methodology took into account the fact that procurement is but one of a number of key, inter-linked functions of the supply chain management for pharmaceuticals, as depicted in the MSH Pharmaceutical Management Framework below. Hence, selection policies, financing mechanisms, distribution models, policy and regulation and management support, together with sound procurement policies and practices, all work in tandem to achieve the ultimate goal of the pharmaceutical supply chain – which is that essential medicines of good quality are made available to those sections of the population that require them, at affordable cost and in constant and sustainable supply.

Pharmaceutical Management Framework

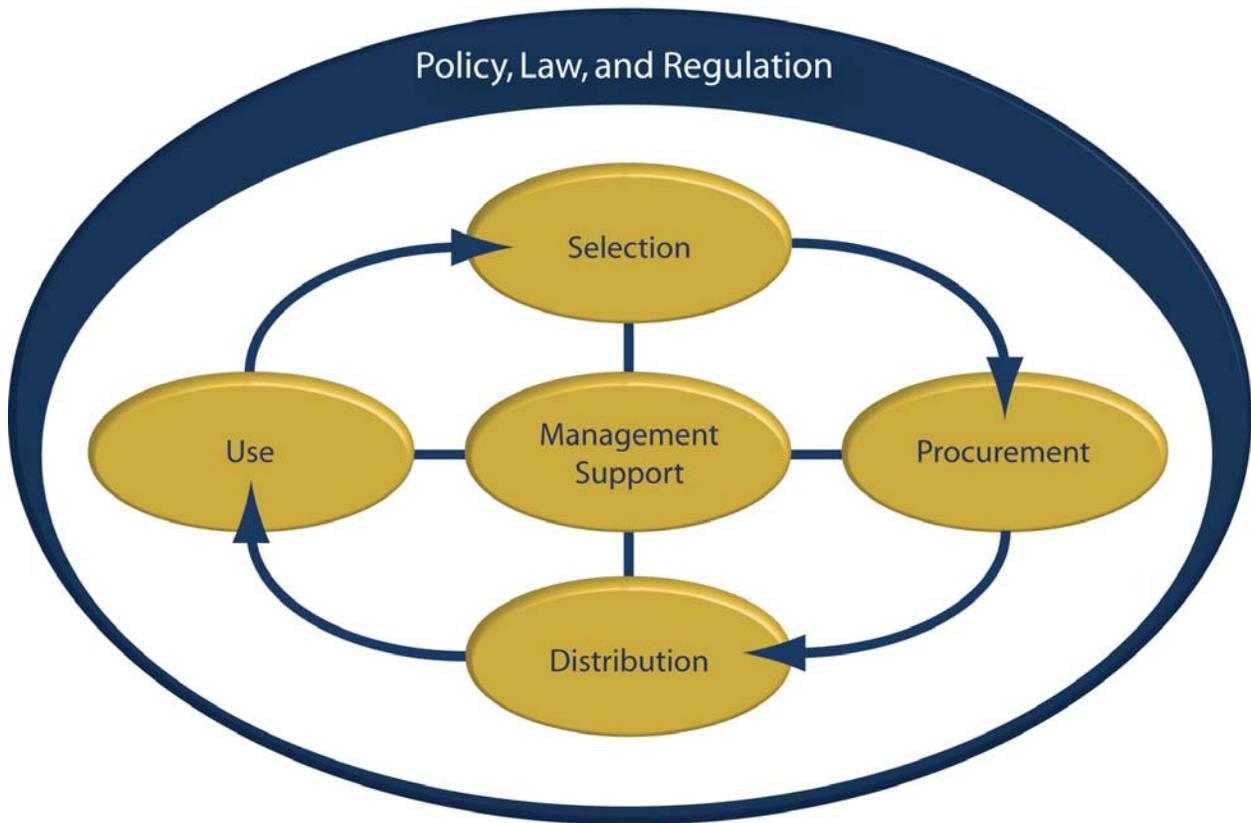


Figure 1: The Pharmaceutical Management Framework

MEDICINES SUPPLY MANAGEMENT CYCLE

Selection

- Review health problems
- Identify treatment
- Choose medicines, dosage form, strength
- Choose levels of care in which the medicines can be used

Distribution

- Customs clearance
- Inventory control
- Stores management
- Transport and delivery

Procurement

- Quantify medicines requirements
- Select procurement methods
- Manage tenders
- Establish contract terms
- Assure medicines quality
- Ensure adherence to contract terms

Use

- Diagnosing
- Prescribing
- Dispensing
- Use by patient

Management Support

- Organization of the system
- Financial management
- Management information systems
- Human resources management
- Monitoring and evaluation

The assessment thus consisted of a desk-top review and in-depth interviews with key informants at the national and provincial levels and at chosen facilities.

A draft of the report was sent to National Treasury and the NDoH's HIV and AIDS Directorate and the Affordable Medicines Directorate in order to afford them an opportunity to correct any misrepresentations that they may have discerned or to provide comment on the report's recommendations, especially in as far as the recommendations affected their areas of responsibility.

5.1 Provincial Level

- a. Open-ended and structured interviews were used to interview provincial heads of pharmaceutical services, depot managers and heads of financial services in order to solicit their views on the issues raised above and on options that could be tabled as possible solutions;
- b. Interviews were conducted with private providers and other stakeholders in order to solicit their views on different procurement models;
- c. Questionnaires were used to carry out assessments of all the provincial depots and selected hospital pharmacies across the country;
- d. Private healthcare providers were interviewed with a view to determining what, if any, role they could play in the distribution of medicines in the public sector and what, if any, workable cost-effective models they could propose. This was done through structured questionnaires.

5.2 National Level

Interviews and questionnaires were used for the purposes of:

- a. evaluating tender regulations and their relevance to policy objectives and economic strategies;
- b. reviewing the relationship between the State's Industrial Policy and a possible preferred future procurement and supply model;
- c. soliciting views on the best mechanism of procuring medical products and devices for the State sector;

- d. bench-marking against best practices around the world, especially in countries with similar health systems and at the same economic level as South Africa.

Data collection was conducted by members of the Task Team and technical staff of SPS/MSH.

Appendix B lists the institutions, companies, organizations and persons interviewed, while Appendix A carries a sample of the questionnaires used.

5.3 Desktop Review

The desk-top (literature) review was conducted in order to understand the various models of procurement and pharmaceutical supply chain management used by other governments. Specific attention was paid to the challenges that have been experienced in pharmaceutical supply chain management, the mechanisms that have been implemented to address these challenges and problems as well as the degree of success experienced.

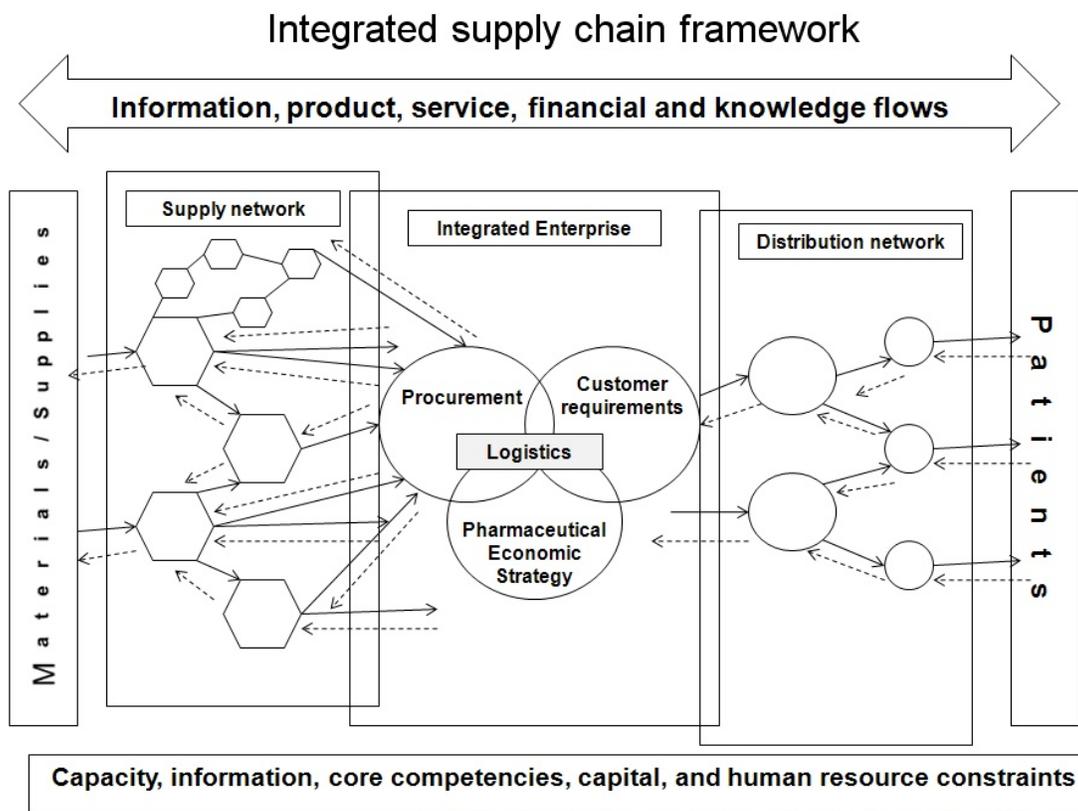
Information was obtained primarily through searching through databases such as Biomed Central, Medline, Health Source: Nursing, CINHARL, Cochrane Library, LWW Journals @ Ovid and Pubmed, internet searches and from existing articles, publications and documentation. The sections below summarise what was discovered during the literature review.

It is generally accepted that an effective public sector supply chain must include the following (2,3):

- **Selection** of the safest and most cost-effective essential pharmaceuticals;
- **Accurate forecasting and quantification** of purchase volumes required;
- **Sustainable funding mechanisms** for the purchase of the essential pharmaceuticals;
- **Effective management of the contracting process**, whether through competitive bidding or tendering; with qualified staff that have high professional and ethical standards, using appropriate policies and regulations
- **Transparency and accountability** to limit fraud and corruption;
- **Effective information management systems** to ensure that accurate and readily accessible information is available to support the planning and decision-making functions;

- **Good quality assurance** to ensure that pharmaceuticals are safe and of good quality, and
- **Regular review and monitoring of the process from quantification to supplier selection, to delivery schedules, product availability, quality and supplier performance.**

An effective procurement process ensures that the right medicines which comply with the relevant standards are available at the right time, in the right quantities, for the right patient, and at reasonable prices. Thus, the fundamental model of an integrated supply chain consists of a multi-firm collaboration within a framework of key resource flows and constraints (1). This can be illustrated by a line diagram between materials on the one side and customers (patients) on the other side and connected to each other through a supply network, an integrated enterprise and a distribution network.



Adapted from: Supply Chain Logistics Management, Donald J Bowersox et al, 3rd Edition

Figure 1: Integrated supply chain framework

The integrated enterprise will include the procurement, industrial policies and customer satisfaction functions as well as production capability. The fundamental model is not only heavily dependent upon the

relationship management between all these different components but also the flow of information, product, service, financials and knowledge. It is ultimately constrained by capacity, information availability, core competencies, capital, and human resources.

Bowersox et al go on to describe the core competencies required for a best practice model.

The World Health Organization (WHO) advocates that procurement should take place against a list of essential medicines (3). This approach has been adopted by most countries, including South Africa. The manner in which medicines are procured against this list of essential medicines is discussed in more detail in the section below.

5.3.1 Overview of Procurement Models in the Public Sector

Procurement models in the public sector are often varied and are influenced largely by country size, procurement legislative frameworks, experience and resources available to manage pharmaceutical procurement and distribution.

The simplest model is the **quotation system** where quotes are requested from suppliers who may or may not have been pre-qualified. This system is often used by individual institutions rather than countries or regions. Chile on the other hand has developed a transparent, electronic system of **competitive bidding** for pharmaceutical purchases that 'has led to tremendous savings and helped increase access of the poor to essential medicines and shown how information technology can put the government at the service of the public.' (3). In this model, the participating facilities submit six-monthly need forecasts. A consolidated list is then presented to manufacturers for bidding. Suppliers are provided with the lowest price received and are allowed an opportunity to submit revised pricing. Bidding continues until equilibrium is reached and a price is agreed upon between the purchasing authority and the successful supplier(s). The purchasing authority also acts as financial guarantor. Chile has found that this open and transparent model has decreased the opportunity for collusion and corruption and also lowered prices (4).

Pooled procurement and variations thereof, are some of the most common procurement models in use by countries which opt to pool their medicines procurement, mainly on the basis of regional grouping globally. Various such models are described by Scherer et al(4).

5.3.2 Pharmaceutical Supply Chain Management Challenges

Challenges faced by public sector supply chains are remarkably similar the world over. Some of the common challenges that were identified during the literature review include:

- Corruption and Fraud (integrity of the supply chain)(5);
- Lack of harmonisation of essential medicines list(2);
- Poor stock management(6);
- Inadequate or erratic funding: High costs for essential medicines(4,5);
- Lack of high quality data: (Leads to poor forecasting etc
- Lack of adequate number of skilled professionals: Lack of distribution efficiencies

5.3.3 Case Studies on the Success of Interventions to Address Challenges

Various case studies were found which demonstrated how specific interventions resolved problems related to deficiencies in the procurement system. These include the combating of corrupt procurement practices in Chile through transformation of the central procurement agency (7); the outsourcing of vaccine warehousing and distribution in the USA in order to ensure timely payment of suppliers and improvements in stock-holding, which also yielded cost savings; pooled procurement on behalf of hospitals in New Zealand on behalf of a group of hospitals, leading to cost savings; ,how medicine stock-outs were eliminated and ARV therapy successfully scaled up in Malawi following the introduction of a structured system of medicine forecasting (6l) and how the merging of 4 independent procurement system in Jordan led to significant cost savings (6).

With regard to vaccines procurement, assessments conducted by WHO in 42 countries between 2003 and 2007 highlighted issues such as poor vaccine arrival management, lack of contingency planning, poor

equipment maintenance planning, transport failure and poor stock control as recurring themes which were predominantly management-related(8).

While many of the examples cited above are of countries which are not necessarily at the same level of economic development as South Africa, the generic problems are basically similar. A lot of lessons, could, therefore, be drawn from some of the interventions described. For instance, the themes of pooled or centralized procurement to reduce corruption, improved forecasting of needs to reduce stock-outs are among the interventions that would find ready support in the South African setting.

6. Limitations and Constraints

Information for this report was gathered within the following limitations and constraints:

- **Short time given:** The task team was convened for the first time on 28 August 2009. Between this date and 14 December when the draft report was required, the task team had to visit and interview:
 - National Government:
 - National Treasury
 - CCMT/HAST Management at NDoH
 - Directorate Affordable Medicines at NDoH
 - Other stake holders as necessary
 - 9 Provinces
 - Heads of Pharmaceutical Services
 - Depot managers
 - HAST/CCMT Managers
 - Hospitals

This gave the task team an effective 3 months to complete the development of questionnaires (9 questionnaires were developed) and conclude the interviews and analyze the results. Although most of the necessary interviews were completed on time, some key interviews could not be conducted before the end of the year and it has proven to be a challenge for the task team to complete all interviews.

- **Difficult time of the year:** Interviews had to be conducted through the months of September, October and November which is traditionally a difficult time of the year due to holidays and year-end exams and completion of projects before the festive season. This made scheduling of the necessary appointments and interviews particularly challenging.
- **Availability of key role players:** It was not always possible to arrange interviews with key role players in the available time period and alternative interviewees had to be found.

- **Medical Devices:** Due to time constraints only pharmaceutical processes were investigated. In many instances medical devices follow the same supply chain processes as for pharmaceuticals and therefore the issues and recommendations raised in the report below are equally relevant. However, differences in the acquisition, planning utilisation and disposal of medical devices will require that much more concentrated work be done in this area..

Interviews and data collection in public sector facilities: The time it took for Task Team members to get approval to conduct interviews and data collection in the provinces added to the delays. When the correct officials were identified for the specific interviews, it became a challenge, in quite a few instances, to get officials to commit to a set date and time. Quite clearly, they were extremely busy, in the majority of cases. But this led to several postponements of interviews.

7. Observations and Findings

Figure 3 depicts in the simplest possible manner the complex pharmaceutical supply chain that exists in the country's public sector. This section will proceed to describe all the activities involved in the entire chain. As will be seen further, some parts of the chain may be too costly and unnecessary, absorbing a lot of the much-needed and scarce resources available in the public sector.

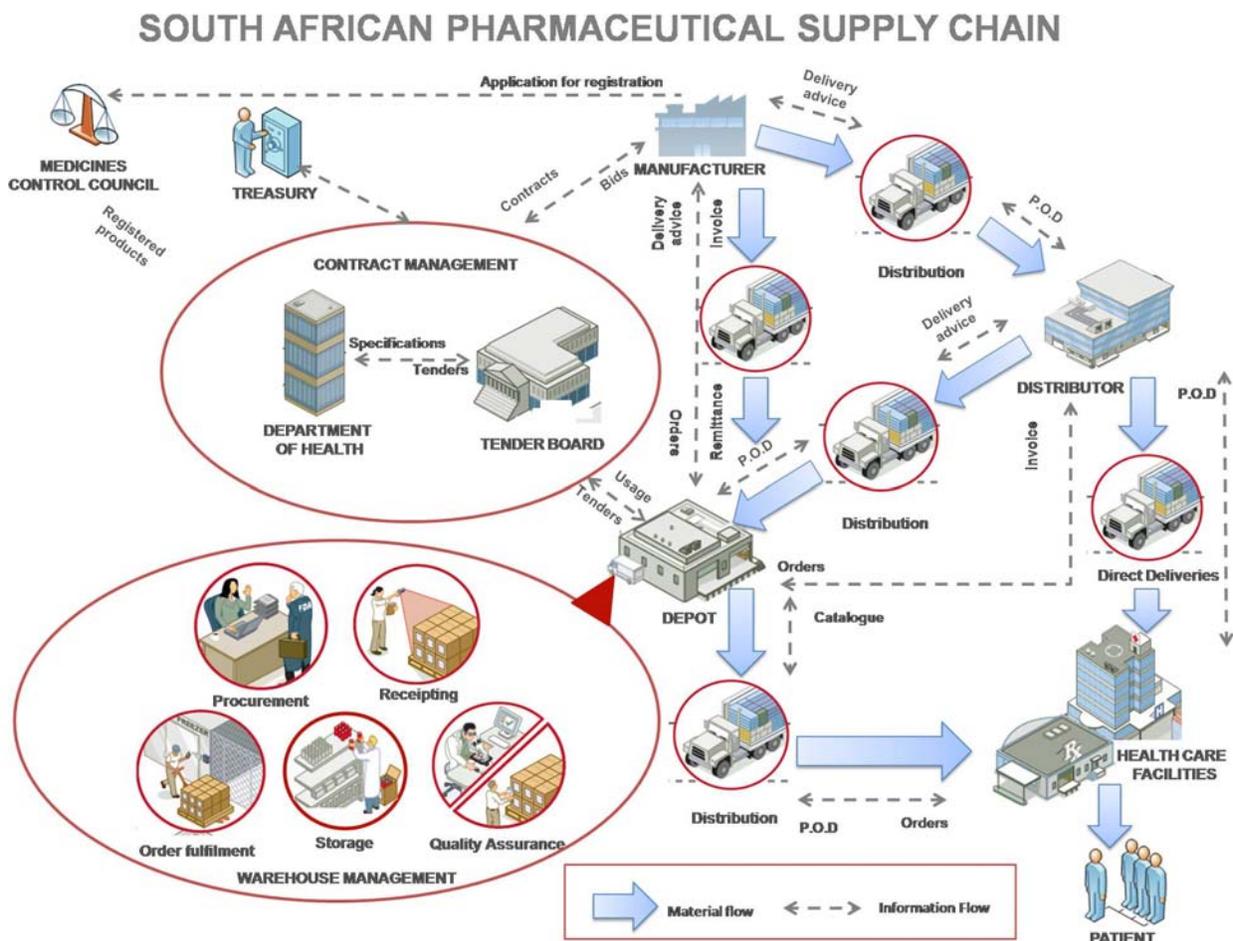


Figure 2: SA Public Sector Pharmaceutical Supply Chain

7.1 Finance and Funding

7.1.1 Description

National Treasury allocates funds to Government departments through two basic funding mechanisms – equitable shares and conditional grants.

- **Equitable shares.** The Constitution provides that each sphere of government is entitled to an equitable share of revenue raised nationally to enable it to provide basic services and perform the functions allocated to it. The equitable division of revenue takes into account the functions assigned to each sphere under the Constitution and the capacity of each government sphere to pay for these functions through own receipts and revenues.

The equitable share is an unconditional allocation to the national government, to each of the nine provinces and to local government. Provincial and local governments, being distinct spheres of government, are fully responsible for these funds and are directly accountable for how they are spent. Government policies influence provincial and local government spending indirectly, through cooperative agreements and framework legislation setting norms and standards.

- **Conditional grants.** These are conditional allocations to provinces and municipalities from national government's share of revenue raised nationally, which are conditional on certain services being delivered or on compliance with specified requirements. An example of a conditional grant is the transfer of funds for the integrated housing and human settlement development grant.

Thus, the funding of HIV and AIDS services is done through a conditional grant, while the funding of all non-HIV and AIDS health services is funded through the equitable share. The National Tertiary Services Grant (NTSG) is another example of a conditional grant. Each conditional grant has its own very specific performance indicators which are reported against and monitored by Treasury and the NDOH.

- **The National Tertiary Services Grant (NTSG).** The NTSG(9) was introduced in the 2002/03 financial year following the Review of Highly Specialised Services (HSS). The

objectives of the review, which was conducted by the NDOH, were to locate and quantify the provision of tertiary services rendered in South Africa. A key finding of the review was the inequitable distribution and access to financing of tertiary services between the nine provinces. The National Tertiary Services Grant (NTSG) sought to rectify historical distortions in resource allocation, and to provide "like for like" funding of public tertiary services as they are currently provided in South Africa.

The Task Team's interest in the funding of tertiary services arises from the fact that medicines expenditure in tertiary institutions is, quite often, related to the treatment of conditions which are not encountered at lower levels, justifying that funding at this level be given special attention. Since such institutions are not equally spread among the provinces and yet tend to be accessible to patients from neighbouring provinces, the funding of services they provide would seem to require funding outside the equitable share allocated to the provinces by NT.

The review found that, while it was questionable as to whether all the units provided a standard level of care that would have them classified as HSS or tertiary and/or quaternary services, it was nevertheless clear that access to tertiary care was significantly inequitable (where location or proximity to a tertiary centre afforded an individual better access to tertiary care); provision was significantly skewed to the extent that the poorer provinces were funding services out of the equitable share and the richer provinces were using conditional grant funds to subsidize lower levels of care.

7.1.2 Observations and discussion

An interview with NT revealed that this department was acutely aware of the increasing expenditure on pharmaceuticals and that NT strongly wanted to support systems in the provinces to improve financial and programme management. This was particularly so because healthcare expenditure had risen dramatically since 2002, i.e. goods and services, including medicines, had risen from 9.8 billion in 2002 to 30.7 billion in 2009. Medicine expenditure alone rose from approximately R3 billion in 2003/04 to R6.5 billion in 2009. According to the DoH, the following is the estimated cost per tender awarded over the past 2 years:

National Tender Split (2009/10)		
Contract	Description	Estimated 2 yr value (in R)
RT280-2007MF	Drops, aerosols, inhalers and inhalants	488,643,690
RT281-2007MF	Semi-solid dosage forms and powders	423,008,822
RT283-2007MF	Family planning agents	204,446,443
RT285-2006MF	Biological preparations	139,179,925
RT289-2007MF	Solid dosage forms	2,520,880,577
RT290-2007MF	Cytostatics	247,501,549
RT75-2005MF	Condoms	191,313,519
RT71-2004MF	Antiretroviral Medicines	3,459,666,799
RT78-2007MF	TB Medicines	382,316,894
RT297-2007MF	Small volume parenterals	726,356,716
RT299-2008MF	Large volume parenterals	712,864,381
RT300-2007MF	Liquids	368,932,923
RT301-2007MF	Antibiotics	710,093,333
TOTAL		10,575,205,571

Table 1: Estimated value of tenders for a two year period

It must be emphasized that these numbers do not represent (eventual) total expenditure. These numbers are estimates, and actual expenditure could only be derived from provincial accounts. However, this is a near impossible task, given that little accounting on expenditure for pharmaceuticals flows back from the facilities, through the Provincial financial departments back to Treasury. Total money allocated does not translate to total money spent. It is virtually impossible to establish what proportion of the total funds allocated to expenditure on medicines actually went towards what they were meant for, and how much was lost through inefficient budgeting, wasteful expenditure, expired medicines due to inefficient procurement and distribution systems, theft and fraud. Pharmaceutical expenditure in any healthcare facility is second only to the salaries bill, and financial management systems have to be put in place which are commensurate with the level of expenditure.

Allocation of the total healthcare funds to Provinces through the equitable share means that it is left to the discretion of every province to decide how much to allocate to medicines. In many of the Provinces, decisions on medicines expenditure are left to the supply chain managers at provincial level and within the districts and facilities. Anecdotal evidence from some of the better managed Provinces suggests that such managers have succeeded in putting in place some solid financial management practices. However, they are not able to “think out of the financial box” when certain key decisions around procurement have to be made on the basis of a sound clinical foundation. The following are some of the consequences, direct or indirect, from the current financing system for medicines:

- The Provincial pharmaceutical budget is not defined, which makes financial planning impossible;
- The Provincial management information system with regard to pharmaceutical expenditure is poor. This makes it difficult for Provinces to reasonably estimate medicine utilization and monitor expenditures;
- Provinces do not pay suppliers timeously. Suppliers respond by withholding deliveries which results in non-availability of medicines at facilities;
- The medicines selection process is not linked to the budget calculation. Changes to the treatment guidelines/ essential medicines list do not result in amendments to the pharmaceutical budget. This results in Provinces being given unfunded mandates;

It would appear that the same considerations that led to the care, treatment and management of HIV and AIDS being funded through a conditional grant could be applied to the procurement of all pharmaceutical products. This would make sense as expenditure on ARVs is only a portion, albeit a significant one, of total medicines expenditure. Moreover, patients on ART invariably end up accounting for high usage of TB and other medicines for opportunistic infections.

What, then, would be the feasibility of allocating all disbursements for pharmaceuticals, including all medicines and ARVs, medical sundries and medical related items, to one national conditional grant, which would be overseen from a national unit within the NDOH? Would it be logical for

such a unit also to take responsibility for specification, procurement and financial management of pharmaceuticals, co-coordinating these functions on behalf of the Provincial health departments?

The Task Team has concluded that such a centralized authority for all pharmaceutical procurement, which would also be staffed by experts in pharmaco-economics and have close links with the National Health Insurance Unit, the National EDL Committee and feed into the provincial Pharmacy and Therapeutics Committees (PTCs), should be considered as a potential integrated total solution in ensuring a steady supply of essential medicines of the highest quality, procured at affordable prices and used in the most cost-effective manner.

National Treasury warns that, while it may be correct that late payment or non-payment of suppliers may be improved if the budget is centralized, this should not be extended to centralizing the payment of suppliers as well, pointing out that this may only be possible with the aid of an integrated financial system (software). If delivery takes place at the depot or hospital level, it is easier to effect payment at that level as well, because you can do the three-way matching at that level as well. NT makes the point that it is only in this way that there can be certainty that the goods were indeed delivered, and in the correct quality and quantities. Thus, the solution to the problem of late or non-payment of suppliers lies in improving materials management processes and procedures and enforcing accountability(10).

However, a counter argument is that facilities do not have the capacity to pay suppliers directly, and the Provincial Treasury offices have clearly not coped with payments. Linkage between the facilities and the national office would be through a simple IT system, and systems are currently in operation which could be used for this purpose.

It is in the context of the possible ring-fencing of pharmaceutical services funding that the issue of Highly Specialized Services (HSS) is taken up here. To reiterate, the review of HSS of 2002/03 discerned a skewing of the funding of services in that the poorer Provinces were funding services out of their equitable share, while the more generously endowed ones were receiving conditional grant funds and utilizing them to subsidize lower levels of care. The question that arose from a discussion the task team had with the head of a specialist quaternary unit was precisely whether it was necessary for each and every Province to have, or to be expected to provide, highly

specialized services(11). Considering the cost of providing some of the HSS and their impact on the healthcare budget, is it necessary for Polokwane, Johannesburg, Pretoria, Cape Town, Nelspruit, indeed, all the Provincial capitals, to each have a specialist oncology or dialysis unit? Surely the result is that, while this may ensure equity among the Provinces in terms of the ability of each one of them to provide HSS, the country now has to spread scarce human resources, expertise and funds in order for each Province to have pride in the fact that it has HSS – but are these really of a standard or level that would justify their being classified as such?

This thus forms the basis of the argument that it would not be realistic to have HSS in each and every one of the country's Provinces. Instead, the best-resourced healthcare institutions, which are not to be found in every Province, ought to be regarded as national centres of excellence, their status thus transcending any Provincial borders. They would be funded from the NTSG for the provision of tertiary/quaternary services. Whereas such centres of excellence would, as with all other hospitals, have their pharmaceutical requirements funded through the conditional grant resting with the national pharmaceutical procurement authority, they would receive additional funding through the NTSG for the provision of medicines for highly specialized services.

An emerging trend giving rise to possible justification of even higher instances of medicines expenditure is that of risk-sharing agreements. A risk-sharing agreement is a tool used to manage the risk of introducing very expensive medicines, whose clinical efficacy may still have to be proven, into the healthcare market for use on a patient with a rare condition that may not have responded to any known treatments. The arrangement would have the manufacturer/supplier share the risk of treatment failure with the payer, which could be a medical scheme, or the State/NHI. The National agency responsible for procurement of pharmaceuticals would need to have the capacity and expertise to handle such cases.

7.1.3 Recommendations

- It is recommended that the national pharmaceutical budget be centralised, ring-fenced and overseen by a central pharmaceutical purchasing authority, henceforth referred to as the CPPA for ease of reference, located within the NDOH. Expenditure on ARVs would be included in the national pharmaceutical budget. Allocation of the funds would be through a conditional grant with special conditions - relating to accounting procedures, regular reporting, implementation of

sound financial and management information systems, etc - attached to it. There are several mechanisms within Government to ring-fence specific budgets. This is usually done through conditional grants where funds are dedicated and these funds are only released when expenditure related to predetermined conditions are met. This way, the public sector would have one mechanism for controlling and disbursing the entire pharmaceutical budget, as opposed to the current arrangement of nine provincial authorities allocating the pharmacy budget arbitrarily through the equitable grants and another national authority controlling a portion thereof through conditional grants, as is the case for ARVs and the NTSG.

It is recognized that the establishment of the CPPA will necessarily have to be preceded by a Cost-Benefit Analysis to justify its viability, and this is recommended as a first step.

Treasury's Comment: You have proposed a centralized procurement and funding approach. In as far as this proposal is concerned there are two issues. You need to first establish what the provisions of the PFMA and Division of Revenue Act (DORA) are in this regard, whether your proposal may need amendments to the current legislation, how long this process would take and whether legislation could be amended solely for the purposes of streamlining processes and creating a special procurement dispensation for pharmaceuticals and other related medical devices to the exclusion of other equally important goods and services. The danger could be that other departments may want similar amendments e.g procurement of textbooks, feeding schemes for schools, payment of social grants, etc.

The Task Team's analysis of the provisions of certain legislation relevant to procurement, which includes but is not limited to the Constitution, The PFMA and Treasury Regulations in terms thereof and National Treasury's Code of Conduct, form the basis for the belief that it would be possible for such an arrangement to be arrived at. This would be in line with the Constitutional precepts of ensuring that procurement policies and practices must enable the state to discharge its constitutional obligations in respect of the Bill of Rights, including – in this case – the right to have access to health care services. Details of the legal arguments can be found in Appendix C: Legislative Framework Analysis.

- The pharmaceutical budget must be clearly defined at the Provincial level. If the public sector pharmaceutical budget is developed into a conditional grant, Provinces would be compelled to keep accurate records of purchases and utilization to satisfy the conditions of the grant. Thus, this

intervention has the potential of resolving the current challenges with regards to information. Good information management systems on procurement and utilization would also assist with the tender process, monitoring expenditure and rational prescribing. The other knock-on effect of a conditional grant is the timely payment of suppliers.

- The identification of certain tertiary institutions, currently jointly referred to as Highly Specialized Services (HSS), as national centres of excellence is strongly recommended. Thus, by way of illustration, if Groote Schuur Hospital were identified as THE national centre of excellence for all specialised cardiac surgery, such as heart transplantation, then the bulk of the country's resources and skills in this area of medical specialisation would be concentrated at Groote Schuur. The budget for the HSS would be funded from the existing NTSG. The pharmaceutical budget for the HSS would be overseen by the CPPA.
- It is recommended that the CPPA have a close link to the national essential medicines list committee to ensure that budgetary implications are considered whenever amendments to the treatment guidelines have to be effected, possibly as a result of new entries into the market.
- The Provinces would then be accountable to the CPPA which, in turn, would be accountable to National government for managing the national pharmaceutical budget. The provincial PTCs will have a major role to play in ensuring that selection, procurement and use of medicines in the provinces is in line with EDL and CPPA requirements. To this end, measures should be put in place to strengthen the provincial PTCs and ensure that all medical and other specialities have full representation and participation on the PTCs.

7.2 Procurement

7.2.1 Description

The bulk of medicines in the public sector are procured through contracts from national tenders. In isolated cases, facilities can procure outside of the tender system, although this should really

mainly happen in emergency situations where the suppliers are unable to fulfill their contractual requirements.

Tenders for medicines are arranged nationally by the Department of Health's Access to Affordable Medicines directorate, in collaboration with National Treasury, the contract manager for all contracts awarded. This is in line with the National Medicine Policy and to take advantage of economies of scale for larger quantities instead of tendering for smaller volumes in nine different provinces.

The National Medicines Policy makes provision for provincial tendering for medical related items* (surgical sundries) although the majority of provinces still participate in the national tenders. The National Department of Health does not participate in any of the tenders; their function is solely one of coordination. In addition to the nine provinces, Correctional Services and the South African Military Health Services also procure medicines on these contracts.

7.2.2 Observations and discussion

This section was compiled from responses to questionnaires sent to provinces, manufacturers and the NDoH. National Treasury was afforded an opportunity to comment on the contents.

7.2.2.1 Tenders

- The NDoH requests estimates from the provinces for each tender contract in sequence. In previous years, these contracts were spaced fairly evenly over a two-year period, medicines in one year and medical related items in the second giving ample time for the preparation of specifications for medicines and medical related products as well as for the special conditions of tender.
- Some of the complaints raised by the provinces relating to the tender processes range from tender delays (between 6 and 12 months) due to failure of NT's electronic system to allegations that tender adjudication is not transparent.

* The other term that is commonly used for this is "surgical sundries", and "medical supplies" finds usage internationally.

- While quite a few of the complaints were cited by a wide range of respondents in the public sector and among suppliers, these remain untested as, due to time constraints, NT could not be engaged in detailed discussions of such complaints and allegations.
- Only a few hospitals could supply data on percentage and value of buy-out items. Upon analysis of the information received, it was clear that the tertiary hospitals spent a far larger proportion of budget on these items compared to the district hospitals. A comparison is presented below in table 3.

Institution Name	Percentage	Value (ZAR)
CMAH Academic	10-15%	24,000,000
Steve Biko Academic	7.87%	6,700,000
Kimberley	1%	428,406
Rob Ferreira	1.69%	376,871

Table 2: Percentage and value of buy-out items at selected institutions.

- A small proportion of pharmaceuticals are delivered by direct delivery (DDV), the most notable exception being the large volume parenterals. Other pharmaceuticals that are delivered directly are very specialized and only used on patient name basis.
- Some of the institutions felt that more DDVs would increase the burden of work of the staff in the hospital, whilst the majority thought that efficiency of delivery would improve and there could be a better relationship with the supplier.
- Penalties are not implemented for suppliers that fail to deliver within the lead time and provincial depots resort to cancelling the orders and writing warning letters to the suppliers. This means that the department rather than suppliers is paying the price difference for buying-out. A distinct view among the provinces was that it was the responsibility of NT as the tender manager to monitor poor performance among suppliers and to take action against them by, for example, excluding them from future tenders. NT, on the other hand, maintains that their role is to facilitate the arrangement and administration of tenders simply to ensure that due process is followed in line with the prescribed norms and standards. According to NT, once contracts are awarded, the Department of Health must manage that contract. It must place orders, receive goods,

distribute goods, expedite late orders, stock control, refurbish stock, pay suppliers, check quality, dispose of obsolete stock and monitor performance and report suppliers who do not perform to the Treasury so that the Treasury can take the necessary corrective action in terms of the contract.

Whoever has to take ultimate responsibility for the failure to act against defaulting suppliers, it is a fact that there is very little, if any, reporting of defaulting suppliers at the provincial level, allowing them to go unpunished, and such suppliers continue to benefit from participation in the tender processes. At the same time, it needs to be pointed out in all fairness to suppliers that the State incurs no penalties for failure to pay suppliers on time and many small companies have had their cash flows severely disrupted as a result of such non-payment by the provinces.

7.2.2.2 Purchase prices

- The data requested and collected via the questionnaires was not specific for pack size and presentation, so a comprehensive comparison of prices reported by the pharmacies is not possible. However, IMS data for Quarter 1 of 2009 was available with details of pack size and presentation. See Appendix C for full details
- Although all medicines are bought from the same contracts, the prices quoted by the different hospitals varied considerably as can be seen from the table below.
- Prices are seen to differ across the provinces for the same manufacturer. For instance, Streptomycin 1g injections varied from R4.04 to R18.90, over 4-fold in difference, Co-trimoxazole tablets varied from R57.86 to 183.35. There is also a considerable difference between manufacturers of the same product, for example in the table below for Stavudine 30mg caps x 60. The 2 main suppliers show a price difference of up to R8 per product with the ethical manufacturer charging up to double the amount of the cheapest available
- There is a discrepancy between most provinces in the cost of identical products from the same supplier as well as between suppliers for the same tender item. While some of these discrepancies may be small, for high volume items this could translate into a considerable difference in budget expenditure. For example, Paracetamol tablets x 1000 vary from R185.10 to R250.86 across provinces.

- The table below also indicates that there are a number of different manufacturers supplying the same tender product to different provinces. This implies a dilution of the negotiation power of the provinces
- This discrepancy in prices across provinces and within tender products could be due to either manufacturers billing provinces at prices that are not the contractual tender price or provinces purchasing from suppliers that have not tendered. A centralised procurement agency would without doubt be in a better position to negotiate to the lowest price (or lower) for the whole country and to ensure improved consistency of pricing and billing within the provinces.

Tracer Products	Description [manufacturer code]	E Cape	Free State	Gtng	KZN	MP	Limp	North West	W. Cape
Amoxicillin 125mg suspension	Amoxicillin syrup 125mg 100ml x1 [unb]	5.44	4.01	3.98	4.12	3.44	3.29	4.64	4.44
	Zoxil susp 125mg 100ml x1 [m/g]						7.41		
Co-trimoxazole tablets	Co-trimoxazole tabs 480mg 0 x1000 [unb]	183.35	57.86	107.46	87.2	94.29	107.29	111.79	75.57
Efavirenz tablets/capsules	Adco-efavirenz caplets 600mg 0 x30 [aoj]			114.01	117.25	100.54	104.39	100.41	126.84
	Aspen efavirenz tabs f.c 600mg 0 x30 [a&g]			119.29	121.72	103.35	106.21	109.16	124.18
	Efavirenz caps 200mg 0 x90 [unb]				142.5				283.55
	Efavirenz caps 50mg 0 x30 [unb]			20.68	24.74	31.14		27.35	27.19
	Efavirenz tabs 600mg 0 x30 [unb]								146.29
	Stocrin caps 200mg 0 x90 [msd]			280.68	303.98	250.01	248.32	254.61	284.9
	Stocrin caps 50mg 0 x30 [msd]			26.66	32.6	23.89	23.26	25.68	26.97
	Stocrin tabs 200mg 0 x90 [msd]								409.52
Paracetamol 500mg tablets	Stocrin tabs 600mg 0 x30 [msd]			161.28	104.13	142.62	143.68	143.38	107
	Pacimol tabs 500mg 0 x10 [aul]					0.72		0.72	0.7
	Pacimol tabs 500mg 0 x100 [aul]	5.71	6.42	6.03	6.31	5.72	5.37	5.97	5.89
	Pacimol tabs 500mg 0 x1000 [aul]	20.52							
	Pacimol tabs 500mg 0 x500 [aul]	30.23	25.15			30.19			40.23
	Paracetamol tabs 0 0 x5000 [unb]	218.65	261.22	185.1	236.24		203.79	250.86	

Tracer Products	Description [manufacturer code]	E Cape	Free State	Gtng	KZN	MP	Limp	North West	W. Cape
	Paracetamol tabs 0.5g 0 x100 [unb]			9.12	4.9	8.32		22.09	6.79
Stavudine capsules	Aspen Stavudine caps 30mg 0 x60 [a&g]			19.32	19	16.92	17.08	17.3	20.95
	Stavir caps 30mg 0 x60 [cd8]			27.07	27.07	23.87	23.75	26.71	23.98
	Stavudine caps 30mg 0 x60 [unb]					15.48			21.8
	Zerit caps 30mg 0 x60 [bse]					39.15		39.15	
Streptomycin 1g injection	Bio-strep vial 1g 3ml x1 [bth]	4.63	4.68	4.72	4.58	4.04	18.9	4.04	5.04

Table 3: Sample of tracer product purchase prices. For full details see Appendix C.

7.2.2.3 Quantification of estimates

- None of the district hospitals reported quantifying for estimates of medicine needs. Some of the academic hospitals, especially those that ordered directly from suppliers, did perform this function.
- It would appear that quantification is regarded as a depot function and these latter facilities use their electronic warehousing software to quantify on past consumption. This in itself is not always accurate because if an item is out of stock and facilities use another pack size or strength instead, this will skew the usage of the product, leading to very inaccurate estimates.
- The majority of hospitals place orders on the depots every two weeks, with the exception of two academic hospitals that order once a month. Most hospitals did report that they also order according to need (presumably for emergency orders). All orders are delivered by the depots through outsourced contractors. State transport is no longer used for the delivery of medicines. The transport companies are monitored for the deliveries in terms of timeliness, quality of service and conformity to orders. Payment to transport contractors varies according to contract, with one contractor being paid according to the weight of the delivery and another on value of goods delivered.

7.2.2.4 Immunization Programme

Products for the country's immunization programme are mostly procured and distributed through the same channels as other pharmaceuticals. The supplier of vaccines has a Public Private Partnership with the Health Department and holds a 40% share in this partnership. The company has its storage facilities in Cape Town and has a special arrangement with the Western Cape to distribute vaccines to selected addresses in both the metropole and the province. In Gauteng, vaccines are delivered to the depot in Auckland Park, as well as to the regional stores in the province. In all other provinces, vaccines are delivered to the pharmaceutical depots from where they are distributed mainly to the primary health care (PHC) clinics.

Hospital pharmacies order and supply mainly non-EPI vaccines for hospital use, but BCG and polio vaccines are stocked for use in immunizing new-born babies. There has always been a recommendation for hospitals to stock measles vaccine to prevent nosocomial spread of measles, but this seldom happens.

Data from the maternal unit on their vaccine usage is poor because the hospitals regard this as a PHC function and do not collect this data. This results in the reported coverage of BCG being very low, but inaccurate.

Since the changes to the South African EPI schedule in 2009, vaccines have become one of the top twenty most expensive groups of pharmaceuticals to manage, and the storage volumes for these have placed a great strain on the programme. The cost for the South African Government will escalate from approximately R100m in 2007 to more than R1billion in 2010. Cold chain management of vaccines can also be seen as a specialized form of pharmaceutical supply chain management and valuable lessons can be learnt from its successes or failures.

Vaccine expenditure is high and most of the newer vaccines fall within the top 10 items on any depot ABC analysis. The newer Rotavirus and Pneumococcal vaccines are extremely costly and the anticipated Human Papilloma virus vaccine will also be costly.

It is known that various reviews of the country's EPI have been carried out in the recent past, the last one as recently as the last quarter of 2009. It would be instructive to have a focused investigation into why EPI vaccines should continue to be procured and distributed outside the conventional pharmaceutical supply chain.

7.2.3 Challenges / problems observed in procurement at the various levels

This sub-section summarizes the challenges and problems observed through interviews with the various stakeholders and assessments carried out at public sector hospitals and provincial medicines depots.

- **At hospital pharmacies:**

- Lack of electronic transfer of contract prices from NT and NDoH to the pharmaceutical systems, both depot and hospital;
- Insufficient funding for medicines and medical related items, both from the conditional grants and the equitable share;
- Late award of tenders, leading to increased work and costs in buying out medicines;
- Often poor quality of products supplied on provincial tenders for medical related items, due to lack of monitoring of quality at this level;
- prices for the same medicines differ between hospitals;
- Hospital pharmacies have not taken ownership of the quantification of estimates, the majority feeling this is a depot responsibility.

- **With tender processes:**

- Inaccurate estimates are supplied by depots for a two-year period, based on consumption history. (This could include medicines stolen, expired or damaged);
- Perceived lack of contract management by Treasury – supplier performance is not monitored, and suppliers are seldom refused contracts for fear of litigation;

- Inability to split large tenders between suppliers to ensure sustainability of supply, based on differences in the point award system;
- Provincial tenders are often not according to the national specifications, but are written in a manner that tends to favour specific companies, leading to sub-standard products being used in the hospitals.
- **At provincial pharmaceutical depots:**
 - Lack of communication between depots and suppliers on quantification of estimates, both before and during the contract periods;
 - Late advertising and award of tenders, leading to time-consuming buy-out procedures for many medicines. For each buy-out, there are 3 quotations needed and companies must submit current tax clearance certificates with each quote, making the process lengthy and cumbersome;
 - Penalties not being implemented for suppliers that fail to deliver within the lead time;
 - Difference in prices quoted for the basket of medicines – these should all be according to contract, and should be the same across the depots;
 - Only two of the provincial depots are aware of the expenditure on buy-outs done at the hospital. According to policy, buy-outs should never exceed 10% of budget, for non-EDL/formulary medicines with the exception of tertiary hospitals that are granted a larger margin.
- **By pharmaceutical suppliers:**
 - Lack of electronic availability of tenders in all the provinces;
 - Lack of standardization of tenders in provinces;
 - Tenders are not issued timeously in order to be finalised before the current contract expires;
 - Late awards of tenders, resulting in immediate orders putting pressure on suppliers with respect to procurement of raw materials (have lengthy lead times);

- Orders from the depots and facilities are erratic and not consistent over the months of the year, resulting in stock-outs and buy-outs; Suppliers have raised concerns regarding the awarding of tenders to companies that are unable to ensure adequate and continuous supply of medicines of acceptable quality and quantity resulting in out of stock situations of essential medicines and some other medicines;
- Reasons for non acceptance of tenders are not given at all.

7.2.4 Procurement Policy and Fragmentation of Procurement Practices

In 1997, Cabinet adopted the Green Paper on Public Sector Procurement Reform which introduced the concept of a "National Procurement Framework" through which it aimed to establish uniformity in procurement procedures, policies and control measures, among others(1). It argued for the abolishment of the state and Provincial Tender Boards and their reconstitution as Procurement Offices in the Ministerial and Provincial Departments, and the establishment of a National Procurement Compliance Office responsible for policy, oversight, standard documentation and procedures, and handling of complaints. To date, no such National Procurement Compliance Office has been established, and the provincial tender boards still exist. This has resulted in the fragmentation of procurement policy and practices. In the absence of an overarching national procurement policy framework, coordination and uniformity in the application of procurement policies is near impossible, given the existence of ten autonomous procurement authorities (tender boards). A few illustrations of the disadvantages of this state of affairs:

- We have seen how, in the absence of a uniform policy and standard practices, some provinces are subjected to prices of medicines that far exceed the national tender prices;
- Specifications for products procured at the provincial level are not uniform from province to province and pose challenges for suppliers and opens the way for corrupt practices. There is a definite need for uniform specifications to be put in place;
- The successful implementation of procurement policy by ten tender boards, instead of one, presupposes that the boards are managed and staffed by highly skilled personnel, given the amount of money expended on medicines alone, let alone other goods and services. This has proven not to be the case. An argument could be made that the

country's resources, both human and financial, are stretched unnecessarily and the perpetuation of weak and inefficient procurement systems repeated nine-fold;

- The envisaged national health insurance (NHI) authority will be faced with a serious challenge procuring services through such a diversity of procurement cultures, each having its own interpretation of the broad procurement principles of the Constitution;
- Currently, certain municipalities and metropolitan councils are excluded from the tender process. This means that they do not receive the benefit of a tendered public sector price. Measures need to be put in place to include such municipalities and metros as part of the state tender process.
- Provinces are not obliged to participate in national pooled procurement and could procure any medical related products at provincial level; this affects the whole purpose of achieving gains through combined and centralized bargaining, some of the reasons provided for this include the need to empower small companies based in the provinces. Typically, what happens is that, where a product was supplied through the existing national tender, this is now provided through a third party based in the respective province, The intermediary procures the product from the same holder of the national tender and sells it on to the province at a higher price without adding any value.

7.2.5 Recommendations

- The late awarding of tenders, the ineffective monitoring of suppliers' performance, the lack of interface between NT's Procure system and the provincial depot systems are some of the factors which strengthen the view that contract management for pharmaceuticals should be the preserve of the NDOH and that NT needs to play a purely financial management role. The involvement of NT merely adds an extra layer to the myriad of control structures involved in the procurement of pharmaceuticals.

It is recommended that NT cede contract management for pharmaceuticals to the NDOH in line with the recommendation for the establishment of the CPPA within the NDOH.

- The Task Team attempted to establish whether the procurement of certain items, especially medical related items, on provincial tender, as opposed to existing national tenders, held any price benefits for the provinces concerned. Anecdotal evidence suggests that this may not be the case, although this could not be proved conclusively owing to the lack of sufficient data available to the Task Team. It is, nevertheless, recommended that, in line with the recommendation for the establishment of the CPPA, all provincial bodies responsible for the management of tenders cease the handling of tenders for pharmaceuticals and medical related items. The benefits of having one central procurement authority, as opposed to several, have already been alluded to, and include the ability to pool scarce national resources into the one authority that would handle all national procurement. This is in line with the concept for a National Procurement Compliance Office.
- Regardless of the location of the ultimate procurement authority for pharmaceuticals, it is imperative that direct price negotiations form part of the procurement strategy of Government. This is advised particularly in situations where there are only one or two suppliers of a particular essential product and the probability of price competition is less likely.
- Sectors of the manufacturing industry point out that, if they were afforded the security of a contract for the supply of a key product for an indefinite period, as opposed to the current two-year period, this would enable them to plough more resources into the operations dedicated to such a contract, leading to increased investment, greater job creation and an embedded and potentially permanent presence in the country's economy by such a company. Of course, the awarding of a tender for a period longer than 2 years would have to be viewed as exceptional, and given the intention for such a contract to continue for an indefinite period, it could also be deemed to be uncompetitive. The argument for such an innovation is that it would be implemented only for those products identified as essential and crucial to the healthcare system, and that it would be competitive initially as all bidders would have an opportunity to bid and demonstrate their ability and capacity to provide the product on a long-term basis. Service Level Agreements would have to be monitored closely to ensure continued standards of quality, supply and price

The recommendation is made in the main Recommendations section that a forum be established which would have representation from all the stakeholders involved in providing or supporting pharmaceutical services in one way or the other. The forum would be convened by the PPP Cluster and meet, say, quarterly. It is recommended that such a forum should best debate proposals such as this one.

- There is a concern by suppliers regarding international companies (such as Indian, Brazilian and other companies from emerging economies) that are given incentives to export their products to markets such as ours. Thus, if such a company offers a product to the South African government at what appears to be a cheap price, such a price is highly subsidized, and thus, the benefits are derived in that country.

Our Government attempts to provide similar incentives to local companies through its industrial policy. There is nothing, in principle, wrong with a country having in place policies that aims to encourage growth in the local industry through various trade incentives. The problem arises, however, when the healthcare area is also targeted for the implementation of such policies. The result is that the industrial policy is pitted against the healthcare objectives and obligations.

The Preferential Procurement Policy Framework Act (PPPFA) and its regulations raise the difficult issue of a potential conflict between the State's industrial policy and its healthcare objectives. While the aims and objectives of the national industrial policy framework and the preferential procurement framework may ordinarily be considered to be reasonable and justifiable, they are problematic in cases where they impose obligations on the NDOH that may undermine access to healthcare services. In short, they cannot be justified to the extent that they require the use of limited health resources to advance legitimate Trade and Industry, Science and Technology and/or Treasury interests, and thereby limit the NDOH's ability to discharge its constitutional mandate.

In short, the State should seek other ways to advance these potentially competing interests. For example, there is nothing in law preventing the Department of Trade and Industry from providing incentives upfront to local producers of medical products. In addition, the Minister of

Finance has the power to table amendments to tax laws that similarly grant incentives to such products. Further, as has already been indicated above, local producers and/or BBBEE suppliers can and should be awarded contracts by the NDOH over competitors in circumstances that do not result in effective subsidies being granted for higher priced medical products.

It is recommended that this conflict be addressed as a matter of urgency. To that end, the departments of Health, Trade and Industry, Science and Technology and National Treasury need to convene a forum where conflicts between and among the different Government policies and objectives can be debated with a view to finding lasting solutions to the conflicts.

7.3 Warehousing and Distribution

7.3.1 Description

Every single province has a provincial medicines depot, with the exception of the Eastern Cape, which has two – one in Port Elizabeth and the second one situated in Mthatha, and the Western Cape, which has the main depot in Cape Town and a smaller one in Oudtshoorn. The Western Cape also has a provincial ARV depot, located in Cape Town. In addition, Gauteng province has two sub-depots. Mpumalanga and North West provinces have depots for the pre-packaging of patient-ready medication. Each one of the metropolitan municipalities – Johannesburg, Ekurhuleni, Tshwane, eThekweni, City of Cape Town and Nelson Mandela – has at least one municipal depot.

The Department of Correctional Services and the South African Health Military Services provide their own pharmaceutical services and thus have their own medicines depots in various provinces.

Although the provincial medicines depots traditionally formed part of the pharmaceutical services structure, with the Head of Pharmaceutical Services (HOPS) having responsibility over their functions, this was changed in some of the provinces following the introduction of supply chain management units as part of procurement reform. The reporting arrangement for provincial depots in the various provinces is as follows:

- In the Western Cape and the Free State, the depots report to Supply Chain Management (the final location of the depot was still being discussed in the Free State when the report was being finalized) ;
- In the North West, Northern Cape, Limpopo, Mpumalanga, the Eastern Cape and KwaZulu Natal, the depots report to the HOPS; and
- Until recently, Gauteng Province's medicines depot reported to the Clinical Support Services Director, who also supervised the HOPS. The latest restructuring has led to the establishment of the Chief Director/CEO: Pharmaceutical Services, which has authority over the Director: Corporate Services, Director: Finance, Director: Pharmaceutical Services and Director: Pharmaceutical Services depot.

The core functions of the depots are quantification (with the exception of the Western Cape and KwaZulu Natal), procurement, warehousing and distribution. Mpumalanga, Limpopo and North West provinces have outsourced the procurement, warehousing and distribution services to private contractors. In these latter provinces, it is the responsibility of the contractor to consolidate all debts and submit the consolidated invoice to the province. The total amount to be paid to the creditors is then paid into the account of the contractor, who is then expected to pay the suppliers within the period stipulated in the tender.

The Eastern Cape Province invited bids for the outsourcing of distribution services and the tender was cancelled soon after the successful bidder had been announced, in 2009. This was actually the second choice, as the consortium that had been preferred split up before the announcement could be made. The cancellation of the tender followed the reporting of allegations that the successful bidder so announced had close links with a top politician. The newly-appointed MEC for Health would not sign the award.

Gauteng province called in consultants in 2009 to carry out a feasibility study into the outsourcing of warehousing services – which was an odd move, when, by all accounts, any problems in the province's medicines supply chain could hardly be linked to any inefficiencies on the part of the province's medicines depot. Although the consultant did submit a report that recommended the outsourcing of the depot services, no further action appears to have been taken. Significantly, the consultants were called in by the MEC for Health without the involvement of functional managers in the decision.

7.3.2 Observations and discussion

7.3.2.1 Procurement

Depot procurement is not only limited to EDL items. Some of the reasons for deviating are prescriber preferences, unavailability of products on tender and named-patient motivations or, at times, simply a decision by a provincial PTC to deviate from the EDL.

Penalties are not implemented for suppliers that fail to deliver within the lead time and provinces, instead, resort to just cancelling the orders, writing warning letters – not in all cases, it has to be pointed out – and simply buying the product from a non-tender holder. This is more expensive and results in the department, rather than the defaulting supplier, paying the price difference for buying-out.

The failure of depots to penalize companies which fail to supply in time places huge financial constraints on the province's coffers, particularly in times of severe financial constraints. None of the depots indicated that expenditure for items bought on buy-out were compiled and analyzed. With regard to the authorizing of buy-outs, it was established that Pharmaceutical and Therapeutic Committees are involved in most of the provinces.

Only two of the provincial depots are aware of the expenditure on buy-outs done at the hospital level.

7.3.2.2 Warehousing Procedures

Only the Gauteng provincial depot is licensed in terms of the Medicines and Related Substances Act, 1965. Some of the major shortcomings in the other depots which lead to non-compliance with the requirements of the Medicines Act are the non-availability of Standard Operating Procedures, security issues, inadequate storage capacity, lack of temperature control and, of major importance, the lack of pharmacy personnel for certain processes. .

Human Resources are one of the greatest challenges in most of the pharmaceutical depots. It is standard pharmaceutical warehousing practice that warehouse should have a pharmacist oversee every operational area, e.g. despatch, cold chain, orders, etc, but this is not the case in most of the provincial depots.

In all but two of the depots there were no records of continuous training offered to staff involved in procurement and supply management, and only three depots were found to be subjected to supervisory visits by the provincial authority on a regular basis.

With the exception of Mpumalanga and North West, there was no insurance cover in place for loss or damage to stock (including cold chain) in case of equipment failure.

Most of the depots did not have updated figures on the value of expired stock. Some of the reasons provided for the expiry of stock at the depots were over-ordering by hospitals, erratic orders by demanders, receiving of short-dated stock, lack of space to organize the stock properly and changes to the Standard Treatment Guidelines (STG) in the course of the financial year.

Stock-outs were found to varying degrees in the depots. A critical percentage (i.e. 29%) of the items on the tracer list[†] used by the Task Team to assess availability were out of stock in more than half of the depots. Delays in national tender awards, erratic orders from demanders (hospitals and clinics), increased demand placed on the depots, changes in treatment patterns, suppliers being out of stock and insufficient staff are some of the reasons given as the main causes of stock-outs at the depots.

Stock cards are not used in some of the depots as stipulated in the Public Finance Management Act (PFMA).

7.3.2.3 Distribution

All depots have outsourced the services of distribution to private companies, applying varying mechanisms of paying for the services rendered. The Free State province pays the contractor on the basis of the weight of the consignment to be moved. This has seen delivery to some of the facilities not taking place for weeks while the consignment is left to accumulate 'meaningful' weight at the depot's dispatch area. Some depots use the same warehousing contractor for distribution, either only as far as the hospitals, or all the way to the clinics as well. The North West province uses the services of SMMEs for distribution from the hospitals onward to the clinics, a policy which has seen employment being created

[†] A tracer list is a basket of medicines identified as essential and the availability of which is used as a measure of general availability in a facility

in poor rural areas, albeit on a small scale. In two of the provinces it is the responsibility of the contractor to insure stock while it is in his care and during transportation.

In emergencies, facilities use their own transport to collect stock from the depots and the average turnaround time is 1 – 2 days.

7.3.2.4 Finance

In the North West, Mpumalanga and Limpopo provinces, bulk payment is made to the outsourced contractor, who will in turn pay all suppliers where pharmaceuticals and medical related items were purchased. Although the maximum period over which the money can be kept in the contractor's account before suppliers are paid is stipulated in the Service Level Agreement, this is not monitored.

Provincial depots charge a handling fee for deliveries to the facilities. In most cases the fee is charged even for direct deliveries from supplier to facility as the orders would have gone from the facility through the depot. The fee varies from 5% to 10% in the different depots.

All the outsourced warehousing services (North West, Mpumalanga and Limpopo) are awarded on three-year contracts. The North West's, where the contractor was paid a total of R20, 693 million as the service fee in the last financial year, expires in June 2010. Whereas in previous years the contractor's service fee was a percentage of the value of the issues from the depot, the basis is different for the current tender. The contractor is responsible for the payment of staff salaries, operational and administration costs, distribution, security and insurance costs, which costs are claimed back from the Health Department. A 50% surcharge is added as the service levy. In other words, for every Rand spent by the contractor, the reimbursement is R1.50. The same contractor also services Mpumalanga, where the service fee is 10% of the value of issues from the depot. This contract ended in 2009 but is currently on extension. The service fee in Limpopo is a fixed amount of R2,3 million per year.

The outsourcing of procurement, warehousing and distribution services needs to be subjected to a more concentrated assessment and analysis in order to determine its value to the province. Given the staff shortages and lack of skills in the provinces, it is natural that many provinces would look to outsourcing these services. There is no doubt that this would, in principle, lead to the attainment of efficiencies and

the transfer of risk to the private contractor, provided the province has in place strong monitoring and assessment mechanisms. Anecdotal evidence shows this not to be the case, for example in Mpumalanga provinces, where the records at the depot and stock-outs in the clinics demonstrate that the outsourcing is not adding much value.

The varying methods of applying service charges are of themselves quite interesting when comparisons are attempted. A 50% surcharge on all expenditure incurred by the contractor appears to be quite easily implementable, but to what extent is the contractor able to inflate expenditures, especially on salaries, and simply collect from the province? Likewise the levying of a fixed fee (e.g. the R2.3m in Limpopo) would appear to have the same effect as a capitation system for medical treatment in that there is no incentive for the provider to go the extra mile

Finally, surely the levying of a fee on the basis of issues from the depot can only serve as a disincentive for the contractor to monitor and curb over-stocking by facilities. Thus, if a hospital ordered double the amount of a particular item than they normally do, and the contractor duly reduced the amount supplied, this would negatively affect the contractor's fee at the end of the month. It has to be assumed, then, that the contractor cannot be relied upon as an ally in combating over-ordering and over-stocking by demanders. Furthermore, the failure by provinces to monitor the length of time money meant for payment of suppliers is kept in the contractor's account means that the provinces have no way of knowing if the suppliers have been paid in time. Potentially, the contractor is able to supplement his income just by having the suppliers' money in his account for a while, and gain the interest earned on this. Thus, they would gain more by keeping it sufficiently longer to make a significant difference in terms of interest accrued.

The true benefits of the outsourcing of the depot services can best be assessed if the costs of operating the depot in-house at optimal staffing levels for all its divisions, with the requisite equipment and the cost of ensuring compliance with the law, are compared with the costs of outsourcing, in a cost-benefit analysis. This is something that the Task Team would not have been able to do in the time available for the assessment. The country needs to be able to draw lessons from the experience of outsourcing depot services in order for informed choices to be made as cost-effective solutions are pursued to ensure value for money characterizes such public/private partnerships.

Contract tenders are often not re-advertised in time, leading to unnecessary extensions and or services offered on monthly contracts/quotations.

The main reason given by the provinces for procuring medical related items on provincial tender instead of utilizing the national tender is the need to promote local business and ensure that the province's funds are spent in the province. The impact of this policy on the finances of the provincial health department is not dissimilar to the effect of the PPPFA – in both cases the health budget ends up being used to subsidize the beneficiaries of Government's preferential procurement policy. Anecdotal evidence exists of a province where the baby formula milk product used to be procured on national tender at R12 per tin. Following an instruction from the province's senior management, the product was procured on provincial tender in 2008, but now at R24 per tin. The original supplier remained the same and continued to take responsibility for deliveries. The intermediary thus kept the extra R12 without adding any value to the service provided.

Finally, it is significant that most medicines depots and heads of pharmaceutical services are not involved in determining the medicines budget of the province. This function is decentralized to hospitals and districts, where the pharmacy departments have little, if any, input in the finalization of the medicines budget.

7.3.2.5 Information Management

In general, provincial medical depots do not get data inputs from the demanders. Those that do, do not make use of it as it is almost always inaccurate.

Reports from medicine management information systems generated at the depots are available, but are hardly ever used and are sent to provincial management or any other authority only upon request.

As mentioned in detail in the section "Information Technology", depots use different medicine information systems, some of which have no field for batch tracking and/or mandatory fields for the

product national stock number. This poses a challenge to the NDOH when attempting to analyze reports from different provinces, applying, for example, the ABC analysis in order to assist with national estimates.

7.3.2.6 Reporting lines for the provincial medicines depot

Among the objectives of the Task Team was to investigate the reasons behind the decision to transfer authority over the provincial medicines depots in some of the provinces to the supply chain management which falls under the provincial Finance Department. This stems from the clear anomaly of the provincial pharmaceutical services unit being responsible for all the outcomes of pharmaceutical services delivery and yet not being accountable for how pharmaceuticals are procured, stored and distributed, which functions are key determinants of the outcomes.

In interviews with Free State Health Department officials, it was revealed that the transfer of the depot from Pharmaceutical Services to Supply Chain Management (SCM) was based on the fact that, by definition, most of the depot functions were SCM functions. The nature of the depot's trading account of R24 million approved by Treasury also required that it become part of SCM. The advantages of the move, according to the Free State officials, were that the depot received support in the SCM function, compliance with PFMA principles and regulations had been achieved and the depot received an unqualified audit report. However, this also necessitated good communication between the depot and Pharmaceutical Services, which was lacking; they had difficulty filling the pharmacist posts and what had effectively become a parallel system was proving difficult to manage. The senior officials expressed the view that management of the depot should be a joint responsibility between SCM and Pharmacy, as among the disadvantages of the status quo was the disconnect between the focus of the depot on financial management and financial directives on the one hand, and the clinically based decisions that had to be taken, on the other hand.

The idea of the depot being a joint function between two units within the province may, understandably, receive little support, as accountability could become problematic. What does come out clearly, though, is the desire by the province to ensure there is good pharmacy practice at the depot while PFMA principles and regulations are adhered to due to the depot's nature as a trading entity. A possible solution, therefore, would be for accountability of the depot to revert to Pharmaceutical Services, which would

appoint a responsible pharmacist as required by law. The responsible pharmacist would also be the depot manager but would require the support of a senior SCM official, located in the depot, to ensure adherence with the PFMA Act. That being said, the point needs to be made that a pharmaceutical depot could just as efficiently be managed by a logistician or suitably qualified SCM official, provided a responsible pharmacist is appointed who is tasked with all decisions relating to the pharmaceutical management of the depot and, crucially, provided the province's head of pharmaceutical services is the official accountable for the depot.

7.3.2.7 What is the value of having the provincial medicines depots?

For a medicines depot to execute its functions successfully, it has to be staffed by suitably qualified and experienced pharmacists, logisticians and accountants and observe standard operating procedures which ensure that warehousing staff are rotated and receive continuous training. It needs to have an efficient information management system that allows it to produce management reports on stock levels, usage patterns and expenditure trends. The very nature of its operations and of the products it handles requires that it has an infrastructure that is safe and secure and has the equipment necessary for the warehousing, storage and distribution functions. It has to pass the stringent requirements of the Medicines Act and the Pharmacy Act in order to be accredited as a facility where good manufacturing, wholesaling and pharmacy practices can be conducted reliably. The combination of all these factors is the pre-requisite for depots to be able to order and receive supplies from suppliers and ensure their smooth and quick onward distribution to the health facilities, while maintaining their security and safety.

This is, unfortunately, not the case with most of the public sector's medicines depots. Some of the problems observed include the following:

- Most of them are short-staffed and do not have the requisite levels of qualified staff that would allow their activities to be conducted legally. For the better part, the depot manager is a pharmacist who does not necessarily have any logistics training. Most do not have a programme for continuous training for staff;

- Cases have been observed of health centres and PHC clinics being without stocks which are actually available at the depot but are not being released for various reasons (poorly managed contracts, staff shortages, non-functioning of equipment, etc);
- Hospitals have reported that direct deliveries from the suppliers are received within shorter delivery periods as opposed to when they have to order from the depot.
- Although depots charge a levy to the facilities they supply, those that do not operate on a trading account[‡] do not seem to be able to retain the revenue so raised, which they could then spend on operational costs and improvement of infrastructure.
- The State simply does not have the ability to spread the scarce skills required for depot management across all the country's depots.

Potentially, the depots could be an unnecessary, expensive and disruptive intermediary in the medicines supply chain, if not properly managed . When systems have all but collapsed, there is no guaranteeing that the supplies that are channeled through the depot to the facilities will reach their targets safely and intact.

The degree of ineffectiveness varies from province to province, it has to be said, but some provinces need to look seriously at gradually reducing the participation of their provincial (and regional depots for those which have sub-depots) depots in the medicines supply chain, in preference either for direct deliveries to the facilities or for the outsourcing of the services. There would be no job losses as most of the staff could easily be accommodated in the hospitals and other facilities. Although no specific calculations were done, there is no doubt that considerable savings could be achieved from shutting down the depots, especially in those provinces where the depots are virtually non-functional and have become liabilities. Such savings could be used to improve the infrastructure of pharmaceutical services elsewhere in the province.

[‡] If a depot operates on a trading account of, say, R50 million, it is not allowed to have stocks the value of which exceeds that amount at any given time. The value of a trading account is that it funds the whole depot including salaries, 13th cheques, bonus awards, and general running costs such as delivery to facilities etc.

The Task Team did encounter views which were in disagreement with the idea of shutting down the depots. Firstly, the case is made that, even though the central hospitals could possibly work more efficiently if they avoided the services of the provincial depot, this is a luxury that could not be afforded by PHC facilities, especially those in the remotest parts of the provinces. They would still require the services of at least a regional or transit depot (e.g. the nearest district hospital) that would keep their buffer stocks and supply them in emergencies. Secondly, from a practical point of view, to have the depot as a central point of delivery for the suppliers would probably still be more effective as the suppliers deliver in bulk to the depot, which then redistributes to the hospitals and clinics. With the number of suppliers to the government, the argument continues, it could cause literal traffic jams at the hospitals as each supplier tries to deliver at the hospitals. South African hospitals are not geared to keeping large quantities of each product in stock and, therefore, the suppliers would have to do regular deliveries of their products in relatively small quantities. Of course, the distributors have indicated that they would be able to do precisely this – more frequent deliveries in smaller quantities, as happens with deliveries to the private hospitals.

Clearly, there can be no ‘one size fits all’ solution for all the provinces as each one will need to review the role of its depot in the supply chain management of pharmaceuticals on its own merits.

7.3.3 Specialized Distribution Mechanisms

7.3.3.1 Description

The link between procurement of medicines and their distribution and eventual dispensing to patients is such that failure to get the medicines to the patients in the most convenient manner (nearer their homes, no expensive transport costs required, no long queues, etc) may lead to patients not deriving any benefits from what appears to be the most effective procurement methods.

This has led to the resorting by public sector officials, especially those in pharmaceutical services, to seemingly extraordinary methods of ensuring desired service delivery levels are achieved in the face of hurdles imposed by the lack of resources, both human and financial, and poor infrastructure. Typically, this would be a response to often unsolicited proposals from private sector providers who would have discerned a gap in the provision of services and come up with an innovative solution the benefits of which

they would want to demonstrate to the authorities. There have been numerous examples in the past. One such collaboration between the public health sector and private providers was seen in the then Orange Free State in the 80's, when community pharmacies were contracted to dispense State medicines to patients seen by the provincial district Surgeons against a fee per prescription. While this succeeded in reducing the long queues of patients at State hospital pharmacies, it proved to be cost-ineffective in the long run due to the absence of treatment guidelines and formularies that would have placed limitations on the prescribing habits of the doctors.

7.3.3.2 Observations and Discussion

Chronic Dispensing Unit (CDU), Western Cape. One of the most impressive illustrations of the public sector utilizing private sector skills and expertise is the establishment of the centralized chronic dispensing unit (CDU) in the Western Cape. This involves the 'off-site' dispensing of medicines for chronic conditions. Once patients have been stabilized on a chronic medicines regimen, their prescriptions are sent to the CDU, where the prescriptions are prepared and sent to the lowest level facility nearest to the patient's home. The benefits of the system appear to be numerous and are explained in great detail in Appendix A[§], which was a response from the Western Cape facility's general manager to questions posed by the Task Team around the benefits or otherwise of the system(12).

Among the benefits of having such a unit in a province are the following:

- The generation of various management reports regarding the usage of medicine for chronic conditions, which could assist in determining medicine utilization trends in the particular province;
- The commencement of efficient chronic disease management models for future healthcare modelling and planning and the availability of, and access to, a national data warehouse on chronic medicine usage and prescribing patterns.

[§] IPM Submission to Task Team

- The enhancement of the provincial referral system. Patients seen at a tertiary hospital are not required to make repeat visits there, instead going back to their local clinic or health centre to collect their monthly repeats.

It has to be cautioned that such a system may not necessarily achieve the level of benefits witnessed in the Western Cape if it were to be implemented around a single tertiary hospital. The differing characteristics of each particular province and/or district would have to be taken into account. It was also found in the Western Cape that, where prescribers were not familiar with the requirements for writing and signing off prescriptions, some prescriptions ended up being rejected by the CDU, leading to inconveniences to patients.

The Task Team did not attempt to estimate how much it cost the provincial government to set up this system and sustain it. It was noted, however, that the fact that the premises and buildings where the CDU is housed belong to the provincial government, which means that the facilities used did not require any extraordinary enhancements. Also, it would be easy to demonstrate the cost-effectiveness of the system when the convenience and benefits are taken into consideration.

It is also worth noting that there are several medical schemes that supply chronic medicines to their members through a CDU.

Dispensing of State prescriptions by community pharmacies through public/private partnerships (PPPs). In 2006, South Africa had 2718 community pharmacies compared with 552 public sector pharmacies, with 4 483 community pharmacists plying their trade in the private sector compared with well under 5 000 in the public sector in the same year(13). There is no doubt, therefore, that any province that suffers serious pharmacy human resource shortages resulting in patients spending hours waiting for their medication, would need to pay serious attention to engaging the private pharmacies in an arrangement that would have State patients receiving their medication from community pharmacies. Depending on the location, the authorities in the bigger cities may have a preference for dealing with an organized grouping of such private providers, but there is no doubt that independently-owned pharmacies, due to their proximity to communities and the intimate relationships that members of the communities eventually develop with the pharmacists, would also potentially be key partners of the provincial government.

Independent pharmacies situated in smaller towns could also have a vital role to play in ensuring that there is a constant source of medicines for patients seen in the public sector.

7.3.4 Recommendations

- A sound balance between the application of financial management requirements and good pharmacy practice principles in the medicines depot is required. There has to be a clear relationship between business decisions taken in relation to the medicines depot and the service delivery mandate placed upon the provincial Pharmaceutical Services. Appropriately skilled professionals should be recruited to take charge of the activities of procurement, warehousing and distribution. Such skills should be complemented by financial skills that would ensure that PFMA principles and regulations are suitably adhered to. To this end, it is recommended that medicines depot be accountable to the provincial pharmaceutical services and that a suitably qualified financial manager be deployed in the depot.
- Whereas the outsourcing of services such as warehousing, procurement and distribution is advocated where provinces lack the skills to carry out these services in-house, anecdotal evidence suggests that no benefits have been derived where these services have been outsourced. In addition, it is alleged that the performance of the private contractors is not being monitored satisfactorily. It is recommended that all such outsourcing contracts be reviewed before any extensions are considered, and that no new bids be invited for outsourcing until such time that the reviews have taken place and provinces are clearly in a position to satisfy the requirements for monitoring and assessment as specified in the Treasury guidelines/regulations for PPPs. Furthermore, all the provinces should observe a uniform set of principles/regulations to guide the outsourcing of depot services.

To this end, it is recommended that an in-depth cost-benefit analysis be undertaken of currently outsourced services of procurement, warehousing and distribution. In particular, the mechanisms applied by the private warehousing contractors to charge for their services should be scrutinized to ensure that the State is not disadvantaged by such an arrangement.

- Central dispensing units, similar to the ones in the Western Cape, the Free State and KwaZulu Natal should be given serious consideration by health authorities who want to improve service delivery.

- The above recommendations relating to improvement of the management of the depots notwithstanding, it is the view of the Task Team that the depots are costly and inconvenient intermediaries in the chain intended to ensure that medicines reach the facilities where patients receive treatment. The alternative recommendation, and certainly the one preferred by the Task Team, is for the gradual phasing out of the provincial depots while a solution is sought to service the PHC facilities and to strengthen the storage and logistics capacity of the hospitals.
- It is recommended that the national and provincial departments of health investigate ways in which chronic medicines can be supplied through community (retail) pharmacies or by direct delivery to State patients.

7.4 Human Resources for Pharmacy: An analysis of staffing constraints

7.4.1 Introduction

The shortage of pharmacy personnel in the country's health sector is well-known. It is, in fact, a problem that affects other healthcare professionals. Furthermore, it is a global phenomenon that does not spare even developed nations, although to a lesser degree than is the case in developing nations. Thus, rather than belabouring this well-known issue, this section seeks to highlight how poor pharmaceutical services delivery in the public sector is aggravated by the inappropriate utilization of scarce expertise and skills, failure to match high expenditure functions with the requisite skills mix, lack of uniformity in the organization of pharmaceutical services across the provinces and the adoption of policies that do not seem to be informed by the country's realities.

7.4.2 Findings and discussion

7.4.2.1 The impact of staff constraints at NDOH

As mentioned in a previous section, tenders for medicines are arranged nationally by the Department of Health's Access to Affordable Medicines Directorate in collaboration with National Treasury. This Directorate has 3 divisions responsible for the following sets of functions:

- Selection of medicines for the Essential Medicines List and rational medicine use;
- Facilitating and co-ordinating the procurement and distribution of medicines via national tenders;
- Licensing:
 - pharmacy premises, private & public sector; and
 - the issuing of dispensing licenses to authorised prescribers.

Participants in the national medicines tender include all the nine provinces, the Department of Correctional Services and the South African Military Health Services. The Directorate, in executing its function of facilitating and co-ordinating the procurement of medicines, provides technical expertise with regard to:

- writing tender specifications;
- verifying provincial estimated requirements for medicines usage;
- preparation of the tender documents including the special conditions for tender;
- preparation and validation of clinical and legal requirements for recommendation meetings; and
- monitoring supplier performance and medicine availability at depot level.

Before the awarding of tenders, price negotiations with the preferred bidders has been shown to be a major cost-saving on medicines expenditure for which significant skills are required. The importance of having all of the above skills is underscored by the huge amounts spent on medicines for the public sector. The estimated cost for the tenders awarded and running over the last two years is, as already mentioned, estimated to be in excess of R10 billion. The technical skills necessary to perform these functions adequately are lacking. This causes delays in the tender process. Proper monitoring and evaluation of supplier performance, medicine utilisation vs. estimates and medicines availability in provinces can thus not be adequately carried out. **Currently, three out of five posts are vacant in this sub-directorate.**

The second sub-directorate is responsible for the rational selection and use of medicines for the Essential Medicines List. The selection of medicines is based on currently available evidence and affordability, thus

involving various cost analyses. In order to ensure buy-in to the EML process, technical experts in different fields of medicine and from various academic institutions form part of this peer review process. The review process is labour intensive and meeting driven.

Attempts have been made to build capacity within the Department to assist with the review. However, due to severe staff and budget constraints, this has been limited. Adequate advocacy and medicine utilisation cannot be performed. This impacts on the implementation of the STG and EDL and consequently has a negative impact on medicine expenditure at provincial level. **Currently, four out of five posts are vacant in this sub-directorate.**

The third sub-directorate, which is responsible for licensing, has similar staffing constraints. The tendering process requires that all manufacturers and wholesalers that submit bids be licensed by both the Licensing Unit and the Medicines Regulatory Authority of the Department of Health. Pharmacy premises in both the private and public sector also need to be licensed in order to be able to render a pharmaceutical service to patients. Before a licence application is approved, it is a legal requirement that these premises be inspected.

It is also a legal requirement that any authorised prescriber who wishes to dispense medicines, be in possession of a licence to dispense. The premises of these licence holders must also be inspected to determine compliance with Good Pharmacy Practice.

Due to the inability to fill pharmacist posts, it has been impossible to carry out inspections of the premises of dispensing licence holders. The inability to carry out these inspections may have a negative impact on the provision of safe, efficacious medicines to patients. **Currently, five out of seven posts are vacant in this Sub-directorate.**

The following table summarises the staff shortage situation within the Directorate Affordable Medicines.

Sub-directorate	No. of Posts Available	No. of Posts Filled	Vacancy Rate
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Selection & Rational Medicine Use	6	1	83%
Procurement & Distribution	6	2	67%
Licensing	7	2	71%
Directorate	19	5	74%

Table 4: Summary of pharmacists' posts filled in the directorate.

According to the Director: Affordable Medicines, this has characterized the directorate's staffing situation over the last 5 years. She believes that these constraints are a direct result of the Department's decision not to pay the scarce skills allowance and uncompetitive remuneration packages for pharmacists compared to those offered at provincial level. This has seriously hampered the operational activities of the Directorate and impacted negatively on its ability to achieve its strategic goals.

The Directorate Affordable Medicines is located within the Pharmaceutical Policy and Planning (PPP) Cluster, which plays a key role in policy coordination, in taking the lead in strategy formulation, in influencing compliance with GPP and implementing a pharmaceutical monitoring and evaluation mechanism. For all of this co-ordination to happen, though, the PPP Cluster of the NDOH will need to be strengthened, firstly, by having the cluster manager position filled and, secondly, by putting in place incentives that will attract competent and experienced candidates to fill critical posts at the national level.

7.4.2.2 The organisation of pharmaceutical services at provincial level has the following characteristics:

- In the Northern Cape, Mpumalanga, Eastern Cape, KwaZulu-Natal, North West and Limpopo provinces, the position of Head of Pharmaceutical Services (HOPS) is at the level of director (although, in the Northern Cape, the HOPS has traditionally been at the level of deputy director. The current HOPS was already a director in supply chain management when he was appointed to the post) and, although they do not report directly to the Head of Department (HOD), the HOPS' at least have access to the provincial management structure in all of these provinces.

What is of further significance in the above provinces is the fact that the HOPS has full responsibility for all pharmaceutical services within the province, including those provided

through the medicines depot. This enables the HOPS to have a comprehensive pharmaceutical strategy for the province that links each and every activity in the medicines supply chain in a logical manner and which they can implement without having to defer to another directorate. Importantly, the HOD has only the HOPS to hold accountable for any medicines shortage or any other problem in the supply chain leading to medicines shortages;

- The HOPS positions in the Western Cape and the Free State are at the level of deputy director. The positions were downgraded from director as a result of reduced responsibility following the transfer of the medicines depots to supply chain management in both provinces. The Western Cape HOPS is not a member of the provincial management structure, while the Free State HOPS currently attends meetings of the provincial executive only when specific pharmacy-related issues have to be addressed. As seen in a previous section, the value added by a situation whereby the depot reports to a supply chain manager or to the chief financial officer is that the depot may be compliant with the FPMA. However, it does not also imply that the funds will be spent cost-effectively, as a rigid application of financial principles may fail to take into account key characteristics of the supply chain for pharmaceuticals and decisions could be taken which could lead to shortages, overstocking or expiry of medicines. It is not surprising that, even in the provinces where the HOPS does not have total responsibility for pharmaceuticals, they are the first to be called to account when there are supply problems;
- As mentioned in a previous section, until recently, the HOPS in Gauteng Province was at the level of deputy director, as was the head of the medicines depot, with both reporting to the Clinical Support Services Director. The latest restructuring has led to the establishment of the Directorate: Pharmaceutical Services and the Directorate: Pharmaceutical Services Depot. Curiously, the two, together with two other directorates, report to the Chief Directorate: Pharmaceutical Services, which bears a similar title as the pharmaceutical services directorate. It was not clear if the title of the chief directorate would be changed to one that is more inclusive of the functions under its wing. While the elevation of the HOPS position to directorate level is commendable, it is potentially problematic that the HOPS is not also responsible for the provincial depot, for the same reasons mentioned earlier with regard to the position of the depot. At the same time, it could be argued that the placing of the position of the head of the depot at the director level is commensurate with the level of responsibility, given the size of the provincial pharmaceutical

budget (turnover in 2008/09 was R1.5 billion). It could be that the chief directorate is, indeed, intended to be mainly pharmaceutical services.

- The HOPS in the Western Cape is at the same level as the district pharmacists, but the officials in her office who have to liaise with the district pharmacists are at a lower level, that of chief pharmacist, which, understandably, affects the clout of the HOPS and her office, making their role of policy coordination somewhat ineffective;
- We thus have fragmentation of pharmaceutical services in some of the provinces, with the medicines depots being accountable to a unit other than pharmaceutical services (Western Cape, Free State and Gauteng). Furthermore, in the Western Cape, in addition to the main depot, the ARV depot and the chronic dispensing unit (CDU) also do not report to the HOPS.
- In many of the provinces, as stated elsewhere in the report, HOPS do not participate in the formulation of the pharmaceutical budget.
- There is a tendency among some of the provinces to have their HOPS represent their provinces at the Pharmacy Council and serve on COMED (the coordinating committee for medical supplies), which leads to them being away frequently from their posts.

7.4.2.4.3. Vacancy rates in the provincial pharmaceutical services vary from a very high 79% in KwaZulu Natal, 40% in Limpopo to a relatively acceptable 20% in Gauteng. Undoubtedly, the introduction of community service pharmacists (CSP) has gone a long way towards easing the shortages in many of the hospitals, although this is only a temporary solution for rural hospitals as they then lose the CSPs to the bigger provinces or to the private sector at the end of their deployment period.

7.4.2.4 Introduction of middle level pharmacy support personnel. Following a request from the NDoH, the South African Pharmacy Council spearheaded the development of a mid-level pharmacy support personnel cadre, the pharmacy technician. The technician will be able to work independently but under the remote supervision of the pharmacist at the PHC level, while their presence in the hospital pharmacy setting will free the pharmacist of the more mundane functions in the dispensary. It will be more cost-effective to train pharmacy technicians and certainly more realistic to go in this direction than to attempt to produce the required numbers of pharmacists for the public sector, although this development will also be beneficial to the private healthcare sector.

7.4.3 Recommendations

- The policy coordinating function of the Pharmaceutical Policy and Planning (PPP) Cluster at the NDoH has been alluded to. It is within this cluster that the medicines procurement functions are located. The staff shortages in this cluster have also been outlined in detail. A recommendation has already been made for the establishment of an authority, the CPPA, that would take all responsibility for the budget, funding and procurement functions for pharmaceuticals for the entire public sector. The CPPA would be located within the NDoH. The Task Team did not attempt to specify the location of the CPPA, nor its relationship with existing structures that are already responsible for any or all of the procurement functions. It seems logical, however, that the CPPA should be located within this cluster or form part of a restructured PPP.

It is recommended that, together with the conducting of a cost-benefit analysis in relation to the establishment of the CPPA as recommended under Section 7.1, a restructuring exercise be carried out that will lead to the existing PPP and envisaged CPPA functions being harmonised into one structure within the NDoH. This should also include a staffing norms exercise to determine the staffing requirements of the cluster and a strategy to ensure that suitably qualified candidates will be attracted.

- it is recommended that all the necessary legal and administrative steps be taken for the establishment of the pharmacy technician course and provision for the first intake of trainees by the beginning of 2011.
- It is recommended that provinces strive towards the attainment of uniformity in the organisation and structure of pharmaceutical services. Thus, based on the preceding arguments, the provincial pharmaceutical services should be located at the level of directorate, which is already the case in 7 of the provinces. The medicines depots and all other structures providing services of a pharmaceutical nature should be placed under the direct and full responsibility of pharmaceutical services. Such uniformity in structure and authority will stand the public sector in good stead in the event that national health insurance is introduced and the responsible authority formulates guidelines for the participation of facilities.

7.5 Care, Management and Treatment of HIV and AIDS

7.5.1 Background

According to the South African National AIDS Survey of 2008, an estimated 10.9% of all South Africans over 2 years old were living with HIV in 2008. Different numbers have been provided depending on the particular model applied and based on various estimates of the South African population, which is a quite

contentious issue. UNAIDS, for example, estimates the HIV and AIDS prevalence in the country to be between 18% and 24%. It gives the actual number of South Africans infected with HIV as 5.6 million, including 280,000 children under the age of 15(15).

According to the Acting Director: HIV and AIDS at the National Department of Health, the total number of patients on ART was 800,000 adult and 80,000 paediatric patients as at the end of Quarter 2 of the last financial year, which constitutes 60% coverage(16). (The Clinton Foundation puts the figures at 616,900 and 59,299 respectively, as at 31 March 2009) South Africa's HIV and AIDS treatment campaign is widely regarded as the biggest of its kind globally. In spite of all the money that has been committed to and spent on the programme, shortages of ARVs have been widely reported in many of the provinces. During the course of 2009, a number of provinces experienced serious stock-outs. In the Free State, when the funds were exhausted, an instruction was given by the provincial authorities that no new patients were to be commenced on treatment as the sustained supply of ARVs could not be guaranteed. Several provinces received additional emergency funding from Treasury, while a few others were recipients of donor funding to supplement their HIV and AIDS budgets.

Preliminary anecdotal evidence that was available to the Task Team suggested that the seeming failure of the treatment programme to ensure a sustainable supply of ARVs to all patients who were identified as **eligible for commencement of anti-retroviral treatment was due to a combination, or some, of the following factors:

- The national and provincial health department entities which had a key role to play in the treatment strategy seemed to be working in their own silos. Thus, whereas the provincial pharmaceutical services participated in quarterly meetings with the national DOH, to which the suppliers were also invited, to determine that the correct quantities of ARVs were ordered and supplied, based on the use of a quantification tool, this was hampered by the fact that provincial pharmaceutical services were not supplied with regular and updated figures of patients on ART. This is key to the successful application of the tool, as it takes into account the numbers of patients, adult and paediatric, on the various regimens and has to be updated regularly. What is more, determination of the ART budget would be finalized between the national CCMT and the provincial HAST divisions without the involvement of pharmaceutical services.

** Tuberculosis has since been taken away from the HAST units, thus HAS is now used to refer to them.

- The ARV medicines budget is not ring-fenced. Block disbursements for the entire HIV and AIDS programme are made by the NDOH to the provinces which, in turn, allocate a certain proportion of the funds to the purchase of ARVs, often, if not always, without taking into account estimates provided by the pharmaceutical depots or the respective ARV pharmacists.
- Most provinces invariably exhausted their HIV and AIDS programme budget some time before the end of the financial year. This would suggest that either the allocation from National Treasury was insufficient to meet the budget or that financial planning or expenditure at the provincial level was poorly executed.
- Suppliers were not paid in time by the provinces, often leading to suppliers withholding supplies.
- Treatment protocols were not adhered to.
- New treatment guidelines were not approved, even though the new ARVs were available on the new contracts.
- Government was not getting value for money, as ARVs purchased from local suppliers were more expensive than those available on international markets.
- Many of the suppliers were simply not able to meet their contractual obligations in terms of quantities to be supplied.

7.5.2 Observations and discussion

In attempting to confirm which of the above factors played a significant role in the problems encountered in the CCMT programme, it was necessary to interview key persons in the provincial CCMT programmes as well as the national HIV and AIDS Cluster. However, time constraints would not allow for all nine provincial CCMT programmes to be interviewed.

Recognizing that the provincial programmes were at different levels of development in terms of resources, infrastructure and outcomes, it was decided that the selected sample should include the best and worst performing provinces.

Hence, Mpumalanga and Free State provinces were selected due to apparent deficiencies (frequent stock-outs, patients dropping out, apparent inability to manage the funds) – albeit under different circumstances – of their programmes; KwaZulu-Natal, as the province with the highest number of patients on the ART programme, would provide unique experiences as far as levels of application were concerned.

Interestingly, the UNAIDS study alluded to at the beginning of this section identified the same three provinces – Mpumalanga, Free State and KwaZulu-Natal as having consistently had the highest HIV prevalence, as shown in the table below.

Province	2002	2005	2008
KwaZulu-Natal	11.7	16.5	15.8
Mpumalanga	14.1	15.2	15.4
Free State	14.9	12.6	12.6
North West	10.3	10.9	11.3
Gauteng	14.7	10.8	10.3
Eastern Cape	6.6	8.9	9.0
Limpopo	9.8	8.0	8.8
Northern Cape	8.4	5.4	5.9
Western Cape	10.7	1.9	3.8
National	11.4	10.8	10.9

Table 5: HIV prevalence (%) by province 2002-2008

The NDOH also confirmed that these three were the provinces with the highest burden of HIV and AIDS and that special attention had been focused on them.

The Western Cape was widely regarded to be running a fairly successful ART programme, and it had the potential of providing valuable lessons to the rest of the provinces.

The Eastern Cape was added simply due to the fact that, by the time the decision was taken that not all provinces would be considered for the exercise, arrangements had already been made with the provincial authorities to conduct the interviews. Its inclusion does, however, provide additional insight into the diversity in the approach of the different provinces to the implementation of the ART programme.

7.5.2.1 Budget and Financing

According to Treasury, funds are generally allocated to the provinces for programmes such as Health (equitable share) and not for specific items, unless it is a national programme identified by Government, such as, for example, "Treatment of specific HIV and AIDS patients", in which case such an allocation would be accompanied by special conditions. Thus, there is no compulsion placed upon provinces by Treasury to ring-fence any particular item. In terms of Schedule 6 of the Constitution, provinces may use their own discretion in the spending of the funds, although it is generally expected that the funds will be used for the purposes for which they were provided.

Importantly, this seems to suggest that the conditional grants, which are the main source of funding for the HIV programmes, do not fall under Schedule 6 and could potentially be provided subject to conditions that Treasury or the NDOH may deem fit to impose. An obvious example of such a condition could be for the budget determination for the ARVs to be based on some or other recognized method/tool of quantification, and that the ARV budget be ring-fenced. This possibility is discussed in some details in the section on "Legal implications and requirements".

The funding of the provincial HIV and AIDS programmes is channeled through the NDOH and is disbursed to the provinces in bulk. Each province determines the percentage to be spent on the various components of the programme – operations, laboratory costs, salaries and medicines. In all the provinces visited, the final breakdown of the funds is the prerogative of the CCMT. Some other units, such as pharmaceutical services, may be consulted for input. In KwaZulu-Natal, the budget for ARVs is determined jointly by the CCMT and Pharmaceutical Services, while the CCMT Directorate in the Western Cape does budgeting for ARVs entirely on its own. The degree of co-operation among the units involved in one way or the other in ART differs from province to province, and much more could be done to ensure greater co-operation.

All the provinces participate in the NDOH's quarterly quantification meetings using the MSH quantification tool for determining quantities of ARVs to be ordered. A number of elements are critical to

the success of this venture. Firstly, the provincial CCMT directorate needs to feed constant information to the provincial medicines depot on the numbers of patients on treatment, the breakdown according to treatment regimens, paediatric versus adult patients, and a regular update on new entrants. It is thus imperative that the two groups have regular meetings and exchange of information and statistics. Secondly, any defaulting on the part of the contracted suppliers needs to be monitored. The quarterly meetings are also attended by the suppliers, who are provided with an opportunity to report on any problems that they may encounter with particular provinces with regard to off-take of quantities not matching the forecasts, or to report on any shortages of active ingredients that they may be experiencing.

Generally, provinces draft business plans in preparation for the new financial year, in line with the national strategic plan. In most provinces, managers at facility and district level seem to be involved by the CCMT directorates in the determination of the budget. However, the provinces contend that the eventual allocation from NDOH is invariably significantly less than the amount requested in the business plan. What compounds the problem is that provinces generally start a new financial year with a shortfall, which has to be funded from the new allocation. There was a R1.2 billion shortfall in the funding of the total HIV and AIDS programme for the 2008/09 financial year. In addition to the budget of R3.4 billion for the current financial year, a funding gap of R900 million has still to be met.

NDOH concedes that, while the Conditional Grant allocation is based on business plans submitted by the provinces, Treasury applies a formula based on population figures and not on the numbers of patients needing treatment. This supports the provinces' contention that the eventual allocation is pre-determined and not related to the figures submitted in the business plans.

In response to questions relating to monitoring of expenditure and whether they had in place early warning systems and contingencies in the event of expenditure shortfalls, the following picture emerged:

- Budgets are monitored monthly. Monthly and quarterly reports are sent to the provincial Treasury and NDOH. Thus, expenditure monitoring and reporting is done meticulously in all the provinces.
- Three of the provinces reported that they had no early warning system for shortfalls as it was already known at the beginning of the financial year that they would have a shortfall. In order to minimize the effects of the shortfall, they resort to the Equitable Share funds and apply measures that include the freezing of "non-essential" posts, minimizing other activities and reducing

training activities. However, an investigation into the Free State ARV stock-out crisis of 2008/09 revealed that Conditional Grant allocations for HIV and AIDS were used to fund non-HIV and AIDS costs^{††}. The Task Team was not able to confirm if this ever happened, either in the Free State or in the four other provinces visited.

- Following pleas to NDOH for additional funds during the course of the year and applications for an adjustment to the budget, usually without much success, the provinces resort to requesting for donor funding.

What was puzzling was the provinces' basis for allocating a portion of the HIV and AIDS budget to the purchasing of ARVs. Whereas it was apparent that the CCMT directorates applied either projections based on past expenditure, or used the quantification tool in conjunction with pharmaceutical services to determine the amount to be spent on ARVs, all their plans are thrown into disarray when their Conditional Grant allocation arrives with a shortfall, and the amount allocated to the purchasing of ARVs becomes purely arbitrary (see table below).

In summary, the following key observations were made regarding ARV budgets, expenditure, provision and monitoring of services in the provinces:

- The amount allocated by NDOH for the provincial CCMT programme is almost always less than the amount requested for in the provincial business plan. Provinces thus begin the financial year knowing that the funds will not suffice for their needs. This shortfall notwithstanding, it would seem that some of the funds have been spent on non-HIV items in at least one province, the Free State.
- Provinces are expected to augment the Conditional Grant from the Equitable Share, but it is not clear to what extent this happens.
- In all the provinces where the CCMT were interviewed, with the exception of the Free State, expenditure on ARVs eventually surpassed the budget in the 2008/09 financial year (Table 7). This probably explains the funding gap in the 2009/10 financial year.

^{††} The investigation was ordered by NDOH but the report was not published.

Province	Population served	Adults on ARVs	Paediatrics on ARVs	Total ARV patients	ART	ART	% of	Exp per patient (R)
					Budget 08/09	Exp 08/09	HIV/AIDS Budget allocated to ARVs	
Mpumalanga	3.6m	55,099	4,416	59,515	43m	156m	39%	2,621
Western Cape	5.3m	59,722	5,148	64,870	82.3m	119m	43%	1,834
E Cape	6.4m	75,555	6,625	82,180	99m	132m	33.5%	1,606
KwaZulu Natal	10.4m	243,704	28,234	271,938	370.2m	403m	50%	1,482
Free State	2.9m	36,913	4,695	41,608	46.9m	43m	25%	1,033
Total	28.6m	470,993	49,118	520,111	641.4m	853m		

Table 6: ARV treatment and expenditure in selected provinces, November 2009

- Expenditure per patient in Mpumalanga is much higher than in the other provinces and more than twice the Free State's figure. This is open to interpretation – it could confirm the Free State's contention that their allocation is almost never sufficient for their needs (but then most of the provinces had this contention), or it could indicate irrational expenditure in Mpumalanga.
- Challenges for maintaining constant supplies of ARVs range, besides the budget shortfall, from inadequate human resources, lack of liaison between Pharmaceutical Services and the CCMT directorate, and the poor quality of data which forms the basis for expenditure
- Four of the CCMT units conceded that prescribers' compliance with guidelines was not monitored and that there were no SOPs in place for switching patients from 1 regimen to another. In KwaZulu-Natal switching has to be authorized by Pharmaceutical Services and is based on SOPs and explicit guidelines. According to the Acting Director: HIV and AIDS, non-adherence to guidelines was mainly due to the guidelines being outdated. The Western Cape and KwaZulu-Natal reportedly had systems in place for monitoring adherence. The Acting Director further stated that for monitoring and general provision of ART services to improve in the provinces, additional posts of Deputy Director Monitoring and Evaluation (1), Deputy Director Finance (1) and Assistant Director (2) would have to be established at the NDOH. She also believed that the Conditional Grant should pay a third of the human resources costs, and that pharmacists needed to be integrated into the system instead of being employed vertically.

- All of the 5 provinces stated that they had a mechanism for controlling the use of items such as Tenofovir and Abacavir. This was controlled by Pharmaceutical Services and was largely applied on a named-patient basis.
- The HIV and AIDS Directorate, in preparing the ARV tender which is expected to commence in May 2010, had made expenditure projections which took into account an expected increase in the number of patients to be treated as a result of the decision to have some patients commenced on treatment at CD 4 count of 350 (not all patients qualify, though). The expenditure projection for 2010/11, calculated on a baseline of 1 million patients, will include R3 billion from the Conditional Grant and R1 billion from the Equitable Share. An additional R8 billion would be required to include Tenofovir for everyone (full unit cost) and commencing treatment at increased CD 4 levels, albeit only for TB/HIV patients, pregnant women and children under 1 year.
- It is the intention of NDOH to include fixed dose combinations in the treatment guidelines as these will improve adherence and bring down costs.

7.5.2.2 WHO Proposal on ARV Funding

A WHO mission that visited South Africa in November 2009 and met with the Minister of Health made the following observations on the challenges associated with the high acquisition prices of ARVs(17):

- Local prices for ARVs were at least 25-30% higher than the average international (Global Fund) prices, largely due to (1) lack of generic competition; (2) lack of standard fixed dose combinations (FDCs) and (3) the 15% preferential pricing for local generic companies. If international price competition were to be initiated, FDCs introduced into the treatment guidelines and responsibility for the payment of incentives for local companies taken over by another Government department, an additional 200,000 patients could be treated with the same medicines budget.
- The tender system was deficient, due to, at least, the following reasons:
 - The two-year fixed price tender period made no use of global price decreases during the period;

- The two-year sole supplier arrangement locked out other suppliers for a long period and did not encourage competition, and
- The involvement of too many parties outside the Health Department (e.g. Treasury) complicated the management of tenders and did not allow for flexibility when the need arose.
- The imposition of VAT on medicines was tantamount to taxing the sick and needed serious review by Government.
- A weak medicines procurement and supply management system, characterized by:
 - The lack of good forecasting of quantities, leading to emergency procurements;
 - The use of the ARV budget by the provinces for other priorities;
 - The lack of common, updated specifications for medical products, leading to the exclusion of other products;
 - The lack of supplier performance monitoring (e.g. quality of products, late delivery, failure to meet contracted quantities);
 - The lack of staff in the NDOH to assist and monitor procurement of medicines in the provinces (The Cluster Pharmaceutical Policy and Planning had been without a head^{††} for some time now and has an extremely high vacancy rate), and
 - Weak information systems to inform procurement planning and management.

Most of the above observations were confirmed during the Task Team' visits to the provinces. Other challenges noted by the Task Team include:

- NDOH's difficulty in collecting accurate, timely data from the provinces;
- The lack of communication between the various units involved in HIV & AIDS work, both at national and provincial levels;

^{††} The post had been advertised by the time the report was finalized.

- The provincial ARV staff do not use the quantification tool regularly to update requirements;
- Provincial ordering patterns are very erratic, leaving suppliers without sufficient lead times for procurement when orders placed are in excess of the estimates, and
- Ordering and payment methods for ARVs differ from province to province, with some being delayed due to strict authorization before orders are placed, and others because payments are made first from the provincial finance section to the depot that then pays the suppliers.

7.5.2.3 International price comparisons of ARVs

Commentators often warn against international medicines price comparisons, as, they contend, such comparisons often “do not compare like with like”. However, comparisons considered by the Task Team have clearly made a distinction between what is often referred to as the “catalogue” price and the “landed” cost, the latter taking into consideration all kinds of tariffs, duties and costs added to the price of the product by the time it is delivered. A joint collaboration by the Strengthening Pharmaceutical Systems (SPS/MSH), Supply Chain Management Systems (SCMS) and the Clinton Foundation (CHAI) initiatives on behalf of the NDOH carried out an exercise to determine the cost of ARVs if the SA Government were to procure ARVs on the international market. Different permutations, depending on standard treatment guidelines and one of which includes the use of fixed dose combinations (FDCs), produced some interesting results which point to the need for the NDOH to review current procurement practices to access international market prices.

PRODUCT	Pack Size	State Tender Delivered Price (Rand)	State Tender	State Tender	SCMS	SCMS
			Delivered Price (\$US)	Delivered Price (\$US)	Indicative Price Ex. Works (\$US)	Indicative Landed Cost (\$US)
Abacavir 20mg/ml	240	R 134.43	\$ 17.92	\$ 13.50	\$ 15.26	
Abacavir 300mg tablets	60	R 320.13	\$ 42.68	\$ 18.90	\$ 21.36	
Didanosine 25mg tablets	60	R 55.70	\$ 7.43	\$ 7.00	\$ 7.91	
Didanosine 50mg tablets	60	R 58.78	\$ 7.84	\$ 9.50	\$ 10.74	
Didanosine 100mg tablets	60	R 72.11	\$ 9.61	\$ 7.40	\$ 8.36	
Efavirenz 200mg capsules	90	R 106.33	\$ 14.18	\$ 10.00	\$ 11.30	
Efavirenz 50mg capsules	30	R 35.55	\$ 4.74	\$ 2.24	\$ 2.53	
Efavirenz 600mg tablets	30	R 108.03	\$ 14.40	\$ 4.40	\$ 4.97	
Lamivudine 10mg/ml solution	240	R 21.68	\$ 2.89	\$ 1.90	\$ 2.15	
Lamivudine 150mg tablets	60	R 29.48	\$ 3.93	\$ 2.38	\$ 2.69	
Lamivudine 300mg capsules	30	R 35.50	\$ 4.73	\$ -	\$ -	
Lopinavir/Ritonavir 133/33mg capsules	180	R 310.69	\$ 41.43	\$ 41.10	\$ 46.44	
Lopinavir/Ritonavir 200/50mg tablets	120	R 310.69	\$ 41.43	\$ 36.16	\$ 40.86	
Lopinavir/Ritonavir 80/20mg/ml solution	60	R 62.14	\$ 8.29	\$ 8.22	\$ 9.29	
Nevirapine 10mg/ml solution	240	R 36.00	\$ 4.80	\$ 1.80	\$ 2.03	
Nevirapine 200mg tablets	60	R 32.70	\$ 4.36	\$ 2.60	\$ 2.94	
Ritonavir 80mg/ml solution	90	R 62.06	\$ 8.27	\$ 8.22	\$ 9.29	
Ritonavir 100mg capsules	84	R 72.48	\$ 9.66	\$ -	\$ -	
Stavudine 1mg/ml solution (fridge)	200	R 13.22	\$ 1.76	\$ 1.34	\$ 1.51	
Stavudine 15mg capsules	60	R 16.79	\$ 2.24	\$ 1.50	\$ 1.70	
Stavudine 20mg capsules	60	R 16.76	\$ 2.23	\$ 1.40	\$ 1.58	
Stavudine 30mg capsules	60	R 16.72	\$ 2.23	\$ 1.40	\$ 1.58	
Tenofovir 300mg tablets	30	R 157.05	\$ 20.94	\$ 8.20	\$ 9.27	
Zidovudine 100mg capsules	100	R 69.96	\$ 9.33	\$ 4.75	\$ 5.37	
Zidovudine 10mg/ml solution	200	R 22.50	\$ 3.00	\$ 2.00	\$ 2.26	
Zidovudine 300mg tablets	60	R 70.13	\$ 9.35	\$ 7.25	\$ 8.19	

PRODUCTS TABULATED HERE ARE BOTH MCC AND FDA APPROVED FOR USE IN SOUTH AFRICA ONLY
PRICES TABULATED HERE ARE INDICATIVE ONLY, ARE SUBJECT TO CHANGE AND CANNOT BE CONSIDERED VALID FOR
QUOTATION PURPOSES

Table 7: International price comparisons of ARVs; Source: SCMS, January 2010

The price comparison was done for adult treatment only. The greatest price difference between the locally supplied products and those available internationally appears to be for efavirenz, which also is dispensed to the largest number of patients, followed by tenofovir, which to date does not have as many users. However, following approval and implementation of the revised treatment guidelines, it is anticipated that this number will increase significantly in the future. There is also a considerable difference in the price of Lamivudine which is used across the board for patients on first line treatment.

Massive potential savings are predicted in respect of Efavirenz and Tenofovir, if they were to be procured on the international market. The savings, it is argued, would allow for more patients to be brought onto

the treatment programme. This would be crucial considering the decision to commence treatment at the CD4 cell count of 350 (albeit for certain categories of patients only), which would see an escalation in the number of patients commenced on treatment. Incidentally, in an analysis of the 2008 South African ARV tender, international prices supplied by the Clinton Foundation are challenged by one of the local suppliers, who contend that their prices are lower than the ones listed by CHAI(18). The analysis also indicates the value share of the 2008 tender of Efavirenz and Tenofovir as 34% and 14% respectively. Considering that the use of Tenofovir has not been high owing to the lack of finalization of the treatment guidelines in time, the savings that would be realized, according to the CHAI prices, if this product were to be included as first line, would be substantial

Fixed-dose combinations were not included in the costing because these are currently not used for any treatment apart from post-exposure prophylaxis, but could reduce the overall costs considerably if introduced.

Interestingly, the lopinavir/ritonavir combination costs less in South Africa, due to the fact that Abbott has not granted any voluntary licenses for manufacturing generic products, and South Africa is included in the sub-Saharan developing countries that can least afford treatment with ARVs. The only ARV that indicates similar pricing both locally and internationally is Zidovudine.

These findings confirm that, through a more aggressive negotiating mechanism, the NDOH will be able to significantly reduce the cost of treatment allowing for more patients to access the AIDS treatment programme.

7.5.3 Recommendations

- The Task Team was impressed by the effort put into preparing business plans by the provincial CCMT units so as to motivate for the allocations for their programmes. There were, of course, instances where the funds received were spent on non-provisional grant items, and the allocation for ARVs appeared arbitrary. Nevertheless, the Task Team has sympathy with the claim that allocations from the NDOH always fell short of the requested amounts based on the business plans. It is recommended that all attempts be made by the NDOH to allocate as much of the total amount requested as possible, as the consequences of shortfalls often include patients not being

able to continue on treatment. In return, NDOH should look at imposing more stringent reporting and accounting requirements on the provinces to ensure, among others, that there are no deviations from the expenditure mandate. Disbursements specifically related to the purchase of ARVs would be the responsibility of the CPPA as recommended in Section 7.1.

- It was explained to the Task Team that provinces were expected to supplement CCMT expenditure from the Equitable Grant, but that this was hardly adhered to. To the extent that officials overseeing the provincial budget would have had priorities vastly different from those affecting healthcare, it would be hazardous to continue to expect that they may be swayed to change their priorities. It is for this reason that it is recommended that the budget for ARVs be ring-fenced as part of the national pharmaceutical budget which would be controlled centrally (see earlier recommendations). Crucially, disbursements to the provinces would still have to be on the basis of submissions from the provinces.
- Business plans presented to the NDOH have to be preceded by co-operation among the provincial units centrally involved in the HIV and AIDS arena. To this end, it is strongly recommended that Pharmaceutical Services, CCMT and HAS units in the provinces be urged to work together. This could be done through a formal structure that would meet on a regular basis.
- The procurement of certain high-cost items for the CCMT programme on the international markets for ARVs is supported if this will ensure that the available funds are stretched long enough to ensure more people get onto the treatment programme.
- It is recommended that NDOH presents a proposal to SARS to investigate the feasibility of the removal of VAT on medicines. This is a growing trend among developing nations.

7.6 Role of Private Sector in Supporting Public Sector Supply Chain

7.6.1 Manufacturers

The South African pharmaceutical industry is “bottom-heavy” with the production of pharmaceutical intermediates (fine chemicals) virtually absent, limited production of pharmaceutical active ingredients (API’s) and relatively well-developed downstream segment, i.e. medicine formulation. There is an excess production capacity in the low-tech medicine formulation segment, with some plants operating at or below 50% of their capacity(19).

The sector’s key weakness is the low level of domestic production of active pharmaceutical ingredients (APIs), which meets just 5% to 10% of the domestic demand. South Africa’s only API plant manufactures about 30 APIs, both of natural origin (morphine alkaloids and other alkaloids, e.g. Vinca) and synthetic. The dependence on API imports raises concerns about security of supply and adds to the sector’s trade imbalance, especially due to the rising demand for anti-retrovirals (ARVs). The APIs account, on average, for 75% of the cost of manufacture of anti-retroviral medicines

Multi-national pharmaceutical corporations control 65% of the South African pharmaceutical market and employ a workforce of 6,200, which is 60% of the sector’s total workforce. The largest multi-national corporations in SA are: Sanofi-Aventis, Pfizer, Merck (MSD) Glaxo-SmithKline (GSK), Sandoz, Novartis, Roche, Astra-Zeneca and Johnson & Johnson (This is as of 2008. Any mergers or take-overs that may have occurred since then have not been taken into account).

The largest South African-owned pharmaceutical companies are:

- Aspen-Pharmacare, which is the largest pharmaceutical manufacturer in Africa and the Southern Hemisphere with an annual (2007) revenue of R4.2 billion (US\$ 600 million) and market capitalization of R13.4 billion (US\$ 1.7 billion). Aspen employs a workforce of 2,500 in 3 manufacturing plants: Port Elizabeth, East London and Cape Town.

Over the past 4 years, Aspen has obtained voluntary licenses for the manufacture of an extensive range of ARVs. Aspen was awarded government ARV tenders in 2008 for the supply of ARVs worth R 2.1 billion over a 24 month's period. Aspen was due to start manufacturing medicines against MDR TB (Capreomycin and Cycloserin) under licence from Eli Lilly. Aspen also acquired from GSK the intellectual property rights to manufacture and market four medicines with combined estimated sales potential of R 1 billion / annum.

- Adcock-Ingram, which has 3 manufacturing plants, all in the Greater Johannesburg area (Wadeville, Clayville and Aerton / Soweto), with total sales R 2.8 billion in 2006, of which pharmaceuticals were R 1.85 billion and hospital products R 0.95 billion. The US company Baxter is Adcock's key technology partner in the production of intravenous medicines.

Adcock started production of ARVs in 2007. In the 2008 ARV tender, Adcock was awarded government contracts worth R 750 million. Currently, Adcock was recently unbundled from the Tiger Brands group.

- Enaleni and Be-Tabs, which until recently were the 3rd and 4th largest SA-owned pharmaceutical companies respectively. They were acquired in 2006 and 2007 by the Indian companies Cipla and Ranbaxy respectively.

The production of vaccines and other biologicals (anti-sera) is the only state-controlled segment of the SA pharmaceutical industry. Veterinary-grade vaccines are manufactured at the Agricultural Research Council (ARC) facility north of Pretoria, while a human-grade vaccine facility is under development in Cape Town, as a public-private partnership. So far, South Africa imports 100% of human-grade vaccines. Anti-sera against snake and scorpion venom are manufactured in a Department of Health research facility in Edenvale, Johannesburg.

According to an analysis of the 2008 ARV tender(18) ,7 companies were awarded one or more products on the tender and had the following share, per contract value, of the award:

Local Companies:

Aspen	48%
Adcock	18%
<u>Sonke*</u>	<u>2%</u>

Total: 68%

Multinational Companies**:

GSK 6%

MSD 8%

Abbott 15%

Cipla*** 2%

Total: 31%

*Sonke is a joint venture between Ranbaxy of India and Phambili, a local empowerment company. Their ARVs are all imported from India;

**These are original research-based companies, for which generics do not exist for their second line ARV products;

***This is an importer, where the products are manufactured in India and imported into South Africa.

Elsewhere in this report, potential advantages of international tendering for some of the country's pharmaceutical requirements, specifically ARVs, are discussed. There is every justification for the Government to source life-saving medicines from the cheapest sources if this means that savings so achieved will ensure that more AIDS patients are included onto the treatment programme. In fact, as is argued in the section on "Legal Implications and Requirements", Government would be guilty of dereliction of duty if it did not shop around for the best prices for life-saving ARVs, including going beyond the country's borders.

It needs to be made clear, though, that the unrestricted resort to international tendering for most of the country's pharmaceutical requirements would not necessarily yield savings, may be counter-productive as far as the country's health objectives are concerned, and may have long-term harmful consequences for the local manufacturing industry and its ability to contribute to overall industrial growth. Representatives of locally-based multinational companies put forward the following arguments(20):

- Whereas on local tender the State secures a price from a provider against an estimated quantity and seldom commits to buying tendered quantities, it is likely that volumes under international tendering would have to be firm and represent a commitment to purchase;
- Locally, goods are delivered by the local manufacturer to any of a number of delivery points as required by the State, while goods delivered from outside the country are likely to be delivered to

one point, with the responsibility for onward distribution and cold chain maintenance resting with the State;

- Local procurement ensures that product back-up is available locally from the manufacturer as required, whereas the State may have little or no recourse if the delivered product from outside our borders does not meet standards;
- Through the State tender system, it is possible to specify that products be supplied in patient-ready packs, whereas internationally tendered products might very often be available in bulk packaging only and require packaging.

These are among some of the key factors that would have to inform any decision to resort to wholesale international tendering.

7.6.2 Wholesalers and Distributors

Wholesalers buy stock from manufacturers and sell it on to pharmacies, while distributors warehouse stock in their premises on behalf of manufacturers. The stock so kept by the distributors remains the ownership of the manufacturers.

The National Association of Pharmaceutical Wholesalers (NAPW) is an association that represents about twenty full line national wholesalers which account jointly for about 58% of the market by volume and about 52.96% by value. Each of these full line wholesalers stocks about 90% of the full range of pharmaceuticals that are available in the South African market.

The Wholesalers and Distributors currently deliver both ambient and cold-chain products to the hospitals. They have Standard Operating Procedures to ensure products are distributed in validated cold chain distribution packaging.

UTi Pharma, formerly known as International Healthcare Distributors (IHD), and Pharmaceutical Healthcare Distributors (PHD) are the main distributors in the South African pharmaceutical market. UTi and PHD jointly account for about 26.18% of the market by value and about 22.44% by volume. The rest of the

market is captured by the small short line wholesalers that are either regional or specialized in nature. Short line wholesalers account for 19.02 % of the market by volume and 20.86 by value.

UTi processes an average of 4,168 transactions per month in the public sector, covering an average of 4,435 line items per month. The company processes an average of 800 transactions per month and 1600 items/month. Currently UTi distributes medicines on behalf of 30 manufacturers, supplying approximately 155 state facilities, including provincial depots, hospitals and clinics. The distributors and wholesalers either deliver directly to the facility or to the depots. UTi has 5 regional depots in the country where large quantities are stored.

For the Public Sector, the delivery time is defined in the Tender document which constitutes a Service Level Agreement between the Manufacturer and the Customer (State). Depending on the destination this will vary between 24 hours and 72 hours. Cold Chain products have a lead time of five days within which they must be delivered to ensure GDP compliance. Emergency Deliveries are done within four hours.

Due to the tender requirements, manufacturers are obliged to do full batch runs and therefore additional storage is required to accommodate full pallets. This carries a cost implication as more labeling is required. Also, more pallet locations are required to accommodate larger volumes.

In response to a question as to whether doing more deliveries to State facilities would require any additional resources, UTi pointed out that distribution to the state facilities is generally not a problem, unless the facility orders large quantities without the required storage capacity or the equipment to handle the unloading, in which case the goods have to be uplifted and returned. This can be a major issue with cold-chain goods.

They explained that the distribution of large quantities in full pallets also places an additional burden on manufacturers to label each box per pallet and often UTi ends up relabeling on their behalf to ensure product identification. Some wholesalers use private contractors (courier companies) to deliver products. However, they do have their own vehicles for delivery if the private contractors are unable to complete the deliveries in time.

Wholesalers and Distributors already carry out direct deliveries to state facilities such as hospitals and clinics. They have indicated that they have the infrastructure in place to immediately roll-out a full distribution and supply function of direct deliveries to the state sector without additional costs being incurred.

UTi has already considered a number of alternative distribution mechanisms resulting in direct delivery to state facilities with an upgrade of the current systems across the supply chain process from manufacturer to end-user to ensure optimum operational functioning. This includes a full costing exercise which gives a total annual cost of the medicines supply chain in the state sector. While this exercise was carried out 2 years ago as part of a proposal to the Gauteng Health Department and therefore the costs are outdated, the concepts are still relevant.

Serious consideration needs to be given to the increased utilization of existing distribution and wholesaling services for the distribution of public sector medical supplies. Distributors already deliver to public sector facilities – depots and hospitals - on behalf of manufacturers, their clients. If tender specifications for the supply of medicines to the State so indicated, the distributors are capable of delivering directly to the hospitals and clinics, bypassing the depots. This, they contend, would be at no additional cost to the provinces, as the distributors' contract is with the manufacturer. Of course, such claims would have to be verified when the services are contemplated. Such an arrangement would also see the hospitals make a saving on the levy that is charged by the provincial depots (obviously, as mentioned in an earlier section, there would be an added administrative burden to the hospitals as they would be placing orders with an increased number of vendors). An example of such an arrangement is the outsourcing in the Western Cape of the distribution of EPI vaccines to a private company. The WHO is also currently conducting a review of the opportunities and challenges of such an outsourcing agreement for EPI vaccines in the Western Cape.

A province such as Gauteng, which, despite its small size, has a provincial medicines depot and a number of sub-depots and several municipal depots, can ill afford to continue its current medicines distribution system which has delivery trucks from the various health authorities driving past each other and past health facilities belonging to another in order to deliver goods to another part of the province. The human and financial resources could be put to more efficient use if all distribution were to be reduced to one distribution system, which could be managed in-house or out-sourced to a distributor. The number of

depots in the province would thus be reduced and the entire province supplied from the provincial depot. A more radical version of this proposal would have even the provincial depot's operations reduced to stocking contingencies only or simply being made redundant and shut down.

The Eastern Cape Province is battling to maintain the management of its two depots – the one in Port Elizabeth and second in Mthatha – in efficient mode. The province has a long history of inviting bids for distribution and/or warehousing, but none have been awarded in the last decade or so. Here, too, arranging for direct deliveries to all the hospitals and main health centres by the suppliers, leaving reduced operations at either or both of the depots to cater for special deliveries, would bring great relief to the province. However, as pointed out earlier, the PHC clinics, especially those in the remotest parts of the provinces, would require the support of a regional or transit depot for their buffer and emergency stocks.

Challenges to the existing system that would need resolution for alternative solutions to be considered, are:

- Accurate forecasting from the facility
- Order planning and consolidation of orders to ensure single delivery per day / week as necessary
- Receiving capacity at the facility
- Storage capacity within the hospitals
- Storage facility for a minimum of stock cover which should be negated by way of proper planning and forecasting.

7.5.3 Recommendations

- The value of the presence of the pharmaceutical manufacturing industry in the country cannot be over-emphasised. This refers to both the multinational and locally-owned manufacturers. Government needs to devise a unified strategy in its approach to the industry. The tensions between the desire to grow the local industry (Industrial Policy Framework) and the Constitutional mandate of the Health Minister to provide healthcare to the citizens of the country and do so cost-effectively, have to be resolved. As has been suggested elsewhere in this report, a meeting of

minds among the Government departments having a stake in medicines procurement is not impossible, and should be pursued with vigour.

- In recognition of the critical lack of skills in the public sector, provincial governments would do well to consider utilisation of the services of private distributors for medicines distribution. This would enable the provinces to move scarce human resources and skills to the hospitals and other functional areas, in addition to reducing the high costs of running ineffectual medicines depots.

7.7 Information Technology

7.7.1 Selection

7.7.1.1 Findings

The main function in the selection process of medicines that would require a database is the essential medicines list. Currently, the maintenance of the essential medicines list is a manual process and office productivity suites, mainly Microsoft Word and Microsoft Excel, are used to maintain electronic lists.

7.7.2 Procurement

7.7.2.1 Findings

Table 5 below lists the current software applications that are used to manage the procurement process in the South African Public Sector Pharmaceutical Supply Chain.

Application	Description	Technology Platform	Owned By
Contract Management System	<ul style="list-style-type: none"> • Used by NDoH to manage and administer tender item specifications and tender life-cycles. • Interfaces with the MEDSAS depot management system and the electronic tender management system used by National Treasury. 	Clipper developed client application with Sybase database.	NDoH and managed and supported by SITA.
Item Identification	<ul style="list-style-type: none"> • Used by NDoH to manage and administer 	Clipper developed client	NDoH and managed and

Application	Description	Technology Platform	Owned By
System	<p>pharmaceutical items, their codification and pharmaceutical classification.</p> <ul style="list-style-type: none"> • Interfaces with the Contract Management system. 	application with Sybase database.	supported by SITA.
RFx	<ul style="list-style-type: none"> • Used by National Treasury to administer the electronic tender process. 	Web-based electronic tender invitation and bid response management software.	Intenda
Sourcelink	<ul style="list-style-type: none"> • Used by the Western Cape Provincial Government Supply Chain function to administer the provincial electronic tender process. 	Web-based electronic tender invitation and bid response management software.	TradeWorld
Remote Demanders Module (RDM)	<ul style="list-style-type: none"> • Used by selected hospitals to place electronic orders against depots that use MEDSAS as warehouse management software. 	Windows based client interface.	Intersolve Health Informatics
EDI	<ul style="list-style-type: none"> • Used by depots that use MEDSAS as warehouse management software to place electronic orders against suppliers. 	Windows based client interface.	Intersolve Health Informatics.
PDSX	<ul style="list-style-type: none"> • Used by depots that have outsourced their procurement, storage and distribution function to Amalgamated Pharmaceuticals. 	Not known	Amalgamated Pharmaceuticals.(Developed by Vuna Healthcare Logistics
JAC Pharmacy System	<ul style="list-style-type: none"> • Used by academic hospitals in PGWC to manage their procurement directly from suppliers. 	Visual Basic 6 Client interface with CACHE database	Health Science Technology is the local vendor; the system is British-owned.
RxSolution	<ul style="list-style-type: none"> • Used for pharmaceutical Inventory, Dispensing and Down referral management in hospitals at hospital & CHC level. Used in 64 facilities in NW, FS, EC & Mpumalanga 	Delphi developed client application	MSH/SPS

Table 8: Software applications that are currently used in the procurement process.

This information technology landscape is further characterised by:

- **Fragmented information stores:** This makes visibility across the supply chain difficult and cumbersome. There is no central location from where information across the country is accessible. The lack of integrated information systems and shared information also leads to inaccuracies in quantification. There is often a discrepancy between usage information obtained from suppliers and that obtained from the facilities and depots.
- **Outdated legacy technology:** The MEDSAS system that is in use at most of the depots has been in use since around 1994. This software is difficult to maintain and cumbersome to modify as a result of the technology limitations.
- **Proprietary technology:** The CACHE database that is used by the JAC system in the Western Cape is a proprietary, non-relational database. There are limited skills available in South Africa to support this database.
- **Failed replacement of legacy technology:** In 2005, Waymark was awarded a tender for the replacement of the MEDSAS system. This contract has been characterised by numerous delays and to date, there has not been a successful implementation of the new solution. The recent pilot project at the Gauteng depot had to be cancelled as a result of problems experienced. An amount of R50 million is said to have been spent on the project to date.
- **Lack of central pharmaceutical data management standards:** There are no documented pharmaceutical data management standards. This has led to extensive problems in the creation of consolidated management information as items are often re-assigned a unique product number at provincial and or facility level. It makes the tracking of products from manufacture through to the patient almost impossible.

7.7.2.2 Recommendations

The following recommendations are proposed:

- **Development of national pharmaceutical data management standards:** This would facilitate the ease with which information is exchanged across the entire supply chain and improve visibility of transactions and material flow along the supply chain.

- **Consolidation of the number of technologies used:** The public sector has an excessive dependence on external vendors for information management as a result of the disparate skills required to support and manage the myriad of technologies in use. Consolidation of these platforms can lead to a decrease in the total cost of ownership of the technologies that are used as enablers in the public sector supply chain.
- **Improved software integration across the supply chain:** Ease of information sharing and exchange is one of the pre-requisites for transparent visibility across the supply chain. Improved integration of software will facilitate the ease of information sharing and exchange and the resultant improvement in managing pharmaceutical availability.

7.7.3 Storage and Distribution

7.7.3.1 Findings

The software applications used in the storage and distribution of pharmaceuticals are listed in table 2 below.

Application	Description	Technology Platform	Owned By
MEDSAS	<ul style="list-style-type: none"> • Used by the depots to manage storage and distribution of pharmaceuticals. 	Clipper client interface with Sybase database.	NDoH and managed and supported by SITA.
PDSX	<ul style="list-style-type: none"> • Used by depots to manage storage and distribution of pharmaceuticals. 	Not known	Developed and owned by Vuna Healthcare Logistics
JAC	<ul style="list-style-type: none"> • Used by Tertiary hospitals in Western Cape to manage storage and dispensing of pharmaceuticals at 	Visual Basic client interface and Cache database.	Health Science Technology

	the relevant facilities.		
Oracle Financials	<ul style="list-style-type: none"> • This is the new system that is supposed to replace MEDSAS as the warehouse management solution. • This system has however not been successfully implemented as yet, despite the contract having been allocated five years ago. 	Oracle.	Oracle and managed and supported by SITA and Waymark.
Basic Accounting Software (BAS)	<ul style="list-style-type: none"> • Used by government departments to manage the payment of suppliers. 	Mainframe-based platform.	National Treasury.

Table 9: Software used in the supply chain

The information technology is further characterised by:

- **Distribution monitoring software:** The use of the distribution vendor specific software to monitor and track orders between depots and facilities and between manufacturers and facilities for direct deliveries.
- **Supporting technology:** Bar-coding and scanning have been introduced in some environments to increase the efficiency of operations in the depots.

7.7.3.2 Recommendations

The following recommendations are proposed:

- **Introduction of innovative technology to facilitate product tracking and picking:** Newer technologies such as radio frequency identification tags and other warehouse automation technologies should be considered to improve the effectiveness and efficiency of government owned depots.

- **Replacement of outdated technology at depot level:** Should the depots remain, the outdated legacy systems at the MEDSAS depots should be replaced. The feasibility of the Oracle-based solution that has still not successfully been implemented should be reviewed for appropriateness.

7.7.4 Management Information

7.7.4.1 Findings

It was found that:

- Silos of information existed across the country and it is difficult to consolidate and compare this information across the country due to the lack of data management standards.
- Information for planning and controlling functions were readily available at depots and facilities where information systems are used.
- Information for decision-making functions (strategic, tactical and technical) was less readily available. The NDoH in particular struggles to obtain a holistic consolidated view of the national pharmaceutical supply chain.

7.7.4.2 Recommendations

The following recommendations are proposed:

- **Introduction of a centralised management information warehouse:** Access to reliable information in a timely manner is one of the critical success factors in managing an effective and efficient supply chain. The current fragmentation in information stores and the cumbersome processes involved in obtaining a consolidated view is seriously hampering planning and decision-making in the supply chain. A centralised management information warehouse would facilitate informed decision-making and increase visibility of problems along the supply chain.
- **Development of a pharmaceutical supply chain information management framework:** The establishment of an information management framework will work towards establishing information and data standards in the public sector pharmaceutical supply chain to facilitate the exchange of information amongst the various stakeholders.

8. Medicines Procurement under NHI

This serves as a mere identification of what could be described as the critical elements of a medicines procurement system under a health insurance system (NHI) for South Africa, based on what is known about such systems in general.

While there is no health insurance template within which South Africa's pharmaceutical services could be fitted to come out with the ideal procurement system under a national health insurance system, there have to be certain infrastructural, systemic, procedural and staffing prerequisites that would have to be observed by those providers of pharmaceutical services who would want to sell their services to the NHI authority.

By its very nature, a NHI system will seek to procure essential healthcare goods, including pharmaceuticals, of appropriate quality at the lowest possible cost. It would also want to ensure that the goods are available at all times in adequate quantities at all NHI-accredited facilities. It is inconceivable that the current decentralized system of medicines procurement will be retained. As it is, the various types of pharmaceuticals, including medicines and medical related items, are procured through the national tender system managed by National Treasury and through the 9 provincial tender processes. In addition, several vertical programmes are in existence, all of which makes it impossible to talk of a national pharmaceuticals budget. The inefficiencies linked with the existence of so many procurement authorities could be reduced drastically and at great savings to the national fiscus by substituting them with one central pharmaceutical procurement authority.

Therefore, a central authority, whether it is purely a pharmaceutical procurement agency or a NHI authority that purchases all sorts of health-related goods, would want to ensure that all procurement of pharmaceuticals on behalf of the NHI authority is coordinated and driven centrally, with accounting mechanisms being put in place in the provinces and, especially, in the tertiary hospitals.

This would be seen as the first requirement.

Secondly, the NHI authority would want to have as a basis an essential medicines list which would be standard for all facilities providing services to it, with the necessary provisions being in place for a specialized list of products to be available at tertiary institutions.

The authority would also want to see a close link between selection and what is procured.

It is also conceivable that any accreditation system put in place for pharmacies that are to be contracted to provide services to the NHI authority would be based on said pharmacies satisfying a set of infrastructural, systemic, procedural and staffing norms as already mentioned above. The basis for such a set of norms already exists in the form of the Good Pharmacy Practice (GPP) regulations published in terms of the Pharmacy Act. The Pharmacy Council is the custodian of pharmacy practice norms for the entire country.

An assumption that has to be made is that the NHI authority would want to have a uniform set of tariffs for services applying equally in public sector and private sector pharmacies, be they in retail or in the hospital setting. This would require that similar levels of compliance with GPP and other statutes be in place across the board. Thus, a lot of work will have to be done to ensure that infrastructure and service provision in the public sector hospital pharmacies are of the highest standards.

Management information systems will also have to be of the highest standard.

9. Medical Devices Procurement

Unlike pharmaceutical procurement which is characterized by various control and regulatory mechanisms, the acquisition of medical devices is very fragmented and there is currently no regulatory framework for the control of the use or procurement of medical devices in the country, despite several attempts by the NDoH at developing policy and regulations. A policy framework which was published in 2001 did not go beyond the publication stage. Health technology regulations were developed from 2003 in a consultative process that included all relevant stakeholders (the medical devices industry, healthcare providers, healthcare funders, the South African Bureau of Standards, the South African National Accreditation Services, the Department of Trade and Industry and academia, amongst others) and finalized in 2005.

Both these processes were intended to, inter alia, curb irrational expenditure on and use of expensive equipment, especially for diagnostic purposes as well as address the safety of medical devices. There has, however, been lack of progress with regard to implementation, which has led to the escalation of problems related to poor planning and lack of sound acquisition processes. As a result thereof, there is no standardization, each province has its own specifications, methodologies, processes and procedures for the procurement of medical devices. Yet, it is not evident that such processes and procedures are observed in any organized manner.

A case in point is the purchasing by Gauteng Province of two sophisticated Positron Emission Tomography and Computed Tomography (PET-CT) scanners for two academic hospitals situated within less than 50km of each other. The scanners are used to assist doctors in the early diagnosis of cancer and assessment of the spread of the disease. The first one was supplied to and installed at the Charlotte Maxeke Johannesburg Academic Hospital in October 2008, while the second one

was supplied in September/October 2009 to the Chris Hani Baragwanath Hospital at a total cost of R36 million(21), reportedly twice the price of the first one due to the second one being an upgrade on the first one. Given the estimated cost of about R14,000 per scan and the report that scans would, therefore, not be performed routinely for all cancer patients, the question has to be posed why the province found it necessary to purchase two such pieces of equipment for two of its hospitals. It was also reported at the time that this brought to seven, 3 in the State sector, the number of such scanners installed by one company in South Africa.

Information available to the Task Team was that this was a very sophisticated market which was prone to abuse. Concerns addressed by the South African Medical Devices to the MPTTT included the following(22):

- Product/service specifications are inappropriate to the most cost effective usage outcomes.
- Product specifications are often outdated and this prevents the introduction of newer, better technology.
- Innovative, cost effective and clinically effective devices not entering public market
- Specifications are company/brand specific
- Poor forecasting capabilities, (lack of historical consumption data) resulting in inaccurate estimated quantities
- Fixed period tenders are extended beyond expiry date or indefinitely. Results in buyouts and increased costs to government.

As mentioned earlier, The Task Team found it best not to spend any considerable amount of time on medical devices procurement, given the little time at its disposal and the fact that a special advisor had recently been appointed in the NDoH to attend to the dearth of policy and controls related to the health technology programme, one of the aims of which is to complete the medical devices regulations.

According to the advisor, it is intended for medical devices to be regulated at 3 levels, as follows(23):

LEVEL 1 - MARKET LEVEL, which includes the following:

- Issues of safety and performance;
- Risk Classification;
- Quality systems, setting of standards and harmonization issues where necessary;
- Good Manufacturing Practices (again where necessary)
- Post Market Surveillance, etc

LEVEL 2 - ADOPTION AND SELECTION, which will address

- Needs Assessment
- Health Technology Assessments
- Acquisition (Cost effectiveness/Benefit issues and other issues of costing in general)
- Alternative care/technologies
- Sales
- Advertising and
- All other considerations to address the upward spiraling cost of technologies.

LEVEL 3 - UTILIZATION AND DISPOSAL:

- User training and skill
- HT Related Clinical Practice Guidelines
- Good Management Practices (including maintenance).

10. Recommendations

10.1 Finance, Funding and Procurement: Proposal for a Central Pharmaceutical Procurement Agency (CPPA)

Medicines procurement, more than just being the simple act of buying, encompasses a complex range of operational, business, information technology, safety and risk management, and legal systems, all

designed to work in unison to address the health system's needs. The system or organization for medicines procurement must determine, accredit, and monitor appropriate supply sources; evaluate suppliers' performance; choose a buying strategy or approach; monitor medicines delivery; assess clinical and use outcomes and evaluate new products and the market(3).

All of the above functions are best achieved if overseen by one central body, as opposed to the current situation whereby responsibilities for medicines procurement are fragmented and some of the key functions are performed by entities whose major functions are not in the healthcare arena.

- The establishment of a central authority within the NDoH, responsible for all issues related to medicines (including ARVs) selection, procurement, distribution and use, is hereby proposed. For purposes of the proposal and for ease of reference, the authority shall be referred to as the Central Pharmaceutical Procurement Agency (CPPA). It may form a key part of the Pharmaceutical Policy and Planning Cluster, or take over its entire responsibilities, pending a restructuring exercise to decide on the best way of accommodating the proposed structure in the NDoH.

It is proposed that the CPPA have the following responsibilities:

- Manage financial allocations to the provinces for all pharmaceutical purchases, in close consultation with National Treasury. In this respect, work closely with provincial pharmaceutical services and provincial treasury departments to assist them with budget-setting and determination;
- Manage procurement contracts on behalf of the provinces, using a combination of tender processes and price negotiation with suppliers. It will be responsible for the writing of product specifications for tender submissions. It will provide oversight over the payment of suppliers of pharmaceutical and pharmaceutically related goods and services. The recommendation is for payment for services and goods to be handled centrally by the CPPA. NT's concerns about centralizing payment have been noted, but a comparison of the pros and cons tends to support centralization of payments.

- Determine a national procurement list which will form the basis for all procurement in the public sector facilities. To this end, the CPPA will have special representation from the National EML Committee, through which it will receive inputs from provincial PTCs;
 - Have a sub-committee which will have oversight over pharmaceutical expenditure in tertiary institutions. This sub-committee will, inter alia, liaise with funders and suppliers in risk-sharing and conditional re-imburement arrangements;
 - Establish a unit responsible for price monitoring and risk analysis and which will also monitor corrupt and collusive practices;
 - Coordinate and manage all donor funding and donations for pharmaceutical and medical items;
 - It may, eventually, be the responsible body for the procurement of all pharmaceutical services and goods on behalf of the NHI authority.
- A Cost-Benefit Analysis (CBA) is recommended to justify the viability and cost-savings of such an agency.
 - To enable the establishment of this entity, it is recommended that a conditional grant be established that will provide for the procurement of all pharmaceutical goods and services for the public sector, including pharmaceuticals, pharmaceutical related items, vaccines and medical devices. It is recommended that all attempts be made by the NDOH to allocate as much of the total amount requested as possible, as the consequences of shortfalls often include patients not being able to continue on treatment. In return, NDOH should look at imposing more stringent reporting and accounting requirements on the provinces to ensure, among others, that there are no deviations from the expenditure mandate.

- It is recommended that the budget for ARVs be ring-fenced as part of the national pharmaceutical budget which would be controlled centrally under the envisaged CPPA. Crucially, disbursements to the provinces would still have to be on the basis of submissions from the provinces.
- Business plans presented to the NDOH have to be preceded by cooperation among the provincial units centrally involved in the HIV and AIDS arena. To this end, it is strongly recommended that Pharmaceutical Services, CCMT and HAST units in the provinces be urged to work together.
- The procurement of certain high-cost ARVs on the international market is supported if this is going to ensure that the available funds are stretched enough to ensure more people get onto the treatment programme. A more detailed health economics analysis would be required to ensure the cost-benefit of such a recommendation
- It is recommended that NDOH approach NT with a proposal to investigate the feasibility of the removal of VAT on medicines. This is a growing trend among developing nations.
- It is recommended that, in line with the recommendation for the establishment of the CPPA, all provincial tender boards cease the handling of tenders for pharmaceuticals and medical related items. The benefits of having one central procurement authority, as opposed to several, have already been alluded to, and include the ability to pool scarce national resources into the one authority that would handle all national procurement.

10.2 Industrial Policy and the Supply of Medicines

- The value of the presence of the pharmaceutical manufacturing industry in the country cannot be over-emphasised. This refers to both the multinational and locally-owned manufacturers. Government needs to devise a unified strategy in its approach to the industry. The tensions between the desire to grow the local industry (Industrial Policy Framework) and the Constitutional

mandate of the Health Minister to provide healthcare to the citizens of the country and do so cost-effectively, have to be resolved. As has been suggested elsewhere in this report, a meeting of minds among the Government departments having a stake in medicines procurement is not impossible, and should be pursued with vigour. This would allow government departments, in their dealings with the pharmaceutical industry, to engage the industry with one voice.

- It is imperative that a forum be established that will enable all the stakeholders involved in providing or supporting the provision of medicines an opportunity to engage Government on an on-going basis. This will provide a platform for either side to table matters that, in their view, will strengthen the relationship between the two parties. It is recommended that such a forum be convened quarterly.
- The PPPFA and its regulations raise the difficult issue of a potential conflict between the State's industrial policy and its healthcare objectives. While the aims and objectives of the national industrial policy framework and the preferential procurement framework may ordinarily be considered to be reasonable and justifiable, they are problematic in cases where they impose obligations on the NDOH that may undermine access to healthcare services. In short, they cannot be justified to the extent that they require the use of limited health resources to advance legitimate Trade and Industry, Science and Technology and/or Treasury interests, and thereby limit the NDOH's ability to discharge its constitutional mandate.

It is recommended that the State seek other ways to advance these potentially competing interests. For example, there is nothing in law preventing the Department of Trade and Industry from providing incentives upfront to local producers of medical products. In addition, the Minister of Finance has the power to table amendments to tax laws that similarly grant incentives to such products. Further, as has already been indicated above, local producers and/or BBBEE suppliers can and should be awarded contracts by the NDOH over competitors in circumstances that do not result in effective subsidies being granted for higher priced medical products.

It is recommended that this conflict be addressed as a matter of urgency. To that end, the departments of Health, Trade and Industry, Science and Technology and National Treasury need to convene a forum where conflicts between and among the different Government policies and objectives can be debated with a view to finding lasting solutions to the conflicts.

10.3 Procurement

- It is recommended that NT cede contract management for pharmaceuticals to the NDOH in line with the recommendation for the establishment of the CPPA within the NDOH.
- It is recommended that, in line with the recommendation for the establishment of the CPPA, all provincial bodies responsible for the management of tenders cease the handling of tenders for pharmaceuticals and medical related items.
- it is recommended that direct price negotiations form part of the procurement strategy of Government. This is advised particularly in situations where there are only one or two suppliers of a particular essential product and the probability of price competition is less likely.
- It is recommended that a forum be established which would have representation from all the stakeholders involved in providing or supporting pharmaceutical services in one way or the other. The forum would be convened by the PPP Cluster and meet, say, quarterly.
-

10.4 Warehousing and Distribution

- It is recommended that medicines depot be accountable to the provincial pharmaceutical services and that a suitably qualified financial manager be deployed in the depot.
- It is recommended that all outsourcing contracts for medicines depot services be reviewed before any extensions are considered, and that no new bids be invited for outsourcing until such time that the reviews have taken place and provinces are clearly in a position to satisfy the requirements for monitoring and assessment as specified in the Treasury guidelines/regulations for PPPs.
- it is recommended that an in-depth cost-benefit analysis be undertaken of currently outsourced services of procurement, warehousing and distribution. In particular, the mechanisms applied by the private warehousing contractors to charge for their services should be scrutinized to ensure that the State is not disadvantaged by such an arrangement.

- Central dispensing units, similar to the one in the Western Cape should be given serious consideration by health authorities who want to improve service delivery.
- The above recommendations relating to improvement of the management of the depots notwithstanding, it is the view of the Task Team that the depots are costly and inconvenient intermediaries in the chain intended to ensure that medicines reach the facilities where patients receive treatment. The alternative recommendation, and certainly the one preferred by the Task Team, is for the gradual phasing out of the provincial depots while a solution is sought to service the PHC facilities and to strengthen the storage and logistics capacity of the hospitals.
- It is recommended that the national and provincial health departments investigate ways in which chronic medicines could be supplied to patients either through community (retail) pharmacies or by direct delivery.

10.5 Information Technology

The following key recommendations are made to improve the information technology situation in the pharmaceutical supply chain:

- **Development of national pharmaceutical data management standards:** This would facilitate the ease with which information is exchanged across the entire supply chain and improve visibility of transactions and material flow along the supply chain.
- **Consolidation of the number of technologies used:** The public sector has an excessive dependence on external vendors for information management as a result of the disparate skills required to support and manage the myriad of technologies in use. Consolidation of these platforms can lead to a decrease in the total cost of ownership of the technologies that are used as enablers in the public sector supply chain.
- **Improved software integration across the supply chain:** Ease of information sharing and exchange is one of the pre-requisites for transparent visibility across the supply chain. Improved integration of software will facilitate the ease of information sharing and exchange and the resultant improvement in managing pharmaceutical availability.

- **Introduction of innovative technology to facilitate product tracking and picking:** Newer technologies such as radio frequency identification tags and other warehouse automation technologies should be considered to improve the effectiveness and efficiency of government owned depots.
- **Replacement of outdated technology at depot level:** Should the depots remain, the outdated legacy systems at the MEDSAS depots should be replaced. The feasibility of the Oracle-based solution that has still not successfully been implemented should be reviewed for appropriateness.
- **Introduction of a centralised management information warehouse:** Access to reliable information in a timely manner is one of the critical success factors in managing an effective and efficient supply chain. The current fragmentation in information stores and the cumbersome processes involved in obtaining a consolidated view is seriously hampering planning and decision-making in the supply chain. A centralised management information warehouse would facilitate informed decision-making and increase visibility of problems along the supply chain.
- **Development of a pharmaceutical supply chain information management framework:** The establishment of an information management framework will work towards establishing information and data standards in the public sector pharmaceutical supply chain to facilitate the exchange of information amongst the various stakeholders.

10.6 Human Resources

- It is recommended that, together with the conducting of a cost-benefit analysis in relation to the establishment of the CPPA as recommended under Section 7.1, a restructuring exercise be carried out that will lead to the existing PPP and envisaged CPPA functions being harmonised into one structure within the NDoH. This should also include a staffing norms exercise to determine the staffing requirements of the cluster and a strategy to ensure that suitably qualified candidates will be attracted.
- it is recommended that all the necessary legal and administrative steps be taken for the establishment of the pharmacy technician course and provision for the first intake of trainees by the beginning of 2011.
- It is recommended that provinces strive towards the attainment of uniformity in the organisation and structure of pharmaceutical services. Thus, based on the preceding arguments, the provincial

pharmaceutical services should be located at the level of directorate, which is already the case in 7 of the provinces. The medicines depots and all other structures providing services of a pharmaceutical nature should be placed under the direct and full responsibility of pharmaceutical services. Such uniformity in structure and authority will stand the public sector in good stead in the event that national health insurance is introduced and the responsible authority formulates guidelines for the participation of facilities.

- It is recommended that a study project be undertaken to determine the total numbers of human resources involved in providing pharmaceutical services in both the public and private sectors in South Africa, including the Department of Health, Correctional Services, South African Military Health Services, municipalities, NGOs, the pharmaceutical manufacturing industry, wholesale, pharmacy schools, research institutions, the medicines regulatory authority and the Pharmacy Council, to extrapolate future pharmaceutical HR requirements and staffing norms and develop short- and long-term strategies to arrive as close to future requirements as possible.

11. Conclusion

The Task Team has put together a set of recommendations based on an in-depth analysis of the problems and challenges besetting the medicines and medical devices procurement systems in the country's public sector. The assignment specifically required of the Task Team to come up with solutions to the public sector's procurement problems, but procurement does not occur in isolation. It is for this reason that it was mentioned upfront that the design of the methodology took into account that procurement was but one of a number of inter-linked functions of the supply chain management for pharmaceuticals. Key elements of the chain include selection policies, financing mechanisms, distribution policies and rational use of medicines. All of these exist within a given policy framework and require management support and, crucially, political will. These are fundamental ingredients to ensuring that essential medicines of good quality are made available to those who require them, at affordable cost and in constant and sustainable supply.

When a nation commits itself to achieving all of the above, such intent is expressed in a written policy that is normally referred to as the National Drug/Medicines Policy. Any improvements effected to medicines procurement in isolation and without taking into consideration the other links in the supply chain, are unlikely to have a long-lasting impact on the healthcare system.

It is thus worth mentioning that current pharmaceutical services policies have their foundation in the National Drug Policy (NDP) which was adopted by the Government as its policy in 1996. By its very nature, the NDP has to be reviewed periodically to ensure that it keeps up with trends and developments. The predecessor to this Task Team, the MPTTT, was tasked with carrying out a review of the NDP and all issues related to medicines use and production in the country. Its existence was, regrettably, short, but it was able to compile a list of issues that needed to be followed up in the future. The MPTTT recommendations are carried at the end of this report as Appendix E. This is done with a view to ensuring that the bigger picture within which the procurement of medicines and medical devices is located receives the necessary attention.

The Task Team has not provided any blue-print on how the recommendations should be implemented, if they are found acceptable. A lot of work would still have to be done within the NDoH with the support of the provinces. What needs to be emphasized above everything else is that, without the requisite human resources, the ideals being supported by the recommendations may never be realized.

References

1. **The World Bank:** *Country Procurement Assessment Report: South Africa, Volume 1: Summary of Findings and Recommendations*, February 2003.
2. **Bowersox, Closs and Cooper.** *Supply Chain Logistics Management*, 3rd Edition. s.l.: McGraw Hill, 2010.
3. *Current status of medicines procurement.* **E. Ombaka.** 66(Suppl 3): S20-8, s.l.: Am J Health-Syst Pharm, 2009.
4. **Scherer, Frederick M. and Jayashree Watal.** *Post-TRIPPS Options for Access to Patented medicines for Developing Countries.* S.l.: Working Group 4 of Commission on Macroeconomics and Health, 2001.
5. *Parallel Trade in Pharmaceutical Products: Implications for Procuring Medicines for Poor Countries.* **Maskus, Keith E and Mattias Ganslndt.** London: The Economics of Essential Medicines, Royal Institute of International Affairs, 10 July 2002.
6. *Ensuring uninterrupted antiretroviral therapy in resource-poor settings.* **Anthony D Harries, et al.** s.l.: Bulletin of the World Health Organization, 2007, Vols. 85:152-155.
7. **Barillas, Edgar.** *Pharmaceutical system performance within the context of health sector reform.* Report No. 70. S.l.: Latin America and Caribbean Regional Health Sector Reform Initiative., May, 2005.
8. **WHO/PATH** Project Optimize, *Landscape analysis of EVSM Indicators*, February 2008.
9. **National Department of Health, South Africa,** *National Tertiary Services Grant*, Budget Bid 2010/11, 19 August 2009.
10. Written response to the Task Team by Mr W. Mathebula, National Treasury, South Africa, February 2010.
11. Interview with Prof P Ruff, Head of Oncology, University of the Witwatersrand Medical School, Johannesburg, South Africa.
12. **Institutional Pharmacy Management (Pty) Ltd** submission to Task Team, November 2009.
13. **Carapinha, J.** (2008) *An Integrated Approach to HIV/AIDS Services in South Africa: Private Pharmacies and Policy Recommendations.* Africa Policy Journal, Spring/Summer 2008 Edition. Volume 4. Available at: www.hksafricapolicyjournal.com/issues/volIV/carapinha
14. Submission to Task Team by Directorate Affordable Medicines, NDoH, November 2009.
15. Technical document presented at South African National EDL Committee meeting on 4th March 2010 in preparation for the review of the musculo-skeletal system chapter of the STGs.
16. Interview with Dr N Dlamini, A/Director, HIV & AIDS, NDoH.
17. Presentation to South African Ministry of Health by Dr H Hogerzeil, WHO, November 2009.

18. **Aspen Pharmacare**. *Analysis of the 2008 South African ARV tender*, November 2009.
19. Submission by Andre Kudlinski, Department of Trade & Industry, to MPTTT, March 2009.
20. Task Team discussion of IMSA/PIASA PTG Tender Pricing Project with IMSA and PIASA executives, January 2010.
21. Article in **The Star** newspaper, Johannesburg, 6 October 2009.
22. Submission of SAMED to MPTTT, March 2009.
23. Discussion with Ms N Moicq̄la, special advisor to NDoH on health technology, February 2010.

Appendix A - Questionnaires

Questionnaires were prepared for each of the focus groups that were identified as stakeholders in the public sector pharmaceutical supply chain. The depot questionnaire contained thirteen dimensions, namely structure, selection, quantification, procurement, ordering, storage and stock, distribution, quality assurance, rational use, financing, information, monitoring and evaluation and private contractors. An excerpt of the depot questionnaire is shown below.

Section B: SELECTION OF PRODUCTS	
B.1.	Are procurements at the PMD limited to the national and/or provincial EML?
Comment	<input type="text"/>
B.2.	if no, please state the reasons
<input type="text"/>	
B.3.1.	Which products are procured out of the EML and why?
Product	Reason
<input type="text"/>	<input type="text"/>

8.3.2. Who authorises the procurement of products out of the EML and what process is followed for this authorisation?

Designation of authority	Process followed
<input type="text"/>	<input type="text"/>

8.4 Who authorises the procurement of products out of the national tender system and what process is followed for this authorisation?

Designation of authority	Process followed
<input type="text"/>	<input type="text"/>

8.5. Which contracts of products were procured on provincial tender during 2007/2008? And why?

Contract	Actual figures	
	Rands	Units
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	

8.6. Which contracts of products were procured on provincial tender during 2008/2009? And why?

Contract	Actual figures	
	Rands	Units
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	
<input type="text"/>	<input type="text"/>	<input type="text"/>
Reason	<input type="text"/>	

Appendix B - Institutions, Companies & Organizations Surveyed

List of institutions, companies, officials and organizations that were interviewed, assessed, responded to questionnaires or whose documentation was consulted for purposes of the Task Team’s objectives

1. Public Sector Academic Hospitals (pharmacy departments)

Western Cape: Groote Schuur Hospital, Red Cross Children’s Hospital;

Kwa-Zulu Natal: Nkosi Albert Luthuli Hospital;

Gauteng: Steve Biko Hospital, Chris Hani Baragwanath Hospital, Charlotte Maxeke Hospital;

Free State: Universitas Hospital;

The Head of Oncology at Charlotte Maxeke was also interviewed.

2. ‘Provincial’ Hospitals (pharmacy departments)

North West: Mafikeng;

Mpumalanga: Rob Ferreira;

Free State: Pelonomi;

Northern Cape: Kimberley Hospital Complex;

Limpopo: Mankweng Hospital Complex;

Eastern Cape: Cecilia Makiwane.

3. Medicines depots

All 10 provincial depots (one in each province and two in the Eastern Cape - these 2 were not assessed physically owing to the absence of a pharmacist to facilitate the interviews, the Chronic Dispensing Unit and the ARV depot, both in the Western Cape, and the eThekweni Metro depot in Durban. Time constraints did not allow for more metro depots to be included.

4. Provincial HAST Managers

Six were chosen, on the basis of the level of organization of the ARV programme in the province: Western Cape (seemingly most organized), Kwa-Zulu Natal (the highest number of patients enrolled for treatment), Free State and Mpumalanga (most challenged) and the Eastern Cape (this province was added in error, but it could be classified as 'moderate').

5. Heads of Pharmaceutical Services (HOPS) in all 9 provinces and Supply Chain Management (SCM) officials in the provinces where the medicine depot reports to SCM (Free State and Western Cape)

6. National Government

NDOH: The Director: Affordable Medicines and the A/Director: HIV & AIDS
NT: Mark Blecher

7. Pharmaceutical Distributors

UTi and PHD.

8. Pharmaceutical Manufacturers

Aspen Pharmcare, Adcock Ingram, Cipla Medpro, Bristol-Myers Squibb, Abbotts, Sonke, Aurobindo, Pharmbili, Sanofi Aventis.

9. Documents submitted to the MPTTT by the following organizations:

Innovative Medicines South Africa (IMSA), National Association of Pharmaceutical Manufacturers (NAPM), National Association of Pharmaceutical Wholesalers (NAPW), Pharmaceutical Industry Association of South Africa (PIASA), , Pharmaceutical Association of South Africa (PSSA), South African Medical Devices Industry of South Africa (SAMEDI) and the United South African Pharmacies (USAP).

Appendix C - Complete Tracer Product Pricing

No	Tracer Products	Description [manufacturer code]	Province								
			E Cape	Free State	Gauteng	KZN	MP	Limp	North West	W.Cape	
1	Adrenaline injection	ADRENALINE ACID T INJ AMP 1MG 1ML X10 [FK2]	11.23			10.4	11.86	10.46	10.01	9.87	11.78
		ADRENALINE INJ IM AMP 1MG 1ML X1 [UNB]					1.1				1.13
2	Amoxicillin 125mg suspension	AMOXYCILLIN SYRUP 125MG 100ML X1 [UNB]	5.44	4.01	3.98	4.12	3.44		3.29	4.64	4.44
		AMOXYCILLIN SYRUP 125MG 75ML X1 [UNB]	3.53						3.31		3.41
		ZOXIL SUSP 125MG 100ML X1 [M/G]							7.41		
3	Amoxicillin 250mg capsules	AMOXICLLIN CAPS 250MG 0 X100 [CP5]	21.37	21.75	19.67	20	18.55	20.19	17.1	19.95	
4	Beclomethazone inhaler	BECLATE INHA 100Y 0 X200 [CD8]			37.97		39.17			34.65	
		BECLATE INHA 50Y 0 X200 [CD8]	22.92		22.25		32.78	16.87			
5	Carbamazepine tablets	CARBAMAZEPINE TABS 200MG 0 X100 [UNB]				18.92				17.95	
6	Co-trimoxazole susp 125mg/5ml	COTRIMOXAZOLE SUSP 0 100ML X1 [UNB]	2.26	3.07	3.16						2.71
		COTRIMOXAZOLE SUSP 0 50ML X1 [UNB]	1.56	2.54							2.06
7	Co-trimoxazole tablets	ADCO-COTRIMOXAZOLE TABS 0 0 X20 [AOJ]	7.04								
		COZOLE TABS 0 0 X100 [RBY]						7.5	7.42	10.85	
		COZOLE TABS 0 0 X500 [RBY]						37.49	37.51		
		COTRIMOXAZOLE TABS 0 0 X1000 [UNB]									100.46
		CO-TRIMOXAZOLE TABS 480MG 0 X1000 [UNB]	183.35	57.86	107.46	87.2	94.29	107.29	111.79	75.57	
		PURBAC TABS D 5 960MG 0 X30 [A&G]	9.85				8.61				
8	Efavirenz tablets/capsules	ADCO-EFAVIRENZ CAPLETS 600MG 0 X30 [AOJ]			114.01	117.25	100.54	104.39	100.41	126.84	
		ASPEN EFAVIRENZ TABS F.C 600MG 0 X30 [A&G]			119.29	121.72	103.35	106.21	109.16	124.18	
		EFAVIRENZ CAPS 200MG 0 X90 [UNB]				142.5				283.55	
		EFAVIRENZ CAPS 50MG 0 X30 [UNB]			20.68	24.74	31.14		27.35	27.19	
		EFAVIRENZ TABS 600MG 0 X30 [UNB]								146.29	
		STOCRIN CAPS 200MG 0 X90 [MSD]			280.68	303.98	250.01	248.32	254.61	284.9	
		STOCRIN CAPS 50MG 0 X30 [MSD]			26.66	32.6	23.89	23.26	25.68	26.97	
		STOCRIN TABS 200MG 0 X90 [MSD]								409.52	
9	Furosemide injection	STOCRIN TABS 600MG 0 X30 [MSD]			161.28	104.13	142.62	143.68	143.38	107	
9	Furosemide injection	FUROSEMIDE INJ AMP 20MG 2ML X1 [UNB]				0.76				0.82	
		FUROSEMIDE INJ AMP 20MG 2ML X10 [A&G]	8.33	8.13	7.8	8.58	6.94	7.41	7.9	8.47	
		FUROSEMIDE INJ AMP 20MG 2ML X10 [FK2]				51.06				29.3	
		FUROSEMIDE INJ AMP 250MG 25ML X10 [FK2]	128.94		130.18		111.4	115.13	111.4	129.89	
		FUROSEMIDE INJ AMP 250MG 25ML X1 [UNB]				12.38				12.64	
		LASDX AMPS 10MG 5ML X1 [S.A]								4.3	
		LASDX INJ AMP 10MG 5ML X10 [S.A]						6.8			
		MICRO-FUROSEMIDE INJ AMP 20MG 2ML X10 [M-H]				7.7	6.74		6.74		
		SABAX FUROSEMIDE INJ AMP 20MG 2ML X10 [ACC]	8.43	8.86	8.3	8.7	7.72	7.74	7.61	8.84	
		10	Furosemide tablets	BEURISES TABS 40MG 0 X250 [RBY]							12.2
10	Furosemide tablets	FUROSEMIDE TABS 40MG 0 X250 [UNB]	7.8	8.93	8.93	6.89		8.47	10.38	8.8	
		LASDX TABS 20MG 0 X30 [S.A]									
		LASDX TABS 40MG 0 X250 [S.A]								285	
		LASDX TABS 40MG 0 X30 [S.A]						50			
		LASDX TABS 500MG 0 X100 [S.A]			721.49	721.48	632.89	632.89	632.88		
11	Glibenclamide tablets	GLYCOMIN TABS 5MG 0 X100 [A&G]		4.42	4.49			4.09		4.43	
		GLYCOMIN TABS 5MG 0 X30 [A&G]							1.32	1.56	
		GLYCOMIN TABS 5MG 0 X500 [A&G]	17.08		17.89	17.77			16.36	17.76	
12	Hydrochlorothiazide tablets	HEXAZIDE TABS 25MG 0 X100 [S/Z]	18.81							17.81	
		RIDAQ TABS 12.5MG 0 X30 [A&G]								0.92	
		RIDAQ TABS 25MG 0 X30 [A&G]			0.99		0.87	0.82	0.93	1.01	
		RIDAQ TABS 25MG 0 X500 [A&G]	17.51	16.33	16.75	17.21		15.62	14.81	16.57	
13	Insulin Isophase	RIDAQ TABS 50MG 0 X500 [A&G]								78.87	
13	Insulin Isophase	INSULIN ACTRAPID INJ SC PENFL 100IU 3ML X5 [N-N]					97.9				
		INSULIN ACTRAPID PENSET 100IU 3ML X5 [N-N]	142.9	148.26	142.9	146.99	126.66	129.11	133.71	146.61	
		INSULIN ACTRAPID VIAL 100IU 10ML X1 [N-N]	35.19	37.74	33.63	35.3	29.83	30.94	30.1	35.52	
		INSULIN PROTAPHANE INJ SC PENFL 100IU 3ML X5 [N-N]					99.85			142.9	
		INSULIN PROTAPHANE INJ SC PENST 100IU 3ML X5 [N-N]	142.9	148.26	142.9	146.99	125.35	129.11	128.49	146.78	
		INSULIN PROTAPHANE VIAL 100IU 10ML X1 [N-N]	34.09	35.27	33.63	34.8	29.73	30.53	30.1	35.42	
14	Lamivudine tablets	ADCO-LAMIVUDINE TABS F.C 150MG 0 X60 [AOJ]			32.49		31.57		31.57	42.61	
		ASPEN LAMIVUDINE TABS 150MG 0 X60 [A&G]	29.88		34.02	34.26	31.3	30.57	30.81	36.13	
		3TC TABS 150MG 0 X60 [GSK]			47.61	47.87	37.66	39.49	41.33	40.22	
		CIPLA-LAMIVUDINE TABS 150MG 0 X60 [CD8]				43.5	46.8				
14	Lamivudine tablets	CIPLA-LAMIVUDINE TABS F.C 300MG 0 X30 [CD8]			42.5			37.28		43.93	
		LAMIVUDINE TABS 150MG 0 X60 [UNB]								38.5	
15	Metronidazole injection	FLAGYL VIAL 0.5% 100ML X1 [S.A]	4.27	4.9	4.06	4.43	3.88	3.88	3.71	4.29	
		METRONIDAZOLE AMPS 500MG 100ML X1 [UNB]	5.1							4.35	
		METRONIDAZOLE-FRES INFUSION BAG 500MG 100ML	4.14	4.43	4.1	4.36	3.77	3.78	3.71	4.33	
16	Nevirapine tablets	ADCO-NEVIRAPINE TABS 200MG 0 X60 [AOJ]			42.84						

		ASPEN NEVIRAPINE TABS 200MG 0 X60 [A&G]	31.02		35.58	37.5	34.08	34.17	33.22	39.45
		CIPLA NEVIRAPINE TABS 200MG 0 X60 [CD8]						54.39		
		VIRAMUNE TABS 200MG 0 X60 [B.I]			0.01	0.01				394.08
17	Oxytocin injection	OXYTOCIN AMPS 10IU 1ML X1 [UNB]								5.95
		OXYTOCIN AMPS 5IU 1ML X1 [UNB]								5.84
		SPEC-OXYTOCIN AMPS 10IU 1ML X10 [SC2]	46.19	46.93	46.25	47.54	41.65	41.5	41.3	51.35
		SYNTOCINON INJ AMP 10IU 1ML X5 [NVR]	30.15	31.31	29.85	30.43	26.68	26.67	26.98	28.62
		SYNTOCINON INJ AMP 5IU 1ML X5 [NVR]	31.29	31.1	29.95	30.27	26.56	26.55	26.55	30.93
18	Paracetamol 500mg tablets	PACIMOL TABS 500MG 0 X10 [AUL]					0.72		0.72	0.7
		PACIMOL TABS 500MG 0 X100 [AUL]	5.71	6.42	6.03	6.31	5.72	5.37	5.97	5.89
		PACIMOL TABS 500MG 0 X1000 [AUL]	20.52							
		PACIMOL TABS 500MG 0 X500 [AUL]	30.23	25.15			30.19			40.23
		PARACETAMOL TABS 0 0 X5000 [UNB]	218.65	261.22	185.1	236.24		203.79	250.86	
		PARACETAMOL TABS 0.5G 0 X100 [UNB]			9.12	4.9	8.32		22.09	6.79
19	Paracetamol syrup	PAINADO PAED SYR 0 100ML X1 [ADD]			8.09					
		PARACETAMOL SYRUP 0 100ML X1 [UNB]	2.43	2.52	2.13	2.51	2.05	2.16	2.04	2.28
		PARACETAMOL SYRUP 0 500ML X1 [UNB]	11.13	9.5		10.76	8.67	10.46	9.54	
		PARACETAMOL SYRUP 120MG 0 X1 [UNB]							1.88	3.25
20	Perindopril tablets	PREXUM TABS 4MG 0 X30 [BG.]	14.41		14.26		12.56	12.65	13.06	12.86
21	Phenytoin capsules	PHENYTOIN SODIUM CAPS 100MG 0 X1000 [A&D]						353.23		
		PHENYTOIN SODIUM CAPS 100MG 0 X1000 [A&G]	381.29	368.82	379.18			337.34	369.31	377.18
22	RHZE									
23	RIF/INH 150/175	RIMACTAZID TAB 150/75 150MG 0 X56 [S/Z]						28.37	30.91	31.02
		RIMACTAZID TAB 150/75 150MG 0 X84 [S/Z]					36.15	39.53	37.57	
24	RIF/INH 60/30	RIMACTAZID PAED T 60/30 60MG 0 X28 [S/Z]						11.07		11.8
		RIMACTAZID PAED T 60/30 60MG 0 X56 [S/Z]					21.8	22.12	21.44	23.67
		RIMACTAZID PAED T 60/30 60MG 0 X84 [S/Z]						32.33	33.72	
25	Ringers Lactate									
26	Salbutamol inhaler	ASTHAVENT INHA 0.1MG 0 X200 [CD8]	11.65							
		ASTHAVENT INHALER 0.1MG 0 X300 [CD8]	15.21	15.99	15.68	16.02	13.89	14.8	14.55	15.88
		SALBUTAMOL INHA 100Y 0 X300 [UNB]								15.39
27	Stavudine capsules	ASPEN STAVUDINE CAPS 15MG 0 X60 [A&G]			16.95		17.53		15.99	19.42
		ASPEN STAVUDINE CAPS 20MG 0 X60 [A&G]			18.69	18.81	1.7	17.32	16.6	19.21
		ASPEN STAVUDINE CAPS 30MG 0 X60 [A&G]			19.32	19	16.92	17.08	17.3	20.95
		STAVIR CAPS 30MG 0 X60 [CD8]			27.07	27.07	23.87	23.75	26.71	23.98
		STAVIR CAPS 40MG 0 X60 [CD8]						25.81		
		STAVUDINE CAPS 15MG 0 X60 [UNB]								19.28
		STAVUDINE CAPS 20MG 0 X60 [UNB]								19.46
		STAVUDINE CAPS 30MG 0 X60 [UNB]					15.48			21.8
		STAVUDINE CAPS 40MG 0 X60 [UNB]								27.07
		ZERIT CAPS 30MG 0 X60 [BSE]					39.15		39.15	
28	Streptomycin 1g injection	BIO-STREP VIAL 1G 3ML X1 [BTH]	4.63	4.68	4.72	4.58	4.04	18.9	4.04	5.04
29	Streptomycin 5g injection	BIO-STREP VIAL 5G 15ML X1 [BTH]	22.53		22.53	22.53	9.4	8.38		16.04
		SOLUSTREP VIAL 5G 15ML X1 [CPS]	9.44	9	8.49	9.03	7.68	7.79	8.09	9.08

Appendix D - Legislative Framework Analysis

INTRODUCTION

The procurement of medical products takes place within a general legislative framework comprised largely of the Constitution of the Republic of South Africa, 1996 (“the Constitution”), non-health specific statutes purportedly designed to give effect to the relevant constitutional provisions, and regulations aimed at fleshing out and giving effect to these statutes. Whilst often considered as cast in stone, this framework can and should be reviewed to consider its impact on public health needs, policies and programmes, and, if necessary, amended.

This section of the report considers this framework and what it means for a procurement system designed to assist the state in discharging its constitutional obligations in respect of the right to have access to health care services (which includes a right to have access to medical products). In particular, this section focuses on the following issues:

- A description of the legislative framework for the procurement of all goods and services by the state (“the legislative framework”);
- Implications of the legislative framework for the procurement of medical products; and
- A consideration of how to reconcile the potential conflict between government’s industrial policy and health care objectives and obligations.

LEGISLATIVE FRAMEWORK

This part deals with relevant provisions of the Constitution and key statutes and regulations. It is largely descriptive in nature, being followed in the next part by an analysis of the implications of the legislative framework for the procurement of medical products by the state.

The Constitution

Procurement is expressly addressed in section 217 of the Constitution of the Republic of South Africa, 1996 (“the Constitution”), which provides as follows:

- (1) When an organ of state in the national, provincial or local sphere of government, or any other institution identified in national legislation, contracts for goods or services, it must do so in accordance with a system which is fair, equitable, transparent, competitive and cost-effective.
- (2) Subsection (1) does not prevent the organs of state or institutions referred to in that subsection from implementing a procurement policy providing for:
 - (a) categories of preference in the allocation of contracts; and
 - (b) the protection or advancement of persons, or categories of persons, disadvantaged by unfair discrimination.

- (3) National legislation must prescribe a framework within which the policy referred to in subsection (2) must be implemented.

Subsection (1) thus sets out the basic elements of any constitutionally acceptable system for the procurement of goods and services by an organ of state. Importantly, it makes no mention of a tender or any other specific procurement mechanism. In other words, any system of procurement is permissible provided it satisfies the principles of fairness, equity, transparency, competitiveness and cost-effectiveness, and is not in conflict with any other provision of the Constitution.

Subsection (2) expressly permits – but does not require – any chosen procurement system to implement a preferential procurement policy based on “categories of preference in the allocation of contracts” and “the protection or advancement of persons, or categories of persons, disadvantaged by unfair discrimination.” Subsection (3) requires national legislation to provide the framework for preferential procurement, which, if implemented nationally, provincially and/or at local government by an organ of state, must be done in accordance with this national framework.

In addition, the Constitution addresses procurement matters in section 216 dealing with treasury control. In particular, subsections (1) and (2) – which are of direct relevance to procurement – provide as follows:

- (1) National legislation must establish a national treasury and prescribe measures to ensure both transparency and expenditure control in each sphere of government, by introducing—
 - (a) generally recognised accounting practice;
 - (b) uniform expenditure classifications; and
 - (c) uniform treasury norms and standards.
- (2) The national treasury must enforce compliance with the measures established in terms of subsection (1), and may stop the transfer of funds to an organ of state if that organ of state commits a serious or persistent material breach of those measures.¹

Aside from sections 216 and 217, a number of other constitutional provisions are relevant to any discussion on the procurement of medical products. In the order in which they appear in the Constitution, these include – but are not necessarily limited to – the following:

- Section 7(1), which declares the Bill of Rights to be “a cornerstone of democracy in South Africa”;

¹ Subsections (3) through (5) deal in detail with stopping the transfer of funds to a province.

Appendix E – MPTTT Key

Recommendations

Area	Recommendations	Duration to complete
Review of NDP	<ul style="list-style-type: none"> • Conduct a stakeholder survey or interviews to assess if further aspects of the NDP have been implemented or assessed • Plans for continuous monitoring and recording of the implementation, successes and failures of the NDP • Significant changes required to update the NDP with regard to legislative requirements, pricing changes, human resource development, traditional medicines, research and development, local production and monitoring and evaluation. 	3 – 6 months
Strengthening human resource in the pharmaceutical sector	<ul style="list-style-type: none"> • Determining the appropriate minimum staffing norms for all hospital pharmacies, in both the public and private sectors. (to be overseen by the Office of Standards Compliance) <ul style="list-style-type: none"> – Based on the above, develop staff establishment numbers in all public sector hospitals • Finalise the OSD and in so doing, learn from the mistakes in implementing the nursing OSD in 2008 • Set special criteria to accredit the training courses that will be necessary to meet those criteria • Finalise the changes to the mid-level worker categories and ensure that training is moved from in-house to appropriate FET institutions (in essence, three levels are needed - basic, post-basic, that can dispense and work under direct supervision in hospitals, and then a technician who can work under indirect supervision at PHC level) • Strengthen the academic workforce and lobby with DoE for additional funding either to enlarge existing Pharmacy Schools or create new ones (the former option is preferable). 	3- 6 months
	<ul style="list-style-type: none"> • Increased recruitment and better training are required, with mid- 	6 – 18

Area	Recommendations	Duration to complete
	<p>level pharmacy worker (PT) being introduced in significant numbers. More and more specialized workers are needed, e.g. pharmacist prescribers, specialist pharmacists (pharmacokinetics, radiopharmacy, public health, manufacturing industry).</p> <ul style="list-style-type: none"> • Government-to-government agreements and public private partnerships (PPIs) may be required to assist with solving the workforce crisis in the region. In some instances broad-based effort is necessary, e.g. the DOH/SAPC recruitment visit to India. • The public sector’s high vacancy rate must be addressed, including the quick introduction of the planned occupation specific dispensation for pharmacists. • Strategies must be developed and implemented to i) increase student enrolment in the pharmacy schools, ii) increase the number of pharmacy schools, iii) recruit foreign pharmacists from the region, particularly those trained in SA, iv) provide incentives for companies to recruit and train pharmaceutical staff for the various sectors, v) train pharmacy technicians. • Introduce a huge staffing norms exercise to determine the types and numbers of staff required, projected forward for a number of years. • In the private sector, the following steps should be considered. <ul style="list-style-type: none"> – Engage the private sector in terms of negotiating to have the private sector absorb a lot of the burden of the public sector. – This is particularly relevant for national health insurance considerations. Examples include PCDT and HIV & AIDS management as innovations of task-shifting and task-sharing; having public sector patients take their scripts to the nearest community pharmacy, etc. – Produce sufficient clinical pharmacy specialists, SAPC specialist registers, and to determine how these factors might impact on the planned OSD for pharmacy personnel. A key immediate priority would be to define the competencies of such specialists (clinical; policy), the 	months

Area	Recommendations	Duration to complete
	<p>qualifications required (and provisions for RPL), and then match these with the NDOH proposed career paths. In addition, task shifting (or multi-skilling) has not been explored in any detail, but promises advantages in efficiency and cost containment (also see legislative review i.t.o. Nursing Act implementation). Buy in from the professional councils would go a long way in assisting with the task shifting process.</p> <ul style="list-style-type: none"> • Lastly, we need to state very clearly that staffing norms are not consistent (and in many provinces, just missing), so that interpretation of vacancy rates is not simple. It may be useful to show the numbers of public sector pharmacists per 100 000 non-insured population per province over time (see SAHR Indicator chapters or the HST health statistics web site). 	
Safety and quality of medicine	<ul style="list-style-type: none"> • A need to assess scientifically the impact of ADRs on the healthcare system. In addition, a critical assessment of the existing pharmacovigilance system in South Africa would need to be conducted. • Support the creation of a National Pharmacovigilance Forum consisting of all public health organisations involved in pharmacovigilance activities in the public sector. This forum is intended to improve communication and collaboration between all national and provincial agencies responsible for public sector pharmacovigilance (e.g. provincial PTC committees, pharmacovigilance units, pharmacovigilance researchers etc.) • Support the establishment of a National Pharmacovigilance Society • Conduct an independent audit of existing pharmacovigilance structures and activities in the country (i.e. the MCC, NADEMC, the MEDUNSA Pharmacovigilance unit, EPI programme's AEFI system, other public health programmes within the National Department of Health, provincial and academic pharmacovigilance programmes for HIV/AIDS, TB, malaria and other diseases). • Identify national and regional institutions for the creation of a 	3 – 6 months

Area	Recommendations	Duration to complete
	<p data-bbox="483 306 938 338">national drug information programme.</p> <ul data-bbox="435 369 1243 590" style="list-style-type: none"> <li data-bbox="435 369 1243 443">• Promote the creation of weekly/monthly morbidity and mortality meetings at all secondary level hospitals. <li data-bbox="435 474 1243 590">• Identify efficient channels of communication of pharmacovigilance information to healthcare professionals and the public. 	
	<ul data-bbox="435 632 1243 705" style="list-style-type: none"> <li data-bbox="435 632 1243 705">• Incorporate pharmacovigilance into the curriculum of medical, dental, nursing and pharmacy students. 	6 – 18 months
Medicines financing	<ul data-bbox="435 741 1243 1808" style="list-style-type: none"> <li data-bbox="435 741 1243 930">• The pricing committee should establish a task team that includes committee members and the secretariat. The team can engage with stakeholders on proposed recommendations and report back to the committee. The Committee has been engaging with stakeholders but this has not been on a regular basis. <li data-bbox="435 961 1243 1119">• The committee must publish clear guidelines on the information requirements for an application for SEPs and other pricing issues, as well as the criteria the committee uses to assess applications. <li data-bbox="435 1150 1243 1308">• The committee has published a notice in the government gazette calling for information on the logistics fee. This information will be used to establish the maximum logistics fee. The committee must ensure that this process is completed. <li data-bbox="435 1339 1243 1612">• The provisions of the National Health Amendment Bill in parliament do make provision for the maximum dispensing fees to be established through negotiation between the funder and provider. While the main reason for the National Health Amendment Bill is sound, much of what it does is problematic. The Bill may need some consideration in how it achieves its purpose <li data-bbox="435 1644 1243 1808">• Consideration should be given to the establishment of a dispute resolution or deadlock-breaking mechanism. This would certainly reduce the possibility of disputes being taken to the courts. 	3 – 6 months
Monitoring	<ul data-bbox="435 1845 1243 1877" style="list-style-type: none"> <li data-bbox="435 1845 1243 1877">• For the next policy process, a system must be carefully designed 	3 – 6 months

Area	Recommendations	Duration to complete
and evaluation	<p>to monitor progress and to evaluate processes. Information should be easy to collect and analyse and should be used for taking corrective action where appropriate.</p> <ul style="list-style-type: none"> • The NDoH needs to set up a unit that will be responsible for translating the policy into action through the development of a pharmaceutical master plan and a priority action plan. • The NDoH should define indicators for monitoring and evaluation of the implementation of the Policy. • The NDoH should set up a system for co-ordinating and monitoring the agencies responsible for implementing the Policy. • Mechanisms for support, monitoring and evaluation of performances and sanctions under the policy shall be strengthened at all levels. <p>The successful implementation of a National Medicines Strategy will involve:</p> <ul style="list-style-type: none"> • Baseline and ongoing data collection, monitoring and research on the impact, successes, and failures of the policies described within this document • Evaluation of the effectiveness of policy interventions for human resources development and distribution, pricing strategies, restructuring of the MCC and legislative amendments. 	6 – 18 month
Medicines supply systems	<p>Public sector</p> <ul style="list-style-type: none"> • DOH needs to strengthen the Pharmacy cluster by appointing a cluster manager as well as putting in place incentives that will attract candidates to fill critical posts at the national level • To fill vacant senior pharmaceutical management posts at national level in order to provide the necessary support to cluster managers <p><i>Warehousing and distribution</i></p> <ul style="list-style-type: none"> • Conduct an audit of the medicines depots to ensure that they comply with the law 	3 – 6 months

Area	Recommendations	Duration to complete
	<ul style="list-style-type: none"> • Reporting lines for provincial medicines depots need to be reviewed; in addition the justification in terms of efficiencies regarding the control of medicines depot needs to be looked into. • The value of outsourcing services such as warehousing, procurement and distribution, especially in province that lack skills to carry out these services in house need to be reviewed. The review needs to include the performance of private contractors, the cost and service efficiencies of private contractors used and the benefits derived from this model. • A review of Treasury guidelines/regulations for PPPs, as part of a wider review of the tender system for pharmaceuticals is advocated. • Improving the logistical efficiencies around the management of chronic medicines supplies needs to be looked into. Further, partnering with private pharmaceutical retailers needs to be investigated. <p><i>Financing and budgeting processes</i></p> <ul style="list-style-type: none"> • A more in depth method of budget allocation, location, and monitoring is required. <p><i>Procurement and the tender process</i></p> <ul style="list-style-type: none"> • Improved coordination between the DOH, State Tender Board and Dti. Local manufacturers should be accorded the appropriate level of participation. • A proposal that a company which is awarded an item on tender for the first time (i.e. one that had never been successful in a DOH Government tender previously) should only be awarded a percentage of the tender in order to provide Government with an opportunity to evaluate their performance and will be considered along with others that seem to be focused on the poor performance of some suppliers. • Greater efforts need to be put into ensuring that Government abides by its payment schedule of 30 days as set out in the Public Finance Management Act ("PFMA") in order to ensure 	

Area	Recommendations	Duration to complete
	<p>the viability of suppliers, especially the smaller ones.</p> <ul style="list-style-type: none"> • Measures need to be put in place to include municipalities and metros as part of the state tender process. • Provinces are seemingly at liberty to move the procurement of any products down to provincial level; this affects the whole purpose of achieving gains through combined and centralized bargaining, and the reasons therefore should be interrogated. • Specifications for products procured at the provincial level are not uniform from province to province and pose challenges for suppliers and opens the way for corrupt practices. <p><i>Platform for engagement with industry</i></p> <ul style="list-style-type: none"> • More regular and consistent communication between Department of Health officials and stakeholders needs to be fostered. It is the view of the Task Team, for example, that the Pharmaceutical Pricing Committee could have been more forthcoming and transparent in affording stakeholders an understanding of the reasons certain proposals have been rejected, and in giving a clearer explanation of the processes which lead to them taking certain decisions. • Consideration could be given to establishing a stakeholders' forum that would meet regularly to consider matters impacting on pharmaceutical policy implementation, or one with a specific focus on medicines pricing. This would be in keeping with the dictates of the NDP and would certainly have the value of fostering a relationship of trust between the DoH and the stakeholders <p><i>Procurement and supply of medical devices</i></p> <ul style="list-style-type: none"> • Problems with the procurement of medical devices stem mainly from the fact that there is no regulatory authority for devices and that there are no clear national specifications or standards. As a result, there is a danger of the situation whereby devices which are unsafe or of poor quality being used on patients, continuing unabated. • The Task Team recommends that medical devices be subjected to regulation by an authority with suitable competencies. In addition, it is vital that team of experts be put together to 	

Area	Recommendations	Duration to complete
	<p>consider standardization in the specifications for medical devices and device a uniform mechanism for the procurement of devices.</p> <p>Compliance of public sector facilities with legislation with regards to:</p> <p><i>Human resources</i></p> <ul style="list-style-type: none"> • The salary structures and post levels for pharmacy personnel need to be addressed as a matter of urgency, as many are being lost to the private sector. • Implementation of the Occupation Specific Dispensation (OSD) for pharmacists needs to be implemented. • Advocacy is required to increase the number of pharmacists trained. • A pool of posts for pharmacist interns needs to be created which would be coordinated at the Provincial level. • Efforts should be made to retain community service pharmacists. • The introduction of the new cadres of mid-level workers in pharmacy, the pharmacy technician, needs to be expedited. <p><i>Infrastructure and equipment</i></p> <ul style="list-style-type: none"> • Legislative requirements need to be taken into account in the planning of new facilities and when renovations are carried out at existing pharmacy facilities. • Pharmaceutical services management <u>must</u> be involved with the signing off of plans that affect medicine supply and storage and any aspect of pharmaceutical services infrastructure. • The upgrading of Provincial pharmaceutical depots and prepacking units needs to be expedited. • There is a need to provide emergency power supply in pharmacies and primary healthcare clinics in order to maintain the cold chain. • Communication between pharmacies and the outside world – medical practitioners, satellite clinics, suppliers, etc – is crucial and basic communication equipment, such as telephones, facsimile machines and internet connectivity in facilities must be provided. • There is a need to provide adequate counselling areas as a priority in order to support the integration of the provision 	

Area	Recommendations	Duration to complete
	<p>of ARVs into existing pharmacies so as to consolidate resources.</p> <p><i>Systems and processes</i></p> <ul style="list-style-type: none"> • Availability of pharmaceutical services on a 24-hour basis needs to be facilitated in all the hospitals and community health centres. • Sustainable referral systems for patient's medicine requirements must be developed at all levels. • Allocation of sufficient resources for the implementation of computerised systems for inventory control and patient medicine management has to be seen as a priority. • The involvement of pharmacy management in budgeting processes is key to ensure the appropriateness of budgetary allocation for pharmaceuticals and medical supplies. • Key indicators must be developed in order to improve the monitoring and evaluation of pharmaceutical services. • Quality improvement strategies for pharmacy must be put in place. <p><i>Patient Care</i></p> <ul style="list-style-type: none"> • Staffing levels for pharmacy personnel need to be increased in line with the increasing numbers of patients and the burden of disease. • Waiting areas for patients must be improved. • Strategies must be introduced to reduce waiting times at pharmacies. • There is a need to develop a tool for patient exit interviews in order to monitor and improve quality of care/patient satisfaction. <p><i>General</i></p> <ul style="list-style-type: none"> • The national patient information system has to be improved. • Service level agreements between provinces and local authorities must be put in place to ensure that services are provided as required. • Similarly, although in a somewhat different context, service level agreements between provinces and NGOs/research organisations that are active in the provinces must be signed to ensure that nothing is done by the NGOs that goes against provincial or national policy, and that all activities are known to and monitored by the provincial authorities. 	

Area	Recommendations	Duration to complete
	<p>Private sector</p> <p><i>Dispensing Licences</i> The National Drug Policy states that medical practitioners and nurses will not be permitted to dispense drugs, except where separate pharmaceutical services are not available. It would appear that current implementation practices whereby dispensing licences are issued to non-pharmacist dispensers tend to deviate from this principle, and it would be instructive to enquire as to what has necessitated this deviation.</p> <p><i>Non-pharmacist Ownership of Pharmacies</i> What was intended to be a measure that would attract the big corporate companies and non-pharmacist business people to open pharmacies in the rural areas and other under-served areas has, instead, led to a concentration of corporate pharmacies in the city centres and large shopping malls, and this may be a factor in the spate of closures of smaller pharmacies. On the other hand, it might also be that the seeming deviation from the NDP has had the unintended consequence of bringing down the cost of medicines to the consumer. This could be an example of some clauses of the NDP being open to interpretation and certainly deserves to be revisited.</p> <p>Public Private Partnerships (Definition: A PPP is a contractual arrangement between a public sector entity and a private sector entity whereby the private sector performs a departmental function in accordance with an output-based specification for a specified, significant period of time in return for a benefit, which is normally in the form of financial remuneration. It furthermore involves a substantial transfer of all forms of project life cycle risk to the private sector. The public sector retains a significant role in the partnership project either as the main purchaser of the services provided or as the main enabler of the project.)</p> <p>Several models are proposed for the distribution of chronic medication. The Task Team is not in a position to make a judgment call on the merits or demerits of the proposals, and recommends that community pharmacy representative organizations be given an opportunity by provincial health</p>	

Area	Recommendations	Duration to complete
	<p>departments to make representations on the proposed models. The models and outcomes following any piloting of the models should be disseminated through the relevant stakeholders' forum for discussion. Examples of PPPs cited by stakeholders include the following:</p> <ul style="list-style-type: none"> • Anti-Retroviral (ARVs) roll out plan; • TB DOT treatment; • Sexually Transmitted Infections (STI); • Chronic medication; • Family Planning and Contraceptives; and • Immunisation. <p><i>Primary Care Drug Therapy (PCDT)</i> means the supplementary training to be undertaken by a pharmacist who wants to sell in his own discretion to any person for personal use certain medicines listed in Schedule 3, Schedule 4 and Schedule 5, published with the regulations in terms of the Medicines and Related Substances Control Act, 1965 (Act no. 101 of 1965) in accordance with the provisions of that Act, following attainment of the necessary additional competencies. This is already provided for in terms of the Pharmacy Act, but all licences already awarded were frozen by the Department of Health.</p> <p>Whereas nothing in the law renders this practice illegal, the NDP needs to be scrutinized to confirm whether this type of service was intended to extend beyond PHC services. It is also known that medical practitioners are not entirely comfortable with this concession for pharmacists, but that there has been intense engagement between the statutory councils responsible for medical and pharmacy practice on the issue. On the other hand, there is evidence, notably in the United Kingdom, of pharmacists increasingly taking on tasks that had traditionally been the preserve of medical practitioners, with the blessing of both medical profession and the NHS. This is an issue that is probably best left to resolution by the councils concerned.</p> <p><i>Further work to be done</i></p>	

Area	Recommendations	Duration to complete
	<ul style="list-style-type: none"> • Drafting one set of regulations for complementary medicines (There are currently two sets of regulations, the 2004 and 2008 regulations). <p><i>Administrative issues</i></p> <ul style="list-style-type: none"> • Fine tuning structure and functions as well as costing the exercise and development of a resource plan to scale up activities in all the regulatory areas and conduct a risk analysis. • Establish operational teams to deal with current crisis <p>Long term measures</p> <ul style="list-style-type: none"> • Acquisition of information technology to allow for the submission of internationally standardised applications and the electronic tracking of all applications; and • Introducing cost-recovery to support MCC operations • Human resource plan and management, including remuneration levels that allow for the recruitment and retention of highly competent scientific, technical and clinical professional staff; • Revising the legislative framework insofar as it deals with clinical trials, medical devices, diagnostics, cosmetics and food substances. • Drafting legal provisions dealing with the audit and inspection of clinical trial sites • Draft laws for clinical trials involving certain medical devices and radiopharmaceuticals, all biotechnology products, CAMS, African Traditional Medicines and foods in respect of which medicinal claims are made 	
R&D, Innovation and Local Production	<ul style="list-style-type: none"> • Establish a health technologies forum that would provide independent and objective scientific advice that will inform health technology policy decisions. The forum will also determine how best to use existing local and international IP policy issues to facilitate access to health technologies by the marginalised. A key outcome of the forum is to create an enabling environment for the transfer of health technologies derived from local R&D and clinical trials work as well as imported technologies from other countries. • Outsource clinical trials assessment to an existing competent facility <ul style="list-style-type: none"> – Such a task team would address the backlog of clinical trials assessment applications – Establish a new system and structure for CTA review 	3 – 6 months

Area	Recommendations	Duration to complete
	<p>processes</p> <ul style="list-style-type: none"> - Improve the efficiency of clinical trial assessments - Advance infrastructural arrangements pertaining to CTA so as to improve the efficiency with which clinical trial applications are assessed. <ul style="list-style-type: none"> • Together with the DST and DOE, establish programmes that would as a minimum, maintain South Africa's current scientific capacity and excellence in the health sciences. • Establish programmes should focus on initiatives aimed at training emerging scientists, encouraging them to stay in the academic system to pursue doctoral studies and to stay in the science system. • <i>Harmonisation of the policy and legislative environment</i> <ul style="list-style-type: none"> ○ IP is one of the pillars on which R&D is translated into products ○ IP is a tool of the translation of science into technology ○ IP protection rules being set under TRIPS for 147 Countries ○ However: <ul style="list-style-type: none"> ▪ There is much confusion surrounding IP and its role in delivering health gain to developing countries ▪ There has been an unhelpful polarisation in debate ▪ The controversy obscures innovation on IP management ○ There are positive and negative aspects to IP protection 	6 – 18 months
Traditional, complementary and alternate medicines	<ul style="list-style-type: none"> • Create a National Centre of Competence on African Traditional Medicine, with support from the DST (research, development & innovation) DoH (regulations, product registrations & THP services) and DTI (IPR protection, industrialization and commercialization) across the value chain. • Publish regulations on African Traditional Medicines. • Clarify the 2002 CAM call-up notice and finalize the CAM regulations. • Short term turn around initiatives to be managed as priority 	3 – 6 months

Area	Recommendations	Duration to complete
	<p>projects</p> <ul style="list-style-type: none"> • Review and re-enforcement of policies covering DOH, DST, DTI, DEAT, NDA, etc. • Harmonization of policies across the DOH, DST, DTI, DEAT, NDA, etc. • Creative universal agreement on IP and ABS for all partnerships between THPs, researchers, government, NGOs, business, etc. • Develop a risk management mechanism system for IKS and ATM • Creating social compact to support IKS and ATM • Develop guidelines on IKS and ATM CPPP • Create an MCC ATM Committee that should urgently develop regulations to register products. 	
	<ul style="list-style-type: none"> • Produce a Traditional Medicine Pharmacopoeia. • Establish a South African Journal on African Traditional Medicine. • Create a CAM Policy Forum and CAM Directorate in the DoH. • Create a School of African Traditional Medicine • Develop primary healthcare facilities for African Traditional Medicine. • Forge Community-Public-Private-Partnerships, to create nat cultivation & manufacturing centres for TCAM • Creating an Institute on ATM for (better/immediate/implementation): <ul style="list-style-type: none"> ▪ Regulations (THP practice systems /etc./institutionalization) ▪ Advocacy (promotion of IKS and ATM) ▪ Communication (SA.J.ATM; Quarterly Bulletin on ATM) ▪ Coordination (connecting the ATM field) ▪ Registration (ATM products) ▪ Protection (IPR must be protected) • Creating a centre of competence to support: <ul style="list-style-type: none"> ▪ Research partnerships between THPs, scientists, business and government ▪ Research, development and innovation of quality, safe and effective ATMs ▪ GAP, GMP, GLP, and GCP for compliance ▪ Development of ATM pharmacopoeia • Ensure that the DTI strategy on local production should include ATMs with an emphasis on: 	<p>6 – 18 months</p>

Area	Recommendations	Duration to complete
	<ul style="list-style-type: none">▪ Incentives▪ Investments▪ Capacity development / Good storage practice, GMP, good distribution practice	