

Pharmaceutical Task Group (PTG)  
Comments in response to the White Paper  
on National Health Insurance

*GOVERNMENT GAZETTE 39506, 11 DECEMBER 2015*

*NATIONAL HEALTH INSURANCE FOR SOUTH AFRICA*

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## 1 THE ROLE OF PTG COMPANIES IN MEDICINE SUPPLY IN SOUTH AFRICA

The Pharmaceutical Task Group (PTG) is an affiliation of associations representing the interests of the pharmaceutical industry in South Africa. The affiliated associations represent both the research-based innovative companies and local and generic companies. The PTG represents: Innovative Pharmaceutical Association of South Africa (IPASA); National Association of Pharmaceutical Manufacturers (NAPM); Pharmaceuticals Made in South Africa (PHARMISA) and the Self-Medication Manufacturers Association of South Africa (SMASA).

PTG member companies play a significant role in the supply of medicines to the public sector as well as the private sector. PTG members supply 75% of the medicines purchased in the public sector and 86% of the medicines in the private sector.<sup>1</sup>

A comprehensive list of member companies is supplied in Appendix 4.

The members of the PTG are thus in a position to make substantiated comments regarding medicines supply and offer proposals relating to medicine benefits under a NHI system.

## 2 EXECUTIVE SUMMARY: RECOMMENDATIONS

The Pharmaceutical Task Group (PTG) recognizes that in contrast to the National Health Insurance (NHI) Green Paper of 2011, medicines and pharmaceuticals enjoy a significantly higher profile in the recently published NHI White Paper.

The PTG recognizes as valuable the inclusion of aspects of pharmaceutical services including medicines supply and supply chain management, procurement, pricing and reimbursement, as well as plans to improve access to medicines (both Over-the-Counter ((OTC)) and Prescription) to the population.

The PTG has concerns regarding statements about price determination and limitations imposed on the NHI benefits, which, it is felt, could adversely affect patient access to medicines under the NHI.

In these substantive comments the PTG examines the evidence base for the current situation related to delivery of medicines in South Africa and identifies particular policy directives which could, in the PTG's opinion, impair patient access to quality healthcare. The PTG makes recommendations as to how its members believe these issues can be addressed in order to improve and increase patient access to medicines.

The PTG is concerned that proposals in the NHI White Paper could potentially affect the economic sustainability of the pharmaceutical industry and, subsequently, of the sustained supply of medicines to patients, who are the recipients of life-saving medicines on a daily basis. The PTG believes that all medicine options should be examined and all potential positive and negative consequences identified and weighed up.

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<sup>1</sup> IMS Public sector sales audit Quarter 4 2015 and private sector sales audit, March 2016 – Units sold.

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In response to the NHI White Paper, the PTG highlights the following:

- a. A **multi-stakeholder pharmaceutical forum / working group** should be constituted to focus on medicines selection, procurement, supply, pricing, and reimbursement within the NHI. There are several elements of the NHI proposals which will warrant in-depth discussion between the NHI and medicines suppliers to ensure successful implementation.
- b. A **comprehensive analysis of factors driving medicines utilization and expenditure** in the public sector should be undertaken, which could inform the decisions in the development of the NHI package of care with the intention, not of rationing medicines access, but of improving patient access to medicines with the aim of improving health outcomes.
- c. The PTG proposes that the **improvement of the pharmaceutical services for the NHI** will involve a necessary increase in the percentage budget allocation to medicine, in line with international- and developing / middle-income country trends.
- d. The NHI should strive to improve access to medicines, not limit or reduce the level of access patients already enjoy in the public sector.
- e. Systems for the setting of **formularies and national treatment guidelines** should be transparent, and governed by a fully representative and publicly known committee to ensure that all aspects of patient benefit, clinical impacts and systems impact can be considered.
- f. The PTG supports a **decentralized system of medicine procurement** with several layers of decision-making to retain responsiveness at a local level.
- g. The expectation that the majority of **medicine purchasing** will move to a state-driven tender-based single purchaser system causes immediate concern about the future security of supply of medicines and the continuing viability of the local manufacturing and locally-based pharmaceutical industry. Currently pharmaceutical companies in South Africa base their business potential and viability on the business they can achieve in the private sector.
- h. The PTG recommends that different **reimbursement models for medicine be explored in detail**. Innovative approaches to reimbursement, such as risk-sharing- and contracting models (such as price modulation) could be considered. The implications of reimbursement proposals, such as capitation and Diagnosis-Related Groups (DRGs) for the availability of appropriate medicines to patients should be thoroughly investigated with the intention of producing a comprehensive set of NHI benefits and services.
- i. **Health Technology Assessment (HTA)** can be an effective instrument to inform what medicines the NHI will provide. As is the case in other jurisdictions, pharmaceutical manufacturers should be

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permitted to interact with the responsible authority in relation to their HTA submissions and the system should be based on a clear legislative framework (as is the case in Australia). Ensuring a sufficient supply of experts in this field should be incorporated into the Human Resource for Health Strategy of October 2011.

- j. Proposals for direct delivery of medicines to patients on a large scale should be critically evaluated and require clarity on where the additional costs for such a system will be covered. If the pharmaceutical industry is expected to cover the costs of direct delivery mechanisms, this will of necessity impact on the price of medicines.
- k. The PTG recommends that the role of medical schemes be carefully considered beyond that of complementary cover for benefits.

More details on these comments, recommendations, and the background and rationale for these are provided in the full submission which follows.

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### 3 INTRODUCTION

The Pharmaceutical Task Group (PTG) welcomes the opportunity to comment on the National Health Insurance NHI White Paper and contribute to the development of the plans for the NHI.

The principles as laid out in the White Paper, i.e. the right of access, social solidarity, effectiveness, appropriateness, equity and affordability are noble objectives for which to strive and will ultimately benefit all South Africans and are supported by the PTG and its participating associations.

The PTG also welcomes the fact that issues relating to medicines and patient access to pharmaceuticals and pharmaceutical services feature far more prominently in the White Paper than they did in the Green Paper on NHI.<sup>2</sup>

The PTG interprets this to be a significant increase in the recognition by the National Department of Health of the importance of medicines in the NHI benefits, and the contribution of medicines to improving patient care and health outcomes. The PTG's comments will focus on the following areas that impact the patients and their access to medicines within the envisaged NHI system:

- Selection of medicines;
- Procurement and supply of medicines;
- Pricing and reimbursement of medicines; and
- The role of medical schemes under NHI.

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<sup>2</sup> South African National Department of Health. National Health Insurance in South Africa – Policy Paper. August 2011.

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## 4 THE KEY ROLE OF MEDICINES IN HEALTHCARE DELIVERY

The recognition of the key role of medicines in achieving universal health coverage is emphasized in the direct link provided by the Sustainable Development Goal 3 which includes “Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all”.<sup>3</sup>

To give effect to this, South Africa has included in its Constitution the right of access to healthcare, as well as the right of access to social security (of which a health insurance system would form part). South Africa already has a fairly well developed case law system on socio-economic rights, which should underpin the consultative processes and ultimately the phased implementation of the NHI. The markers established by the Constitution and case law<sup>4</sup> include:

- All measures have to be reasonable i.e. be based on well-reasoned premises.
- Competing interests have to be balanced. For example, access is not only about affordability or price; it is also about the impact of price pressures on the availability of services or goods.
- Measures have to be progressive in nature and depend on the available resources. This means that the implementation of NHI has to be systematic and careful, and build up towards more comprehensive cover over time.
- Limitations of rights, which might take place through formularies as an example, must to be reasonable and justifiable.

Principles of administrative justice would also be critical in an NHI, and actions that affect the rights or legitimate expectations of patients or the providers of services or goods, have to be handled accordingly. This means, for example, participation in such decision-making processes and the provision of reasons for decisions taken.

To this end the PTG proposes that a pharmaceutical forum be established in order to look into the various models of pharmaceutical supply in NHI, as well as to look into the measures required to transition from the current public- and private systems into an NHI. PTG companies could contribute to such a forum utilizing local and international exposure in medicines supply.

*The PTG proposes that a multi-stakeholder pharmaceutical forum be established to address the issues raised in these comments as well as to find ways to best serve the interests of patients within the NHI.*

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<sup>3</sup> United Nations. Sustainable Development Goals: 17 Goals to transform our World. Available at <http://www.un.org/sustainabledevelopment/sustainable-development-goals/>.

<sup>4</sup> The cases of Soombramoney, Grootboom and the TAC (nevirapine).

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## 4.1 Medicines in Health System Performance

The WHO has recognized medicines and technologies as one of the six health system building blocks (along with governance, financing, information, service delivery and human resources).<sup>5</sup>

It is in the interests of all South Africans for government to adopt a system that ensures timely and universal patient access to quality medicines.

This can be done by striking a balance that achieves:

- a. A reliable supply of quality medicines at the most reasonable cost to taxpayers<sup>6</sup>, the healthcare financing system and patients; and
- b. A sustainable, viable and stable pharmaceutical industry.

The PTG is concerned that proposals in the NHI White Paper could prove detrimental to the sustained supply of medicines for patients, if all potential positive and negative consequences of policy proposals are not thoroughly explored.

*The PTG is concerned that some of the proposals in the NHI White Paper could be detrimental to the sustained supply of medicines for patients. We thus request engagement on issues and proposed systems changes envisaged by the NHI White Paper.*

## 4.2 Medicines as a Cost Element in the Public Healthcare Sector

The NHI White Paper identifies medicines as amongst the cost drivers in the public healthcare sector (para 65). This assertion needs to be explored particularly in light of the significant reductions achieved in the prices of antiretroviral medicines over the past few tender periods. Substantive evidence needs to be evaluated as to whether utilization or price is driving incremental medicines expenditure in the public sector.

It is virtually impossible to extract information on medicines expenditure data from the published National Budget Documents or National Department of Health reports, and because South Africa has no reliable system of published National Health Accounts in place yet, we have had to use proxies and what evidence is available, to estimate the expenditure on medicines in the public sector.

An ABC analysis<sup>7</sup> of the Master Procurement Catalogue for the Public sector (2015), which details the overall expenditure on National Medicines Tender, shows that 80% of the total Rand value for tenders is allocated to just 122 line items, which make up only 11% of the total volume of medicines utilized. (Appendix 1).

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<sup>5</sup> World Health Organization. 2010. Key components of a well-functioning health system. Available at [http://www.who.int/healthsystems/publications/hss\\_key/en/](http://www.who.int/healthsystems/publications/hss_key/en/). Accessed 10 February 2016

<sup>6</sup> "Taxpayers" is used here to refer to organizations and individuals who directly or indirectly (through the healthcare funding system or otherwise) fund or subsidise the procurement and distribution of medicines.

<sup>7</sup> Management Sciences for Health. 2012. Managing Drug Supply. Edition 3. Chapter 40: Analysing and controlling pharmaceutical Expenditures.



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50% of the total expense according to this analysis is attributable to HIV/AIDS treatments alone (ATC2 level J05). Antiretrovirals account for ZAR14 billion of the total ZAR29 billion in national medicines tenders. Thus the PTG would argue that the expenditure on other items is considerably lower and that the whole of medicines expenditure is skewed by this therapeutic area and that cost driving does not extend to “medicines” in general.

A similar picture of expenditure emerges in the analysis of IMS sales data for the public sector, although the skewing is less pronounced. HIV antiretrovirals and antitubercular products make up 26% of the expenditure and only 8% of the volume. HIV antiretrovirals and antitubercular have also been responsible for 25% of the total increase in medicines expenditure increase since 2011. (Appendix 2).

The National Antiretroviral treatment program is regarded as a significant success in dealing with the current pandemic, and we would expect that medicines for tuberculosis and HIV would occupy significant amounts of the medicines budget. However we urge the National Department of Health not to allow this single large area of expenditure to influence perceptions about medicines as a general cost driver in the public sector.

If the PTG extends the tender expenditure analysis to an annual medication cost per capita in the population served by the public sector (approximately 45.5 million people), this equates to an expenditure of ZAR322 per person per annum in the public sector (USD50, converted at current prices PPP, average 2015 exchange rate of ZAR12.76 per USD).

The PTG considers this to be a relatively lower spend on medicines versus international figures (as demonstrated by figure 2 in Section 7.3 of this document).

The PTG suggests that the public sector spends significantly less on medicines versus peer countries, despite the inclusion of the large amounts spent on antiretrovirals. It is proposed that a more detailed study of use and expenditure on medicines in the public sector should be undertaken to better understand the factors driving costs in medicines expenditure.

*The evidence presented does not support the fact that medicines generally are a significant cost driver in the public sector, as stated in the White Paper.*

*It is proposed that a more detailed study of the use and expenditure on medicines in the public sector should be undertaken to better understand the factors driving costs in medicines expenditure.*

*This will assist in targeting interventions to address these.*

*The PTG would avail itself to assist with such a study.*

### 4.3 Treatment Guidelines

The Standard Treatment Guidelines for the South African public sector have been in existence since 1998. The PTG is encouraged that particularly in the last few years, the update of these STGs has been regularly undertaken and is currently ongoing. The Standard Treatment Guidelines and Essential Medicines List for Primary Healthcare is currently in its fifth edition (2014) while the STGs and EML for adults and paediatrics hospital level are both in their third versions (2012 and 2013 respectively). The PTG wishes to applaud the Department on the launch of the Primary Health Care Standard Treatment Guidelines and Essential Medicines App, 25 November 2015.

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By comparison, in the existing private sector reimbursement structures, where legislation requires a review of the Prescribed Minimum Benefits every two years, a successful review has not been completed since 2003.

This situation will need to be addressed for NHI as the oversight in the private sector has resulted in significantly outdated treatment algorithms for chronic diseases and a general lack of any benefit definition to apply to the 270 DT-PMBs, which can result in patients being excluded from appropriate care for their condition.

Treatment guidelines not only guide the rational use of medicines but will also ensure that the right patient gets the right medicine at the right time (appropriateness).

It is not clear from the NHI White Paper where the responsibility will lie for guideline development, nor how processes will be governed in defining the new guidelines to which the White Paper refers.

As the PMB experience in the private sector has shown, guideline development is a complex process, particularly where issues of costs and cost effectiveness are also to be taken into consideration, alongside clinical considerations, as the primary inputs into treatment guidelines.

It is also important to ensure that these guidelines are set with the active involvement of various healthcare professional groups who are the technical experts on the treatment of patients and who are also involved in clinical research of new and existing medicines and technologies. All elements of care (not only medicines), including prevention, rehabilitation and health education, compliance and follow-ups should be integrated.

The PTG proposes a transparent, open and scientific process, driven by experts in the various fields to set national treatment guidelines, and that the allocation of specific medicines, devices and other technologies, be made within the frameworks of these national guidelines, bearing in mind the needs of specific populations and individuals.

In addition, many more treatment options beyond the Standard Treatment Guidelines are currently made available to patients within the public sector as discussed in Section 5.1. Many of these treatments serve patients whose conditions are not addressed by the STGs, or who fall outside of the standard management recommended by the STGs.

The PTG proposes that the NHI structures should retain an appeals process and access to treatments which may not be included in guidelines, where clinical need requires it.

*The PTG proposes that the clinical guidelines for patient management in NHI be reviewed on a regular predefined basis to ensure that as new evidence becomes available, patient access remains current and in line with new developments in healthcare. The PTG proposes that the process of developing, reviewing and implementing such guidelines be a completely transparent and multi-stakeholder one.*

*Furthermore, guidelines should allow medicine coverage flexibility in order to ensure that 'outlier' patients' needs and rights are not compromised, where they are not adequately treated by guideline listed options.*

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## 4.4 Administration of a Medicines Claims System

Another important part of medicines in the health system is reimbursement to patients or dispensers of medicines.

The NHI White Paper states that “The NHI Fund will then reimburse the cost of the subsidised drugs and other health products as well as pay a capitated administration fee to the retail pharmacies” (para. 139).

The PTG interprets this statement to mean that each claim will be reimbursed separately and not on the basis of a bulk budget allocation, as each item, it appears, will be reimbursed with the addition of an administration fee.

This system will presumably require the development of a detailed medicines claims and reimbursement system, capable of supporting the claims of the 55 million individuals in South Africa, and potentially reimbursing thousands of pharmacy practices.

Currently the largest claims databases in South Africa support at most 2.5 million patients. Large systems in the United States of America also support multiple million claimants, but administration systems are regarded as costly and overly complex.<sup>8</sup>

To support such a claims system, a national coding convention will have to be developed, to address product claims as well as a diagnostic coding system.

The Private Healthcare Information Standards Committee has been in existence since the 1980s, and has been examining the need for and potential of a National Pharmaceutical Coding Scheme.<sup>9</sup>

*The PTG recommends that a multi-stakeholder forum be set up to address issues related to: clinical coding, product coding, administration systems, tracking of prescriptions from source to patient and capture at the point of dispensing.*

*The PTG proposes that all medicines systems are integrated within the NHI management systems in order to provide adequate input for monitoring and evaluation activities to measure detailed trend analyses which can form the basis of ongoing medicines policy development.*

*Caution with respect to the cost and complexities involved in large claims databases should be noted and carefully considered.*

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<sup>8</sup> Cutler D, Wikler E, Basch P. Reducing Administrative costs and Improving the Healthcare System. N Engl J Med 2012; 367:1875-1878

<sup>9</sup> Private Healthcare Information Standards Committee (PHISC). 2013. Pharmaceutical Coding sub-committee. Available at <http://www.phisc.org.za/>. Accessed 21 February 2016.

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## 5 SELECTION OF MEDICINES

The selection of medicines relates also to Treatment Guidelines as discussed in Section 4.3.

### 5.1 Current Medicines Selection Situation in the Public Sector

The medicine options currently available to patients in the public sector are considerably wider than the Essential Medicines List (EML), to which the White Paper refers.

In addition to the three levels (Primary Healthcare, Adult Hospital and Paediatric Hospital) to which the White Paper refers, the National Department of Health has made public more recently the Tertiary and Quaternary EML, which contains additional treatment options, largely at a specialised care level. This EML is not tied to any specific public treatment guidelines, but does specify medicines which have been assessed, as well as their indication and accompanied by a recommendation for use in these indications.<sup>10</sup>

The full EML contains approximately 440 molecules at International Non-proprietary Name (INN) level.

In addition, there are another 90 molecules not on the EML, but purchased on the existing set of national medicines tenders.<sup>11</sup>

Individual provinces also maintain their own provincial “code” lists of medication<sup>12</sup>, some of which include considerably more molecules and products than the national lists. Most of these have been considered and included by the provincial Pharmaceutical and Therapeutics Committees.

Thus the numbers of scheduled products currently available to patients in the public sector number at least 850 – substantially more than are represented on the current EML.

In addition, patients in the private sector currently access a further 300 molecules (schedule 1 to 6).<sup>13</sup>

Thus, the level of access to medicine in the current health system in South Africa is considerably greater than the EML, in terms of numbers of active pharmaceutical substances.

Figure 1 demonstrates diagrammatically the current state of access for patients in the public sector (as at December 2015). While many of the products purchased in addition to the EML are provided at specialist level of care in the public sector, patients currently have access, through a variety of mechanisms, to far more treatments than those which are listed on the current EML.

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<sup>10</sup> SA National Department of Health. Tertiary and Quaternary Essential medicines recommendations. April 2015.

<sup>11</sup> National Department of Health Master procurement catalogue, 2015

<sup>12</sup> Western Cape Department of Health. 2013. Catalogue of Approved Pharmaceuticals for use in the Department of Health. Available at [https://www.westerncape.gov.za/assets/departments/health/pharmacy\\_code\\_list\\_june\\_2013.pdf](https://www.westerncape.gov.za/assets/departments/health/pharmacy_code_list_june_2013.pdf). Accessed 21 February 2015.

<sup>13</sup> IMS Total Private Market Sales, to February 2015.

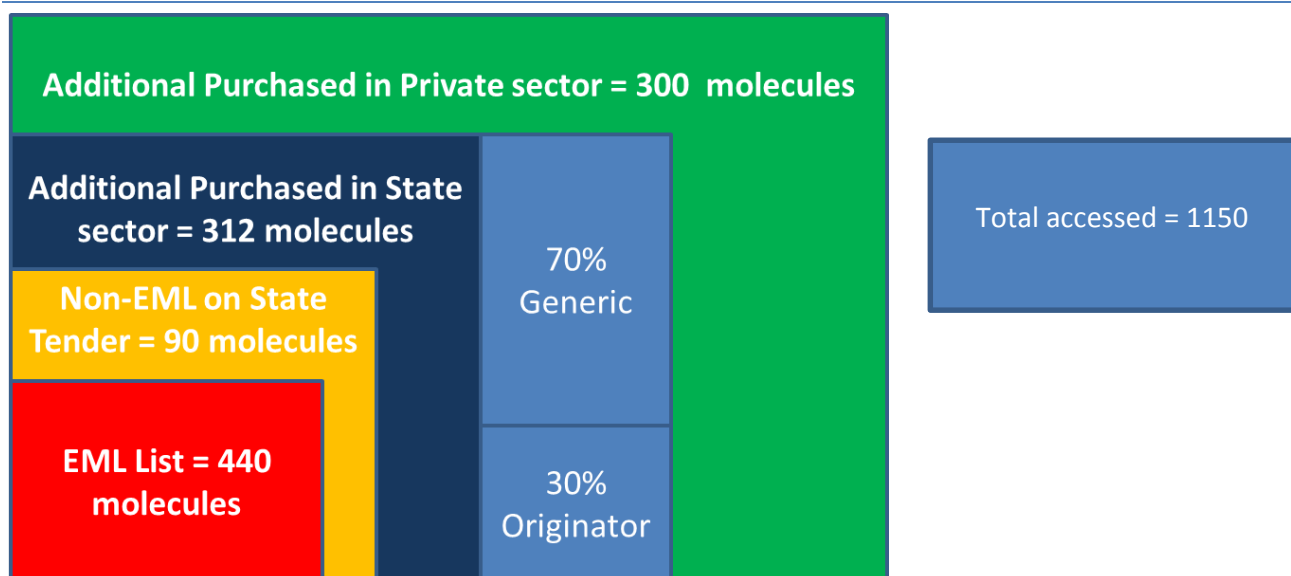


FIGURE 1: DIAGRAMMATIC REPRESENTATION OF THE EXTENT OF ACCESS TO PHARMACEUTICAL MOLECULES IN THE PUBLIC AND PRIVATE SECTORS

*The PTG recommends that in developing the comprehensive medicines benefits for NHI, the Benefit Committee should examine in more detail the levels of access currently enjoyed by public and private sector patients and that the NHI should seek to broaden the accessibility to different medicines for different patient needs, rather than attempting to ration or restrict this.*

The PTG believes that selection of medicines in a future NHI package should incorporate two key patient-centric principles:

- That a step therapy approach is adopted that allows for medicine options to be customized on the basis of individual patient need
- That patient choice of medicine be part of the NHI package philosophy in terms of where patients access their medicines

### 5.1.1 Generic Selection and Prescribing

The White Paper states, “The most cost-effective, evidence-based interventions should be provided, which can be ensured by developing an essential list of generic drugs...” (para 393.a.iv) and that strategic purchasing involves “Develop formulary (of generic drugs, surgical supplies, prostheses etc.) and standard treatment guidelines” (pg. 65, Box).

While there is no doubt that generic products form the backbone of medicines provision in the public sector and are utilized by the majority of patients, 30% of the medicines currently purchased by the public sector on the national tenders are in fact originator products.<sup>14</sup>

The EML is determined by INN generic medicine names as recommended by WHO, but this in no way excludes originator products, or those which are still patent-protected, provided they meet all the current criteria for inclusion on the EML.

<sup>14</sup> National Department of Health Master procurement catalogue, 2015

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EML listing is done on the basis of generic INN names, however the actual product selection for tender is determined by competitive tendering which is not only dependent on price. Several factors are currently considered for product inclusion on national tenders. (See Section 6 on Procurement)

## 5.2 Medicines Selection as Envisaged by the White Paper

According to the White Paper, the selection of medicines and other health technologies will be based on (paragraph 389):

- Burden of Disease;
- Efficacy;
- Safety;
- Quality;
- Appropriateness; and
- Cost-effectiveness.

The PTG is comfortable with the above list of criteria informing the selection of medicines for NHI Benefits as these criteria are similar to those for the current EML process.

However, we hope that these criteria can become better defined before they are actually used to enable or deny patients access to care. For example, “cost-effectiveness” means different things to different stakeholders and there is currently no cost-effectiveness threshold in South Africa to guide resource allocation decisions. It is not clear how considerations for burden of disease and efficacy would be weighted against cost factors and cost-effectiveness considerations.

All the above considerations are part of health technology assessment processes and should be applied transparently and consistently to decision processes.

*The PTG proposes that the processes for considering the multiple criteria for selection should be transparent and that decision-making processes should be published in detail.*

In addition, the PTG seeks to recommend that:

- All products considered must be registered with the soon to be established South African Health Products Authority (SAHPRA).

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The PTG also requests that the medicines selection be based on:

- **Good quality** evidence available for efficacy;
- **Improved** pharmacokinetic properties;
- Considerations of improved patient compliance and adherence; and
- Reliability of manufacturer supply.

The PTG is pleased that the White Paper does not limit NHI medicines selection only to the EML as did the Green Paper – the numbers from Section 5.1 above demonstrate that this is not an appropriate approach, if the objective is to offer appropriate patient access to medicines.

The PTG hopes that the selection of medicines will be based on substantial and transparent consideration of evidence as well as systems and economic evidence available.

While the White Paper does not specify at this early stage any processes for the consideration of new and existing treatment options, such a process will be imperative going forward to ensure transparency and acceptability of the defined benefits to patients and healthcare providers.

The White Paper also states that Health Technology Assessment (HTA) will inform prioritization, selection distribution, management and introduction of interventions for disease prevention, diagnosis, and treatment. As is the case in other jurisdictions, pharmaceutical manufacturers should be permitted to interact with the responsible authority in relation to their HTA submissions and the system should be based on a clear legislative framework (as is the case in Australia). Ensuring a sufficient supply of experts in this field should be incorporated into the Human Resource for Health Strategy of October 2011.

The continuing development of new medicines and new research knowledge means that systems that allow for decision-making relating to the selection of medicines need to be evolving and flexible so that the most appropriate decisions are made for patients.

*It is proposed that the medicines selection process should make room for essential as well as specialist level of care medicines, and that evidence of effectiveness and improvement in patient care feature high in the criteria for selection of NHI medicines. The PTG also recommends that only products registered with SAHPRA be considered for inclusion.*

### **5.2.1 Criteria of Burden of Disease in South Africa**

Addressing the Burden of Disease in South Africa will not be achievable through a funding mechanism such as the NHI alone. PTG however believes medicines will play a major role in optimising health outcomes of all South Africans.

Fortunately, in the last few years, the South African Medical Research Council (SAMRC) has been able to publish some of the results of the Second National Burden of Disease (BoD) study.<sup>15</sup> With increased

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<sup>15</sup> South African Medical Research Council. Burden of Disease Unit. 2015. Second National Burden of Disease Study for South Africa: Cause of Death profile Report 1997 – 2010.

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recognition of the burden of HIV/AIDs, tuberculosis and non-communicable diseases (NCDs) in the country since 2000, there is likely to be a considerable shift in the 2000 BoD Study versus the next BoD study.

The second BoD study is currently underway and preliminary results: 1997 -2010 have indicated that in terms of proportion of causes of death in 2010:

- HIV/AIDs and tuberculosis – 38.9%;
- Cardiovascular disease – 17.6%;
- Other infectious and parasitic diseases – 10.6%;
- Injuries – 8.7%;
- Cancers – 7.3%;
- Diabetes – 3.1%;
- Other Type 2 (non-communicable) – 10.9%; and
- Other Type 1 (communicable) – 2.8%.

The mortality spectrum paints only part of the picture of the overall BoD. Morbidity from conditions which are not necessarily fatal such a non-communicable diseases, mental illness, chronic inflammatory conditions (e.g. arthritis, back pain) can be considerable. South Africa does not have recently published disability adjusted life-year (DALY) statistics from the new BoD study.

In line with the BoD, HIV/AIDS and tuberculosis medicines currently occupy more than 50% of the current tender monetary allocations<sup>16</sup>. However, we consider that there is potentially considerable underinvestment in other areas such as NCDs which have been growing dramatically in prevalence in the country. The above means that budget prioritization and allocation must change to reflect the estimated resources required to effectively respond not only to communicable diseases, but also to non-communicable diseases and injuries.

*The PTG recommends that NHI prioritization considerations of the burden of disease for decision-making be made transparent and consultative, lest patients experiencing significant disability are not adequately considered, due to too much emphasis being placed on treatments which serve to address only the mortality burden.*

#### 5.2.1.1 Provincial Burden of Disease

The SAMRC Burden of Disease Study 1997 to 2010, showed that *“all provinces are experiencing the quadruple burden of disease. This requires a broad range of interventions, including improved access to healthcare, promotion of a healthy lifestyle and ensuring that basic needs such as water and sanitation are met.”*<sup>17</sup>

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<sup>16</sup> National Department of Health – Master Procurement Catalogue. 2015

<sup>17</sup> Bradshaw, *et al.* South African National Burden of Disease Study 2000. Estimates of Provincial Mortality.



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Mortality levels currently differ among the provinces, with a variation in life expectancy from 68 years in the Western Cape to 53 years in KwaZulu-Natal<sup>18</sup>, which suggests that the overall BoD impacting on these provinces might also be different.

The league table of life years lost per province, 2010, produced by the SAMRC indicates that beyond HIV/AIDs, which occupies the number one rank for ALL provinces, the next highest causes of death differ across the provinces (Table 1).

The National Health Act currently empowers provinces and provincial health councils to make decisions on *“policy concerning any matter that will protect, promote, improve and maintain the health of the population within the province including:*

- (i) Responsibilities for health within the province by individuals and the public and private sector;*
- (ii) **Targets, priorities, norms and standards within the province relating to the equitable provision and financing of health services;***
- (iii) **Efficient co-ordination of health services within the province and between neighbouring provinces;***
- (iv) Human resources planning, production, management and development;*
- (v) **Development, procurement and use of health technology within the province;***
- (vi) Equitable financial mechanisms for the funding of health services within the province;*
- (vii) **The design and implementation of programmes within the province to provide for effective referral of users between health establishments or healthcare providers or to enable integration of public and private health establishments;***
- (viii) Financial and other assistance received by the province from foreign governments and intergovernmental or nongovernmental organisations, the conditions applicable to receiving such assistance and the mechanisms to ensure compliance with these conditions;*
- (ix) Epidemiological surveillance and monitoring of provincial trends with SO regard to major diseases and risk factors for disease; and*
- (x) Obtaining, processing and use of statistical returns. “*

Thus provinces are currently empowered to make decisions about their own populations with regard to priorities and services to be offered, where these are in line with national policy. However they are not limited by national policy, allowing for responsiveness at local level to local needs of the health system, and the provincial burden of disease.

At least three provinces currently have functioning Pharmacy and Therapeutics Committees (PTCs) (Gauteng, Western Cape and KwaZulu Natal), which contribute to decisions for access and incorporation of medicines into the provincial medicines code lists, and in addition considerable amounts of training and development for PTCs have been provided since 2010.<sup>19</sup>

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<sup>18</sup> South African Medical Research Council. Burden of Disease Unit. 2015. Second National Burden of Disease Study for South Africa: Cause of Death profile Report 1997 – 2010.

<sup>19</sup> Strengthening Pharmaceutical Systems and USAID. 2012. Promoting the rational use of medicines through pharmaceutical and therapeutic committees in South Africa: Results, challenges and the way forward.

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The Gauteng PTC, as an example, functions on a number of levels to monitor medicine stock-outs, quality assurance, expenditure and rational medicine use. Therefore, selection of medicines to be provided in the province over and above EML and medicines on national tender, is only one of their functions.<sup>20</sup>

There is thus a concern about the proposed centralization of decision-making and what this will mean for the provinces regarding their autonomy and priorities at a local level.

*The role of the provincial departments, which currently enjoy a significant level of autonomy, will be impacted by the proposed changes in the NHI policy document. The potential impact of this loss of autonomy in determining priorities and provision of health technology and medicines specific to the needs of the province and the level of health facilities available should be thoroughly evaluated.*

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<sup>20</sup> USAID, SIAPS and Gauteng Department of Health. 2014. Gauteng Provincial Pharmacy and Therapeutics Committee Biennial Report, 2012-2014.

## LEAGUE TABLE OF YEARS OF LIFE LOST BY PROVINCE, 2010

Rank	Western Cape	Eastern Cape	Northern Cape	Free State	KwaZulu Natal	North West	Gauteng	Mpumalanga	Limpopo	South Africa
1	HIV/AIDS (23.2%)	HIV/AIDS (36.0%)	HIV/AIDS (37.8%)	HIV/AIDS (46.1%)	HIV/AIDS (47.9%)	HIV/AIDS (48.9%)	HIV/AIDS (40.9%)	HIV/AIDS (47.5%)	HIV/AIDS (38.5%)	HIV/AIDS (42.0%)
2	Interpersonal violence (7.2%)	Tuberculosis (7.5%)	Tuberculosis (6.9%)	Lower respiratory infections (5.9%)	Diarrhoeal diseases (4.4%)	Lower respiratory infections (3.9%)	Interpersonal violence (5.3%)	Diarrhoeal diseases (5.5%)	Lower respiratory infections (7.0%)	Cerebro-vascular disease (4.2%)
3	Ischaemic heart disease (6.4%)	Diarrhoeal diseases (5.6%)	Lower respiratory infections (4.6%)	Diarrhoeal diseases (4.0%)	Cerebro-vascular disease (4.4%)	Cerebro-vascular disease (3.9%)	Road injuries (5.1%)	Road injuries (5.1%)	Diarrhoeal diseases (6.8%)	Lower respiratory infections (4.1%)
4	Cerebro-vascular disease (5.2%)	Lower respiratory infections (4.9%)	Interpersonal violence (4.4%)	Cerebro-vascular disease (3.8%)	Interpersonal violence (3.9%)	Hypertensive heart disease (3.8%)	Cerebro-vascular disease (3.7%)	Lower respiratory infections (4.7%)	Road injuries (5.4%)	Diarrhoeal diseases (4.1%)
5	Road injuries (4.8%)	Interpersonal violence (4.3%)	Cerebro-vascular disease (4.2%)	Tuberculosis (3.7%)	Lower respiratory infections (3.5%)	Road injuries (3.7%)	Ischaemic heart disease (3.2%)	Cerebro-vascular disease (4.2%)	Cerebro-vascular disease (4.5%)	Interpersonal violence (3.9%)
6	Tuberculosis (4.3%)	Cerebro-vascular disease (4.2%)	Diarrhoeal diseases (3.5%)	Road injuries (3.6%)	Tuberculosis (3.4%)	Diarrhoeal diseases (3.0%)	Lower respiratory infections (2.9%)	Tuberculosis (3.0%)	Tuberculosis (3.9%)	Tuberculosis (3.9%)
7	Trachea/bronchi/lung cancer (3.5%)	Road injuries (2.7%)	Ischaemic heart disease (3.5%)	Interpersonal violence (2.8%)	Ischaemic heart disease (2.6%)	Tuberculosis (2.5%)	Hypertensive heart disease (2.4%)	Hypertensive heart disease (2.2%)	Diabetes mellitus (2.7%)	Road injuries (3.8%)
8	COPD (3.1%)	Hypertensive heart disease (2.2%)	Road injuries (3.3%)	Ischaemic heart disease (2.5%)	Road injuries (2.5%)	Interpersonal violence (2.1%)	Meningitis/encephalitis (2.2%)	Diabetes mellitus (2.2%)	Interpersonal violence (2.3%)	Ischaemic heart disease (2.7%)
9	Diabetes mellitus (2.5%)	Diabetes mellitus (2.1%)	COPD (2.2%)	Hypertensive heart disease (2.4%)	Diabetes mellitus (2.2%)	Diabetes mellitus (2.0%)	Diabetes mellitus (2.1%)	Ischaemic heart disease (2.1%)	Hypertensive heart disease (2.3%)	Hypertensive heart disease (2.4%)
10	Lower respiratory infections (2.5%)	Meningitis/encephalitis (2.0%)	Hypertensive heart disease (2.0%)	Meningitis/encephalitis (1.8%)	Hypertensive heart disease (2.2%)	Ischaemic heart disease (2.0%)	Self-inflicted injuries (2.1%)	Meningitis/encephalitis (2.0%)	Meningitis/encephalitis (1.9%)	Diabetes mellitus (2.2%)

TABLE 1: LEAGUE TABLE OF LIFE YEARS LOST PER PROVINCE, 2010

SOURCE: SAMRC Second Burden of Disease Study 1997 to 2010. Available at <http://www.mrc.ac.za/bod/reports.htm>

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### 5.2.1.2 Facility-Specific Burden of Disease

As the NHI White Paper envisions, different levels of facility will be able to provide different levels of care. The proposal that primary healthcare forms the backbone of the NHI system, and that the primary vehicles of this delivery will be the District Health Authorities, seems sound. The PTG also understands that the District level of care will provide the most basic services for the NHI Comprehensive Package.

Different districts in the country face different challenges in terms of the burden of disease in the population they serve, as well as the infrastructure and human resource capability.

Given the proposed referral system from PHC level to hospital and specialist level, it is likely that district, regional, tertiary, central and specialized hospitals as discussed in the White Paper (para 192) will need varying levels of treatment according to referral level.

In the current situation with budget allocations, regional, central and tertiary and specialised hospitals have autonomy to decide on what medications to select to best serve their referred patients. This enhances the ability of these hospitals to provide adequate access to medicines while managing a medicines budget.

*It is proposed that higher-level institutions retain the ability to select products specific to their own environment and patient needs.*

### 5.2.2 Medicine Efficacy, Safety and Quality

The NHI White Paper states that the healthcare interventions in the NHI system will be based on evidence-based medicine, and that effort will be directed at ensuring that the covered evidence-based services are medically necessary and have a positive impact on population health outcomes (para 136).

The PTG welcomes this approach which speaks to a desire to fund interventions which improve patient outcomes.

Medicines efficacy, safety and quality must be assured throughout the pharmaceutical system, not only at the point of selection.

*The PTG recommends that medicines selected for the NHI benefits be those approved by the South African Health Products Regulatory Authority.*

### 5.2.3 Appropriateness

Appropriateness is one of the main principles of the NHI (para 61). The White Paper considers that “*The health system will adopt innovative service delivery models that are tailored to local needs of the population and delivered at appropriate levels of care*”.

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This principle speaks to the issues addressed in Sections 5.2.1.1 and 5.2.1.2 which address the differences in the burden of disease, levels of care and decision-making capabilities in the provinces and at facility level.

Appropriateness of medication is dependent on multiple factors, and because of patient-specific and system-specific factors, is really a composite of a multitude of contributions, including correct indication, dosage, and duration of therapy, use directions, other medications a patient may be taking, and underlying patient characteristics such as co-morbid disease.<sup>21</sup>

Not all patients treated will fit neatly into guidelines, making strict adherence to guidelines in these instances result in inappropriate treatment for subsets of patients.

Medicine treatment is becoming increasingly personalized, and the PTG would argue that it is a form of irrational use of medicines to treat patients as per guidelines when their particular clinical situation is not adequately served by the options on these guidelines.

*The PTG recommends that in order to ensure medication appropriateness, there is opportunity beyond basic treatment guidelines for patients to be offered the most appropriate treatments based on their particular situation.*

#### **5.2.4 Cost-Effectiveness**

Cost-effectiveness analysis compares the costs and health effects of an intervention to assess the extent to which it can be regarded as providing value for money.

Cost-effectiveness analysis directly relates the financial and scientific implications of different interventions, and as such, cost-effectiveness is always expressed as a ratio between costs and health gains.

The PTG is entirely comfortable with cost-effectiveness as a criterion for medicines selection for the NHI.

However, the PTG urges the NHI Benefits Committee to apply cost-effectiveness analyses and their outcomes as technically appropriately and transparently as possible.

South Africa currently has no formal threshold for judging cost-effectiveness, in either the public or private health sectors, and many analyses performed for the public sector make use of the WHO CHOICE suggested threshold of one to three times GDP per capita as a threshold.<sup>22</sup> However it has been argued that this

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<sup>21</sup> Hanlon J, Schmader K, Samsa G, Weinberger M, Uttech KM, Lewis IK, Cohen HJ, Feussner JR. A method for assessing drug therapy appropriateness. *J Clin Epidemiol.* 1992;45(10):1045-1051.

<sup>22</sup> WHO CHOICE. 2003. Guide to Generalized Cost-effectiveness. Available at [http://www.who.int/choice/publications/p\\_2003\\_generalised\\_cea.pdf](http://www.who.int/choice/publications/p_2003_generalised_cea.pdf). Accessed 1 March 2016.

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approach has major shortcomings and that new, more pragmatic methods might be preferable and should be debated.<sup>23</sup>

Currently the methods to be used for cost-effectiveness analysis for the selection of medicines for the NHI are not clear. The South African Guidelines for Pharmacoeconomic Submissions (2013)<sup>24</sup>, which are the most defined methodology available for pharmacoeconomic and cost-effectiveness analyses, currently apply to the private sector, and do not discuss methodologies for programmes in the public sector – for which cost effectiveness analysis of medicines is likely to use different costing methodologies as well as program evaluation which is currently not the norm in the private sector.

*The PTG recommends that in order to ensure that cost-effectiveness analysis contributes transparently and consistently to decision-making, that guidelines and processes be developed to ensure consistent and transparent consideration of cost-effectiveness arguments.*

### 5.2.5 Health Technology Assessments

Health Technology Assessment (HTA) may play a role in the selection of medicines.<sup>25</sup> However, the limited resources in South Africa both in the private and public sector should be strong considerations for such policy implementation. South Africa, furthermore, has limited prior experience in such assessments.<sup>26, 27, 28</sup>

Since HTA uses scarce resources, the opportunity costs may substantially exceed wages and overheads associated with HTA submission and review. The clinical benefit risk determination for an individual medicine is likely to be similar in different countries. If both the FDA and EMA have decided that a product's benefit-risk balance is favourable enough to allow a product on the market, it makes sense for emerging markets like South Africa not to spend substantial scarce resources to re-address this question in our local context. The "efficient" solution will involve some degree of "free-riding" of information.

Should such policy implementation be considered going forward, then a phased in approach based on the relevant legal frameworks should be considered so as to maximize the opportunity for success by allowing

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<sup>23</sup>Marseille E, Larson B, Kazi DS, Kahn JG and Rosen S. Thresholds for the cost-effectiveness of interventions: alternative approaches. Bulletin of the World Health Organization 2015;93:118-124.

<sup>24</sup> South African National Department of Health. Guidelines for Pharmacoeconomic submissions. December 2012. Government Gazette No. 36118. 1 February 2013.

<sup>25</sup> The circumstances listed in this section were extracted from a working paper published by the European Commission's High Level Pharmaceutical Forum (2008) which combined the experience of the Commission's Member States over the period 2005 to 2008. The work done by the Forum was intended to assist States **to address pharmaceutical costs while providing reward for innovation**. The working paper is referenced as follows: European Commission: High Level Pharmaceutical Forum. October 2008.

<sup>26</sup> Kriza C, Hannas-Hancock J, Odame EA, Deghaye N, Aman R, Wahlster P, Marin M, Gebe N, Akhwale W, Wachsmuth I and Kolominsky-Rabas PL. A systematic review of Health Technology Assessment tools in Sub-saharan Africa: methodological issues and implications. BMC Health Research Policy and Systems. 2014, 12:66

<sup>27</sup> Gavaza P, Rascati KI, Oladapo AO, Khoza S. The state of health economic research in South Africa: A systematic review. Pharmacoeconomics. 2012; 30(10).

<sup>28</sup> Hofman K, McGee S, Chalkidou K, Tantivess S, Culyer AJ. National health Insurance in South Africa: Relevance of a National Priority setting agency. South African Medical Journal. 2015. 105 (9):739-740.

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adequate time for technical/scientific process development and human resource and skills development. Furthermore, no accurate public sector data is available in terms of costs, utilisation, disease profiles, amongst others, which would be key inputs into HTA.

In principle, HTA policy consideration should include the following, taking into consideration that HTA is very context specific:

- HTA should be based on reliable data and information (evidence) in order to achieve certainty and reliability for all stakeholders. Where reliable local data is not available, international data should be considered.
- The decisions taken in one country may differ from decisions taken in other countries using the same data and information. This is because differences between the objectives and priorities of different national healthcare systems may create differences in the way in which healthcare interventions will be valued relative to one another.

HTA may also lead to increased medicine prices, especially where local studies are a pre-requisite for entry into the NHI market, and add to the costs of bringing a new product to market. Listing and procurement of medicines can be optimized by implementing scientifically validated and/ or properly formulated mechanisms, which:

- Are not themselves cumbersome or costly to implement and maintain, and do not cause unnecessary delays<sup>29</sup> or inequity in the availability of treatment;
- Facilitate competitive, sustainable and fair pricing;
- Ensure the effective allocation of resources on a prioritized basis;
- Introduce new innovations that improve clinical outcomes cost-effectively.

The structures within which HTA and possible price/reimbursement negotiations take place will be critical. In countries such as Australia, this is done by means of legislation, and formal dispute resolution procedures are included, as well as mechanisms to ensure independence in initial assessments and processes of interaction and negotiation.

*The PTG believes that the true value of HTA will only be realised once efficient systems are implemented in the NHI system as well as the human and other resource capacity is developed. A phased-in approach should be considered to develop expertise and experience over time. Since HTA are context-specific, accurate local data should be collected over time, since this will be a critical input.*

## 6 PROCUREMENT AND SUPPLY OF MEDICINES

The NHI White Paper makes reference to the fact that the procurement for NHI will be centralized, and presumably housed within the NHI Procurement unit.

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<sup>29</sup> While delays are inevitable, they should be in line with international norms and standards.

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The paper goes on to discuss central procurements in that *“The benefits of central procurement derive from leveraging the economies of scale of NHI to obtain the best possible price. The advantages of price determination could save millions of Rands every year. Improving systems and processes within the procurement system will bring greater efficiencies, fewer stock-outs and better access to health products for the patient.”* (para 387)

*The PTG does not support a single source “winner takes all” national system for the procurement of medicines.*

*The reference to “price determination” is also concerning, and the PTG is not in favour of an NHI price determination mechanism as it believes this has the potential to affect security of supply of medicines.*

“Procurement” actually has significant components in addition to the acquisition price.

An effective procurement process ensures the availability of the right medicines in the right quantities, available at the right time, for the right patient and at reasonable prices and at recognizable standards of quality. Thus, procurement is not simply the act of buying but encompasses a complex range of operational, business, information technology, safety and risk management and legal systems, all designed to address an institution’s needs.<sup>30</sup>

Medicine procurement is a complex process involving many different stakeholder groups, who although they have a common interest in terms of equity and efficiency, will also have more interest in certain aspects of the procurement process versus others.

## **6.1 Current Procurement of Medicines in the Public Sector**

As discussed in Medicines Selection (Section 5), the public sector medicines tender system addresses the pricing and procurement of medicines on the national purchasing catalogue. However, this system, while serving to determine prices and agreed contracts for supply, does little to address the actual act of procurement locally.

Procurement of medicines involves several procedures including estimation of quantities required for a given period, choosing procurement methods, receiving and checking of ordered products, making payment for goods received, distribution of products and collection of consumption information.<sup>31</sup>

In the current public sector processes, only the national tender processes, which involve determining quantities and locating and selecting suppliers, take place at a national level. All the other decisions and actions of the procurement cycle are handled by the provincial and hospital authorities, which have the purchasing systems and payment mechanisms to manage this process.

Proposals for a completely centralised procurement function cause some concern as it is unlikely that the central NHI fund will be able to manage all procurement functions adequately to make provision for all patient needs on a local level – hence the PTG’s recommendation of a decentralized medicines procurement system.

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<sup>30</sup> Ombaka, E. 2009. Current status of medicines procurement. American Society of Health-System Pharmacists, 66 (Suppl 3):S20-8

<sup>31</sup> Management Sciences for Health. 2012. Managing Drug Supply 3. Chapter 18: Managing Procurement.



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The need for appropriate healthcare delivery including getting the right medicines to the right people cannot be underestimated in light of the impact of the quadruple burden of disease. It is evident that the provinces have different health profiles and will therefore require different health services, including medicines, in order to ensure improved health outcomes in the populations that they serve.

Within the general framework of national formularies, based on national consensus treatment guidelines, local health authorities (whether at provincial, district or even hospital level) should be empowered to ensure the best possible health outcomes by means of medicines selection and procurement that addresses the health priorities and challenges of that particular region.

For example, districts that comprise large geographical areas without major towns would face significantly different health and service delivery challenges and should be able to respond to these without being constrained by national processes.

*The PTG proposes that decentralized procurement processes be retained as far as possible. While national level processes may assist in terms of achieving competitive pricing and reliable suppliers for essential products, these processes alone do not constitute a responsive and functional procurement system. The PTG believes that the most appropriate way to deal with provincial differences and sub-population differences within provinces is the utilisation of a decentralised approach to procurement in the form of contracting, which is cited by the IMF<sup>32</sup> as a desired method of cost containment, more successful than that of price regulation and price control. The appropriateness and responsiveness of districts to the specific healthcare needs of the populations they serve would be greatly enhanced.*

## 6.2 Supply of Medicines to Patients

The White Paper reflects the following with regard to supply of medicines to authorities and patients:

- Pharmaceutical depots are no longer the preferred method for ensuring sustainable supply of medicines because of inherent risk of pilferage, expired stocks, lack of security of supply, drug stock outs and inefficient distribution to healthcare facilities. A mechanism of direct delivery from suppliers to facilities will be implemented.
- Various interventions are currently being assessed and initiated, including direct deliveries by suppliers to health facilities

*The PTG requires additional clarity on how this direct delivery system is envisaged, and where the cost burden of the direct deliveries is likely to fall.*

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<sup>32</sup> IMF “Macro-Fiscal Implications of Healthcare Reform in Advanced and Emerging Economies” report prepared by the Fiscal Affairs Department, Approved by Carlo Cottarelli, December 28, 2010.

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If “suppliers” in this context refer to pharmaceutical manufacturers, this will mean manufacturers will have to put into place national supply mechanisms in the absence of central depots to which to deliver bulk stock. This could become quite a costly exercise for manufacturers and some consideration of these additional costs would have to be included in the prices of medicines.

The PTG currently estimates that only 30% of products reach public sector patients through direct delivery mechanisms to hospitals (DDVs). The majority (70%) is currently channeled through provincial depots.

While PTG member companies are cognizant of the significant challenges experienced within provincial depots the PTG is concerned that completely doing away with these centralized supply mechanisms may work out very expensive for the pharmaceutical supply chain.

*The PTG recommends that an opportunity be provided to debate, discuss and cost the various interventions currently being assessed.*

The White Paper also formalises the Centralized Chronic Medication Dispensing and Distribution (CCMDD) programme, which is currently being piloted:

- To improve access to needed medicines, especially for patients on chronic medication, as well as to assist with decongesting public clinics, the department implemented the CCMDD. This program is composed of two components: CCMDD and pick up points. (para 233)
- To date the implementation of the CCMDD has focused primarily on the provision of antiretrovirals (ARVs), fixed drug dose combinations (FDCs) in particular to stable patients on ART; however, this programme is eventually intended to encompass all stable patients within chronic conditions whose management consists of bi-annual visits and check-ups. Over 260 000 patients have been registered on the programme and this has helped to improve access to chronic medications. (para 234)

The PTG anticipates that the studies demonstrating improvements in access to medicine through the CCMDD will be published soon and would be in support of any programme which can successfully relieve the burden of provision from congested public clinics.

The PTG is potentially in favour of this as a mechanism for improving patient access to medicine. Substantial benefits have been claimed with the Chronic Dispensing Unit (CDU) in the Western Cape Province. However, it is to be noted that this CDU programme was outsourced to UTI Pharma, with expertise in logistics and medicines supply.

### **Pick-up Points**

The CCMDD program also proposes pick-up points in the community.

It is unclear from the current policy how and where these will be set up, and how good pharmacy practice and pharmaceuticals care will be ensured at the point of dispensing to patients.

It is also not clear who will be responsible for the logistics of ensuring medicines arrive at these pick-up points, monitoring patient pick-ups, following up with medications not collected, or how uncollected but dispensed medicines will be managed.

*While not opposed to the concept of pick-up points for medicines in communities, this decentralized supply chain poses considerable logistical challenges to the National Department of Health. The PTG requires additional clarity on how this CCMDD is envisaged, for where the additional costs for the distribution and pick-up points will be accounted and how this will be addressed in the funding for medicines under NHI.*

## 7 PRICING AND REIMBURSEMENT OF MEDICINES

The NHI White Paper states in Para 393:

*“Affordability and sustainability can be ensured through what is termed “strategic or active purchasing”.*

*b. “The service providers that will be accredited and contracted to provide services that are covered by the NHI Fund. The essential considerations here include the following:*

*iii. Government will put into place the necessary regulatory and policy interventions **to determine tariffs for health services** (including provider tariffs, and prices for pharmaceuticals and related products). **The law will equally apply to public and private providers including suppliers of medicines.”***

### 7.1 Sustainability of Supply of Medicines under an NHI System

While the PTG appreciates that one of the focuses of the White Paper is cost containment and ensuring sustainability of the NHI through managing expenditure, we are concerned by what seems to be policy statements threatening the sustainability of medicines supply.

The legal frameworks under which products find their way into the public and private systems are significantly different. In the private sector, the current Single Exit Price (SEP) system<sup>33</sup> is combined with a system of cost-effectiveness motivations to medical schemes and tender-type submissions to private hospitals. In contrast, procurement in the public sector rests solely with the systems created under the PFMA, but is effectively under the control of the National Department of Health. It has also become customary that bidders are invited after the closing of bids to discuss and further lower their prices.

Pharmaceutical companies in South Africa base their business potential and viability on the sales they can achieve in the private sector, which potential market is based on less than 20% of the total population. The sales to the private sector must cover both the variable and fixed costs for the company to remain secure in business. State tender business is neither consistent nor guaranteed, considering that new tenders are called for approximately every two years and winners of tender awards change with each tender cycle. Business won in one tender cycle can reduce to nil in the next and *vice versa*.

Therefore, state sector business is approached from a marginal income point of view. It is a fact that state tender pricing is usually below that of the private market and this varies according to a number of factors including volume called for. The state business which is usually additional to private sector business, makes

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<sup>33</sup> South African National department of Health. Regulations relating to a Transparent Pricing System for Medicines and Scheduled substances. 2004.

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some contribution after covering variable costs and a contribution towards overheads if there is sufficient production capacity. Thus medicines can be offered to the state at lower prices, rendering a smaller margin than private sector business. This differential pricing is permitted by the transparent pricing regulations, allowing the state to gain an advantage for the larger volumes that it purchases, while the existence of locally invested companies is secured by the more profitable private sector business.

It must also be considered that there is a social commitment on the part of the pharmaceutical industry to supply the state sector, (which is the regulator, the biggest provider of healthcare in South Africa and purchaser and supplier of medicines), with medicines at competitive prices, at cost or below cost, when required, as can be seen in the supply of antiretroviral medicines. Further, not all manufacturers supply the state with medicines, for various reasons and some as simple as not having an appropriate product portfolio.

*The expectation that the majority of medicine purchasing will move to a state-driven tender-based single purchaser system, causes immediate concern about the future security of supply of medicines and the continuing viability of the local manufacturing and locally-based pharmaceutical industry.*

## 7.2 Medicine Prices in the Public Sector versus International Benchmarks

South Africa is one of the few countries where published medicine prices in the public and private sectors are actually representative of prices paid. In most countries, systems of discounting, budget caps, rebates and contractual agreements result in prices which are lower than those publicly announced.

Management Sciences for Health publish the International Drug Price Indicator Guide<sup>34</sup>, which contains a spectrum of prices from pharmaceutical suppliers, international development organizations, and government agencies. The Guide aims to make price information more widely available.

South Africa public sector prices are included in this guide and allow for comparison with international purchaser prices, although the extent of these is limited to other countries and purchasers which participate.

An analysis of the 2014 International Drug Price Indicator reveals a mean price level per unit for South Africa of 3.32USD, versus an average of median prices for the same products of 4.33USD. (Appendix 3).

Thus the PTG believe that generally prices in the South African public sector are currently comparable and on average lower than those available for similar countries.

These favourable prices have been obtained through competitive tenders and negotiations, where essentially the decision as to whether or not a company supplies at a given price resides with the company, its costs and profitability of a given product or basket of products.

The proposals for tariff and presumably price determination in the NHI White Paper are concerning as they fail to adequately address the sustainability of supply of medicines.

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<sup>34</sup> Management Sciences For Health. 2015. International Drug Price Indicator Guide. Available at <http://erc.msh.org/mainpage.cfm?file=1.0.htm&module=DMP&language=English>. Downloaded 20 February 2016.

The PTG believes that prices in the public sector are currently competitive versus other countries and that the sector is able to leverage off its purchasing mechanisms to obtain fair prices while allowing for the sustainability of pharmaceutical suppliers. The sustainability of supply of medicines must be given adequate attention in the planning

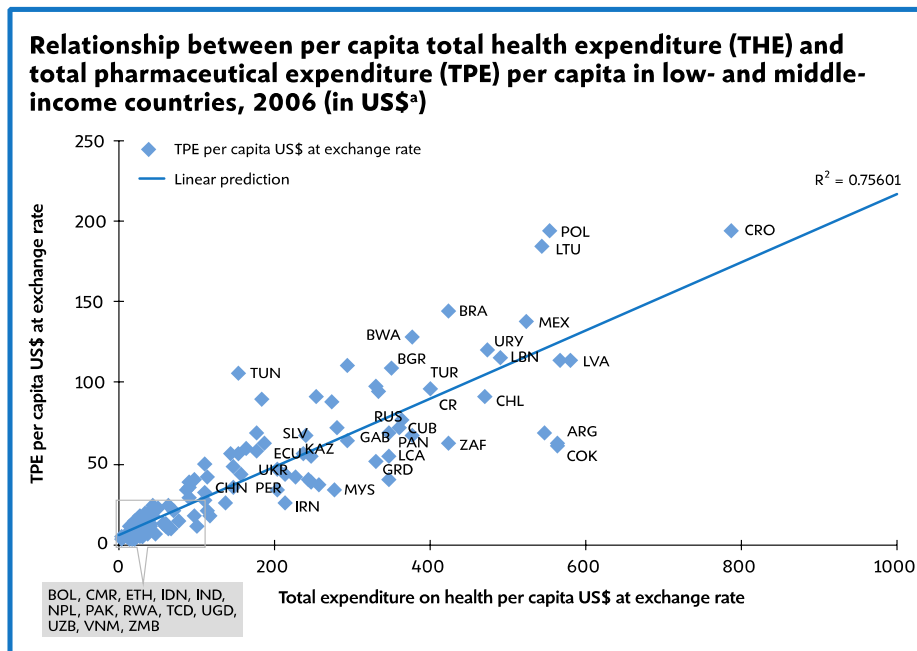
### 7.3 Current Insufficient Expenditure on Medicines

The NHI White Paper describes medicines as one of the cost drivers in the public sector health services.

In fact, given the value of medicine in healthcare, a key consideration is whether sufficient budgetary allocation is made for medicines, as compared to other expenditure line items.

Should South Africa want to improve its health outcomes, consideration should be given to increasing the spend on medicines.

The WHO *World Medicines Situation 2011* plots South Africa (“ZAF”) on pharmaceutical expenditure below peer countries such as Russia, Brazil and Mexico:



<sup>a</sup> National currency units converted to US\$ at 2006 exchange rates.  
Source: WHO NHA database

Figure 2: Pharmaceutical expenditure per capita vs. total health expenditure per capita (low & middle income countries)

## 7.4 Reimbursement Models

The PTG has highlighted above that South Africa should consider increasing the proportion of the health budget allocated to medicines in order to appropriately address healthcare needs and secure optimal health outcomes.

Most of South Africa's international peers have systems where public and private sectors co-exist to give patients access to healthcare. The World Health Statistics Report 2015 shows the following mix in public-private sector spend for the BRICS countries:

	Total (public and private expenditure on health as % of GDP		Split of expenditure on health (%) 2012		Per capita govt expenditure on health (US\$ average exchange rate		General government expenditure on health as % of total government expenditure
	2000	2012	Government	Private	2000	2012	
Brazil	7.2	9.5	47.5	52.5	107	512	7.9
China	4.6	5.4	56.0	44.0	16	180	12.5
India	4.3	4.8	30.5	69.5	5	18	4.3
Russia	5.4	6.5	51.1	48.9	57	467	8.9
South Africa	8.3	8.9	48.4	51.6	102	315	14.0

TABLE 2: PUBLIC AND PRIVATE EXPENDITURE ON HEALTH AS % OF GDP ACROSS BRICS

In such countries, the way in which the public- and private sectors interface in the national systems is important. A key consideration is the way in which contracted-in private providers are reimbursed. Such a system also affects the availability and cost of pharmaceutical care.

In many national systems, price- and reimbursement levels are not set, but negotiated with sub-units of the national system, in order to ensure responsiveness. In South Africa the envisaged District Health Authorities and Central Hospitals are permitted to procure medicines not only based on formularies (core and supplementary), but in also to procure additional medicines on the basis of negotiated prices or medicine trade-offs. Appropriateness, treatment guidelines and the healthcare needs of patients would guide the process.

These models of reimbursement and negotiation merit further investigation and the PTG proposes that a pharmaceutical multi-stakeholder forum/working group investigates these models and makes recommendations for consideration in the NHI developmental processes. Given the necessity of contracting-in private sector providers (e.g. pharmacists, GPs and specialists and private hospitals on the basis of Diagnosis-Related Group (DRGs) which would include medicine), the place of the current medicines pricing regulations in an NHI would also require review by such a proposed stakeholder team. Some

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schemes, such as those in the UK, include Patient Access Schemes within the voluntary price regulation agreement, which is an agreement between the industry and government.

Frameworks could also be price-based and include negotiating and modulating<sup>35</sup> price cuts or increases under abnormal circumstances including significant exchange fluctuations; negotiating special supply arrangements such as the guaranteed supply of certain brands; etc. Properly structured “risk sharing procurement arrangements”<sup>36</sup> constitute another alternative.

If a *tender process* is adopted as a major component of the statutory pricing system, such as the tender system currently in operation in the South African public health sector, then such a system should be designed to avoid the pitfalls of a “sole source tender” approach of the type implemented in New Zealand<sup>37</sup>. This is particularly pertinent if the medical scheme pricing system falls away under a national health insurance programme and a voluntary pricing scheme does not exist. A “winner takes all” approach could result in the following undesirable outcomes, such as:

- Reduced investment in the local pharmaceutical industry raising dependency on fewer players and potentially impacting adversely on local innovation;
- Delayed access to and slower uptake of new clinically-effective and cost-effective innovations;
- Adverse impact on the professional development of leading medical practitioners; and
- Sub-optimal health profile and reduced ability to favour medicines with lower side-effects.

The NHI White Paper also states that:

- *“Accredited and contracted retail pharmacies will be able to order drugs and other health products from the nationally agreed pharmaceutical contracts and will be required to dispense drugs that are procured at subsidized prices.”* (para 139)

There is no clarity in the White Paper of at what point in the supply chain this “subsidisation” of prices is to be implemented. It is also not clear how subsidies will be implemented in a system where it is envisaged that prices will be pre-determined (see Medicine Pricing).

Medicine subsidies operate in several public health systems worldwide as a way to assist patients in accessing medicines within national health systems.

*A single source procurement system could threaten investment in the local pharmaceutical industry with knock-on effects on medicines availability and sustainability of supply. The PTG requires clarity and debate on how subsidisation will take place.*

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<sup>35</sup> **Price modulation** refers to an arrangement whereby a pharmaceutical supplier offers different price adjustments across each of its range of products so that the predicted cumulative price cut adds up to the agreed average price cut. This arrangement is sometimes preferred to an “across the board” price cut. In the event that the average price cut does not add up to the agreed average cut the supplier will make an additional payment or receive a refund.

<sup>36</sup> *Risk pricing arrangements* incorporate a price based on estimated volume or treatment outcomes. Variances result in price adjustments payable to or from the pharmaceutical companies participating in such arrangements.

<sup>37</sup> In **New Zealand**, for patients NOT in hospital - Government reimburses medicine costs for products which appear on a formulary. If a patient chooses to select a product which is not on the formulary, the patient pays in full i.e. there is no co-payment system for non-formulary medicines. The PHARMAC formulary comprises medicines sourced using “sole source tenders” to bid down prices. This tender system results in only ONE or a very limited number of products being listed per category. The lowest bidder gets the TOTAL New Zealand business.

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## 8 THE ROLE OF MEDICAL SCHEMES ONCE NHI IS OPERATIONALISED

The NHI White Paper addresses the future role of medical schemes as:

*“In future, all medical schemes will only offer complementary cover for services that are not included in the health service benefits and medicines approved by the NHI Benefits Advisory Committee. The cover provided by medical schemes must only complement (and not duplicate) the NHI service benefits.” (para 401).*

Given the taxation mechanisms proposed to fund the NHI, a decrease in the size of the medical scheme beneficiary pool seems inevitable, but will depend on the quantum of additional taxation as well as the perceived benefit of retaining medical scheme cover, even when a functioning NHI is available. This choice will likely be made on the quality of care available to those using NHI services.

The PTG believes that patient choice of where to access healthcare based on their individual circumstances should be a key principle informing the development of a comprehensive NHI package. The PTG believes that the constitutionality of the NHI proposals be clearly tested before passing legislation rendering medical schemes in the position to reimburse services complementary to the NHI offering only.

In addition, this requirement will involve a very detailed and transparent benefit definition for the NHI – meaning there will have to be a “positive” (included) as well as a “negative” (excluded) for the NHI benefits, in order for medical schemes to ensure that they offer supplementary services.

From a medicines point of view, to enable medical schemes to offer ONLY complementary cover, The NHI benefits will have to be clearly defined in terms of:

- Conditions covered (or conversely not covered);
- Specific diagnostics methods covered and not covered; and
- Specific medicines treatments covered and not covered for various indications (many medicines can be used for more than one indication and command different efficacy, appropriateness and cost-effectiveness for these different indications).

Currently, the public sector does not have a list of interventions, medicines or technologies, which are EXCLUDED for patients.

The NHI benefit definition will require policies which would deliberately exclude certain patient groups from care in the NHI, and overtly exclude patient access to certain healthcare interventions, even where they may be appropriate for a particular individual patient.

The PTG also questions the constitutionality of this process of exclusion.

In addition, updates, additions and changes to the NHI benefits will require that medical schemes also change their benefits in order to remain “complementary” to the NHI benefits. This will require ongoing adjustment of medical scheme benefits, based not on scheme consideration of appropriateness and cost effectiveness of technologies, but simply because they will no longer be able to pay for services they deem appropriate.

This scenario is also likely to contribute to lack of continuity of care of patients, who may make use of an NHI accredited practitioner to access NHI benefits, but have to abandon this provider and course of treatment when excluded from the NHI benefits and included in private medical scheme benefits.



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*To enable medical schemes to offer ONLY complementary cover, the NHI benefit definition will require policies which would deliberately exclude certain patient groups from care in the NHI, and overtly exclude patient access to certain healthcare interventions, even where they may be appropriate for a particular individual patient.*

*Based on freedom of choice enshrined in the constitution, having to clearly define benefits excluded from the NHI, appear to create a challenge. Problems likely to arise from lack of continuity of care should also be a concern.*