CANCER ALLIANCE

Collective Voices for Cancer in South Africa

ACCESS TO CANCER MEDICINES IN SOUTH AFRICA

> Health cannot be a question of income; it is a fundamental human right.
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> **NELSON MANDELA**

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Cancer Alliance Report CA03/2021

Report prepared by Salomé Meyer, Dr Gcinashe Nqabeni, Neo Tsotetsi

April 2021

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DISCLAIMER

Compiling patent, access and pricing landscapes for medicines is a complex process, due to the lack of transparency from government-led information sources, and the tactics commonly used by pharmaceutical companies to create ambiguity within applications and hide information on pending and granted patents. Prices and patent status may also change.

We have obtained information from various sources as quoted to ensure that information is correct at the time of publishing and have sought to ensure accuracy in this report to the best of our abilities through a process of peer review.

All references were checked for accuracy and availability on websites where applicable at the time of publication. Cancer Alliance cannot accept responsibility for links to references that are no longer available.

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FOREWORD

Fatima Hassan, Head – Health Justice Initiative, Cape Town

We have a crisis in respect of access to the pharmaceutical treatment of cancer in South Africa. This report by the formidable Cancer Alliance paints a bleak picture regarding access to oncological interventions. It also explains, in detail, the worrying limitations of our health system, especially for patients living with cancer.

The ability of South African patients to access the best and most affordable cancer treatments in both public and private sectors is fast eroding as a result of the hollowing out of local state institutions due to poor planning, incapacity and corruption, especially in the health sector. Combine these problems with state capture and set it against the backdrop of a worsening local and global economy, exacerbated by Covid-19, and it becomes clear why cancer patients and their loved ones have to deal with much more than just the illness.

Despite having some of the foremost oncology experts in the world, this report shows that scientific progress in the management of different types of cancer, does not always result in immediate or affordable treatment for the majority of cancer patients. The public and private health sectors, policy makers, medical-scheme administrators and drug-company executives are failing patients with cancer in South Africa. Most patients cannot afford the medicines and treatment because they are priced for first-world markets and often excessively so – without any penalty or repercussion. Some also enjoy extended periods of exclusivity, which means they have little or no competition.

This is often due to the state's inexplicable deference to an industry that relies on a patent system, protecting the market at all costs, and long-term exclusivity and patent rights that government grants too favourably, and often unfairly, to multi-national and local companies. These companies then amass monopolies accompanied by unjustifiable profit margins.

Despite the many awareness campaigns, charity walks and pink events, our government has not taken the most basic measures to broaden access to medicine, namely, to grant compulsory licences against drug companies charging too much for life-prolonging or life-saving treatments. This report also highlights that, while the South African antitrust authority has for several years been investigating pharmaceutical companies selling their cancer treatments here while profiteering, this investigation is far from complete. It is effectively kept hostage to jurisdictional matters and a lack of costing transparency by drug manufacturers.

In addition, the report shows that this price-regulatory quagmire is worsened by the inability of the State and the Department of Health to complete and then implement a proper, fair, transparent and rational pricing regime for medicines in South Africa, rooted in constitutional imperatives.

The industry's oppositional stance to regulatory measures and reforms to expand access and realise the patient's right to the highest attainable standard of health, including opposition to the much-needed amendments to the Intellectual Property Framework for South Africa (Patents Act), makes this struggle even more difficult for our government and patient groups.

Although South Africa, post-apartheid, has high incidences of cancer, TB and HIV/AIDS, there are huge racial, gender and income disparities where access to medical care is concerned. Despite these inequalities and the fact that the health system is underfunded, our rules and laws are increasingly beginning to mirror that of high-income countries. Add the lack of transparency and justification in patent application and medicine pricing, and it becomes all too clear why our government must remedy these difficulties now, or our national health outcomes will deteriorate further, and thousands more patients and families will suffer.

I trust that Parliament will study the extensive analysis and recommendations in this report closely, and then initiate a series of Parliamentary hearings and inquiries to find out why our country is unable to access key medicines at affordable prices, why there is limited competition in the market, and why exclusivity, which drives high prices, is permitted when dealing with a grave health crisis such as cancer. Second, I hope that government, in cooperation with the Cancer Alliance and all other stakeholders, will use the report to bring about much-needed change in the pricing of key medicines for the effective management and treatment of all forms of cancer in South Africa.

Fatima Suleman, Professor of Pharmaceutical Sciences, University of KwaZulu-Natal, Durban

The issues around the pricing of and access to medicine are not new. There have been many debates over the last decade regarding the need for affordable medicines, and transparency in respect of the components used to determine medicine prices. Cancer treatment is no different. A World Health Organization report on the pricing of cancer medicine and its impact, issued in 2018, stated that the delivery of cancer care in recent years had been challenged by two main factors: the high prices, and growing expenditure on cancer medicines at rates higher than the growth in either patient population or overall health expenditure.

Many actors in South African civil society and other stakeholders have been vocal about the high prices of cancer medicines; the impact it has on the availability and affordability of these medicines to patients, and the difficulties in sustaining health systems under these circumstances. In 2011, the Lancet Oncology Commission called for a radical shift in cancer policy. They advised that patients and those involved in cancer care should demand more from the pharmaceutical industry. Patients should, namely, have better and long-term benefits from fairly priced, new oncology therapies and technologies. In 2012, the New York Times published an article on cancer-treatment costs after a hospital refused to buy a drug priced at $11 000 per month, highlighting the indefensibility of ignoring the cost of cancer treatment.

South Africa has come a long way in managing medicine prices with the implementation of the single exit price (SEP), but there are limitations to this policy. Other policy interventions, like international benchmarking and a compulsory pharmaco-economic review of a specific medicine, are still under review. The South African Affordable Medicines Directorate (AMD) as well as the Pharmacoeconomic Evaluation Directorate needs to strengthen their ability to review and adjust prices, and divest if required, based on routine monitoring and the evaluation of evidence on utilisation, clinical value, prices, quality and supply. Some cancer medicines do not add enough gain in life years to justify high prices.

These prices would thus have to be adjusted considering the outcomes.

Providing medicines to patients before product registration with the South African Health Products Regulatory Authority (SAHPRA) or outside of the regular reimbursement system creates challenges for many parties after registration. Once registered, the medicines may be priced higher than they were under the patient access programmes during the applicant's SEP-application phase. There is a need for policies to ensure patients' continued access to medicines provided under the access programmes for their lifetime or until the disease is under control. Further information is required about the impact of such access programmes on health systems and health or economic outcomes.

The pharmaceutical industry needs to be transparent about the public sources of funding available for the research and development of new products, and how these funds are utilised.

This report outlines the challenges patients face when trying to access cancer treatments. Policy interventions to address this issue need to consider cost-containment strategies, other pricing interventions, incentives for innovation, promotion of local production and the use of generics or biosimilars.

ACRONYMS AND ABBREVIATIONS

A2M

Access to Medicine Campaign

API

Active Pharmaceutical Ingredient

AMD

Affordable Medicines Directorate

EML

Essential Medicines List

NCR

National Cancer Registry

NDoH

National Department of Health

NHI

National Health Insurance

OOP

Out-of-Pocket Expense

PFMA

Public Finance Management Act

PMB

Prescribed Minimum Benefit

SAHPRA

South African Health Products Regulatory Authority

SEP

single exit price

SUS

Sistema Único de Saúde – Brazilian Unified National Health System

TRIPS

Trade Related Aspects of Intellectual Property Rights

WHA

World Health Assembly

WHO

World Health Organization

1. THE CANCER ALLIANCE

The Cancer Alliance is a group of non-profit organisations and advocates for the prevention and control of cancer. Their mandate: to provide a collaborative platform for cancer civil society to speak with one voice and thus become a powerful tool to affect change for all South African adults and children living with cancer.

The Cancer Alliance is a member of the Fix the Patent Law Campaign that focuses on the call for patent-law reform (1).

The Companies and Intellectual Property Commission (CIPC) is responsible for the registration of patents. The fact that this process is not open and transparent, however, largely contributes to the inequitability of access effected by the patent law. The Fix the Patent Law Campaign strongly believes that the following changes are required:

- stricter patentability criteria to combat patent evergreening
- stricter examination of patent applications to ensure the patentability criteria have been met prior to the granting of patents
- proper implementation of patent-opposition procedures
- the use of more workable procedures for granting compulsory licences.

Report CA01/2017 of the Cancer Alliance highlighted 24 specific medicines affected by the current patent law (2). This has an influence on equitable access for all South Africans, and many life-saving cancer medicines under patent will remain unaffordable and thus unavailable to the majority of patients.

In August 2018, the Department of Trade and Industry, dti at the time, released the cabinet-approved new Intellectual Property Policy – Phase I (A1). Now, with Covid-19, there is a renewed call on the South African Government to finalise the patent reform and ensure equitable access for all.

The Access to Medicine Campaign, also known as the A2M Campaign of the Cancer Alliance is funded by the Open Society Foundation (3).

2. EXECUTIVE SUMMARY

The latest report from the National Cancer Registry (2017) and the preliminary results of the PERCEPT Study about the cost of cancer (2021) confirm that, in sync with global trends, cancer incidence in South Africa is on the rise. This will place further demand on the already crippled public health systems. The CA01/2017 report by the Cancer Alliance highlighted the availability and affordability issues resulting from the patent rights on specific cancer medicines.

Regardless of whether treatment takes place in the public or private healthcare system, the patient is the main beneficiary of cancer treatment. Finding themselves in the position of being diagnosed with a life- threatening disease is a frightening experience, and the cancer patient must be able to trust the ethical integrity of the healthcare professionals on this uncertain path (A16).

Availability and affordability are the two main determinants of access to treatment, and this report aims to investigate the supply-chain management of cancer medicines in both the public and private health sectors of South Africa.

Through the use of the latest data, and engagement with the National Department of Health (NDoH), pharmaceutical companies, the South African Health Products Regulatory Authority (SAHPRA) and other stakeholders, this report seeks to highlight the existing problems around access to cancer medicines throughout the supply chain, which leads to inequitable access to medicine for the majority of people. Finally, the report offers a number of recommendations on how stakeholders may approach these challenges.

In South Africa, access to medicine is legally informed by Section 27 of the Constitution and multiple sections of Acts related to medicines, procurement, and patents, as set out in Appendix A. These pieces of legislation govern the tender process in the public sector, as well as the single exit price (SEP) in the private sector. Even though the legal framework is structured to help facilitate access to medicines and prevent corruption, the bureaucratic red tape adds to the inefficiencies within the public health system.

Section 18A is very specific about unlawful activities, and yet it seems to be the order of the day. Section 22G of the Medicines Act aims at pricing transparency and appropriate fees for medicines (A11), but the fixed SEP does not necessarily cater for unaffordable oncology medicines, which leaves many cancer patients with no choice but to forfeit treatment – a rather startling, very non-fictional case of 'your money or your life'.

Resources such as the pricing guideline and Fair Pricing Forum of the World Health Organization (WHO), and the example of countries like Brazil, can help improve pricing transparency, and, ultimately, access to affordable cancer medicines.

Regulatory bodies are responsible for facilitating the availability and access to good quality, efficacious and safe medicines to the public. According to the WHO, the mean registration time of products should be 90 days. In South Africa, however, some products have taken up to five years to be registered by SAHPRA, for example, Teva Pharmaceutical's filgrastim, which was the first biosimilar introduced to the South African market. Generic lenalidomide, advocated by the Cancer Alliance since 2018, and used in the treatment of multiple myeloma, was only registered in July 2020.

Multiple factors have contributed to the lack of access to cancer medicines in the public sector. Initially, we had wanted to investigate the 40 unawarded medicines of the oncology tender for 2018, but a new tender was published in September 2019 and came into effect on 1 July 2020. In this tender round, 54 medicines were unawarded, 13 of which had been carried forward from the previous tender.

A supplementary tender showed a further 12 medicines not awarded, meaning they would have to be obtained by special request through a Section 21 application. There were multiple reasons for non-awards, ranging from late bids, non-adherence to bidding requirements, poor performance by pharmaceutical companies, financially unviable tender prices and quantities for companies, delayed payments by government, and manufacturing problems like shortages of active pharmaceutical ingredients (APIs).

It is unacceptable that the current tender regulations for the procurement of cancer medicines in the public sector are the same as for basic goods. The regulation of life-saving medicines must match their vital importance.

Another factor that contributes to the inequitability of access to medicine in South Africa is the disparity between the public and private health sectors. There are more patients in the public sector, but 80% of medical staff works in the private sector. Patients in private healthcare tend to be diagnosed earlier and the procurement of cancer medicines depends on the patient's health plan.

The available treatments in the private sector include newer, patented medicines, which the public sector simply cannot afford. The inertia around the reform of patent law remains one of the major stumbling blocks in the quest for equitable healthcare. The use of the competition law is yet to be tested for the pharmaceutical market, and a market inquiry, specifically focusing on the inequities relating to medicine, is becoming imperative if we ever want to improve cancer-care services.

Recent reports such as the Mediscor Medicines Review show that even though oncology constitutes only 1% of the pharmaceutical market, it remains the second highest therapeutic group at 6.6% of the overall expenditure. Four new entrants into the top 15 specialty medicines were medicines used for the treatment of cancer, including pembrolizumab, which had made a dramatic jump from position 223 to 11 in the rankings over the space of one year. This further demonstrates the high costs associated with oncology medicines more often resulting in a financial crisis for the patient. One of the concepts that we would like all the important stakeholders to consider is value-based care – a concept that emphasises quality over quantity.

Cancer treatment and care in the future National Health Insurance (NHI) is still vague. The projected increase in the incidence rate demands solutions sooner rather than later. The complex process of medicine procurement, particularly for oncology, will be even more intricate when the NHI becomes operative, and will require transparent, patient-centred solutions. The time to start with appropriate cancer control and management for all is now.

The Cancer Alliance would like to offer specific recommendations to the main stakeholders involved in the access-to-medicine space. With concerted political will and collective effort, it can be achieved.

ReThink – ReDesign – ReEngineer

and

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3. CANCER CARE IN SOUTH AFRICA

It is commonly acknowledged that South Africa's healthcare system is highly inequitable. Only 15% of the population have access to private healthcare like that of high-income countries, while the remaining 85% have to get by with the inadequate public healthcare services.

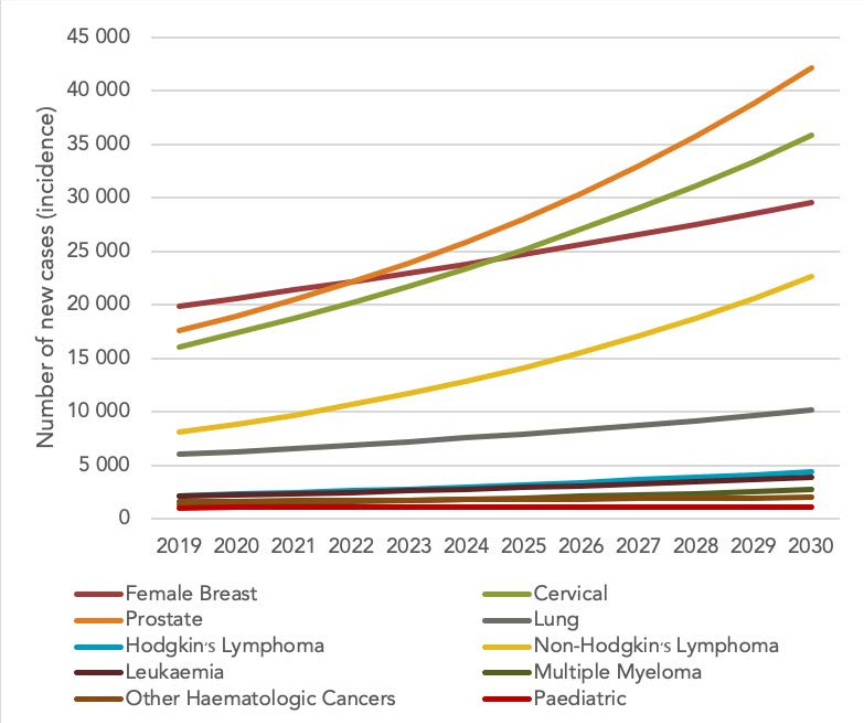
According to the 2017 Advocacy Toolkit series of the Cancer Alliance, the opposite is true for healthcare professionals in the field of oncology (4). Fewer than 20% of them work in public treatment centres while more than 80% are associated with the private sector.

The rate of under-reporting is estimated to be high, which can be associated with under-diagnosis and the efficiency of reporting mechanisms:

- Not all cancers are diagnosed through pathology.
- Not all laboratories report their pathology-based diagnoses to the National Cancer Registry (NCR) as per regulation of the NDoH, especially those in the private sector.
- The reporting mechanism is still paper based, consuming time that medical practitioners do not have to spend on administrative jobs.
- It is expected that the head of the health establishment will report cancer incidences – not the person who diagnoses the patient (A2).

Cancer incidence in southern Africa is set to increase dramatically, partly because of the ageing population, but also because of the increased success rate of HIV management. The preliminary results from a study commissioned by the Cancer Alliance specifically confirm the rise of cervical cancer and non-Hodgkin's lymphoma, both of which are directly linked to HIV. The fact remains that, no matter how successful HIV is managed, people with a weakened immune system are more susceptible to cancer.

The increase of prostate cancer, on the other hand, is directly related to the non-health-seeking behaviour of men in a patriarchal society. The focus of the Cancer Alliance's A2M Campaign will now shift onto medicines associated with these specific cancers.



Ten-year Projected Cancer Incidence

The increase in incidence will result in an expenditure increase of nearly R50 billion over a ten-year period for the public sector alone. Cancer-care services would require a dedicated focus from the National Treasury and the NDoH if we want to avoid a further crisis in healthcare services in the future (5).

As it is, cancer services in the public sector are already facing a multitude of critical problems. Bhekisisa reported on the break-down of cancer services in KwaZulu-Natal in 2018. Radiology machines were broken. A shortage of oncologists in public hospitals inevitably caused long waiting times. Medicine shortages and stockouts have further crippled the treatment of cancer, and patients fell victim to an increasingly dysfunctional healthcare system, stripping away their human dignity (6).

According to a more recent article on Spotlight, there have been significant improvements over the past three years but there is still a long way to go (7).

3.1 CANCER INCIDENCE

In 2011, the Cancer Registration Regulation 380 of the National Health Act 61 of 2003 (A3) was promulgated as part of the health legislation (A2) to make cancer a registerable disease. The NCR currently uses pathology-based data to record cancer incidence (8). Their latest report recorded the cancer incidence for 2017 at a total of 81 607 cases (9). This is 7 030 cases more than in 2014 (10).

Table 1 lists the top cancers for females and males in 2017, excluding basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) (9).

	Female	New Cases	% of All Cancers	Male	New Cases	% of All Cancers
1	Breast	9 624	23.11	Prostate	8 937	22.37
2	Cervix	6 600	15.85	Colorectal	2 182	5.46
3	Colorectal	1 981	4.76	Lung	1 879	4.70
4	Uterus	1 570	3.77	Non-Hodgkin's Lymphoma	1 380	3.45
5	Lung	1 055	2.53	Melanoma	1 187	2.97
6	Non-Hodgkin's Lymphoma	1 128	2.71	Bladder	1 058	2.65
7	Melanoma	1 024	2.46	Oesophagus	1 007	2.52
8	Oesophagus	787	1.89	Kaposi's Sarcoma	986	2.47
9	Ovary	590	1.42	Stomach	827	2.07
10	Kaposi's Sarcoma	578	1.39	Larynx	482	1.21

From these figures, it is not possible to determine the number of patients from the public and private sectors respectively. The NCR receives the figures for cancer incidence in the public sector through pathology reports from the National Health Laboratory Service (NHLS). Several factors make reporting from the private sector more complicated, however. While the public sector receives all pathology reports at one central point, namely the NHLS, there are many laboratories in the private sector like Ampath, Lancet and many smaller laboratories besides, leaving a fragmented reporting system. In addition, this reporting system is still paper based; private medical practitioners have little time to spend on administrative jobs, and the reported information is, therefore, not always comprehensive (11).

Most cancer medicines used in the public sector are linked to the treatment of the top 10 cancers. Many of the old mainstay cancer medicines that have been off-patent for years now, like paclitaxel, docetaxel, cisplatin, carboplatin, cyclophosphamide, doxorubicin, vincristine, vinblastine, bleomycin, 5-fluorouracil, calcium folinate, oxaliplatin, irinotecan, etoposide and gemcitabine are used for the treatment of cervical, breast, prostate, colorectal, head and neck cancers, as well as Kaposi's sarcoma, and Hodgkin's and non-Hodgkin's lymphomas. Many of the medicines are listed with more than one supplier at SAHPRA (12). These medicines are also used within the private sector, which means the demand and supply are influenced by both sectors.

3.2 CANCER TREATMENT

Cancer can be treated with surgery, chemo, radiation and hormone therapies, as well as bone-marrow and stem-cell transplants, or a combination of these treatments. For chemotherapy, specialists need access to cancer medicines in accordance with international guidelines as adapted for local circumstances and considering the availability of medicines. Pharmaceutical companies who want to market specific oncology products in South Africa must register the products, which will then be made available in the public or private sector, depending on their affordability.

In the public sector, cancer treatments are mainly provided at oncology treatment centres associated with Academic Hospitals. Not all provinces have the capacity to provide all the cancer treatments (13).

Patients who access oncology treatment in the public sector pay for services relative to their income. Most patients' treatments are subsidised. Patients with medical schemes and non-South Africans pay a facility fee that will include the pharmaceutical costs as well as a professional fee. Once budget allocations are made, all cancer medicines must be approved in accordance with the EML through the Pharmaceutical Therapeutics Committee of each treatment centre.

Private healthcare in South Africa is ruled by the Medical Schemes Act 131 of 1998 (A4). This Act makes provision for the establishment of medical schemes regulated by the Council for Medical Schemes, an autonomous statutory body created by Parliament (14). A set of Prescribed Minimum Benefits (PMBs) ensures that all medical-scheme members have equitable access to minimum healthcare services on a continual basis, regardless of their treatment plan, and cancer may qualify as a PMB condition (15). The EML is used as a benchmark to stipulate the conditions for the minimum PMB medicines that a member is entitled to.

Each medical scheme has its own oncology benefits specified for each of the treatment plans with an indication of the treatment allowed and whether excess payments are required.

A managed-care company will submit treatment protocols to the medical scheme to ensure that treatment corresponds with the approved clinical guidelines. Each treatment centre will procure their own medicine through their own pharmacy or commercial pharmacies.

Prescribed medicines not on the EML will become an out-of-pocket (OOP) expense for the patient over and above their contribution to the medical scheme and the payments the scheme has made – *if* that treatment is approved by the scheme. Schemes will often not approve treatments if they do not offer overall lifetime-survival benefits for patients, leaving them to deal with the financial burden of the situation in addition to the chemo and radiation (16).

The number of cancer treatments over the last 10 years have increased systematically, but the cancer-benefit packages for medical schemes have not been adapted accordingly. The results of a comparative study of 10 medical schemes by the Cancer Alliance is due for release in 2021.

The National Planning Commission's 2020 report on Pharmaceutical Pricing indicates that 19% of private healthcare expenditure is related to OOP expenses. The actual figures relevant to cancer medicines is unknown (17).

3.3 THE ROLE OF THE CANCER ALLIANCE

In October 2017, the Cancer Alliance released report CA01/2017 about the patent barriers in the way of equitable cancer care in the public and private health sectors of South Africa (2).

Subsequently, with the release of report CA02/2018, they established the A2M Campaign to improve access to eight specific cancer medicines (18). But since these medicines were still protected under the patent law at the time of publication, they could not be regarded as mainstay treatment options for most cancers. The Cancer Alliance, therefore, needed to become involved in the quest to regain access to older, off-patent mainstay medicines, abandoned by the pharmaceutical industry because they have lost their profitability (19).

In this report, CA03/2021, the Alliance would like to explore the supply and demand of cancer medicines in both the public and private health sectors. In the private sector, we focus on the high cost of cancer medicines as already discussed at the World Health Assembly (WHA) in 2017 and reported on by the director-general of the WHO in 2019 (20).

While rituximab was available in the public sector prior to the publication of report CA01/2017, and trastuzumab since entered that market due to the efforts of the Cancer Alliance, most of the newer patented treatments will remain out of reach for the cancer patients in public care. The Western Cape does not even provide trastuzumab treatment because they regard it as an unfunded mandate (21).

In their case, we aim to identify some of the pricing issues that affect affordability for both sectors. Because of the extensive supply chain in the public sector, different levels of service delivery may cause stockouts at different points – from local treatment centres and pharmacies right through to provincial depots and the Affordable Medicines Directorate (AMD) at the NDoH (2).

We also want to broaden the engagement with the NDoH, SAHPRA and all existing and prospective pharmaceutical stakeholders to discuss the options that may ensure equitable access to medicines across the cancer community.

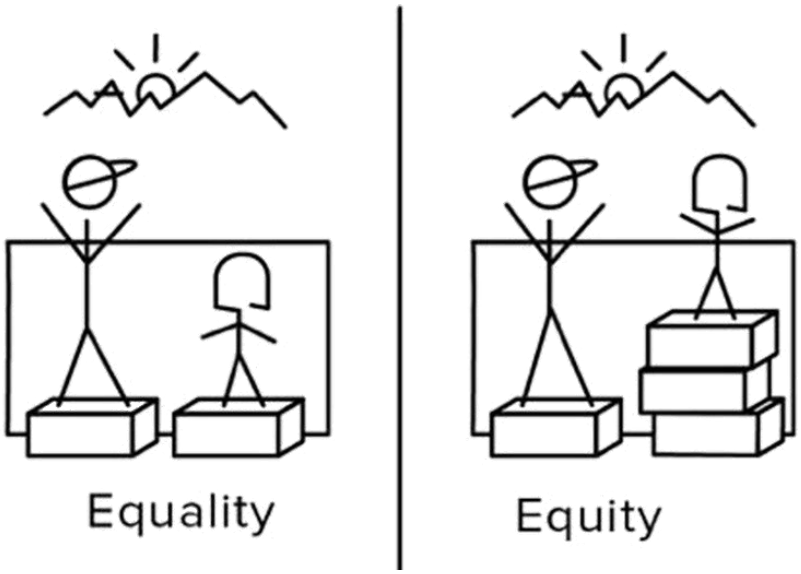
The availability of cancer medicines in the South African public environment should not be limited to medicines of which the patent rights have lapsed, however.

Although many newer therapies such as immuno- and CAR T-cell therapies are available on a global scale, they will remain too expensive for most of the South African population if pharmaceutical companies are not forced to adjust their prices to a more sustainable level (22).

4. ETHOS

Although the South African legislative framework for the health system, set out in Appendix A, tries to ensure equality for all its people, in its current form, it is insufficient to guarantee that health resources are distributed in an equitable manner.

But before we discuss what needs to be done, it is important to understand the difference between equality and equity. Even the dictionaries falter, and many people think the two terms are synonymous.



Equality means that each individual or group of people is given the same resources or opportunities.

Equity, on the other hand, takes into account that each person or group has different circumstances. Resources must therefore be distributed unevenly to reach an equal outcome (23).

The implication of these two principles, then, is that the availability of cancer medicines on the market does not mean they are practically affordable for all South Africans, and that is the core problem in the current health system.

The proposed NHI is set to establish a more equitable health service, but it is still in its concept phase and it is unclear how specialty diseases such as cancer will be managed in the NHI (A5).

5. THE ESSENTIAL MEDICINES LIST

The WHO publishes the model Essential Medicines List (EML) every two years. A panel of international experts considers applications from the pharmaceutical industry, clinical groups and patient groups, and then evaluates the products for their efficacy and estimated benefit ratio, but affordability is not a key aspect in making these decisions. The additions as well as the rejections are published. In 2019, 10 new cancer medicines were added to the EML of the WHO (24).

In South Africa, clinical evidence and cost effectiveness are the main criteria in the decision-making process to include a medicine on the EML (25). An expert committee is appointed by the Minister of Health to advise on the inclusion of medicines in collaboration with the AMD (26). Once these medicines are added to the EML, they are procured through a government tender advertised every two years. Each province manages their own cancer budget, and it is not clear how these budgets are allocated and managed for cancer treatment. Equity between provinces may thus be an issue.

Any medicines required for cancer treatment but not on the EML must be motivated to the Pharmaceutical Treatment Committee of each treatment centre and procured through the buyout system. If the product is not registered but available from another country, Section 21 authorisation through SAHPRA must be obtained for patients. This is an extensive and elaborate process because it requires re-application every six months. The originator lenalidomide is one of the patented medicines too expensive to be added to the EML (27), but generic substitutes have been available since July 2019, and they should therefore now be included as a matter of course.

As availability and affordability are the key components of access to medicine, the A2M Campaign focuses on medicines that have been recommended for inclusion in the country EML. Inclusion on the EML consequently should lead to PMB status, but the process takes time before private-sector patients can also benefit (26).

6. MEDICINE PRICING IN SOUTH AFRICA

Each of the two health sectors sets their medicine prices according to their own system. The procurement of health products like medicines in the public sector, is administered by the NDoH's Affordable Medicines Directorate through an open, centralised tender system, sometimes in collaboration with the National Treasury.

The National Treasury uses a single online platform, the Central Supplier Database (CSD), to manage the tender process for all government departments. The Office of the Chief Procurement Officer (OCPO) has been mandated to ensure that public-sector organisations honour section 217 of the Constitution – which is fair, equitable, transparent, competitive and cost-effective provision of goods and services (A6).

Prior to 2018, medicine tenders were managed by the NDoH, but the 2018 tender process was managed by the National Treasury (B1). At the time, all contracts were taken over by the Treasury to ensure policy and regulatory compliance, but the NDoH was still responsible for the management of the contracts. Many administrators and healthcare professionals criticised this move due to inefficiency and problems with the approval of many essential medicines. The NDoH worked tirelessly for the reversal of this decision and succeeded in taking back the responsibility for medicine tenders in 2020 (28).

The NDoH has established the Forum to Promote Transparency and Multi-Stakeholders Engagement regarding Medicines Availability, consisting of representatives from the NDoH, provincial health departments, pharmaceutical services and other relevant stakeholders. The pharmaceutical industry is well represented through the various bodies.

In the private sector, the pharmaceutical industry determines the SEP, which is then approved and published by the NDoH.

The sections below will show the disparities between the public and private supply chains for cancer medicines. They will also clearly indicate why drastic reform is an imperative if we ever hope to ensure equitable healthcare for all South Africans.

6.1 PRICING IN THE PUBLIC SECTOR

For contracts less than R500 000, the South African government departments must approach three suppliers for quotations, but for larger contracts, a tender must be advertised and bids examined by a tender board (29).

Tenders are then advertised on the website of the NDoH with a list of documentation, procedures, and terms and conditions for bidding, clearly set out in the bid pack (B2).

The NDoH enters into a contract with pharmaceutical suppliers and notifies the provinces of the awarded contracts. The provincial depots are then responsible for the quantification and procurement, warehousing, and distribution of pharmaceuticals to the hospitals and other facilities in their province (30).

Tender procedures in South Africa are mainly governed by four pieces of legislation:

6.1.1 THE PUBLIC FINANCE MANAGEMENT ACT

The PFMA aims to secure transparency, accountability and sound management of the revenue, expenditure, assets and liabilities of institutions such as departments and public entities to which the Act applies (A7). The Act is the financial guide for all government departments and the head of each department is the accountable officer who ensures compliance with all the provisions of the Act.

6.1.2 THE PREFERENTIAL PROCUREMENT POLICY FRAMEWORK ACT

The PPPFA sets out a system of preferential procurement where one bid is preferred over another because it meets or exceeds specific criteria. The Act is intended to enhance the participation of historically disadvantaged individuals and small, medium, and micro enterprises in the public sector procurement system (A8).

6.1.3 THE PREFERENTIAL PROCUREMENT REGULATIONS

The Preferential Procurement Regulations of 2017 serve as a guide for the implementation of the PPPFA. A fundamental assumption of the regulations is that the state is prepared to pay a premium in order to transform the South African economic landscape, which means that all government entities must adhere to the Act and the Regulations (A9).

6.1.4 THE NATIONAL DRUG POLICY

The National Drug Policy was adopted in 1996 to improve medicine access in both the public and private health sectors (A10). The key objectives of the policy focus on health, economics and national development and, as such, the policy has paved the way for the selection process of the EML and the centralised procurement through the NDoH rather than the National Treasury.

It is doubtful, however, whether the economic and national development objectives discussed in Chapter 14 of the Health Systems Review of 2013, were achieved (31).

6.2 BUYOUTS

Procuring medicines outside of the tender system through buyouts should only occur under exceptional circumstances, for example

- when facilities need to purchase medicines that are on the EML but are infrequently used or not on tender
- when tenders are advertised and awarded late
- when suppliers are unable to fulfil their contractual obligations for reasons beyond their control
- when the supplier does not perform as agreed, for example, by not observing lead times, not maintaining good quality products and delivering incomplete orders
- when limited usage negates the need for a contract
- when tenders are not awarded, and medicines are required to ensure continuation of treatment.

The buyout process is treacherous because it is long and involves a considerable amount of paperwork. Regulations require a minimum of three quotations and multiple approvals when the time and effort can be spent elsewhere (32).

6.3 PRICING IN THE PRIVATE SECTOR

South Africa uses a transparent pricing system, stipulated in Section 22G of the Medicines and Related Substances Act 101 of 1965 (A11). The pharmaceutical companies submit the SEP, which comprises the sum of the ex-factory price, the suggested logistics fee and VAT. This price is considered the fixed selling price of medicine, excluding the dispensing fee issued by a pharmacy. The SEP is then published by the NDoH to govern medicine prices in the private sector and make them more accessible and affordable to patients with private healthcare (33).

At the time of planning the SEP, medicine-price inflation, transparency, uniformity, bonusing and discounts were significant problems in an unregulated medicines market, but the SEP didn't provide the solution everybody had anticipated (20).

The SEP is a fixed-price policy intended to provide equal opportunity for patients to pay the same price regardless of where they are in SA, or in which income category they find themselves. In an unequal society, equality is not much use, however, and the benefits of price negotiations should be provided equitably to all patients and

not only to medical-scheme members with a louder voice. Transparency is extremely important in the setting of the SEP because kickbacks or incentives in these negotiations are forbidden.

Finally, pharmaceutical companies need to be held accountable for the high prices of cancer medicines (20).

Further to the inequity of the SEP, there is little if any scrutiny of the actual manufacturing prices indicated by the pharmaceutical companies. The NDoH manages the SEP purely as an administrative function and, therefore, does not take international benchmarking tools and research on the actual cost of production into consideration. Most originator companies argue that research and development costs (R&D) are included in the manufacturing costs, thus justifying their very high prices (20). Although a health-market inquiry was established for private healthcare in terms of Section 4A of the Competition Act 89 of 1998, this inquiry did not include medicine pricing (34). The recent report of the National Planning Commission also refers to the need for such an inquiry.

Transparency and fairness in the setting of prices are essential for designing and implementing sound pricing policies. This was a furiously debated issue at the WHO Fair Pricing Forum of 2019 in South Africa, which, eventually, resulted in the transparency resolution submitted by Italy and co-sponsored by South Africa to the World Health Assembly (WHA) in May 2019 (20). Italy became the first country to enact this resolution, which forces pharmaceutical companies to provide an economic evaluation as justification for the prices they propose if no other reference comparators are available.

Such an evaluation should include factual information about the costs incurred during the different phases of research, development, production, marketing and logistics (35).

Subsequently, in September 2020, the WHO published 10 pricing policy guidelines to improve transparency and fairness through a range of mechanisms:

- **External referencing** ensures that prices are benchmarked against the same medicines in other comparable countries.
- **Internal referencing** ensures that prices are benchmarked against products with the same or similar medicinal value in the same country.
- **Value-based pricing** considers the medicines' worth compared to existing available treatments for the same conditions. This includes assessing factors such as the number of life years a patient can gain, the extent to which the patient's quality of life will improve, and whether or not treatment can save the system resources by avoiding hospitalisation or longer-term care.

- **Government regulation of mark-ups** sets the limits of what pharmaceutical suppliers can add to the costs of medicine as they sell it along the supply chain and eventually to patients.
- **Price transparency** ensures that all relevant stakeholders know the prices of medicines and the way in which they are set.
- **Tendering and negotiation** ensure that prices are set according to the best offer from suppliers.
- **The use of quality-assured generic and biosimilar medicines** encourages the use of other versions of brand-name products that have exactly the same or similar characteristics as the original product.
- **Pooled procurement** ensures that financial and non-financial resources are pooled to create greater purchasing power and improve efficiency.
- **Cost-plus pricing** ensures that prices are set by assessing the costs of producing the medicines and adding a profit margin.
- **Tax exemptions or reductions** ensures the removal or reduction of taxes on pharmaceutical products (36).

The report of the International AIDS Vaccine Initiative (IAVI) on expanding access to monoclonal antibody-based products also considers six factors that influence global mAb prices, including competition in the market, international reference pricing, cost-effective thresholds, tiered pricing, direct price negotiations and the introduction of second brands (37).

Introducing generic or biosimilar brands into the South African public sector like Herclon®, the trastuzumab clone of Herceptin®, is a perfect case in point (37).

The discussions around the proposed NHI should feed into the debate around value-based healthcare that fits in with the 4P principle of the Cancer Alliance's patient-centred care model, namely Patient-Public-Private-Partnership where the patient is first and not last (38).

7. THE BRAZILIAN MODEL OF HEALTHCARE

In the new National Constitution of Brazil, which they enacted on 5 October 1988, Article 6 proclaims health a fundamental social right, and in articles 196 to 200 the guidelines for establishing a single, unified national health system are set out (39). The Sistema Único de Saúde (SUS), Brazil's Unified National Health System, is the largest government-managed healthcare system in the world that is free of charge for any person, including foreigners (40).

Two years later, the Organic Health Law was published under the number 8.080. According to article 7, public health actions and services, combined with private services under contract or agreement would be part of a unified national health system (41). It would be developed according to the guidelines in article 198 of the National Constitution (39) and in compliance with the principles of universal access to health services at all levels of care as per definition of the WHO (42).

According to the 60-Day Law in Brazil, every patient diagnosed with cancer should begin treatment within 60 days of diagnosis. These deadlines are difficult to meet, however, especially when radiotherapy is required in the public network (43).

In some cases, authorisation for drug treatment may take less time through SUS than through the private system because some health plans require prior authorisation, which may take 10 to 15 business days. In SUS, if the drug is available, they can start treatment immediately (43).

But, according to oncologists, SUS does not always run as smoothly as it sounds because sometimes it takes 60 days just to make an appointment. Other problems include drug-access restrictions because a limited number of patients need a specific drug. The authorisation process may limit the supply of medication at the hospital pharmacy and may thus become unavailable in the chemotherapy unit (43). These problems should be taken into careful consideration in the planning of the proposed NHI or we will encounter the same difficulties that cripple the Brazilian cancer-care system.

Through a knowledge-transfer agreement with the pharmaceutical industry, the Brazilian government studied the production processes at Bio-Manguinhos, the Institute of Technology in Immunobiology, and Fiocruz, the Oswaldo Cruz Foundation, which is directly linked to the Ministry of Health. This facility provides vaccines as well as biopharmaceuticals like trastuzumab and rituximab, thus allowing for access to high-technology products, which strengthens the principles of universality, inclusivity and equity that guide the actions of SUS (44).

8. METHODOLOGY

There are two focal points in this report. First, it investigates the reasons for non-bids and non-awards in the government's oncology tender process. Second, it explores the high cost of medicines still under patent protection in the private sector, which makes them unaffordable for the public sector.

Unawarded medicines can cause essential cancer-treatment shortages and stockouts at public health facilities. In line with the conditions of contract, the onus rests upon the supplier to notify the NDoH as soon as possible. There are two main mechanisms available to suppliers and public treatment centres for reporting medicine shortages. The efficiency of these mechanisms, however, relies heavily on consistent implementation, communication and accountability between suppliers, tertiary-level pharmacy managers, and the provincial and national health departments.

- Contracted suppliers must report to the AMD twice weekly about possible supply disruptions and shortfalls, which may result from global API shortages, manufacturing constraints, and incorrect stock estimates. Uncontracted suppliers do not have such binding obligations, however, and unfortunately, not reporting possible shortages impairs the forecasting ability of the NDoH in terms of overall supply.
- Public treatment centres report their stockouts to their provincial depots and/or the NDoH directly. A dedicated WhatsApp line has recently been established to facilitate the reporting process of the tender period starting in 2020 and ending in 2022.

Unfortunately, neither the suppliers nor the treatment centres necessarily fulfil these obligations with diligence.

The stockouts of cancer medicines in public hospitals called attention to the urgent need to investigate and discuss pharmaceutical suppliers' ability to fulfil the demand of the public sector.

In April 2019, the Cancer Alliance facilitated a meeting with the members of the pharmaceutical industry and a representative of the NDoH to discuss the reasons for non-awards and non-bids in the 2018 tender process:

- **Communication between the National Treasury and the NDoH:** First, during the two-year period of the 2018 tender, when the National Treasury took over all tenders from the NDoH (B1), there seemed to have been little or no communication between the NDoH and the Treasury, and the Treasury had no real insight into the issues around medicine. The problem was resolved, however, when the mandate for medicine tenders was returned to the NDoH.
- **Communication between the industry and the NDoH**: The pharmaceutical industry needed to know why certain medicines were not awarded, and, by the same token, the NDoH needed to know why certain medicines were not bid upon.
- **Delay in the awarding of tenders:** An initial lead time of three to six months from award to delivery is required for the manufacturing of most oncology medicines, but the tender specifications only allow for 75 days initial lead time, which is roughly two and a half months. A delay in the awarding of tenders inevitably causes a knock-on effect in their procuring and eventual supply of medicines to the government.
- **Financial risk:** There are strict penalties for companies who are not able to supply within the lead time, and, consequently, suppliers become wary of the commitment since they have no control over the delays from the NDoH or international suppliers.

The following recommendations resulted from the discussions in that meeting:

- **Follow-up Stakeholders' Meeting:** The pharmaceutical industry felt it necessary for both sides of the tender process to discuss their specific needs and requirements if they wanted the supply chain to function properly without interruptions.
- **Tender Extensions:** If awarded contracts could be extended for a short period, the supply of medicines could carry on uninterrupted while the new tender company is in production, especially if the lead time is too short. If such a change-over process could be arranged, there will be no need to get quotations, which is a longer and more expensive process.
- **Supplementary Tender:** Unawarded medicines on the EML should be advertised as soon as possible (B3).

The Cancer Alliance communicated the meeting recommendations and information on the availability of specific unawarded medicines to the AMD, who followed them up and subsequently entered into buyout contracts where possible. The NDoH indicated, however, that

- a supplementary tender was not possible as the new tender for 2020 was due to be advertised in September 2019
- the department did not have the capacity to manage various lead times and a six-month lead time would impact tender prices due to the exchange rate.

The suggested follow-up meeting did not take place as the NDoH's briefing session for the 2020 tender was scheduled with the industry for 8 October 2019.

8.1 THE 2020 TENDER

The oncology tender for the public sector, HP04-2020ONC, was advertised on 27 September 2019 with a closing date of 28 October 2019 at 11:00 (B2).

The Cancer Alliance notified all industry stakeholders with known contact details of the tender and advocated for the industry to participate actively in the tender process to avoid the same difficulties that caused all the non-awards in the 2018 tender process. The briefing session on 8 October 2019 was well attended by most of the oncology suppliers. The Cancer Alliance met with the AMD on 17 February 2020 to discuss their prospective in-house research on the causes of oncology stockouts in the public sector from the suppliers and from government.

The AMD advised us to narrow down our focus to the supplier level, and to determine the API sources and the registration status of the various medicines by engaging SAHPRA and the industry. At the time, it was not clear when the outcome of the oncology tender would become available, and, eventually, the tender HP04-2020ONC was only awarded in May 2020 (B2).

A total of 16 companies were awarded tenders for 54 products. The tender called for a total of 115 specific oncology medicine formulations, which means 61 medicines were not awarded. The outcome was thus even worse than in 2018. (*Please note that the 61 unawarded products included more than one kind of dose form of the same API)* (B2).

The 40 and 61 unawarded medicines from the 2018 and 2020 oncology tenders were analysed to establish their registration status with SAHPRA and their availability on the South African market. We asked for information from the suppliers of

unawarded medicines about the API sources, licence holders and availability of the medicines outside South Africa.

We thus established an overview of the existing supply issues possibly posing a threat to the long-term accessibility of these medicines in the public sector. Consequently, we could also establish which suppliers needed to be engaged to ensure that these risks could be mitigated by the NDoH. In terms of availability on the market, the question was whether a certain medicine was registered with SAHPRA and could be procured through a national tender. If deregistered or discontinued, would it be available via Section 21 of Act 101 of 1965 (A11)?

The following information for each medicine was considered:

- date of registration
- name of licence holder
- source of API
- availability outside South Africa, with particular focus on India because most of the generic suppliers source their APIs from there.

The analysis would provide a broader understanding of the availability of these medicines in South Africa and the channels the NDoH would need to use to procure them.

Data regarding the date of registration and the name of licence holder was extracted from SAHPRA's searchable online database (12). Further information about the product and supplier names were extracted from MIMS (45) and The Generics Dictionary (46). Information about the available manufacturers of these products in India were extracted from 1mg.com (47).

MIMS (45) and The Generics Dictionary (46) were used comparatively to verify the information available on generic medicines and ensure research accuracy. They are two similar databases, providing information about the APIs and brand names of the different medicines, as well as the strength and dose required for each. They differ, however, in that The Generics Dictionary provides the NAPPI code used in the private sector instead of the SAHPRA (12) registration number of a medicine, which is provided by MIMS. The private sector was not under scrutiny in this study, however, and, therefore, the NAPPI codes were not considered. Also, unlike MIMS, The Generics Dictionary does not provide information on whether or not specific medicines are used for the treatment of cancer, or for which cancers specific medicines are used.

The problem is that none of these databases provide information about the availability status of a medicine in real time. A medicine may, therefore, reflect as a registered product on the SAHPRA database, price and supplier name included, but there would be no information on its market availability in South Africa or its possible discontinuation or deregistration.

Suppliers should be able to update information about the discontinuation and/or deregistration of a product, or the selling of marketing rights to another company in a real-time database. Currently, the company needs to inform SAHPRA of its intention to discontinue or deregister a product in the country. Some suppliers stated that the next step would be to inform the NDoH to remove the product from the system.

There is an evident disconnect in the communication between the NDoH and the regulator because suppliers rely on the NDoH to communicate such information to the provinces. The provinces should inform their facilities, and the health workers should then inform the patients, who are the most important end user in the supply chain.

Patients are often left unaware, however, of the reasons behind medicine shortages, changes in doses or the complete unavailability of a medicine at a tertiary facility. The Cancer Alliance believes that there is an urgent need to revisit the role of the clinical team in communicating the reasons for medicine shortages. Patients have a right to health and should be able to use the official complaint system of the government.

In addition, the source of the API is not indicated in any of the three databases. Considered to be intellectual property, this information is confidential and can only be provided by the manufacturing company. Also, more than one manufacturing plant may be involved in the production of an API and is subject to change. Most APIs for cancer medicines originate from India, China and some European countries.

8.2 THE SUPPLEMENTARY TENDER

Prior to the commencement of the tender period of 1 July 2020, a supplementary tender was advertised by the NDoH. The large number of unawarded medicines linked to the mainstay cancer treatments in the public sector forced the NDoH to immediately advertise a supplementary tender to prevent a crisis in cancer treatment. This tender was advertised on 22 May 2020 and closed on 22 June (B3).

The medicines on the tender list would therefore only have been available on contract from possibly December 2020 or January 2021. But the NDoH had made interim arrangements for the supply of most of the medicines on the list through buyouts. The supplementary tender was allocated on 30 October 2020 and 17 out of 25 unawarded medicines will continue to be supplied on quotation. Most of them would only be available from 13 January 2021 onwards, but the NDoH remains committed to monitoring the supply of these medicines. Products such as fluorouracil 5% ointment 20 mg, mycophenolate mofetil 500 mg tablets, oxaliplatin

100 mg injection, and zoledronic acid 4 mg injection had significant issues in terms of supply and were hotlisted for monitoring.

Through the telephonic mapping of the medicine suppliers on the 2020 non-award list we found that, out of 15 contacted suppliers, 8 companies would be bidding and retendering on the supplementary tender. Some companies indicated their willingness to retender, even though they were not awarded any tender.

Cipla-Medpro offered to supply most of the medicines on the supplementary tender, but only on a Section 21 basis. It should be noted that Section 21 is a last resort for the department. Suppliers should rather work towards obtaining registration exemption from SAHPRA for a fast-tracked registration of an essential medicine or to purchase the medicine on an existing dossier of another company.

The rest of the companies said they were unable to retender because of

- stockouts
- supply constraints from global API manufacturers
- product discontinuation
- products not being actively marketed in South Africa.

Three of the suppliers did not respond to emails and chose not to provide this information, stating that they deal directly with the NDoH.

Medicines such as asparaginase, melphalan and interferon alfa-2a that appear on the supplementary tender as non-awards, which are all registered with SAHPRA, each under a separate, single supplier. Asparaginase and melphalan are both registered under Pharmacare Limited, but they will not be tendering for these medicines because of supply constraints reported by the manufacturing plant.

Below is a list of medicines that were unawarded on both tenders. There is thus a high probability that they may be difficult to procure in the long term. These medicines need to be included in the updated medicines stockout list published by the AMD.

Thirteen products were again not awarded in the supplementary tender round and the NDoH called for Section 21 suppliers to contract for the medicines in **Table 2** (12).

API Name	Dose	Units Required in Tender	Number of Products Registered with SAHPRA
Bleomycin	15 IU injection	23 260	4
Carboplatin	450 mg injection	20 840	5
Carboplatin	150 mg injection	7 020	5
Cisplatin	50 mg injection	49 540	6
Cisplatin	10 mg injection	1 815	6
Dactinomycin	50 mg injection	2 000	0
Doxorubicin	50 mg injection	81 440	7
Doxorubicin	10 mg injection	7 830	6
Epirubicin	50 mg	23 660	11
Epirubicin	10 mg	1 320	9
Etoposide	100 mg/5 ml injection	53 410	4
Gemcitabine	1 g injection	23 530	7
Vincristine	1 mg injection	5 380	6

Most of these products have been awarded under Section 21 to either Equity or Cospharma. Section 21 will run only for six months. The SAHPRA registration of Dactinomycin by Key Oncologics is pending. Bleomycin has been discontinued by Teva. Cipla-Medpro indicated that their product will be available again once production at the manufacturing site has resumed. Vincristine 1 mg has been discontinued but will be available in a 2 mg injection. For epirubicin 10 mg and gemcitabine 200 mg injection, other doses were available.

The most recent statement of the International Pharmaceutical Federation addressed both local and global medicine shortages. Medicine shortages are a mismatch between supply and demand, which causes changes or delays, reduced commitment to patients and discontinuity of treatment and care. The statement deals extensively with the responsibilities of governments, regulatory authorities and suppliers (48).

The 2017 policy recommendations on cancer-medicine shortages in Europe, provide insights regarding the prevention of medicine shortages that is relevant in the South African context (49).

Medicine availability at the designated treatment centres in the various provinces remains problematic. Although some provinces like Gauteng and the Free State have more than 90% of essential medicines available, other provinces such as the Western Cape, Northern Cape and KwaZulu Natal have only between 80.6% and 88.9% available. Rural provinces like Limpopo recorded even less at only 57.9%. The official target is to have 90% of medicines available at hospital level, but the NDoH reported only 76.2% (50).

Subsequently, the Cancer Alliance scrutinised the SAHPRA database and found 10 companies who had some of the unawarded medicines registered. These companies were contacted via email and telephone to find out whether their registered products appearing on the 2020 non-award list were available on the South African market, deregistered or discontinued, and whether the company would bid on the supplementary tender.

This information is tabled in the list of unawarded medicines from the 2018 and 2020 tenders as set out in Appendix C.

A research questionnaire was emailed to the 32 pharmaceutical companies that appeared

- on the bidders' and contractors' lists for the 2018 oncology tender
- on the bidders' list for the 2020 tender.

The purpose of the questionnaire was to gather insight into the position of each company regarding stockouts and other issues in the supplying of oncology medicines. Questions about product availability, API origins, relations with the NDoH and provincial health departments, and the root causes of stockouts were asked.

Some companies sent their responses via email in PDF documents while others' responses were recorded during self-administered telephonic or virtual interviews. The information and findings were synthesised to present an overview of the medicine-manufacturing landscape and the impact of current problems on the adequate supply of oncology treatments in the public sector.

Although every effort was made to send the research questionnaire to every company that appeared on the suppliers' lists, an overwhelming 68.75% (n=22) did not respond to the questionnaire. Some companies could not get global compliance authorisation to engage with a patient-advocacy group. Others simply refused to participate, however, claiming to deal only with the NDoH directly.

While only 31.25% (n=10) of suppliers responded to the survey, the findings do provide a view of the gaps and systemic issues present at the supplier level subsequently causing medicine stockouts at facility level.

9. LIMITATIONS

The Cancer Alliance is aware of the lack of research into the government's side of the procurement process. Comprehensive research at the level of provincial health is necessary to investigate medicine procurement through buyouts, the existing problems with reporting mechanisms, and the causes of stockouts. Such research should also examine the lengthy buyout system used in hospitals for the procurement of EML medicines not on tender or inadequately supplied, and how it affects the availability of medicines when required.

None of the respondents who electronically completed the surveys or interviews represented the views of their companies. They might also have responded in a way favourable to them and their company. Therefore, while the contributions from suppliers might have highlighted the inefficiencies of the NDoH and their large role in medicine stockouts, the results might not have exposed all the shortcomings of the suppliers.

Telephonic and virtual interviews provided comprehensive and in-depth answers and insights, while the electronic questionnaires were mostly kept to a maximum of two sentences. Questions regarding views on the causes of stockouts and how to improve the system, for example, were not conclusive.

A considerable number of companies chose not to participate or disclose any information because of binding internal and global policies regarding their relationship with patient-advocacy organisations. It should be noted that the non-participation of the companies was not because of their unwillingness to do so.

A further limitation of this report is that all the suppliers registered with SAHPRA were not contacted to participate in the survey. It is unclear whether smaller companies with registered products have the capacity to supply any medicines. This may require further investigation.

The Provincial Health Departments and pharmacy managers in treatment facilities were not engaged regarding the reporting mechanisms used to report oncology shortages at hospitals and provincial depots. Neither were they questioned about the buyout system used when EML medicines were not on the oncology tender or when suppliers did not perform as per contract. This was an important group to ask for insights into how cancer patients, specifically, could be educated about stockouts and their right to medicine.

Many patients spend money to travel long distances for treatment, only to arrive at the clinic and be sent back home because they were not informed of the medicine stockout. Stockout reporting through direct involvement of patients and advocacy groups, linked to satisfaction-reporting surveys of the various treatment facilities could contribute to the improvement of the supply-chain management.

10. RESULTS

Before we shift our focus onto cancer-medicine access in South Africa, we first need to understand the regulatory process. Since our report is framed on equitable access for both the public and private sectors, each sector's specific availability issues should be investigated. In the public sector, we focus specifically on the tender system that has been problematic for the last four years, resulting in cancer medicines not being available for standard treatments. In the private sector, we emphasise the exorbitant prices for cancer medicines, far beyond the financial reach of many patients. This is especially the case with newly developed cancer treatments which provide better overall survival benefits. Finally, we discuss anti-competitive behaviour and how this could be curbed to provide better access to cancer medicines in the future.

10.1 THE REGULATORY PROCESS

SAHPRA was established on 1 February 2018 as an independent entity of which the board reports to the Minister of Health. The organisation took over the roles of both the former Medicines Control Council (MCC) and the Directorate of Radiation Control (DRC), and is mandated to regulate all health products in South Africa according to the three pillar criteria of safety, efficacy and quality.

Not all pharmaceutical companies involved in cancer medicines, whether originators or generics, have a physical presence in South Africa. Some companies are represented by local pharmaceutical companies. Companies registered with SAHPRA for cancer medicines are listed in Appendix D. SAHPRA uses these criteria to monitor, evaluate, investigate, inspect and register all health products (51). The Medicines and Related Substances Act 101 of 1965 (A11), as amended, makes provision for SAHPRA to collect annual fees to fulfil its various functions (52).

For medicines not registered in South Africa, the treating clinician should obtain special authorisation from SAHPRA for its use in terms of Section 21 of the Medicines and Related Substances Act as amended (A11). Such applications are also subject to a small fee and approval is normally granted for a six-month period. The NDoH must ensure that the procedures for the approval of Section 21 medicines for the public sector is well established to avoid delays in procurement (53).

South Africa's general involvement in the rest of Africa inevitably also traverses the medical field, and, as such, we participate in ZaZiBoNa, the collaborative medicines registration initiative of SADC. The purpose of the initiative is to harmonise, in accordance with the guidelines for good practice of the WHO, the fragmented

regulatory systems on the continent where ineffective legislation, long registration times, and inadequate technical capacity causes delayed or inadequate supply of medicines to the patients who need them most urgently (54).

The WHO further initiated a voluntary pre-qualification programme for biosimilars in May 2017 to ensure faster access for patients to more efficient products. Rituximab and trastuzumab were added as the first biosimilars to be evaluated in this programme. Celltrion's rituximab product was approved in May 2020, and the Samsung Bioepis and Mylan trastuzumab products were approved in December 2019 and May 2020 respectively (55).

South Africa has not yet benefited from the WHO's pre-qualification system for trastuzumab because SAHPRA approved and registered Mylan's trastuzumab in May 2019, before any of the international products were pre-qualified by the WHO. However, Adcock Ingram's rituximab, Blitzima® IV infusion, is the Celltrion pre-qualified product and was registered in August 2020. It is expected on the shelves in the first quarter of 2021 (12).

Any company interested in registering a specific health product with SAHPRA must submit a dossier containing the specific information supported by evidential proof that the medicine complies with the international standards of safety, efficacy and quality. In the case of originator medicines, the outcome of clinical trials is required, and, in South Africa, our regulatory body would require that all of South Africa would benefit from specific products, not only certain subsets of the population.

For generic products, international generic companies such as Mylan, Cipla and Dr. Reddy's can apply for registration of their products. The process of evaluation also includes the verification of the generic product against the originator product through bioequivalence studies. Samples of the originator as well as the generic product has to be supplied. If a patent is still valid on the specific product, and generic products are entering the market, it remains the prerogative of the originator company whether or not to provide samples for bioequivalence studies (A11). This may be one of the factors that prohibits equitable access to medicines and should be considered for review by SAHPRA and the NDoH in the interest of public health.

Where generics for unregistered products are already available elsewhere, patients may access the generic products through a Section 21 authorisation, enabling the patient to import the medicine from a foreign supplier for six months. The administration of having to resubmit the application every six months with progress reports is a cumbersome process, however. And if the originator company decides to register their product, patients lose their access to the Section 21 authorisations for those products (A11).

Lenalidomide is a perfect example of a generic product that patients could import for less than R5 000 before the registration of the originator product, but after its

registration, most patients could not afford the 20% excess payments on the R75 000 per treatment cycle in accordance with their medical aid benefits (27). An appeal on behalf of 11 patients against the decision of the MCC was granted for those patients specifically in 2017 (56), but new patients were forced to buy the unaffordable originator product. Since 2018, the Cancer Alliance has been investigating all other avenues to appeal this ruling without any success. Many other activists in the access-to-medicine space have also tried, in vain, and the problem remains an unresolved legal issue requiring urgent attention. Five different companies have finalised the registration of their generic products with SAHPRA since July 2020 (27).

The WHO indicates that the median time of product registration should be 90 days, but this is not the case in South Africa. The registration process has been dragged out for some products over a period of 5 years (57). Although SAHPRA launched their backlog initiative in February 2018 (58), it is still unclear what their median time of evaluation is, even though they have confirmed that oncology products have been prioritised.

Many suppliers complain about the registration process and SAHPRA losing dossiers on a regular basis, which delays the evaluation process even further (59) (60).

10.2 MEDICINES IN THE PUBLIC SECTOR

At a meeting of the Forum to Promote Transparency and Multi Stakeholders Engagement regarding Medicines Availability on 25 June 2019, the NDoH announced its intention to advertise the oncology tender at the end of September 2019. The representatives at the meeting seemed not to have communicated this information to their members, however, but the Cancer Alliance did send out an email, dated 1 October 2019, advising suppliers of the tender notice and encouraging all of them to participate in the tender process (61).

According to the South African EML, 115 cancer medicines are required in the public sector. A total of 75 and 54 medicines were awarded in the first tender rounds of 2018 and 2020 respectively. That means the number of unawarded medicines increased from 40 in 2018 to 61 in 2020. Although there seemed to be no problem in supplying the awarded medicines, the oncology department was concerned about the steep increase in the number of unawarded medicines in the 2020 tender (B2).

10.2.1 NON-AWARDS AND NON-BIDS

The initial scope of this research report was to investigate the availability and status of the 40 unawarded medicines from the 2018 oncology tender, but the 2020 tender was added to the investigation and a comparative analysis of the two tender documents was done in order to investigate the rise in unawarded medicines over the past two tender periods (C). A supplementary tender in May 2020 resulted in a further 19 medicines unawarded. These medicines will have to be procured through the Section 21 process.

Of the 40 unawarded products from the 2018 oncology tender, the following products are not registered with SAHPRA:

- Antilymphocyte immunoglobulin (horse) 250 mg injection
- Dactinomycin 0.5 mg injection
- Pamidronic acid 15 mg injection
- Hydroxyurea 500 mg capsules

Although the first three have alternatives available on the market, the hydroxyurea does not, and, if required, will have to be supplied through the Section 21 process.

From the listed medicines on the 2018 and 2020 tenders, the interferon alfa-2b 3M, 5M and 10M IU injections, and the 100 mg etoposide injection, have been deregistered by MSD and Pfizer respectively.

More than one supplier is registered with SAHPRA for most of the listed medicines, but only one supplier is registered for the medicines in **Table 3** (12):

* Product as listed on the tender

* Second product registered by SAHPRA

Product	Registration Number	Registration Date	Company
Buserelin Nasal Spray	V/21.10/170	19.07.1988	Sanofi-Aventis
Buserelin Implant	32/21.10/0345	03.06.1999	
Dasatinib 50 mg Tablets	41/26/1040	09.12.2008	Bristol-Myers Squibb
20 mg Tablets	41/26/1039	09.12.2008	Bristol-Myers Squibb
70 mg Tablets	41/26/1041	09.12.2008	Bristol-Myers Squibb
100 mg Tablets	44/26/0205	07.12.2012	Bristol-Myers Squibb
Interferon alfa-2a 3 MIU prefilled syringe	38/26/0180	11.02.2005	Roche
Melphalan 2 mg Tablet	27/26/0505	29.12.1993	Pharmacare
50 mg Injection	H/26/2744	14.03.1994	Pharmacare
Mesna 400 mg injection	S/18/306	23.11.1989	Baxter
1 000 mg injection	S/18/307	23.11.1989	Sanofi-Aventis
100 mg injection	S/18/304	23.11.1989	Sanofi-Aventis
200 mg injection	S/18/305	23.11.1989	Sanofi-Aventis
1 g/10 ml injection	29/18/0355	29.03.1999	Sanofi-Aventis
5 g/50 ml injection	29/18/0356	29.03.1999	Sanofi-Aventis
Thalidomide 50 mg capsules	38/24/0258	05.10.2007	Key Oncologics

Buserelin can be substituted with its class equivalent, goserelin. The registered dasatinib product is an originator with three patents expiring between August 2021 and July 2026 (2). Although two generics, Zentiva® (62) and Investa® (63), are already available, they have not yet been registered in South Africa (12).

Interferon alfa-2a is no longer used, and Roche is in the process of transferring it to another company. The fact that mesna has two different strengths on the tender list strongly suggests the urgent need for greater synergy between the treatment centres, the AMD and SAHPRA, to ensure that products no longer in use are removed from the tender list.

If only one strength of a product is commercially available, the National Treasury should have a special set of conditions in the tender regulations to allow for the procurement of different strengths or class equivalents.

The two mesna products in the table above is a good example of how this could be implemented since both products are registered with SAHPRA even though only one is on the tender list. Being able to deviate from the regulations in this way would allow the continuation of treatment without interruption because cancer does not wait for treatment to arrive. Every second counts.

For such measures to be successfully implemented, however, better communication and cooperation between treatment centres, the AMD and SAHPRA are essential.

10.2.2 REASONS FOR NON-AWARDS AND NON-BIDS

There are many reasons for tenders going unawarded by the NDoH, and equally so for tenders not bid upon by the pharmaceutical industry. This section is an exploration of the reasons given by both entities to try and solve the current problems around government tenders (64).

FROM THE NATIONAL DEPARTMENT OF HEALTH

Good governance requires the NDoH to comply with the regulations as set out in the PFMA, which states that tenders are not awarded when:

- **companies did not perform to the satisfaction of the NDoH** in the previous tender. The NDoH would have communicated with the said company about contract performance during their contract period and is, therefore, not obliged to continue the discussion unless the company requests feedback in writing.
- **bids are late** on the closing date at 11:00 sharp. At that time, bid boxes are opened and bids read aloud and registered while the companies are present. Any late bids will be registered as no bids, irrespective of whether companies may think this is unreasonable. It is one of the measures put in place to prevent corruption.
- **bid requirements are not adhered to**. Many companies submit incorrect, incomplete, or unsigned bidding forms, often without the required documentation. The bidding process is complicated, and companies should make sure that the people responsible for submitting the bids are professionally trained and capable of applying their minds.

Although many may argue that these strict rules are unnecessary bureaucratic red tape, the purpose of the bidding conditions is to avoid any possible corruption.

Although the NDoH remains responsible for the monitoring and evaluation of the procurement process, the Auditor-General is responsible for auditing the implementation of that process, as well as the procedures followed by the NDoH and provincial health departments.

The onus thus rests upon the accountable officer of the various departments to ensure that this process is adhered to.

It is essential to note that the NDoH is not required to communicate the tender outcome with bidding companies who are unsuccessful. Only on specific enquiry will the NDoH reply to the reasons for non-awards. It is also not a prerequisite of the tender system to send reminders to potential bidders about the bid advertised. Companies who want to tender successfully should take responsibility for their own tenders.

In a letter of concern to the Minister of Health on 8 June 2020, the academic heads of department at the treatment centres and other stakeholders requested split contracts amongst multiple suppliers for the HP04-2020ONC/01, which had been advertised. In his response, Dr Mkhize stipulated that they do award contracts to multiple suppliers whenever possible, but it requires more than one responsive bid, and that they also consider the

- **nature and quality** of the API source and manufacturing site
- **capacity** of the company to meet the expected demand
- **estimated volume** to be supplied
- **risk to public health** if the item is not available
- **compliance** of the bidder with respect to contractual obligations in the past (B3).

FROM THE SUPPLIERS

The oncology market share is only 1% of the total pharmaceutical industry, and, therefore, a company cannot participate in the tender if the price and quantities per medicine required are not financially viable for the company. It remains the prerogative of a company with registered products to participate or not, and they have become reluctant to bid for several reasons:

- Over and above their **registration costs**, suppliers have to pay annual fees to maintain their dossiers with SAHPRA, which may be too expensive relative to the actual cost of the product. If it becomes too expensive to maintain a specific dossier, companies may decide to deregister and/or discontinue the product.
- The SEP in the private sector protects their **profit margins**, but for government tenders, the profit margins for most of the products are minimal and generic equivalents are often referenced to determine the prices government is willing to pay for originator products.
- Many companies, especially generic companies, have experienced increasing **manufacturing problems** because of supply constraints over the past two years, especially during the Covid-19 pandemic. This has caused numerous API stockouts, which makes it impossible for companies to guarantee the supply of medicines for the entire contract period, and since they are subject to penalties, they choose not to tender.
- The private sector usually pays contractors within 30 days while government contracts are associated with **payments** delayed up to 90 days or even longer, especially from Kimberley and Klerksdorp hospitals in the Northern Cape and North West, as well as the entire Western Cape. Suppliers are, therefore, not willing to bid on high-risk products in a high-debtor's environment that also imposes stringent penalties.
- The **estimates** of the NDoH for the required medicine quantities are not always correct. This may mean that the demand may unexpectedly increase, and, even though a supplier may not be experiencing shortages or supply constraints, they may need to supply much more than the tender estimates and exhaust their buffer stock.

The current oncology tender will effectively run until June 2022. This means that a new tender will be advertised by September 2021. Time is of the essence to find solutions for the supply of mainstay medicines.

10.3 MEDICINES IN THE PRIVATE SECTOR

Since the NCR does not differentiate between patients in the public and private sectors, the number of patients in the private sector is unknown, but the number of patients treated for breast cancer in the public and private sectors is approximately the same. The difference is that, in the private sector, screening methods allow for earlier diagnosis (Stage I and II), whereas most patients in the public sector are diagnosed with late-stage disease (Stage III and IV) (65).

The cancer medicines in the public sector are generally also used in the private sector as standard care for most cancers, but the private sector has more products available, with a choice between generic and originator treatments. It is clear, however, from the Mediscor Medicines Review and Appendix E, which tables the volumes of medicines used in the private sector, that, although they have more originator products available, the private sector as a whole also prefers generic products if available (66).

Although the volumes for some medicines in the private and public sectors are comparable, most volumes in the public sector are higher than in the private sector, and the income from the two sectors is not comparable at all (E).

The procurement of cancer medicines in the private sector is linked to the treatment plan of the patient. The South African Oncology Consortium (SAOC) (67) and Icon Oncology (68) are the two managed-care companies responsible for the developing of treatment guidelines in line with research findings and clinical evidence.

These guidelines include a unique set of treatment codes for reimbursement by the medical schemes. They will approve treatment in accordance with the patient's oncology benefits and, once approved, dispense the medicine according to existing oncology practices at the treatment centres.

Some medical schemes have their own designated service providers such as Dis-Chem or Medipost, or wholly owned subsidiaries in the case of Southern RX and Discovery. Pharmacy courier companies distributed less than 10% of oncology medicines while other providers, such as oncology practices and subsidiaries, accounted for approximately 60% of the volume of private-sector oncology medicines in 2019 (69).

Section 18A of the Medicines Act prohibits incentive schemes (A11) and draft regulations to rule bonusing were published for comment in December 2017 (A12), but, to date, the regulations have not been finalised by the NDoH's Pricing and Economic Division. It is therefore of great concern that some pharmaceutical companies, clinicians and pharmacies involve themselves in agreements referred to as data agreements and all manner of suspect incentive schemes.

10.3.1 mAbs IN CANCER TREATMENT

The 2020 report of the International AIDS Vaccine Initiative (IAVI) focuses specifically on recommendations for expanding access to affordable medicines. The report emphasises that 43 monoclonal antibody-based products (mAbs) are either approved or under investigation in the United States and European Union. It further indicates that, for cancer, mAbs could be introduced before older medical options, leapfrogging radiation and chemotherapy, for example, which are more challenging to implement in resource-poor settings (37).

The use of mAbs should then be coupled with the ability to diagnose cancer at the earlier stages, much earlier than the current trend in the public sector. The WHO initiated the pre-qualification program in 2017. Clinical trials for candidate bevacizumab biosimilars are registered by Amgen, Biocad, Boehringer Ingelheim and Pfizer. One of the patents for the originator, Avastin®, expired in the US in July 2019 and another will expire in January 2022. Avastin® had worldwide sales of $7.4 billion in 2014, making it a lucrative target for biosimilar manufacturers (70).

In Europe, Avastin® was the second biggest overall seller in 2016 followed by trastuzumab. Bevacizumab, alongside trastuzumab, is the most sold Roche oncology medication worldwide. Since 2004, the accumulated sales of bevacizumab surpassed €61 billion and, despite the imminent loss of the patent, it is expected that sales will remain relatively stable until 2022. The drug has numerous indications, which widens its market and increases the sales figures. In the 12 years since its approval in 2004, eleven different indications have been approved. Furthermore, in 2018, the combination of bevacizumab with atezolizumab was also added to treat renal-cell carcinoma and non-small cell lung cancer (71).

Table 4 lists the monoclonal antibodies included on the EML of the WHO (37).

Antibody	Originator Brand Name	First Approved Indication	Year of Inclusion on the EML of the WHO
Nivolumab	Opdivo®	Melanoma, non-small cell lung cancer	2019
Pembrolizumab	Keytruda®	Melanoma, non-small cell lung cancer	2019
Rituximab	MabThera®	Non-Hodgkin's lymphoma	2015
Trastuzumab	Herceptin®	Breast cancer	2015
Bevacizumab	Avastin®	Colorectal cancer *	2013

* The EML of the WHO approved Avastin® only for age-generated macular degeneration- not for cancer. Source: WHO (2019) Model List of Essential Medicines (24)

The most expensive mAbs are used in oncology and haematology, with annual treatment prices approximately $100 000 higher than mAbs for other diseases. The median price of mAbs in this speciality field for January 2017 was $142 833. The subcutaneous (SC) versions of these mAbs are subject to patents and, until the Patents Act (A13) is changed, could potentially block this form of administration should they become available. SC treatments, in essence, will ease access and impact on overall affordability.

10.3.2 SPECIALITY MEDICINES

Even though the oncology sector represents only about 1% of the pharmaceutical market in South Africa, it constituted 53.6% of the overall speciality-medicine expenditure in 2019, of which only 36.1% was on PMB. It makes cancer a costly disease to manage for patients who must deal with the OOP excess payments themselves.

Seven of the top ten speciality medicines are used for cancer indications, namely rituximab, trastuzumab, pembrolizumab, octreotide, imatinib, bevacizumab and azacitidine. Imatinib and bevacizumab (Avastin®) are the only two products not listed under the top 50 most expensive medicines.

Table 5 lists the most expensive speciality medicines ***for cancer*** according to their active ingredients (69).

Trade Name Active Ingredient	Rank	Expenditure	Volume in %	Cost per Patient (R)	*Cost per Item (R)	Prevalence per 10 000 Lives	Items Required per Patient
MabThera® Rituximab	1	9.0	6.1	92 440	15 478	3.0	6.0
Herceptin® Trastuzumab	2	5.9	4.6	108 827	13 464	1.7	8.1
Keytruda® Pembrolizumab	5	4.0	0.5	500 671	92 908	0.3	5.4
Sandostatin® Octreotide	6	3.9	1.3	274 250	31 568	0.4	8.7
Imatinib	7	2.9	2.1	132 598	14 767	0.7	9.0
Avastin® Bevacizumab	8	2.9	14.2	6 592	2 130	13.7	3.1
Vidaza® Azacitidine	9	2.8	0.5	366 036	53 185	0.2	6.9

* The Cost per Item is not the same as the SEP, which is reflected as a unit price.

Although bevacizumab and imatinib are not included in Mediscor's top 50 list of all therapeutic conditions, we include them in the top 10 list of most expensive ***cancer medicines***:

- Avastin® (bevacizumab) because it is more often used for other indications where much less of the API is required for successful treatment. The cost is therefore not as high as it would be for the treatment of cancer.
- Imatinib because there are too many products in the market to identify its position on the list. Its use, however, is a prime example of how successful generic equivalents can be when originators become unaffordable. Item 69 in Appendix E clearly illustrates the preference of the private sector for generic products because the volume of the Novartis originator used was only two-thirds of the generic volume of Cipla's and Accord's products combined.

The Mediscor Medicines Review reported an increase of 8.1% in the expenditure for speciality medicines per beneficiary per annum from 2018 to 2019 (69).

Cancer medicines ranked third on the expenditure list in 2018, but second in 2019 when it accounted for 6.6% of the medicine expenditure while only representing 0.4% of the volume of medicines used in the private sector. Only hypertension medicines rank higher.

The use of generics in oncology went up from 87.1% in 2018 to 87.5% in 2019. In 2018, the average cost of generic equivalents was R119 compared to R153 for originators with expired patents (28% more expensive) and R287 for originators with valid patents (141% more expensive).

In 2019, the cost of generic medicines increased by 1.7%, medicines with expired patents by 2.4%, and patented medicines by 2.6%. This is another indication of the private sector's preference for generics. Medicine and treatment costs for cancer patients increase annually, but medical-scheme benefits do not adjust accordingly.

MABTHERA® (RITUXIMAB)

Since MabThera® is listed on the South African EML, it is also a PMB for treatment in the fields of rheumatology, nephrology and neurology. The public-sector price is considerably lower at R7 618 per item for the 500 mg/50 ml vial and R1 987 for the 100 mg/10 ml vial.

In the private sector, the 500 mg vial moved up from fourth place in 2018 to second in 2019 – two places with a cost of R21 585 per item and R72 295 per patient at 3.3 units per treatment cycle. The MabThera® 100 mg vial moved up from number 48 to number 40. Roche registered the originator in 1999, their clone product, Ristova®, in 2012, and the subcutaneous (SC) version in June 2019.

The first rituximab biosimilar, Blitzima®, was registered in South Africa by Adcock Ingram Limited on 25 August 2020 (12). It will stimulate competition in the market but has only become available on 8 April 2021 with an SEP of R5 790 per 100 mg/10 ml vial. The Roche SC product is patented until 2030, which is why the Cancer Alliance listed it as one of their priority medicines for the A2M Campaign (18).

HERCEPTIN® (TRASTUZUMAB)

Roche registered Herceptin® (trastuzumab) with SAHPRA in 2001, and it was added to the South African EML in 2017 after the approval of the Breast Cancer Policy, which allowed for the treatment of HER2-positive early breast cancer with trastuzumab (A14). Subsequently, the National EML Committee (NEMLC) aligned the South African treatment guidelines with international guidelines.

The Persephone Study (72) and the Phare Study (73) indicated that nine cycles of treatment were not inferior to 18 cycles, and the Council for Medical Schemes (CMS) therefore confirmed trastuzumab as a PMB for early breast cancer treatment (14). Only about 26% of women diagnosed with breast cancer is HER2-positive and only 20% of those will be eligible for treatment according to clinical guidelines. In the Brazilian health system, trastuzumab is available for adjuvant, neo-adjuvant and metastatic breast cancer.

In the public sector, Roche registered their clone, the Herclon® IV infusion, in 2012, and offered it to the NDoH. At R6 531 per unit for the 18 cycles, or a total cost of R117 558 per patient, the supplier was contracted for a total of 990 units that equated to 55 women for the tender period of 2018-2020. Strict treatment guidelines were followed for trastuzumab treatment and the clone product was never made available to the private sector.

Equitable and affordable access to trastuzumab treatment became the initial focus of the joint campaign by Fix the Patent Law and the Cancer Alliance. The campaign was renamed the Tobeka Daki Campaign after the death of the activist. She had been diagnosed with HER2-positive breast cancer and was denied access to the treatment by her medical scheme. She died two years later.

Theoretically, in the private sector, people had already had access to Herceptin® for many years – ever since Samantha Galliet successfully litigated against Discovery for covering the cost of the trastuzumab treatment. The price tag dictated the access to the treatment for many women, however, for as long as Roche maintained their market exclusivity (74).

It only changed when Mylan registered the first biosimilar, the Ogivri® IV infusion in May 2019, and entered it into the market in September that same year.

Subsequently, two other biosimilars, Kajinti® and Hersimi® IV infusions, were registered with SAHPRA by Amgen and Cipla respectively in February and April 2020.

It is unclear, however, whether these products will enter the market, as the overall market for trastuzumab usage remains small. It may change if locally advanced and metastatic breast cancer is added to the EML and recognised as a PMB illness.

Roche registered the Herceptin® 600 mg/5 ml subcutaneous (SC) injection in 2017. It was much easier to administer and more cost-effective than the IV infusion, for which a room had to be prepared and the patient kept for two hours. Quite understandably, then, the IV infusion moved down from position three in 2018 to 63 in 2019, and the SC injection moved up from position 106 to position five in 2018 and four in 2019, thus virtually replacing the IV infusion.

In 2018, the SC injection cost R19 008 per unit and R162 086 per patient for their 8.5 units per treatment cycle. After the global approval of biosimilars, the cost suddenly

reduced in 2019 to R13 040 per unit and a total of R104 087 per patient. A saving of nearly R58 000 for one cycle of treatment.

Apart from the reduced cost, the increased usage may further be associated with the availability of pertuzumab (Perjeta®) in the private sector for the treatment of early and metastatic HER2-positive breast cancer in combination with trastuzumab. In Brazil, trastuzumab is available for adjuvant, neo-adjuvant and metastatic breast cancer, while pertuzumab is only available for metastatic breast cancer (75). In the United States, the trastuzumab biosimilar is available at $75 (approximately R1 110) per 150 mg vial, while the pertuzumab originator is available for $2 030 (approximately R30 000) per 420 mg vial. The South African price for Perjeta® is R20 000. This is a clear indication that the pricing of trastuzumab in South Africa is still too high.

Herceptin® SC 600 mg injection was registered with SAHPRA in April 2017, and the patent registered at the Companies and Intellectual Property Commission (CIPC) until 2033 so that the originator company can retain its market exclusivity. The trastuzumab timeline clearly indicates the price history of this medicine, ranked second in the top 10 most expensive medicines (76). The Mylan IV biosimilar is now available in the public sector at a tender price of R4 950. A total of 1 952 units were awarded for the 2020 tender, enough for the treatment of 216 women over the two-year period.

The Mediscor Medicines Review 2019 does not specify the use of biosimilars in the private sector (69), but there will hopefully be more differentiation in their review as more biosimilars become available. Although Filgrastim Teva® was the first biosimilar to be approved by SAHPRA in 2017, the trastuzumab biosimilar remains the more significant one that will dictate biosimilar usage in South Africa. The Cancer Alliance's biosimilar fact sheet is the first educational fact sheet available for clinicians and patients (77).

PATIENT STORY

NO ACCESS TO LIFE-SAVING MEDICINES

Tobeka Daki was a single mother of two boys who lived in Mdantsane, East London in the Eastern Cape. In November 2013, she was diagnosed with HER2-positive breast cancer. In 2014, her doctor recommended trastuzumab (Herceptin®), marketed by Roche at the time. Her medical scheme did not approve the treatment, however, as it was too expensive.

At the time, trastuzumab cost approximately R500 000 for 12 months. Tobeka became too ill to work and lost her medical aid cover in the process. She was also not able to receive trastuzumab through the public healthcare system because it was not listed on the South African EML due to its cost.

Tobeka decided to take up the fight for equitable access to medicine and was trained to be an advocate by the Cancer Alliance in September 2014. She continued her advocacy efforts despite the fact that, in 2015, the cancer had spread to her spine and left her paralysed by late 2016.

She was recognised globally for her activism for equitable access to medicines.

In March 2016, Tobeka related her story to the UN High-Level Panel on Access to Medicines in Johannesburg. She also led a protest, organised by Fix the Patent Law Campaign, at the Roche offices in Johannesburg to protest the high cost of medicines. In July 2016, the company reported a $5.57 billion dollar income in the first six months of the year, a 4% increase over the previous six months.

In July, Tobeka led a protest targeting Roche at the International AIDS Conference in Durban. In September 2016, she gave a moving testimony at a protest organised by the Fix the Patent Law in Pretoria outside the offices of the dti. Tobeka passed away on 14 November 2016.

She was one of many women around the world who had no access to trastuzumab before its biosimilar, Ogivri®, was approved by regulatory authorities globally and SAHPRA.

Video: South Africa: Access to critical breast cancer drug trastuzumab limited by patent laws

KEYTRUDA® (PEMBROLIZUMAB)

This is an MSD immunotherapy used in the treatment of cancers such as melanoma, non-small cell lung carcinoma and bladder cancer, which was registered in September 2017, three years after Yervoy®. Its availability is restricted to the private sector, only for patients whose medical-scheme coverage would allow for these treatments, and only if said patients can afford the excessive co-payments.

It was the only new cancer medicine in the top 50 expenditure list in 2019, moving from position 223 in 2018 to 11 in 2019 at a cost R500 671 per year or R92 908 per item. Keytruda® is proposed for inclusion in the Brazilian public health system from 2021. The approved SEP for this product is R40 993 for 25 mg/1 ml injection. The WHO added this medicine to their EML in 2019 for melanoma of the skin specifically. The application for neoplasms of the lung or bronchus was rejected (78).

Opdivo® (nivolumab), another patented immunotherapy in the same class as Keytruda®, is not yet registered with SAHPRA. Section 21 applications for nivolumab are rejected in accordance with the legislation, therefore not allowing Section 21 applications when an alternative medicine is available in the market. Opdivo® will only become available if this originator is approved by SAHPRA. In Brazil, nivolumab will be available from 2021 in the public health system. This medicine was added to the EML of the WHO in 2019 for melanoma of the skin.

The application for specified malignant neoplasms of the bronchus or lung was rejected.

Yervoy® (ipilimumab), the second patented immunotherapy in the same class as Keytruda®, was registered with SAHPRA by Bristol-Myers Squibb in October 2014, and is available in the private sector at R48 471 per 5 mg/ml infusion. Despite it being available since 2014, this medicine has not been listed by Mediscor as a top expenditure product. Yervoy® is used for the treatment of metastatic melanoma and is also used in combination with Opdivo® for other cancer indications. It is listed on the Cancer Alliance's Access to Medicine Campaign as a priority medicine (78).

The availability of immunotherapies in the public sector will have to be reviewed. Although immunotherapies were added to the EML of the WHO in 2019, they were not added to the South African EML because of the exorbitant cost.

PATIENT STORY

FIGHTING TO LIVE

Daniel (not his real name) was 63 when he was diagnosed with metastatic melanoma in 2017. His doctors recommended immunotherapy with pembrolizumab (Keytruda®) but, as in Tobeka's case, his medical scheme did not approve his application. Daniel's doctors then reverted to two operations, targeted therapy and radiation treatment, which did not work. The cancer grew bigger and spread around the vena cava, decreasing the blood flow to his heart, head and neck, upper body and limbs. As a result, he developed ascites and pleurisy, and his doctors gave him only a few days to live.

Daniel's fight for survival had begun. With the financial assistance of his family, Daniel received his first treatment with Keytruda®. Four months later, the ascites had cleared, and the cancer growth had reduced. By March 2021, Daniel had gained back all the weight he had lost and was running seven kilometres a day. Scans confirmed that there was no evidence of cancer. Keytruda® was a miracle drug for him. To date, Daniel has received 21 treatments – all at his own cost. He buys his medicine from outside of South Africa at approximately R150 000 for three treatments.

If Daniel's medical scheme had approved Keytruda® for his treatment, it would have cost about 45% more, and he would have had to pay OOP expenses of up to 75%. He is still fighting his medical scheme to approve Keytruda ® for the maintenance period. Daniel's story is a perfect case in point for arguing that making this drug equitably available to all South Africans must be a priority. 'Cancer medicine prices in South Africa are exorbitant. This should be addressed by the authorities. We all have a right to live!' says Daniel.

SANDOSTATIN® LAR (OCTREOTIDE)

Octreotide is a hormone inhibitor used in many cancer treatments, especially for Neuro Endocrine Tumours (NET), although for a relatively small group of patients. This product is not available in the public sector for NETs, but it is available on the EML for carcinoid syndrome and acromegaly. The prefilled syringe moved from position 111 on the expenditure list in 2018 to position 49 in 2019 at a cost of R315 492 per year or R36 403 per item.

Although Hexal Pharma has also registered another product, it is unclear whether it is commercially available. The product was registered by Novartis in 1990 and, in 2018, it was listed in report CA02/2018 as one of the priority medicines for the Cancer Alliance's A2M Campaign (18).

IMATINIB

Imatinib is used for the treatment of chronic myeloid leukaemia (CML). Several products have been registered with SAHPRA. Novartis registered the originator Gleevec® in May 2002, and two clone versions, Vativio® and Nazzec®, in September 2016. Cipla-Medpro registered Imavec® in March 2012, Ranbaxy Pharmaceuticals registered Sunmatin® in December 2013, and Accord Healthcare registered Imatinib Accord® and Mivesta® in September 2016. Imatinib is listed on the national EML and is therefore available in the public sector.

The Max Foundation initiated a global Patient Access Programme in partnership with Novartis for affordable access to this life-saving medicine (79). Many patients in the private sector in South Africa were willing to forfeit their medical schemes to access Gleevec® in the public sector where it was offered for free at the time. Imatinib is now listed on the EML and consequently recognised as a PMB condition. Imatinib is thus a prime example of generic preference in the private sector (E69).

AVASTIN® (BEVACIZUMAB)

In South Africa, Avastin® is commonly used for the treatment of other illnesses than cancer because it is so expensive. The volume required to treat one cancer patient is exponentially more than the volume required for the treatment of an illness like macular degeneration, where one drop is enough to treat many patients. The SEP for Avastin® is R17 915 for 400 mg/16 ml and R4 478 for 100 mg/4 ml, while the 100 mg/4 ml was supplied to the public sector in 2020 at R2 668 per unit. A total of 5 416 units were required for non-oncological use. Until more affordable biosimilars are available in South Africa, it will be difficult to advocate for the inclusion of bevacizumab on the national EML for cancer conditions.

VIDAZA® (AZACITIDINE)

Registered by Key Oncologics in May 2009, Vidaza® is used for the treatment of myelodysplastic syndromes (MDS), a group of blood and bone-marrow disorders. It is not listed on the South African EML because of the exorbitant costs. The Vidaza® 100 mg/4 ml injection cost R53 185 per item at the time of registration, and, in total, R311 130 per patient for 5.9 treatments. According to Mediscor, it is the second most expensive medicine *per patient.* (See highlights in Table 4.)

Key Oncologics maintained their initial, unaffordable unit price of R5 904 for nearly 12 years until Dr. Reddy's Laboratories launched Azacitidine DRL® at R2 952 per unit in March 2021. Within two days of the announcement, Key Oncologics were suddenly able to reduce the price for Vidaza® by half.

There are three more cancer medicines, excluded from the top 10 list of most expensive cancer medicines, but listed on the Mediscor top 50 list:

- **Xtandi® (enzalutamide)**, registered by Astellas in September 2019, is used in the treatment of advanced prostate cancer. It moved from position 168 in 2018 to position 32 in 2019 at a cost of R160 771 per year, or R30 200 per item.
- **Faslodex® (fulvestrant)**, registered by AstraZeneca in February 2006, is a hormone inhibitor used in breast cancer. It was the only oncology medicine added to the top 50 list in 2018 at number 49. In 2019, it moved to position 38 at a cost of R74 238 per year, or R11 837 per item.
- **Erbitux® (cetuximab)**, registered by Merck in August 2006, is used in advanced colorectal cancer. It moved from position 82 in 2018 to position 44 in 2019 at a cost of R190 810 per year, or R23 291 per item.

Many of the medicines listed among South Africa's top 50 most expensive products, such as rituximab, Herceptin®, Keytruda®, Xtandi® and Revlimid® also appear in the US top 100 list for 2018–2019.

The price for Revlimid® increased by 79% since 2012 as Celgene effectively blocked any possibility of access to affordable generics for 40 years. The price for rituximab increased by 25% since 2012 and, in similar fashion, Roche successfully blocked any competition for 47 years. The I-MAK report also mentions that the patent rights of Roche/Genentech for Herceptin®, rituximab and Avastin® have the potential to block access to affordable medicines for between 43 and 48 years (80).

In 2019, ICER undertook research to assess whether the steep price increases for rituximab and Revlimid® were justifiable. They concluded in their report that their study supported the Revlimid® price increases because of a substantial improvement in net health benefit, but their evidence did not find justification for the rituximab price increase (81).

In 2018, the private sector usage of generic equivalents for oncology medicines was recorded at 87.1% with 68.8% of medicine genericised (66). Appendix E reflects the various preferred suppliers for products in the private sector against the company that was awarded the public sector tender. Accord, Aspen, Cipla and Eurolab are the generic companies used most frequently in the private sector. It is not clear whether the products are distributed through retail pharmacies or pharmacy couriers.

The Dis-Chem Pharmacy Group is the biggest distributor of cancer medicines for the private sector, supplying oncology practitioners registered with ICON and the SAOC (67) according to the approved managed-care guidelines for oncology treatment.

The recent collaboration announcement between Roche and Eurolab to market trastuzumab is an interesting development. Eurolab will market trastuzumab on behalf of Roche, and Roche will focus on the marketing of their next generation of

treatments for HER2-positive metastatic breast cancer, namely Kadcyla® (trastuzumab-emtansine) and Perjeta® (pertuzumab) (82).

Neither of the two treatments are included on the EML of the WHO, although various motivations have been submitted for the inclusion of Kadcyla®. The SEP for Kadcyla® is currently registered at R15 385 for the 110 mg infusion and R24 617 for the 160 mg infusion, while Perjeta® 420 mg/14 ml infusion is registered at R20 000. At the current costs, these targeted treatments may remain out of reach for many women, which will be a challenge for all parties involved in the discussions of cancer care in the proposed NHI (A5).

10.3.3 UNLISTED MEDICINES ON THE A2M CAMPAIGN

Several medicines not listed in the Mediscor top expenditure list, form part of the A2M Campaign, specifically because they are included on the model EML of the WHO and would be invaluable in the public sector.

LENALIDOMIDE

Generic lenalidomide, used in the treatment of multiple myeloma, was previously available under Section 21 for any self-paying patient at less than R5 000 per month for 28 tablets. After the registration of the Celgene originator, Revlimid®, to Key Oncologics in February in 2016, however, private patients had to pay R75 000 for one month's treatment in 2017 and were not allowed to get the Section 21 generic lenalidomide any longer. But the R75 000 suddenly dropped to R60 781 for one cycle soon after the Cancer Alliance focused their attention on the affordability and availability of generics in the A2M Campaign (18).

Lenalidomide, a derivative of thalidomide, was listed by the WHO as an essential medicine in 2019, but due to its unaffordability, lenalidomide could not be added to the South African EML (78). Thalidomide was added to the national EML in 2019 after the inclusion on the EML of the WHO (78). Key Oncologics remains the only company with a registered product. Revlimid® is the Celgene originator that has many secondary patents. Thalidomide 50 mg capsules are now supplied on tender to the NDoH at a price of R1 484 for 28 capsules. A total of 5 000 units were requested, equating to nearly 208 patients over the tender period.

Since the registration of lenalidomide generics in July 2020, the price of Revlimid® has dropped even more, to R46 901 for the 28 capsules. The generic pricing initially started at 50% less than the originator price at R20 474 for the Cipla 25 mg, but the Eurolab price for the same strength is R10 017. More price reductions are expected once all five generic companies have their products available on the market (83).

It is a perfect illustration that competition in the market stimulates lower prices, and lower prices will provide enough data for the Cancer Alliance to make lenalidomide one of their next priority medicines for inclusion on the South African EML together with bortezomib, which is often used in combination with lenalidomide (24).

In August 2020, Key Oncologics registered Imnovid® (pomalidomide), the second derivative of thalidomide, with an initially approved SEP of R95 532 for 21 capsules, but subsequently reduced it to R83 895.

PATIENT STORY

DYING WHILE WAITING IN VAIN

Teboho Shai, was a self-employed consultant who lived in Pretoria. He was married to Veliswa, a stay-at-home mother, and the proud father of six children. In April 2016, at age 57, he was diagnosed with stage 3B multiple myeloma, which eventually paralysed him.

He received treatment at a Mediclinic hospital, and the doctors prescribed thalidomide from 2016 to 2017. His medical scheme covered the cost of the treatment in full. Then, in October 2017, Teboho had to have an autologous stem cell transplant, which was done at the Life Groenkloof Hospital in Pretoria.

However, in August 2018, Teboho's cancer cell count increased dramatically. His haematologist prescribed Revlimid®, the Celgene originator medicine. His medical scheme approved the treatment, but required a 20% excess payment, which Teboho could not afford while supporting his family and maintaining their medical aid benefits. (In 2019, Thalidomide cost approximately R4 000 for 28 capsules, while Revlimid® cost R60 781 for 21 capsules.)

Teboho's income was dependent on SME contracts, when they were available or awarded. Unfortunately, at the time, Teboho had no work, so he had to rely on family assistance to fund the medical fees and the generic treatment. He also tried to access cheaper lenalidomide options from India with his limited funds, which he would not be able to reclaim from his medical scheme.

He courageously gave evidence of his access issues and the unaffordability of Revlimid®, while more affordable generic products were available, at the 2019 World Fair Pricing Forum in Johannesburg.

Teboho passed away in March 2020 without ever being able to afford equitable access to medicines from South African sources. Baba Shai, his widow, asks. 'Why must patients resort to these measures to access life-saving medicines?'

The South African patent law and SAHPRA regulations restricted affordable access to lenalidomide for many people like Teboho who needed it. Lenalidomide is still too expensive to be added to the South African EML.

BORTEZOMIB

Bortezomib is used in combination with other standard medicines like lenalidomide for the treatment and maintenance of multiple myeloma. It was added to the EML of the WHO in 2019 (78).

Bortezomib, a first-in-class selective and reversible inhibitor of the 26S proteasome, has demonstrated superior clinical activity and revolutionised the treatment of multiple myeloma. Inclusion on the South African EML will improve the patients' chances of survival. Several generic products are already available in the private sector, starting from approximately R4 945 per 3.5 mg/ml injection.

BENDAMUSTINE

Bendamustine has been indicated for the treatment of chronic lymphocytic leukaemia, non-Hodgkin's lymphoma, and multiple myeloma on the EML of the WHO since 2015, but it is not included on our national EML. The originator product from Astellas, Ribomustine® 100 mg powder for injection, is available at R4 373 per unit (84).

Adcock Ingram registered their generic products in August 2020, but Cephalon Inc may most likely block affordable access to bendamustine for patients in the public sector until 2031 (78).

ABIRATERONE

Prostate cancer has the highest cancer incidence in men and is set to increase exponentially. Abiraterone is indicated specifically for the treatment of advanced and metastatic prostate cancer and was added to the World Health Organization's EML in 2019 (78). The originator product, Zytiga® 250 mg tablets, is available at R29 750 per pack of 120. Dr. Reddy's generic product, Teronred 250®, was registered with SAHPRA in September 2020 and is available in the private sector at R17 850 per pack of 120. The prostate cancer policy has been on the table for approval since 2017, and abiraterone could be listed on the South African EML with the accompanying guidelines. Currently, patients in the public sector cannot access this medicine because of the cost.

10.4 NEW DEVELOPMENTS

In 2015, the United Nations accepted the 17 Sustainable Development Goals (SDGs). In 2019, the WHO called for greater political leadership and accountability on non-communicable diseases (NCDs) and mental health (85). The NDoH has largely

ignored NCDs over the past 25 years, focusing mainly on HIV and TB, and their NCD strategic framework is yet to be finalised. While it is possible to manage most of the NCDs at primary healthcare level, cancer remains the one disease that spans all three levels.

The breast cancer and palliative care policies, which have been approved by the National Health Council, are yet to be approved for implementation at provincial health departments. Policy implementation requires budget allocation, job descriptions and appropriate training for healthcare workers. Each year, healthcare budget cuts impede the implementation of policies. There is a severe treatment shortfall in rural provinces, and the predicted increase in cancer incidence will further impede the ability of the various health departments to manage the disease.

Public private partnerships (PPPs) are the proposed way forward. The first PPP for cancer was established early in 2004 between Groote Schuur Hospital and GVI Oncology (now CancerCare) for the rendering of palliative radio-oncology services at the George Provincial Hospital. Since then, many calls for such partnerships have been made. As a result of the KwaZulu Natal cancer crisis, an agreement was reached with Wits Health Consortium for the delivery of oncology services. Mpumalanga Provincial Health has also signed an agreement with Wits Health Consortium for the delivery of oncology services. These agreements are confidential.

A new oncology unit will open with funding from the pharmaceutical industry at the Chris Hani Baragwanath Hospital in the second quarter of 2021, also as part of Wits Health Consortium. The industry also contributes to policy development and implementation at the NDoH.

The close involvement of the industry in cancer care because of the lack of funding by NDoH creates a deep cause for concern. Public private partnerships should be transparent and agreed upon within a pre-agreed set of principles, developed by all the stakeholders in the industry. Without these principles, agreements will be questionable and open to corruption. The level of corruption present in the health sector has already been exposed by Covid-19.

Following the opening of a South African pilot API manufacturing plant in 2017 (86), the NDoH, in partnership with Department of Science and Innovation and the Department of Trade, Industry and Commerce (the dtic), should investigate the feasibility of manufacturing APIs to reduce the potential shortages in essential medicines.

Such a venture would have the potential to service the entire SADC region if managed properly. The same principle was extraordinarily successful in the transition to Brazil's SUS system.

The Public Health Program, an access-to-medicine initiative of the Open Society Foundation, initiated a discussion on the development of a decentralised,

hospital-based small-scale production or compounding system. Although still in its initial stages of development, such a concept should be embraced, and its potential should be investigated to ensure that the required resources, and legal and regulatory frameworks are set up. This is also in line with the proposal submitted by Ethiopia, and supported by South Africa, to the WHO Executive Board meeting in January 2021 on the strengthening of local medicine production and other health technologies. South Africa is ideally situated to advance this concept in the SADC region (87).

Cell- and gene-based therapies are already available in some countries. This is another potentially lucrative market for the exploitation of patients. Services like autologous CAR T treatments are already patented. The NDoH and the dtic should ensure that exceptions to patent rights for treatments that can be classified as services are included in the South African patent-law reform process (88). At the recent WHO Executive Board meeting in January 2021, EB 148, South Africa committed to submitting a proposal to expand access to effective treatments and other health technologies for cancers and rare and orphan diseases.

Expensive treatments with minimal benefits are contributing to the rising cost of cancer care because patients overestimate potential drug benefits. Spending a six-figure sum to prolong life by a few weeks or months is unaffordable and wrong for many who will inevitably die from solid tumour metastases. The approval of drugs with such small survival benefits raises ethical questions:

- Are recipients aware of the drugs' limited benefits?
- Are the prohibitive cost vs benefit ratios justified?
- Do trial participants get correct information before they decide to participate?

In our view, intensified prevention, early detection, prompt and radical treatment of localised and regional disease, together with highly skilled and earlier, supportive care, are the essential yet under-financed priorities in cancer control.

Value-based care is one of the concepts currently being explored in the private sector to replace the traditional fee-for-service model (89). The goal is to cut rising cost by switching from a model based on quantity to a model based on quality, which is aligned with patient-centred care.

It will require a far more elaborate conversation between clinicians and their patients.

The survival benefits of expensive treatments that have little value in relation to the quality of life they may have left as well as the physical impact that cancer medicines have on their body, should be explained honestly and clearly. It may not be the message that a cancer patient would want to hear and will need to be conveyed in a way that would not leave the patient hopeless (90).

This care option may most likely have to be custom-designed to fit high-cost medicines such as cancer medicines. The question is, who will benefit from this

so-called value? Will it be the patient – for whom it is intended? Or will it bring even more money to the already lined pockets of the provider, the payer and the industry? Patients should be the most important party in this discussion and should get enough information on the possible outcomes of treatment to make informed choices (91).

The design of future business models will have to be a collaborative effort between the industry, the payers, the NDoH, the Pricing Committee and cancer-advocacy groups. It should be designed for the treatment of cancer as a speciality disease within the proposed NHI and will require dedicated attention to the specific cancer policies already approved, namely cervical, breast and the palliative-care policies, as well as the policies proposed for prostate, lung and childhood cancers. Ideally, it should also be designed to encourage collaboration between research institutions and the private sector, where more than 80% of the oncology healthcare workforce serves 20% of the population. The latest NDoH Human Resources for Health Strategy (March 2020) (92) incorporated the Percept Study of 2019 to indicate the shortages in the healthcare professionals for the public sector (93). Only with a collaborative approach between the public and private sector can we move towards equity in respect of access to cancer care.

10.5 ANTI-COMPETITIVE BEHAVIOUR

The role and function of the Competition Commission (CompCom) in relation to the anti-competitive behaviour of cancer-medicine suppliers in South Africa has been questioned by many stakeholders (94). There is also the consequential use of the Patents Act to maintain market exclusivity (A13).

Intellectual Property law should dovetail with competition law to effectively promote access to medicine as part of a sound economic and social welfare system.

While patent laws provide incentives for innovation and technology, local legislation should not become an instrument for pharmaceutical companies to extend their patents beyond the initial 20-year period to block access to essential medicines.

In 2011, the Treatment Action Campaign (TAC), Section27, and Doctors without Borders (MSF) initiated the Fix the Patent Law Campaign to specifically advocate for the reform of the patent law. The amendments must still be finalised and will continue to block access to essential medicines until it is done (1).

Competition law may, in turn, be used to protect the consumer against anti-competitive behaviour that enhances market power or promote competition in the market (95).

Although the World Trade Organization Agreement on TRIPS flexibilities makes provision for the use of competition law it remains one of the least used tools in the healthcare environment (96).

The need for greater use of competition law was highlighted by the Global Commission on HIV and the Law, an independent body tasked with the investigation of the relationship between human rights, law and public health in the context of HIV. In the South African context, competition law is designed to reduce the structural imbalances resulting from apartheid.

The CompCom, constituted by the Competition Act (A15), would consider the following principles when analysing a situation with an interface between Intellectual Property rights and competition law:

- Competition law should recognise the basic rights granted under Intellectual Property law. The creation and maintenance of innovation markets are necessary for economic progress and development.
- Intellectual property does not necessarily create market power.
- The legal protection for intellectual property doesn't cover practises that are anti-competitive.
- The long-term pro-competitive benefits should outweigh the short-term anti-competitive effects of Intellectual Property rights (97).

The case of activist Hazel Tau in 2003 was the first successful case in respect of excessive pricing to be brought to the CompCom (98).

In June 2017, the SA CompCom announced their investigation of Roche for the anti-competitive pricing of trastuzumab (99).

To date, this investigation has not resulted in any conclusive outcome. The CompCom has limited jurisdiction to investigate originator companies with principal offices abroad. They cannot force the companies to supply the information necessary for a proper investigation, for example.

The successful conclusion of the Roche investigation thus remains to be seen.

Even though biosimilars are now available and far more affordable than the originator products, it will be a sad day for the access-to-medicines movement in South Africa if this investigation cannot be concluded. The investigation should cover the whole pharmaceutical sector, including originator and generic companies, as well as independent pharmaceutical suppliers.

As recently as 10 September 2020, both Novartis and Roche were fined $525 million for anti-competitive practises in France. This relates to Lucentis®, manufactured by Roche for macular degeneration, a common disease in the elderly (100). The more affordable option in Europe is still Avastin® (bevacizumab).

The European Commission launched an investigation into Aspen for excessive pricing of six off-patent cancer medicines. On 10 February 2021, Aspen Pharmacare Holdings reached an agreement to cut their prices by as much as 73% (101). Although some of these medicines are no longer in use in South Africa, they are still listed on the national EML. Melphalan, in particular, was one of the medicines not awarded in the 2020 tender due to supplier constraints at the manufacturing plant.

The CompCom launched the market inquiry into the private healthcare sector in 2014, but this inquiry did not include the pharmaceutical industry (34). As part of the Presidency, the National Planning Commission (NPC) completed their Pharmaceutical Pricing Policy report in February 2020 and published their position statement in April 2020 (17).

In the 15 recommendations, reference was made to the fact that such an inquiry would serve the country as a whole. It would especially benefit the cancer community in light of the many allegations of illegal incentive schemes, exorbitant pricing of cancer medicines, and collusion practises. Such an inquiry should also include the relationship between the listing of medicines for the EML and PMBs. Competition policies should be used effectively to promote access to medicines at the lowest cost for all (102).

11. CONCLUSIONS & RECOMMENDATIONS

Through the findings of this report, it is evident that the medical supply chain is complex and involves several role players, dependent on clear communication, efficient stock-reporting and accountability.

It is also clear that the pharmaceutical industry prefers to deal with the private sector rather than the public sector. This has resulted in a multitude of non-awarded medicines over the past two tender periods. In the face of the projected cancer incidence increase over the next 10 years, however, there is an urgent need to initiate the discussion on where and how cancer as a speciality disease will be managed in the proposed NHI. It has thus become crucial for the two sectors to find a solution suitable for both.

Cancer is a complex disease and there cannot be a one-size-fits-all solution. The problem in respect of expensive cancer medicines is not unique to South Africa. It is a worldwide phenomenon, and governments are being urged from all sides to intervene on behalf of their citizens.

The objectives of the National Drug Policy are clear, but once again, they are not executed. It is evident that we have brilliant policies, but their implementation falls short.

The problems in the Brazilian SUS system should be taken into careful consideration in the planning of the proposed NHI because we should try to avoid the same pitfalls discussed in the section on the Brazilian Model. South Africans deserve a broad array of affordable health choices so they can find those that will best fit their individual or family needs.

The purchase price of cancer medicines in the private sector and eventually in the proposed NHI should also relate to their therapeutic performance and take into account national socioeconomic factors as there cannot be a single approach to the regulation of medicine prices across countries.

Benchmarking may not be the suitable mechanism to use for newly patented medicines. Local and international researchers, however, have not yet found a way to close the gap between highly priced medicines and a fixed SEP.

As a solution, we propose a patient-centred approach to cancer treatment which acknowledges the patient's dignity in their decision-making process:

nothing about us without us

Such a value-based care model and its applicability within the proposed NHI should be thoroughly investigated. One of the burning questions is how cancer medicines

will be procured to serve the cancer community as a whole, by whom, and at what price.

The model should then be negotiated between the public and private sector, ideally, before September 2021 when the new tender is released. Considering the slow turn of the South African healthcare wheels, however, March 2023 would probably be more realistic.

There is an urgent need for the convergence of thought and action between the dtic, the NDoH, and SAHPRA, to ensure that patents are not the biggest obstacle in the quest to make essential medicines available until the patent-law reform has taken effect.

11.1 FOR THE NDoH

11.1.1 Cancer registries remain the only tool to effectively plan and manage cancer but without proper data, it is an impossible task. The Cancer Registration Regulation of 2011 must be revised urgently to make provision for the reporting of cancer through a database at each treatment facility. The current regulation only makes the head of the establishment responsible, thus omitting the diagnosing clinician – the most important person in the reporting chain. Ideally, people should be held accountable for incomplete reporting on the database because it will limit the facility's information sources and thus impair their ability to do proper planning in respect of cancer management.

11.1.2 We recommend the urgent promulgation of the Regulations pertaining to Bonusing in Section 18A of the Medicines and Related Substances Act 101 of 1965. These regulations were already published for comment in December 2017 in order to give effect to the prohibition of activities that undermine the transparent pricing of medicines, medical devices and IVDs. More specifically, the goal was to prohibit the supply through a bonus or rebate system, or any other incentive scheme, as envisaged in regulation 18A.

11.1.3 The feasibility of exempting expensive oncology and other speciality medicines in terms of Section 36 of the Medicines Act, in consultation with the Pricing Committee, must be investigated to promote equitable and affordable access for all.

11.1.4 The NDoH must determine the appropriate relationship between competition law enforcement and Intellectual Property protection. This involves a policy choice and effective use of these two mechanisms.

11.1.5 In line with the decision of the NDoH in respect of the balance between competition and IP rights, the Pricing and Economic Directorate must align the South African pricing policy with the policy guidelines of the WHO to improve transparency and fairness. The current SEP may be regarded as transparent, but it serves the industry – not the patients dependent on the medicines.

11.1.6 The NDoH must align the Medical Schemes Act with the Medicines and Related Substances Act to ensure that the decisions of the Minister and the Pricing Committee compel medical schemes to abide by the decisions. Trastuzumab was included on the South African EML in 2017, and it took three years before the Council included trastuzumab as a PMB for early breast cancer. Aligning the acts will force the Council for Medical Schemes (CMS) to align the PMB List with the South African EML, thus ensuring equitable access to healthcare for all. Medical schemes should also reimburse patients for unreasonably expensive medicines. In addition, manufacturers should not be allowed more than six months to adjust their prices for medicines after inclusion on the PMB list.

11.1.7 The public private partnership criteria for cancer must be set as a matter of urgency. It must be a transparent process where all stakeholders can participate. The favouring of a single service provider is a seedbed for excessive pricing and corruption.

11.1.8 The Minister of Health must follow through on the recent commitment at the EB 148 meeting of the WHO to submit a proposal to the World Health Assembly on expanding access to effective treatments and other health technologies for cancers and rare orphan diseases. South Africa is ideally placed to submit such a proposal as it would serve low-middle- and middle-income countries.

11.1.9 The NDoH, in cooperation with the dtic, must consider investing in the local production of APIs and specific medicines that can serve the continent. South Africa supports the proposal submitted by Ethiopia to the WHO Executive on 21 January 2021. This should be followed through and would strengthen the country's economic development plan.

11.1.10 Pooled procurement mechanisms between SADC countries that could lead to a reduction in purchase unit prices should be investigated as another option to support the growing cancer incidence and subsequent supply of essential medicines.

11.2 FOR SAHPRA

11.2.1 While affordability has never been a key principle for SAHPRA's evaluation of medicines, it plays a vital role in ensuring equitable healthcare. The NDoH and SAHPRA should therefore commit to collaboration where priority cancer medicines are concerned.

11.2.2 The Section 21 authorisation process must be reviewed as a matter of urgency. It must be streamlined to expedite the registration of medicines already available in Section 21. It is necessary to compare the length of time that a product is authorised under Section 21 with the time it takes to submit that product for registration. Section 21 authorisation should be the exception to the rule and not become the norm for the supply of essential medicines. Manufacturers should also be obliged to offer the same price when enlisting the SEP for the Section 21 product after its registration.

11.2.3 The approval of Section 21 access to generic lenalidomide for only a small group of patients after the registration of the originator in 2018 has set an untenable precedent that must be investigated from a legal perspective. It is unacceptable for SAHPRA to remain undecided about the way forward. Public access to medicine is as much part of their obligation as it is the responsibility of the Minister of Health.

11.2.4 SAHPRA must have the authority to force an originator supplier to provide samples for bioequivalent studies to complete the evaluation of medicines for safety, efficacy and quality. Registration by other health authorities, such as the US Food and Drug Agency, the European Medicines Agency, Therapeutic Goods Administration in Australia, and the Canadian Health Authority, should be referenced in these cases. Public health benefit is more important than a company's profit margin, which may be affected with the potential registration of a competitive product.

11.3 FOR THE NATIONAL TREASURY

11.3.1 The Chief Procurement Officer must investigate the deviation process of the supply-chain management system for buyouts and off-contract procurement, especially for oncology medicines. Such a request was submitted to the CPO and the Minister of Finance on 26 August 2020. No response has been received to date.

11.3.2 The tender regulations for the procurement of medicines and basic goods in the public sector cannot be the same. Buying out life-saving medicines cannot be subject to three quotations, especially when there are only one or two suppliers for the product in the market. The procurement should be expedited because sending a patient home with no means to complete their treatment is untenable.

11.3.3 As discussed in this report (CA03/2021), there were numerous problems with the tender procedure over the last two tender periods. The next tender is due in September 2021, and if the Public Finance Department, the NDoH and the pharmaceutical industry do not communicate and cooperate in order to streamline the procurement of speciality medicines, we are heading for the same disaster.

11.1.4 Where buyouts are more feasible than tenders, procurement should be dealt with at national level to prevent delays from the provinces and treatment centres.

11.1.5 The Public Financing Division must consider the increased funding to support the expenditure associated with the projected increase in cancer incidence over the next 10 years.

11.4 FOR THE dtic

11.4.1 The dtic must finalise the patent-law reform as a matter of urgency. This process has been dragged out for the last 12 years. On the international front, South Africa and India's campaign with regards to the TRIPS waiver indicates South Africa's influential position on the international stage, but we cannot be asking for global change if our own house is not in order.

11.4.2 The patent-registration process of the CIPC must be open and transparent, especially for medicine. Open access to the information of a patent that potentially can block access to essential medicines remain part of the call for patent-law reform.

11.4.3 The CompCom must implement the National Planning Commission's proposition to urgently launch an inquiry into the pharmaceutical industry. Such an inquiry should investigate the anti-competitive behaviour of the complete value chain of the pharmaceutical industry, including pharmaceutical companies, wholesale and retail pharmacies, distributors of medicines as well as the specific links they may have with the clinical community.

11.5 FOR THE PHARMACEUTICAL INDUSTRY

11.5.1 The pharmaceutical industry must urgently convene a meeting with all the stakeholders involved in the medicines supply chain about the pricing of cancer medicines in South Africa and the whole of the SADC region. Although there is no consensus yet on what fair pricing actually is, it was concluded at the Fair Pricing Forum in 2019 that the WHO will take this discussion forward. These discussions will then assist the South African stakeholders to decide on fair pricing in the context of South Africa and the SADC region.

11.5.2 In collaboration with the various health authorities, the pharmaceutical industry must commit to investigate different pricing strategies, like pooled procurement, to make medicines more affordable. Since cancer medicines will remain relatively small in relation to the overall medicines market, pooled procurement as an affordable pricing strategy in the SADC region must be investigated.

11.6 FOR FUNDERS

11.6.1 Cancer treatments are expensive and will remain one of the largest expenses for medical schemes. Out-of-pocket expenses for patients are increasing annually, forcing patients to access public services. The cancer-benefit packages for patients need urgent revision to ensure that patients have access to cancer treatment.

11.6.2 A value-based care model for cancer treatment should be designed specifically in collaboration with managed-care organisations to provide therapies, which provide economically viable treatments with the best possible survivor benefit.

11.7 AN ONLINE MEDICINES PORTAL

We have discussed at length the problems associated with the registration of medicines with SAHPRA – the resubmission of lost dossiers, the time it takes to evaluate applications, and so on, because, despite the backlog project, the registration of priority cancer medicines still takes more than a year to finalise with little feedback to any stakeholder.

While many regulatory offices around the globe have long had transparent registration processes in place, the confidentiality of SAHPRA's registration allows for all manners of mischief from the applicant and the authority alike.

11.7.1 We recommend the development of an open, transparent registration portal with three-way access managed in real time where every step in the registration process is recorded as it happens. Delays caused by either the applicant or by SAHPRA would reflect clearly on the database.

- Pharmaceutical companies should be obliged, through legislation, to provide information about the source of the API, its manufacturing and quality, the registration of the product with SAHPRA, and the contact details of the supplier and contractor. The active market status of a medicine, current availability and possible shortages that may occur, as well as reasons for discontinuation must be kept up to date in real time.
- Cancer registration information from all sources, including private laboratories, cancer treatment facilities and clinicians should be synchronised to this online portal in real time.
- The NDoH must have access to this main frame because the real-time data will help them streamline the procurement of essential medicines.

This recommendation is in line with that of the International Pharmaceutical Federation and the Economist Intelligence Unit on shortage reporting.

11.7.2 The possibility and viability of such an e-portal will largely depend on close collaboration between SAHPRA, the industry and the NDoH on the establishment of such a database. The management of the data should fall within the ambit of the Access to Information Act and, as such, should be coordinated by the NDoH.

11.7.3 The possibility of collective funding for the e-portal involving all stakeholders in the medicine-supply chain should be investigated.

11.8 FOR THE CANCER ALLIANCE

The Cancer Alliance, as representative of the patient community, remains one of the very few active organisations involved in the advocacy for equitable and affordable access to cancer treatment. The Cancer Alliance adopted a human rights-based approach to advocacy, and thus works with other likeminded organisations in the field, for example, Section27, the Treatment Action Campaign (TAC), the Rural Health Advocacy Project (RHAP), and the Health Justice Initiative (HJI) to achieve its objectives.

The Cancer Alliance has therefore built strong relationships with the NDoH and various oncology units in the public sector across the country, as well as the industry, mainly in respect of availability and affordability issues. Although our focus remains on public health, equity in the private sector is just as important.

11.8.1 The Cancer Alliance intends to collaborate more with other cancer groups and the Stop Stockout Project (SSP) in facilitating community workshops to educate cancer patients on stockouts and their right to medicine. Training on the proper use of the hotline to report medicine stockouts, and on how to address these challenges should be included in the workshops.

11.8.2 We want to use social media for an online cancer-stockout campaign with infographics and interactive posts that will raise awareness of cancer stockouts and the serious impact of cancer-medicine shortages.

11.8.3 We plan to continue the discussions with different stakeholders on the supply of cancer medicines within the proposed NHI. The reality is that the procurement of cancer medicines in both the public and private healthcare systems of South Africa is becoming more and more of a challenge. Many pharmaceutical companies are opting out of the South African market, which, for them, is becoming too small and affects their profit margins. We will have to

ReThink – ReDesign – ReEngineer

the supply of cancer medicines for the entire health sector, knowing full well that the NHI will be a reality in the future.

APPENDIX A – LEGISLATIVE FRAMEWORK

A1. South Africa. Department of Trade and Industry. 2018. National Policy for Patents Act 57 of 1978: Intellectual Property Policy of The Republic of South Africa Phase 1. Government Gazette 41870:518 31 Aug. https://www.gov.za/sites/default/files/gcis_document/201808/ippolicy2018-phasei.pdf

A2. South Africa. 2011. National Health Act of 2003. Regulations: Cancer Registration. Government Gazette 34248 26 April (Published under Government Notice R380). https://www.gov.za/sites/default/files/gcis_document/201409/34248rg9527gon380.pdf

A3. South Africa. National Health Act 61 of 2003. https://www.gov.za/sites/default/files/gcis_document/201409/a61-03.pdf

A4. South Africa. Medical Schemes Act 131 of 1998. https://www.gov.za/documents/medical-schemes-act?gclid=CjwKCAiAgc-ABhA7EiwAjev-jwPW_EovPdrLw0aH26tgtfenh_WvIpupfaeQFRu1NWyS182dbcDGfBoC6AEQAvD_BwE

A5. South Africa. [Date Unknown]. National Health Insurance Bill, B11-2019. First version: Published 26 Jul 2019. Commencement Date: [Date Unknown] https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf

A6. South Africa. Constitution of the Republic of South Africa. Act 108 of 1996. https://www.justice.gov.za/legislation/constitution/SAConstitution-web-eng.pdf

A7. South Africa. Public Finance Management Act 1 of 1999. https://www.gov.za/documents/public-finance-management-act?gclid=CjwKCAiAn7L-BRBbEiwAI9UtkAlGCVfuey8sgpTtf8cMnuoUKSpViWf3eUN3FykToIYGOSr5f6XPcRoCDCMQAvD_BwE

A8. South Africa. Preferential Procurement Policy Framework Act 5 of 2000. https://www.gov.za/documents/preferential-procurement-policy-framework-act

A9. South Africa. 2017. Preferential Procurement Policy Framework Act of 2000. Regulations: Preferential Procurement. Government Gazette 40553 20 January (Published under Government Notice R32). http://www.thedtic.gov.za/wp-content/uploads/PPPFA_Regulation.pdf

A10. South Africa. Department of Health. 1996. Medicines and Related Substances Act 101 of 1965: National Drug Policy. https://www.gov.za/documents/national-drugs-policy

A11. South Africa. Medicines and Related Substances Act 101 of 1965. (Previously Drugs Control Act) http://www.saflii.org/za/legis/consol_act/marsa1965280.pdf

A12. South Africa. 2017. Medicines and Related Substances Act 101 of 1965. (Previously Drugs Control Act) Regulations: Request for Comment on the General Regulations to Bonusing. Government Gazette 41287 1 December (Published under Government Notice 1321). https://www.gov.za/sites/default/files/gcis_document/201712/41287gon1321.pdf

Important Note: Although a request for comment on the draft regulations relating to bonusing were published in December 2017, to date, the regulations have not been finalised by the Pricing and Economic Division of the NDoH. It is therefore with reservation that we add it to the legal framework.

A13. South Africa. Patents Act 57 of 1978. https://www.gov.za/sites/default/files/gcis_document/201504/act-57-1978.pdf

A14. South Africa. National Department of Health. 2018. National Policy for Health Act 116 of 1978: Breast Cancer Control Policy. Government Gazette 41870:518 31 Aug. https://canceralliance.co.za/wp-content/uploads/2019/09/Breast-Cancer-Control-Policy-June-2017.pdf

Important Note: Since there is only a National Cancer Strategic Framework but no official Cancer Policy in South Africa, this reference to the Breast Cancer Control Policy is added to the legal framework with reservation. Although it has been approved by the National Health Council as a policy, it has neither been gazetted nor approved by all the provincial health departments.

A15. South Africa. Competition Act 89 of 1998. https://www.gov.za/sites/default/files/gcis_document/201409/a89-98.pdf

A16. Kekana RM, Dhai A, McQuoid-Mason J, Amrit V, Moerane G, Vincent-Lambert C, et al. Ethical Guidelines for Good Practice in the Health Care Professions [Internet]. Pretoria: Health Professionals Council of South Africa; 2016. [Cited 17 Dec 2020]. Available from: https://www.hpcsa.co.za/Uploads/Professional_Practice/Ethics_Booklet.pdf

APPENDIX B – ONCOLOGY TENDERS

B1. South Africa: National Treasury. Special Conditions of Contract – Supply and Delivery of Oncology and Immunological Agents for the Period 1 July 2018 to 30 June 2020. RT 290-2018. Pretoria: South African Government; November 2017. 62 pages. https://drive.google.com/drive/folders/1I-s3zCrZgGprQSlMHQvuNHyUyBglXe_y

B2. South Africa: National Department of Health. Supply and Delivery of Oncology and Immunological Agents to the Department of Health for the Period 1 July 2020 to 30 June 2022. HP04-2020ONC. Pretoria: South African Government; September 2019. 92 pages. https://drive.google.com/drive/folders/154p_C3pAJMks5oqAMdSjyGZt-kmDx5Lk

B3. South Africa: National Department of Health. Supply and Delivery of Oncology and Immunological Agents to the Department of Health for the Period 1 July 2020 to 30 June 2022. HP04-2020ONC/01. Pretoria: South African Government; May 2020. 92 pages. https://drive.google.com/drive/folders/1-Ws1pKwcTa7YL-nFM-jnETOobG4GZpNn

APPENDIX C – NON-AWARDS 2018 AND 2020

Products listed as non-awards from the 2018 and 2020 tenders

* Non-awarded products listed for 2018
* Non-awarded products listed for 2020ONC
* Non-awarded products listed for 2020ONC1 (Supplementary Tender)

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
1	Anastrozole 1mg tablet	Arimidex	09.09.1996	AstraZeneca Pharmaceuticals (Pty) Ltd			Akumentis Healthcare Ltd AstraZeneca Sun Pharmaceutical Industries Ltd
		Accord Anastrozole	26.11.2010	Accord Healthcare (Pty) Ltd			
		Stradexa	26.11.2010	Eurolab (Pty) Ltd			
		Anastrozole Sandoz	05.08.2011	Sandoz SA (Pty) Ltd			
		Mylan Anastrozole	30.09.2011	Xixia Pharmaceuticals (Pty) Ltd			
		Acrovic 1	02.03.2012	Dr Reddy's Laboratories (Pty) Ltd			
		Everdex 1mg	20.04.2012	AstraZeneca Pharmaceuticals (Pty) Ltd			

Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
	Castra 1	27.07.2012	Zydus Health Care SA (Pty) Ltd			
	Aspen Anastrozole	27.07.2012	Pharmacare LTD		Unavailable Product not active	
	Anamast 1mg	27.07.2012	Dezzo Trading 392 (Pty) Ltd trading as Indo Pharma			
	Medivision Anastrozole 1	14.09.2012	Medivision (Pty) Ltd			
	Teva Anastrozole 1mg	07.12.2012	Teva Pharmaceuticals (Pty) Ltd		Unavailable in South Africa Cost too high	
	Bredex 1mg	20.06.2013	Akacia Health Care (Pty) Ltd trading as Akacia Medical and Healthcare Group			
	Anabrez 1	05.12.2013	Ranbaxy Pharmaceuticals (Pty) Ltd			
	Anastrozole Watson	05.12.2013	Actavis Pharma (Pty) Ltd			
	Anasta	06.03.2014	Pharmaplan (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Oncomam	13.07.2014	Ranbaxy Pharmaceuticals (Pty) Ltd			
		Carmi	30.09.2016	Equity Pharmaceuticals (Pty) Ltd			
		Anastrozole Fresenius 1mg	11.26.2016	Fresenius Kabi Manufacturing South Africa (Pty) Ltd		Product discontinued	
2	Antilymphocyte Immunoglobulin (Horse) 250mg injection		No registration on SAHPRA			Only Rabbit strain available for Fresenius Medical Care SA (Pty) Ltd	
3	Asparaginase 10 000 IU Injection	Laspar	03.22.1971	Aspen Pharmacare Holdings Limited	Europe	On tender Unavailable due to supply constraints reported by manufacturing site	Biochem Pharmaceutical Industries Ltd Celon Laboratoies Ltd Sun Pharmaceutical Industries Ltd
4	Bevacizumab 100mg injection Avastin	Avastin 100	07.04.2006	Roche Products (Pty) Ltd		Available	Alkem Laboratories Ltd Hetero Drugs Ltd Intas Pharmaceuticals Ltd

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
5	Bicalutamide 50mg Tablet	Casodex 50	18.01.1995	AstraZeneca Pharmaceuticals (Pty) Ltd			Celon Laboratories Ltd Cipla Ltd Dr. Reddy's Laboratories Limited
		Bicadex	06.10.2006	Cipla Medpro South Africa (Pty) Ltd			
		Cipla-Bicalutamide	06.10.2006	Cipla Medpro South Africa (Pty) Ltd			
		Bicalox 50mg	06.10.2006	Pharmaplan (Pty) Ltd			
		Caloxa 50mg	26.11.2010	Eurolab (Pty) Ltd			
		Teva Bicalutamide 50	25.11.2011	Teva Pharmaceuticals (Pty) Ltd			
		Mylan Bicalutamide 50	02.03.2012	Xixia Pharmaceuticals (Pty) Ltd			
		Xixia Bicalutamide 50	02.03.2012	Xixia Pharmaceuticals (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Anandroca 50 Tablets	02.03.2012	Zydus Healthcare (Pty) Ltd			
		Spec-Bicalutamide 50	01.03.2013	Specpharm (Pty) Ltd			
		Tasdiam 50	19.04.2013	Ranbaxy Pharmaceuticals (Pty) Ltd			
		Adco-Bical 50mg	11.06.2018	Adcock Ingram Limited			
6	Bicalutamide 150mg Tablet	Casodex 150	25.02.2000	AstraZeneca Pharmaceuticals (Pty) Ltd			
		Teva Bicalutamide	25.11.2011	Teva Pharmaceuticals (Pty) Ltd			
		Tasdiam 150	19.04.2013	Ranbaxy Pharmaceuticals (Pty) Ltd			
		Spec-Bicalutamide 150	05.03.2014	Specpharm (Pty) Ltd			
		Adco-Bical 150mg	11.06.2018	Adcock Ingram Limited			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
7	Bleomycin 15 U injection	Blenamax 15 U	05.09.2003	Teva Pharmaceuticals (Pty) Ltd		Teva discontinued	Celon Laboratories Ltd Cipla Ltd United Biotech Pvt Ltd
8	Buserelin Acetate 9.9mg injectable depot implant Single disposable applicator	Suprefact 3-month Depot	03.06.1999	Sanofi-Aventis South Africa (Pty) Ltd		Sanofi not registered as applicant	Cadila Pharmaceuticals Intas Pharmaceuticals Ltd Samarth Life Sciences Pvt Ltd
9	Calcium Folinate Equivalent to Folinic Acid 200mg injection	Abic Leucovorin 200mg/20ml injection	28.08.2000	Teva Pharmaceuticals (Pty) Ltd		No tender This product needed to be procured on a Section 21 basis	Biochem Pharmaceutical Industries Ltd Celon Laboratories Ltd Samarth Life Sciences Pvt Ltd
10	Calcium Folinate Equivalent to Folinic Acid 100mg injection	Abic Leucovorin 100mg/10ml injection	28.08.2000	Teva Pharmaceuticals (Pty) Ltd		1000 unit available under Section 36 Lead time 4-5 months	
11	Calcium Folinate equivalent to Folinic Acid 300mg injection	Abic Leucovorin 300mg/30ml injection	28.08.2000	Teva Pharmaceuticals (Pty) Ltd		No stock available This product needed to be procured on a Section 21 basis	Biochem Pharmaceutical Industries Ltd Celon Laboratories Ltd Samarth Life Sciences Pvt Ltd

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
12	Calcium Folinate equivalent to Folinic Acid 50mg	Rescuvolin Powder for Injection 50mg	06.08.1987	Teva Pharmaceuticals (Pty) Ltd		This product needed to be procured on a Section 21 basis	
13	Capecitabine 150mg tablet 60 tablets	Capecitabine Specpharm 150	09.06.2016	Specpharm (Pty) Ltd		No stock since November 2019 Did not submit tender because of stock issues Unsure of API origin but stock is procured from Europe	Abbot India Ltd Biochem Pharmaceutical Industries Ltd Dr. Reddy's Laboratories Limited Intas Pharmaceuticals Ltd Roche Products India
		Xubix 500	10.10.2013	Roche Products (Pty) Ltd			
		Xeloda 150	31.07.2000	Roche Products (Pty) Ltd		Available PPQ in place	
		Pecaset 150mg	30.09.2016	Accord Healthcare (Pty) Ltd		No response	
		Capexa 150mg	30.09.2016	Accord Healthcare (Pty) Ltd		No response	
		Capecitabine Cipla 150	26.06.2019	Cipla Life Sciences (Pty) Ltd		Product available	

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Capeloda 150	26.06.2019	Cipla Medpro South Africa (Pty) Ltd		Registered but not yet launched	
14	Capecitabine 500mg tablet 120 tablets	Capecitabine Specpharm 500	09.06.2016	Specpharm (Pty) Ltd		Currently unavailable Lead time of 4-5 months	
		Xeloda 500	24.08.2000	Roche Products (Pty) Ltd		Available PPQ in place	
		Pecaset 500mg	30.09.2016	Accord Healthcare (Pty) Ltd			
		Capexa 500mg	30.09.2016	Accord Healthcare (Pty) Ltd			
		Capecitabine Cipla 500	06.26.2019	Cipla Life Science (Pty) Ltd		No response	
		Capeloda 500	06.26.2019	Cipla Medpro South Africa (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
15	Carboplatin 150mg injection	Carbosin 150	13.05.1996	Teva Pharmaceuticals (Pty) Ltd			Fresenius Kabi India Pvt Ltd Hetero Drugs Ltd Mylan Laboratories Ltd Pfizer Limited
		P& U Carboplatin CSV 150mg/5ml Injection	05.06.1996	Pfizer Laboratories (Pty) Ltd			
		Kemocarb 150	23.09.2005	Cipla Medpro South Africa (Pty) Ltd			
		Aspen Carboplatin 150mg	20.04.2012	Pharmacare LTD			
		Mylan Carboplatin 150mg/15ml	20.04.2012	Xixia Pharmaceuticals (Pty) Ltd			
		Asplata 150mg/15ml	01.10.2015	Pharmacare LTD			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
16	Carboplatin 450mg injection	Carbosin 450	13.05.1996	Teva Pharmaceuticals (Pty) Ltd		Available	
		P & U Carboplatin CSV 450mg/45ml Injection	06.05.1996	Pfizer Laboratories (Pty) Ltd			
		Kemocarb 450	23.09.2005	Cipla Medpro South Africa (Pty) Ltd			
		Aspen Carboplatin 450mg	20.04.2012	Pharmacare LTD			
		Mylan Carboplatin 450mg/45ml	20.04.2012	Xixia Pharmaceuticals (Pty) Ltd			
		Asplata 450mg/45ml	01.10.2015	Pharmacare LTD			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
17	Cisplatin 10mg injection	Abiplatin-10	14.02.1983	Teva Pharmaceuticals (Pty) Ltd			Alkem Laboratories Ltd Celon Laboratories Ltd Fresenius Kabi India Pvt Ltd Hetero Drugs Ltd Mylan Laboratories Ltd
		P & U Cisplatin CSV 10mg/0ml Injection	28.06.1997	Pfizer Laboratories (Pty) Ltd			
		Cisplatin-Hexal 10mg/20ml	25.11.2005	Sandoz South Africa (Pty) Ltd			
		Blastolem RU 10mg	05.10.2007	Teva Phamaceuticals (Pty) Ltd			
		Platosin 10mg/10ml	05.10.2007	Teva Pharmaceuticals (Pty) Ltd			
		Cipla-Cisplatin 10	14.08.2009	Cipla Medpro South Africa (Pty) Ltd			
		Kemoplat 10	25.11.2011	Cipla Medpro South Africa (Pty) Ltd			
		Cisacor 10	07.12.2012	Accord Healthcare (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
18	Cisplatin 50mg injection	Abiplatin 50	06.08.1987	Teva Pharmaceuticals (Pty) Ltd			
		P & U Cisplatin CSV 50mg/50ml Injection	28.06.1997	Pfizer Laboratories (Pty) Ltd			
		Cisplatin-Hexal 50mg/100ml	25.11.2005	Sandoz South Africa (Pty) Ltd			
		Blastolem RU 50mg	05.10.2007	Teva Pharmaceuticals (Pty) Ltd			
		Platosin 50mg/50ml	05.10.2007	Teva Pharmaceuticals (Pty) Ltd			
		Cipla Cisplatin 50	14.08.2009	Cipla Medpro South Africa (Pty) Ltd			
		Kemoplat-50	25.11.2011	Cipla Medpro South Africa (Pty) Ltd			
		Cisacor 50	07.12.2012	Accord Healthcare (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
19	Ciclosporin 50mg injection	Sandimmun Ampoules 50mg per 1ml	25.04.1983	Novartis South Africa (Pty) Ltd		On tender Available in South Africa for transplants only.	Biocon Ltd Cadila Pharmaceuticals Lupin Ltd, Sun Pharmaceutical Industries Ltd
21	Cyclophosphamide 1g injection		No registration on SAHPRA				Biochem Pharmaceutical Industries Ltd Cadila Pharmaceuticals Celon Laboratories Ltd Neon Laboratories Ltd
22	Cyclophosphamide 500mg injection		No registration on SAHPRA				
23	Cyclophosphamide 50mg tablet 50 tablets	Endoxan 50mg Tablets	23.09.2005	Baxter Healthcare SA (Pty) Ltd		Available	
24	Cytarabine 100mg injection	Alexan 100mg	27.03.1990	Adcock Ingram Limited	China, India, France, Ireland		Celon Laboratories Ltd Cipla Ltd Fresenius Kabi India Pvt Ltd Pfizer Limited
		Cytarabine-Faulding 100mg/ml	09.01.1996	Pharmaplan (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		P & U Cytarabine CSV 100mg/5ml Injection	05.06.1996	Pfizer Laboratories (Pty) Ltd			
		Laracit 100	29.07.2005	Teva Pharmaceuticals (Pty) Ltd		This product needed to be procured on a Section 21 basis	
		Cipla Cytarabine Injection 100mg (1ml)	17.04.2009	Cipla Medpro South Africa (Pty) Ltd	India		
		Cipla Cytarabine Injection 100 (5ml)	17.04.2009	Cipla Medpro South Africa (Pty) Ltd			
		Cipla Cytarabine Injection 100 (10ml)	17.04.2009	Cipla Medpro South Africa (Pty) Ltd			
25	Cytarabine 500mg Injection	Cytosar 500mg	18.11.1987	Pfizer Laboratories (Pty) Ltd			
		Alexan 500mg	27.03.1990	Adcock Ingram Limited			
		P& U Cytarabine CSV 500mg/25ml Injection	05.06.1996	Pfizer Laboratories (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
26	Dacarbazine 200mg injection	Dacarbazine-Faulding 200mg	07.05.1996	Pfizer Laboratories (Pty) Ltd			Alkem Laboratories Ltd Celon Laboratories Ltd, Intas Pharmaceuticals Ltd
		Aspen Dacarbazine	25.11.2011	Aspen Pharmacare Holdings Limited	Europe		
		Dacarbazine 200	23.11.2017	Key Oncologics (Pty) Ltd		Section 21	Section 21
27	Dactinomycin 0.5mg injection		No registration on SAHPRA.			Deregistered Section 21	Celon Laboratories Ltd, Neon Laboratories Ltd Wockhardt Ltd
28	Dasatinib 100mg tablet	Sprycel 100mg Tablets	07.12.2012	Bristol-Myers Squibb (Pty) Ltd		Available but not on tender	BMS India (Pty) Ltd Dr. Reddy's Laboratories Limited
29	Dasatinib 70mg tablet	Sprycel 70mg Tablets	09.12.2008	Bristol-Myers Squibb (Pty) Ltd		Available but not on tender	

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
30	Dasatinib 50mg tablet	Sprycel 50mg Tablets	09.12.2008	Bristol-Myers Squibb (Pty) Ltd		Available but not on tender	
31	Dasatinib 20mg tablet	Sprycel 20mg Tablets	09.12.2008	Bristol-Myers Squibb (Pty) Ltd		Available but not on tender	
32	Daunorubicin 20mg injection	Daunoblastin	05.12.1988	Pfizer Laboratories (Pty) Ltd			Cipla Ltd Pfizer Limited United Biotech Pvt Ltd
		Hemadaun	09.06.2016	Cipla Medpro South Africa (Pty) Ltd			
		Cipla Daunorubicin	09.06.2016	Cipla Medpro South Africa (Pty) Ltd			
33	Doxorubicin 10mg injection Items 37 and 36 will be considered as a series	Adriblastina RD 10mg	30.07.1974	Pfizer Laboratories (Pty) Ltd			Celon Laboratories Ltd Cadila Pharmaceuticals Sun Pharmaceutical Industries Ltd Zuventus Healthcare
		Doxorubicin PHC	07.11.1990	Teva Pharmaceuticals (Pty) Ltd			
		Doxorubicin HCL-Faulding	19.04.1996	Pharmaplan (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Adriblastina CSV 10mg	27.06.2000	Pfizer Laboratories (Pty) Ltd			
		Bio-Doxorubicin Hydrochloride 10	25.10.2001	Biotech Laboratories (Pty) Ltd			
		Doxorubicin-Hexal 10mg/5ml	06.06.2003	Sandoz South Africa (Pty) Ltd			
		HX-Doxorubicin 10mg/5ml	06.06.2003	Dezzo Trading (392) (Pty) Ltd trading as Indo Pharma			
		Doxorubicin "Ebwe" 10mg	13.04.2007	Key Oncologics (Pty) Ltd			
		Cipla-Doxorubicin	27.07.2012	Cipla Medpro South Africa (Pty) Ltd			
		Doxorubicin Accord 10mg/5ml	02.10.2014	Accord Healthcare (Pty) Ltd		Registered and available in the market	
		Rubexet 10mg/5ml	02.10.2014	Accord Health (Pty) Ltd			
34	Doxorubicin 50mg injection	Adriblastina RD 50mg	30.07.1974	Pfizer Laboratories (Pty) Ltd			

Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
	Doxorubicin PCH 50	07.11.1990	Teva Pharmaceuticals (Pty) Ltd			
	Adriblastina CSV 50mg/25ml	27.06.2000	Pfizer Laboratories (Pty) Ltd			
	Doxorubicin HCL-Faulding 50mg	11.10.2000	Pharmaplan (Pty) Ltd			
	Bio-Doxorubicin Hydrochloride	25.10.2001	Biotech Laboratories (Pty) Ltd			
	Doxorubicin-Hexal 50mg/25ml	06.06.2003	Hexal Pharma SA (Pty) Ltd			
	HX-Doxorubicin 50mg/25ml	06.06.2003	Dezzo Trading 392 (Pty) Ltd trading as Indo Pharma			
	Doxorubicin "Ebewe" 50mg	13.04.2007	Key Oncologics (Pty) Ltd			
	Cipla-Doxorubicin 50	27.07.2012	Cipla Medpro South Africa (Pty) Ltd			
	Doxorobucin Accord 50mg/25ml	02.10.2014	Accord Healthcare (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Rubexet 50mg/25ml	02.10.2014	Accord Healthcare (Pty) Ltd			
		Merck-Epirubicin 10mg	18.02.2016	Xixia Pharmaceuticals (Pty) Ltd			
35	Epirubicin 10mg injection	Farmorubicin RD 10	01.04.1992	Pfizer Laboratories (Pty) Ltd			Cadila Pharmaceuticals Glenmark Pharmaceuticals Ltd RPG Life Sciences
		Farmorubicin CSV 10mg/5ml	16.03.2000	Pfizer Laboratories (Pty) Ltd			
		Epirubicin HCL-Hexal 10ml/5mg	05.09.2003	Hexal Pharma SA (Pty) Ltd			
		HX-Epirubicin 10mg/5ml	03.06.2005	Hexal Pharma SA (Pty) Ltd			
		Epirubicin-Lemery 10mg	01.12.2006	Teva Pharmaceuticals (Pty) Ltd			
		Aspen Epirubicin 10mg	09.12.2008	Pharmacare LTD			
		Aspen Epirubicin 10mg/5ml	12.06.2009	Pharmacare LTD			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Cipla-Epirubicin 10	01.10.2010	Cipla Medpro South Africa (Pty) Ltd			
		Epicord 10	05.08.2011	Accord Healthcare (Pty) Ltd			
		Epirubicin-Fresenius 10mg/5ml	26.11.2015	Fresenius Kabi Manufacturing SA (Pty) Ltd			
		Merck-Epirubicin 10mg	18.02.2016	Xixia Pharmaceuticals (Pty) Ltd			
		Epirubicin-Fresenius 50mg/25ml	26.11.2015	Fresenius Kabi Manufacturing SA (Pty) Ltd			
		Merck Epirubicin 50mg	18.02.2016	Xixia Pharmaceuticals (Pty) Ltd			
36	Epirubicin 50mg injection	Aspen Epirubicin 50mg	12.06.2009	Aspen Pharmacare Holdings Limited		Unavailable Supply constraints indicated by manufacturing site	
		Farmorubicin RD 50	01.04.1992	Pfizer Laboratories (Pty) Ltd			

Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
	Farmorubicin CSV 50mg/25ml	16.03.2000	Pfizer Laboratories (Pty) Ltd			
	Epirubicin-Hexal 50mg/25ml	05.09.2003	Hexal Pharma SA (Pty) Ltd			
	HX-Epirubicin 50mg/25ml	03.06.2005	Hexal Pharma SA (Pty) Ltd			
	Epirubicin-Lemery	01.12.2006	Teva Pharmaceuticals (Pty) Ltd			
	Aspen Epirubicin 50mg	09.12.2008	Pharmacare LTD			
	Cipla-Epirubicin 50	01.10.2010	Cipla Medpro South Africa (Pty) Ltd			
	Epicord 50	05.08.2011	Accord Healthcare (Pty) Ltd			
	Accord Epirubicin 50	08.05.2011	Accord Healthcare (Pty) Ltd			
	Epirubicin-Fresenius 50mg/25ml	26.11.2015	Fresenius Kabi Manufacturing SA (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Merck Epirubicin 50mg	18.02.2016	Xixia Pharmaceuticals (Pty) Ltd			
37	Etoposide 100mg injection	Etoposide – Hexal 100mg/5ml	03.06.2005	Sandoz South Africa (Pty) Ltd			Cipla Ltd, Celon Laboratories Ltd Cadila Pharmaceuticals
		P & U Etoposide CSV 100mg/5ml Injection	05.03.1997	Pfizer Laboratories (Pty) Ltd		Deregistered	
		HX- Etoposide 100mg/5ml	03.06.2005	Dezzo Trading (392) (Pty) Ltd trading as Indo Pharma			
		Kemosid 100	29.07.2005	Cipla Medpro South Africa (Pty) Ltd	India	Available	
		Aspen Etoposide 100mg/5ml	19.04.2013	Pharmacare LTD	Europe	Available	
38	Fludarabine Phosphate 10mg tablet	Fludara Oral	11.02.2005	Sanofi-Aventis South Africa (Pty) Ltd		Available in South Africa On tender	Celon Laboratories Ltd Intas Pharmaceuticals Ltd United Biotech (Pty) Ltd
39	Fludarabine Phosphate 50mg injection	Fludara	10.11.1995	Sanofi-Aventis South Africa (Pty) Ltd		Available in South Africa On tender	

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Cipla Fludarabine	14.09.2012	Cipla Medpro South Africa (Pty) Ltd	India		
40	Fluorouracil 500mg injection	Fluroblastin	15.12.1982	Pfizer Laboratories (Pty) Ltd			Biochem Pharmaceutical Industries Ltd Cadila Pharmaceuticals Celon Laboratories Ltd
		Noracil Injection 500mg	22.03.1988	Sanofi-Aventis South Africa (Pty) Ltd			
		Fluorescite 10%	08.02.2008	Alcon Laboratories (SA) (Pty) Ltd			
		Fluroplex	06.03.2014	Cipla Medpro South Africa (Pty) Ltd			
		Cipla Fluorouracil	06.03.2014	Cipla Medpro South Africa (Pty) Ltd			
41	Gemcitabine 1g injection	Gemzar 1g	12.01.1995	Eli Lilly (Pty) Ltd			Celon Laboratories Ltd Dr. Reddy's Laboratories Limited Emcure Pharmaceuticals Ltd

Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
	Hexal Gemcitabine 1g IVI	09.10.2009	Dezzo Trading 392 (Pty) Ltd trading as Indo Pharma			
	Sandoz Gemcitabine 200mg IVI	09.10.2009	Sandoz South Africa (Pty) Ltd			
	Cytigem 1g	09.10.2009	Eurolab (Pty) Ltd			
	Accord Gemcitabine	09.10.2009	Accord Healthcare (Pty) Ltd			
	Gemtaz 1g	23.07.2010	Ranbaxy Pharmaceuticals (Pty) Ltd		Available but currently out of stock.	
	Mylan Gemcitabine 1g	20.04.2012	Xixia Pharmaceuticals (Pty) Ltd			
	Oncogem 1000	14.09.2012	Cipla Medpro South Africa (Pty) Ltd			
	Gemcitabine Teva	23.03.2015	Teva Pharmaceuticals (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Gemnil 1g	29.07.2016	Safeline Pharmaceuticals (Pty) Ltd			
		Rogem 1	30.09.2016	Zydus Healthcare (Pty) Ltd			
		Gemcitabine Zydus 1g	30.09.2016	Zydus Healthcare (Pty) Ltd			
42	Gemcitabine 200mg injection	Gemzar 200mg	12.02.1995	Eli Lilly SA (Pty) Ltd			
		Hexal Gemcitabine 200mg IVI	09.10.2009	Dezzo Trading 392 (Pty) Ltd trading as Indo Pharma			
		Sandoz Gemcitabine	09.10.2009	Sandoz South Africa (Pty) Ltd			
		Accord Gemcitabine 200mg IVI	09.10.2009	Accord Healthcare (Pty) Ltd			
		Cytigem 200mg	09.10.2009	Eurolab (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Gemtaz 200mg	23.07.2010	Ranbaxy Pharmaceuticals (Pty) Ltd		To be discontinued	
		Mylan Gemcitabine 200mg	20.04.2010	Xixia Pharmaceuticals (Pty) Ltd			
		Oncogem 200	14.09.2012	Cipla Medpro South Africa (Pty) Ltd			
		Gemcitabine Teva 200	23.03.2015	Teva Pharmaceuticals (Pty) Ltd			
		Gemnil 200mg	29.07.2016	Safeline Pharmaceuticals (Pty) Ltd			
		Rogem 200	30.09.2016	Zydus Healthcare (Pty) Ltd			
		Gemcitabine Zydus	30.09.2016	Zydus Healthcare (Pty) Ltd			
43	Goserelin 10.8mg injection	Zoladex 10,8mg	07.01.1997	AstraZeneca Pharmaceuticals (Pty) Ltd		Available	AstraZeneca

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
44	Granisetron 1mg injection	Kytril 1mg/1ml	19.05.1999	Roche Products (Pty) Ltd	Europe	Available in South Africa.	Cipla Ltd Hetero Drugs Ltd Sun Pharmaceutical Industries Ltd
		Adco Granisetron 1mg/1ml	12.05.2009	Adcock Ingram Limited			
		Sandoz Granisetron 1mg/1ml IVI	09.10.2009	Sandoz South Africa (Pty) Ltd			
		Aspen Granisetron 1mg	09.10.2009	Pharmacare LTD			
		Granitril	26.11.2010	Ranbaxy Pharmaceuticals (Pty) Ltd	Unavailable	India	
		Granisetron Teva 1	26.11.2010	Teva Pharmaceuticals (Pty) Ltd			
		Granisetron-Fresenius 1mg/ml (1 ml)	02.10.2014	Fresenius Kabi Manufacturing South Africa (Pty) Ltd			
		Aspen Granisetron 1mg/1ml	27.11.2014	Pharmacare LTD			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Grantryl 1mg/1ml	27.11.2014	Brimpharm SA (Pty) Ltd			
		Granisetron Brimpharm 1mg/1mg	27.11.2014	Brimpharm SA (Pty) Ltd			
		Grantyl 1mg/1ml	23.03.2015	Akacia Health Care (Pty) Ltd			
45	Granisetron 3mg injection	Kytril 3mg/3ml	19.02.1991	Roche Products (Pty) Ltd			
		Xixia Granisetron Injection	09.01.1997	Xixia Pharmaceuticals (Pty) Ltd			
		Adco Granisetron 3mg/3ml	12.06.2009	Adcock Ingram Limited			
		Mylan-Granisetron 3mg/3ml	09.10.2009	Mylan (Pty) Ltd			
		Sandoz Granisetron 3mg/3ml IVI	09.10.2009	Sandoz South Africa (Pty) Ltd			
		Granisetron Teva 3	14.09.2012	Teva Pharmaceuticals (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Granisetron 1mg/ml (3ml)	10.02.2014	Fresenius Kabi Manufacturing South Africa (Pty) Ltd		Available in South Africa On tender	
		Aspen Granisetron 3mg/3ml	27.11.2014	Pharmacare LTD	Europe		
		Grantyl 3mg/ml	27.11.2014	Brimpharm SA (Pty) Ltd			
		Grantyl 3mg/3ml	23.03.2015	Akacia Health Care (Pty) Ltd			
46	Granisetron 1mg Tablet	Kytril 1mg Oral	27.10.1994	Roche Products (Pty) Ltd			
		Granicip 1mg	12.06.2009	Cipla Medpro South Africa (Pty) Ltd			
		Cipla Granisetron 1mg	12.06.2009	Cipla Medpro South Africa (Pty) Ltd			
		Aspen Granisetron 1mg	09.10.2009	Pharmacare LTD			
		Granitril 1mg Tablet	26.11.2010	Ranbaxy Pharmaceuticals (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
47	Hydroxyurea 500mg capsule, 100 capsules		No registration on SAHPRA	Equity Pharmaceuticals (Pty) Ltd			Cadila Pharmaceuticals, Cipla Ltd United Biotech Pvt Ltd
48	Ibandronic acid 6mg injection	Bondronat 6mg/6ml	18.04.2008	Roche Products (Pty) Ltd			Medley Pharmaceuticals Ltd Natco Pharma Ltd
		Sandoz Ibandronate 6mg/6ml	05.12.2013	Dezzo Trading 392 (Pty) Ltd trading as Indo Pharma			
		Bonate 6mg/6ml	05.12.2013	Sandoz South Africa (Pty) Ltd			
		Bonrix 6mg/6ml	11.06.2018	Accord Healthcare (Pty) Ltd		Available No tender	
49	Idarubicin 10mg injection	Zavedos 10mg	01.08.1991	Pfizer Laboratories (Pty) Ltd			Pfizer Limited
		Zavedos RTU 10	07.08.2002	Pfizer Laboratories (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
50	Ifosfamide 1g injection Items 61,62 and 60 will be considered as a series	Holoxan 1g Injection	30.05.1979	Baxter Healthcare (Pty) Ltd			Celon Laboratories Ltd Fresenius Kabi India Pvt Ltd Neon Laboratories Ltd Vhb Life Sciences Ltd
		Ifolem 1g	25.11.2011	Teva Pharmaceuticals (Pty) Ltd			
51	Ifosfamide 2g injection	Holoxan 2g Injection	30.05.1979	Baxter Healthcare SA (Pty) Ltd			
52	Ifosfamide 500mg injection	Holoxan 500mg Injection	23.05.1978	Baxter Healthcare SA (Pty) Ltd			
		Ethyol	22.03.1996	Equity Pharmaceuticals (Pty) Ltd			
53	Interferon Alfa-2a 3M IU prefilled syringe	Pegasys 180	11.02.2005	Roche Products (Pty) Ltd	Europe	Discontinued Unavailable in South Africa	Cadila Pharmaceuticals Roche Products India

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
54	Interferon Alfa-2b 10M IU Injection	Intron-A (HSA-Free) Redipen 10 Million IU	31.07.2000	MSD (Pty) Ltd		Deregistered Unavailable in South Africa	Sanofi India, Intas Pharmaceuticals Ltd Reliance Life Sciences
		Viraferon (HSA-Free) Redipen 10 Million IU	05.10.2001	Schering-Plough (Pty) Ltd			
55	Interferon Alfa-2b 3M IU Injection	Intron-A (HSA-Free) Redipen 3 Million IU	31.07.2000	MSD (Pty) Ltd		Deregistered Unavailable in South Africa	
		Viraferon (HAS-Free) Redipen 3 Million IU	08.10.2001	Schering-Plough (Pty) Ltd			
56	Interferon Alfa-2b 5M IU Injection	Intron-A (HSA-Free) Redipen 5 Million IU	31.07.2000	MSD (Pty) Ltd		Deregistered Unavailable in South Africa	
		Viraferon (HSA-Free) Redipen 5 Million IU	08.10.2001	Schering-Plough (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
57	Interferon Beta- 1a prefilled syringe containing 12M IU			Bayer (Pty) Ltd		Available for multiple sclerosis only	Available for multiple sclerosis only.
58	Imatinib 400mg Tablet	Gleevec 400	25.11.2005	Novartis South Africa (Pty) Ltd			Celon Laboratories Ltd Intas Pharmaceuticals Ltd Natco Pharma Ltd Zuventus Healthcare
		Sunmatin	05.12.2013	Ranbaxy Pharmaceuticals (Pty) Ltd		Available	
		Vativio 400	30.09.2016	Novartis South Africa (Pty) Ltd			
		Nazzec 400	30.09.2016	Novartis South Africa (Pty) Ltd			
		Imatinib Accord 400	30.09.2016	Accord Healthcare (Pty) Ltd			
		Mivesta 400	30.09.2016	Accord Healthcare (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
59	Letrozole 2.5mg tablet, 28 tablets	Medpro Letrozole 2,5	14.09.2012	Cipla Medpro South Africa (Pty) Ltd		Registered but long term out of stock Unavailable	Akumentis Healthcare Ltd Emcure Pharmaceuticals Ltd Sun Pharmaceutical Industries Ltd
		Femara 2,5	23.05.1997	Novartis South Africa (Pty) Ltd			
		Accord-Letrozole 2,5 mg	26.11.2010	Accord Healthcare (Pty) Ltd			
		Laradex	26.11.2010	Eurolab (Pty) Ltd			
		Letrzole Adco 2,5	05.08.2011	Adcock Ingram Limited		Available However, have pricing issues of which NDOH is aware of.	
		Femzole 2,5	05.08.2011	Adcock Ingram Limited			
		Femtoz	02.03.2012	Brimpharm SA (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Trozolt	02.03.2012	Brimpharm SA (Pty) Ltd			
		Letoz 2,5 Tablets	26.10.2012	Zydus Healthcare (Pty) Ltd			
		Rozara	10.10.2013	Akacia Health Care (Pty) Ltd			
		Letraz	10.10.2013	Equity Pharmaceuticals (Pty) Ltd			
		Zetra	09.06.2016	Pharmaplan (Pty) Ltd			
60	Melphalan 2mg tablet, 25 tablets	Alkeran 2mg	29.12.1993	Aspen Pharmacare Holdings Limited		Will not bid due to supply constraints indicated by manufacturing site.	
61	Melphalan 50mg injection	Alkeran 50	29.12.1993	Pharmacare LTD	Europe	Available Tender for IV not oral.	Celon Laboratories Ltd Natco Pharma Ltd Zuvius Life Sciences Pvt Ltd

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
62	Mesna 400mg injection	Uromitexan 400mg Injection	23.11.1989	Baxter Healthcare SA (Pty) Ltd		Available	Cadila Pharmaceuticals Dr. Reddy's Laboratories Limited Neon Laboratories Ltd
63	Mesna 100mg injection	Uromitexan 100mg injection	23.11.1989	Sanofi-Aventis South Africa (Pty) Ltd			
		Uromitexan Solution for Injection 1g/10ml	29.03.1999	Sanofi-Aventis South Africa (Pty) Ltd			
		Uromitexan Solution for Injection 5g/50ml	29.03.1999	Sanofi-Aventis South Africa (Pty) Ltd			
64	Mesna 1g Injection	Uromitexan 1000mg injection	23.11.1989	Sanofi-Aventis South Africa (Pty) Ltd			
65	Methotrexate 500mg injection	Abitrexate 500	07.06.1986	Teva Pharmaceuticals (Pty) Ltd		Available On tender	Cadila Pharmaceuticals Ipca Laboratories Ltd Wallace Pharmaceuticals
		Emthexate 500	02.07.1987	Charmachemie (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		P & U Methotrexate CSV 500mg/20ml Injection	27.05.1996	Pfizer Laboratories (Pty) Ltd			
66	Methotrexate 50mg injection	Abitrexate 50	07.07.1986	Teva Pharmaceuticals (Pty) Ltd		Available	
		Emthexate 50mg	02.07.1987	Pharmachemie (Pty) Ltd			
		P& U Methotrexate CSV 50mg/2ml injection	05.03.1997	Pfizer Laboratories (Pty) Ltd			
67	Methotrexate 25mg injection	Methotrexate-Faulding 25mg/ml	09.05.1996	Pharmaplan (Pty) Ltd			
		Methacor 25mg/ml injection	18.04.2008	Accord Healthcare (Pty) Ltd			
68	Mitoxantrone 20mg injection	Mitoxantron "Ebewe" 20mg	05.08.2011	Key Oncologics (Pty) Ltd			Intas Pharmaceuticals Ltd Sun Pharmaceutical Industries Ltd

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
69	Mycophenolate mofetil 200mg/ml suspension, 175ml	Cellcept OS	07.03.2003	Roche Products (Pty) Ltd			Ipca Laboratories Intas Pharmaceuticals Ltd Roche Products India
70	Ondansetron 8mg tablet, 10 tablets		No registration on SAHPRA.				Alkem Laboratories Ltd Ipca Laboratories Ltd Mankind Pharma Sun Pharmaceutical Industries Ltd
71	Oxaliplatin 100mg injection	Exiplat 100	05.08.2011	Ranbaxy Pharmaceuticals (Pty) Ltd	India		Dr. Reddy's Laboratories Limited Intas Pharmaceuticals Ltd Sun Pharmaceutical Industries Ltd
		Oxaliplatin PCH 100	27.07.2012	Teva Pharmaceuticals (Pty) Ltd			
		Watson Oxaliplatin 100	20.06.2013	Arrow Pharmaceuticals SA (Pty) Ltd			
		Oxaliplatin Key 100	26.11.2015	Key Oncologics (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Intaplat 100mg	18.02.2016	Accord Healthcare (Pty) Ltd			
		Oxaliplatin "Ebewe" 100mg	09.06.2016	Sandoz South Africa (Pty) Ltd			
		Aspen Oxliplatin 100mg/20ml	29.07.2016	Pharmacare LTD	Europe		
		Goxyral 100	29.09.2017	Pharmaplan (Pty) Ltd			
		Oxaliplatin 100 Cipla	23.11.2017	Cipla Medpro (Pty) Ltd	India		
		Oxaviatin 100mg/20ml	11.06.2018	Safeline Pharmaceuticals (Pty) Ltd			
72	Oxaliplatin 50mg injection	Eloxatin 50mg/10ml RTU	11.08.2006	Sanofi-Aventis South Africa (Pty) Ltd			Celon Laboratories Ltd Dr. Reddy's Laboratories Limited Fresenius Kabi India Pvt Ltd Sun Pharmaceutical Industries Ltd
		Oxaliwin 50mg/10ml	05.10.2007	Zentiva (South Africa) (Pty) Ltd			

Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
	Oxaliwin 50mg/10ml	05.10.2007	Sanofi-Synthelabo (Pty) Ltd			
	Exiplat 50	05.08.2011	Ranbaxy Pharmaceuticals (Pty) Ltd		Not available	
	Oxaliplatin PCH 50	27.07.2012	Teva Pharmaceuticals (Pty) Ltd			
	Watson Oxaliplatin 50	20.06.2013	Arrow Pharmaceuticals SA (Pty) Ltd			
	Oxaliplatin Key 50	26.11.2015	Key Oncologics (Pty) Ltd			
	Intaplat 50mg	18.02.2016	Accord Healthcare (Pty) Ltd			
	Aspen Oxaliplatin 50mg/10ml	29.07.2016	Pharmacare LTD			
	Eloplat 50	23.11.2017	Sandoz South Africa (Pty) Ltd			
	Oxaliplatin 50 Cipla	23.111.2017	Cipla Medpro South Africa (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Oxaviatin 50mg/10ml	11.06.2018	Safeline Pharmaceuticals (Pty) Ltd			
73	Paclitaxel 100mg injection	Teva-Paclitaxel 100	31.07.2002	Teva Pharmaceuticals (Pty) Ltd		Available	Dr. Reddy's Laboratories Limited Fresenius Kabi India Pvt Ltd Hetero Drugs Ltd Lupin Ltd
		Taxol	17.11.1993	Bristol-Myers Squibb (Pty) Ltd			
		Sandoz Paclitaxel 100	09.12.2008	Sandoz South Africa (Pty) Ltd			
		Loxat 100	14.08.2009	Sandoz South Africa (Pty) Ltd			
		Ebetaxel 100mg	09.10.2009	Adcock Ingram Limited			
		Genexol 100mg	30.04.2010	Pharmacorp CC			
		Cipla-Paclitaxel 100mg/16,7ml	04.03.2011	Cipla Medpro (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Aspen-Paclitaxel 100mg/6,67ml	30.09.2011	Pharmacare LTD			
		Mylan Paclitaxel 100	30.09.2011	Xixia Pharmaceuticals (Pty) Ltd			
		Paxitas 100	02.03.2012	Eurolab (Pty) Ltd			
		Accord-Paclitaxel	02.03.2012	Accord Healthcare (Pty) Ltd			
		Plixel 100mg	27.11.2014	Safeline Pharmaceuticals (Pty) Ltd			
		Litha Paclitaxel 100	26.11.2015	Litha Pharma (Pty) Ltd			
		Abraxane	29.09.2017	Key Oncologics (Pty) Ltd			
74	Paclitaxel 30mg injection		30.09.2011	Aspen Pharmacare Holdings Limited		Product to be discontinued	
		Taxol	17.11.1993	Bristol-Myers Squibb (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Sandoz Paclitaxel 30	09.12.2008	Sandoz South Africa (Pty) Ltd			
		Loxat 30	14.08.2009	Sandoz South Africa (Pty) Ltd			
		Ebetaxel 30mg	09.10.2009	Adcock Ingram Limited			
		Genexol 30mg	30.04.2010	Pharmacorp CC			
		Aspen Paclitaxel 30mg	30.09.2011	Pharmacare LTD			
		Mylan Paclitaxel 30		Xixia Pharmaceuticals (Pty) Ltd			
		Paxitas 30	02.03.2012	Eurolab (Pty) Ltd			
		Accord Paclitaxel	02.03.2012	Accord Healthcare (Pty) Ltd			
		Litha Paclitaxel 30	26.11.2015	Litha Pharma (Pty) Ltd			
75	Pamidronic Acid 15mg injection		No registration on SAHPRA		Unavailable	Not registered.	Unavailable

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
76	Ribavirin 200mg tablet	Copegus 200	11.02.20051	Roche Products (Pty) Ltd	Europe	Available Antiviral not for oncology.	Cadila Pharmaceuticals Fulford (India) Ltd Lupin Ltd
		Auro Ribavirin Tablets 200mg	30.04.2010	Aurobindo Pharma (Pty) Ltd			
		Dorik Tablets 200mg	30.04.2010	Aurobindo Pharma (Pty) Ltd			
77	Rituximab 100mg injection	Mabthera 100	01.09.1999	Roche Product (Pty) Ltd			Alkem Laboratories Ltd Cipla Ltd Dr. Reddy's Laboratories Limited Hetero Drugs Ltd Intas Pharmaceuticals Ltd
		Ristova 100	07.12.2012	Roche Products (Pty) Ltd		Available	
		Blitzima 100mg	25.08.2020	Adcock Ingram Limited			
	Rituximab 500mg injection	Mabthera 500	01.09.1999	Roche Products (Pty) Ltd			
		Ristova 500	07.12.2012	Roche Products (Pty) Ltd		Available	
		Blitzima 500mg	25.08.2020	Adcock Ingram Limited			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
79	Tamoxifen 20mg tablet	Neophedan 20	21.07.1986	Aspen Pharmacare Holdings Limited		Unavailable Supply constraints indicated by manufacturing site.	AstraZeneca Biochem Pharmaceutical Industries Ltd Cipla Ltd Hetero Drugs Ltd
		Nolvadex-D	24.09.1985	AstraZeneca Pharmaceuticals (Pty) Ltd		Available Currently supplying NDOH as Aspen is out of stock.	
		Kessar 20	12.02.1986	Pfizer Laboratories (Pty) Ltd			
		Cytofen 20mg Tablet	14.08.1992	Noristan (Pty) Ltd			
		Lexifen 20mg	13.05.1997	Alliance Pharma (Pty) Ltd			
		Tamoplex 20mg	13.12.2001	Teva Pharmaceuticals (Pty) Ltd			
		Tamoxihexal 20	23.09.2005	Sandoz South Africa (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
80	Thalidomide 50mg capsules	Thalidomide Celgene 50mg	05.10.2007	Key Oncologics (Pty) Ltd			Cadila Pharmaceuticals Fresenius Kabi India Pvt Ltd Hetero Drugs Ltd
81	Tretinoin 10mg capsule	Roaccutane 10mg	18.09.1984	Roche Products (Pty) Ltd	Europe		Janssen India Pharmaceutical LLP Menarini India Pvt Ltd
		Vesanoid	25.10.1995	Pharmaco Distribution (Pty) Ltd		Available in South Africa On tender	
		Oratane 10mg	25.04.2003	Pharma Plan (Pty) Ltd			
		Acnetane 10mg	24.10.2003	Adcock Ingram Limited			
		Acnetret 10	17.02.2006	Cipla Medpro South Africa (Pty) Ltd	India		
82	Vincristine 1mg injection	Abic Vincristine Sulphate 1mg/ml	28.11.1987	Teva Pharmaceuticals (Pty) Ltd		Unavailable Long-term stockouts	
		Norcristine 1mg injection	04.02.1985	Noristan (Pty) Ltd			
		P & U Vincristine CSV 1mg/ml	27.05.1996	Pfizer Laboratories (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Vincristine RTU 1	23.09.2005	Pharmachemie (Pty) Ltd			
		Accord-Vinscristine 1mg/ml injection	14.08.2009	Accord Healthcare (Pty) Ltd			
83	Vincristine 2mg injection	Abic Sulphate 2mg/2ml	28.11.1988	Teva Pharmaceuticals (Pty) Ltd		Available	Biochem Pharmaceutical Industries Ltd Celon Laboratories Ltd Neon Laboratories Ltd United Biotech
		Norcristine 2mg Injection	04.02.1985	Noristan (Pty) Ltd			
		Vincristine RTU 2	23.09.2005	Pharmachemie (Pty) Ltd			
84	Vinorelbine 10mg and 50mg injection	Navelbine 10	25.10.1995	Tema Medical (Pty) Ltd			Abbott India Ltd Alkem Laboratories Ltd Fresenius Kabi India Pvt Ltd Health Biotech Ltd
		Navelbine 50	25.10.1995	Tema Medical (Pty) Ltd			
		Vinorel 10 and 50	17.04.2009	Pharma Plan (Pty) Ltd			
		Sandoz Vinorelbine	14.08.2009	Sandoz South Africa (Pty) Ltd			

	Item Description	Proprietary name	Date of Registration	License Holder (s)	Source of API	Current Status	Availability in India
		Cipla-Vinorelbine	09.10.2009	Cipla Medpro South Africa (Pty) Ltd	India	Available On tender	
		Teva Vinorelbine	04.06.2010	Teva Pharmaceuticals (Pty) Ltd	India	Available	
		Vinorelbine "Ebewe"	01.10.2010	Key Oncologics (Pty) Ltd			
		Aspen Vinorelbine	04.03.2011	Pharmacare LTD	Europe		
85	Zoledronic Acid 4mg injection	Cipla Zoledronic Acid	02.03.2012	Cipla Medpro South Africa (Pty) Ltd	India	Available On tender	Abbott India Ltd Cadila Pharmaceuticals Natco Pharma Ltd
		Zolapor	19.04.2013	Activo Health (Pty) Ltd	India		
		Zoledronic Eurolab	16.02.2017	Eurolab (Pty) Ltd	India and China		
		Zoledronic Acid DRL 4 mg/5ml	20.04.2017	Dr. Reddy's Laboratories (Pty) Ltd	India	Unavailable No stock	
		Zoclast 4mg/5ml	25.09.2018	Camox Pharmaceuticals (Pty) Ltd			

APPENDIX D – COMPANIES LISTED AT SAHPRA

* This list is subject to change at any time since the medicine market is a dynamic and ever-changing environment. Active Molecules in the market must be SEP approved and are listed annually. Molecules may also change between companies.

	Company Name	Type of Company
1	Accord Healthcare (Pty) Ltd	Generic
2	Acino Pharma (Pty) Ltd *acquired* Litha Pharma (Pty) Ltd Acino Pharma acquire Litha July 2017. https://acino.co.za/news/acino-south-africa-here-to-stay	Generic
4	Activo Health (Pty) Ltd	Generic
5	Actavis Pharma (Pty) Ltd *See* Teva Pharmaceuticals (Pty) Ltd *and* Cipla-Medpro South Africa (Pty) Ltd	Generic
6	Actor Pharma (Pty) Ltd	Generic
7	Adcock Ingram Limited	Originator/Generic
8	Akacia Health Care (Pty) Ltd	Generic
	Alcon Laboratories SA (Pty) Ltd	Generic
9	Alliance Pharma (Pty) Ltd	Generic
10	Amgen SA (Pty) Ltd	Generic/Biosimilar
11	Arrow Pharmaceuticals SA (Pty) Ltd	Generic

	Company Name	Type of Company
12	Aspen Pharmacare Holdings Limited	Generic
13	Astellas Pharma (Pty) Ltd	Generic
14	Aurobindo Pharma (Pty) Ltd	Generic
15	AstraZeneca Pharmaceuticals (Pty) Ltd	Originator
16	Aurobindo Pharma (Pty) Ltd	Generic
17	Austell Laboratories (Pty) Ltd	Generic
18	B Braun Medical (Pty) Ltd	Generic
19	Baxter Health Care SA (Pty) Ltd	Generic
20	Bayer (Pty) Ltd	Originator
21	Biotech Laboratories (Pty) Ltd	Generic
22	Bodene (Pty) Ltd trading as Intramed	Generic
23	Boston Scientific South Africa (Pty) Ltd	Generic
24	Brimpharm SA (Pty) Ltd	Generic
25	Bristol-Myers Squibb (Pty) Ltd	Originator
26	Camox Pharmaceuticals (Pty) Ltd	Generic

	Company Name	Type of Company
27	Cipla Life Sciences (Pty) Ltd	Generic
28	Cipla-Medpro South Africa (Pty) Ltd *partnered with* Teva Pharmaceuticals (Pty) Ltd *acquired* Actavis Pharma (Pty) Ltd (2016) *and* Pharmascript Pharmaceuticals Ltd (2016) 30 September 2016 https://www.cipla.co.za/?s=teva	Generic
29	Dr. Reddy's Laboratories (Pty) Ltd	Generic
30	Dezzo Trading (392) (Pty) Ltd *trading as* Indo Pharma Dezzo trading is now Ascendis Health Sept 2020 https://www.iol.co.za/business-report/companies/ascendis-health-enters-sales-agreement-for-dezzo-trading-for-r25m-bdefe74a-0a27-455f-aabd-c5d45a271bf0	Generic
31	Eli Lilly SA (Pty) Ltd	Originator
32	Equity Pharmaceuticals (Pty) Ltd	Generic
33	Eurolab (Pty) Ltd	Generic
34	Forrester Pharma (Pty) Ltd	Generic
35	Fresenius Kabi Manufacturing SA(Pty) Ltd	Generic
36	GlaxoSmithKlein South Africa (Pty) Ltd	Originator
37	Hetero Drugs Ltd	Generic
38	Hexal Pharma SA (Pty) Ltd	Generic

	Company Name	Type of Company
39	Hoechst Pharmaceuticals (Pty) Ltd *acquired* Noristan (Pty) Ltd Hoechst formed in 1863 merged in 1999 with Rhône-Poulenc SA to create AVENTIS. Hoechst SA acquired Noristan a SA company 11 Oct 1992. https://www.icis.com/explore/resources/news/1992/10/12/13576/hoechst-south-africa-merges-with-noristan/	Generic
40	Indo Pharma See Dezzo trading 392 (Pty) Ltd	Generic
41	Ingwe Lifescience (Pty) Ltd	Generic
42	Janssen Pharmaceutica (Pty) Ltd	Originator
43	Key Oncologics (Pty) Ltd	Originator
44	Litha Pharma (Pty) Ltd *acquired* Pharmafrica (Pty) Ltd (2010) *acquired* Pharmaplan (Pty) Ltd (2012) *acquired by* Acino Pharma (Pty) Ltd (2017) Litha acquires Pharmafrica June 2010. https://www.news24.com/Fin24/Litha-Healthcare-to-acquire-PharmAfrica-20100608	Generic
45	Medivision (Pty) Ltd	Generic
46	Merck (Pty) Ltd *acquired* Schering-Plough 2009 Schering-Plough https://www.msd.co.za/about-us/merck-schering-plough-merger/ https://blogs.sciencemag.org/pipeline/archives/2015/04/14/looking_back_at_merckscheringplough	Originator
47	Merck Sharp & Dohme Corp. (MSD), subsidiary of Merck & Co., Inc.	Originator
48	Mylan (Pty) Ltd	Generic

	Company Name	Type of Company
49	Noristan (Pty) Ltd *See* Hoechst Pharmaceuticals (Pty) Ltd	Generic
50	Novartis South Africa (Pty) Ltd *acquired* Sandoz South Africa (Pty) Ltd (1996) Merger between Sandoz and Ciba-Geigy in 1996 lead to Novartis. 2003 Novartis merged all their generic under SANDOZ https://www.sandoz.com/about-us/who-we-are/sandoz-brand	Originator
51	Pfizer Laboratories (Pty) Ltd	Originator
52	Pharmafrica (Pty) Ltd *See* Litha Pharma (Pty) Ltd	Generic
53	Pharmacare LTD *acquired* Aspen Pharmacare acquisition Aspen https://www.aspenpharma.com/wp-content/uploads/2017/12/Aspen-Nov-2017-Fact-Sheet-HR.pdf	Generic
54	Pharmachemie (Pty) Ltd	Generic
55	Pharmaco Distribution (Pty) Ltd	Generic
56	Pharmacorp CC	Generic
57	Pharmaplan (Pty) Ltd *See* Litha Pharma (Pty) Ltd Litha Pharma acquisition Pharmaplan March 2012 https://www.iol.co.za/business-report/economy/litha-buys-pharmaplan-in-sadc-generics-drive-1246027#:~:text=Paladin%20owns%2044.99%20percent%20of,half%20their%20shares%20for%20R2	Generic
58	Ranbaxy Pharmaceuticals (Pty) Ltd *See* Sun Pharmaceuticals SA (Pty) Ltd	Generic

	Company Name	Type of Company
59	Roche Products (Pty) Ltd	Originator
60	Schering-Plough (Pty) Ltd *See* Merck 2009	Originator
61	Safeline Pharmaceuticals (Pty) Ltd	Generic
62	Sandoz South Africa (Pty) Ltd *See* Novartis South Africa (Pty) Ltd	Originator
63	Sanofi *merged with* Synthélabo 1999, *acquired* Aventis 2004, Sanofi-Aventis South Africa (Pty) Ltd *changed name* to Sanofi 2011 https://www.britannica.com/topic/Sanofi-Aventis SANOFI-AVENTIS became SANOFI in 6 May 2011 http://www.pharmatimes.com/news/sanofi-aventis_splits_name_for_simplicity_981093#:~:text=Shareholders%20at%20Sanofi%2DAventis%20have,is%20not%20a%20surprising%20one	Originator
64	Specpharm (Pty) Ltd	Generic
65	Sun Pharmaceuticals SA (Pty) Ltd *acquired* Ranbaxy Pharmaceuticals (Pty) Ltd Sun Pharma acquired Ranbaxy Pharmaceuticals on 25 March 2015. https://sunpharma.com/wp-content/uploads/2020/12/Press-Release-Closure-of-Sun-Pharma-Ranbaxy-merger.pdf	Generic
66	Tema Medical (Pty) Ltd	Generic
67	Teva Pharmaceuticals (Pty) Ltd *See* Cipla-Medpro South Africa (Pty) Ltd	Generic
68	Triomed (Pty) Ltd	Generic
69	Xixia Pharmaceuticals (Pty) Ltd	Generic

	Company Name	Type of Company
70	Zentiva (South Africa) (Pty) Ltd acquired by SANOFI 2008 acquired by Advent 2018 from SANOFI-Zentiva https://www.adventinternational.com/advent-international-completed-acquisition-of-zentiva-from-sanofi/ Aventis founded in 1999 through merger with Hoechst was acquired by SANOFI 2004 https://www.dw.com/en/aventis-accepts-sanofi-bid/a-1182263 https://www.britannica.com/topic/Sanofi-Aventis	Generics
71	Zydus Healthcare (Pty) Ltd	Generics

APPENDIX E – EML

EML Oncology Medicines Required in the Public Sector

* Deregistered or non-registered products
* Medicines on the oncology tender which are not used for cancer treatments
* Not listed on the 2020 -2022 contract circular of National Department of Health
* Generic companies with more than one SEP listed have more than one registered product in the market.
* Not listed on the 2018-2020 contract circular of National Treasury
* Originator companies with more than one SEP listed have an originator product and a clone available

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded 2020 contract	Volume Private Sector	SEP Price in Private Sector
1	Anastrozole 1mg tablet 28 tablets	71 939 107 140	Accord – R28.18 (2020) Accord – R29.38 (2020)	Eurolab – 17 297 Accord – 5 477 Cipla – 3 518 Mylan – 2 760 AstraZeneca – 2 234 Aspen – 1 608 Novartis – 302 Ranbaxy – 0	Zydus – R206.00 Eurolab – R215.16 Sandoz – R216.31 Mylan – R227.15 Teva – R236.94 Ranbaxy – R434.28 Medivision – R747.52
2	Antilymphocyte immunoglobulin (Horse) 250mg injection	3 700	Not awarded in 2018, no quote Not awarded in 2020		Pfizer – R10 152.23
3	Antithymocyte immunoglobulin (Rabbit) 100mg injection	2 554 770	Fresenius Kabi – R4 423.99 (2018) Fresenius Kabi – R4 424.74 (2020)	Sanofi – 894 Pfizer – 725	Fresenius – R9 940.85

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
4	Asparaginase 10 000 KU injection	4 060	Not awarded in 2018, no quote Not awarded in 2020	Aspen – 2 078	Bodene – R1 470.63
5	Azathioprine 50mg tablet 100 tablets	67 480 76 124	Litha – R94.23 (2018) Litha – R94.23 (2020)	Cipla – 22 838 Ethicare – 10 330	Teva – R655.72 Pharmaplan – R795.00 Pharmacare – R888.39 Sandoz – R899.51 GlaxoSmithKline – R964.20 Pharmacare – R2 069.10
6	Bevacizumab 100mg injection	2 901 5 416	Roche – R2668.01 (2018) Roche – R2668.00 (2020)	Roche – 5 270	Roche – R4 478.80
7	Bicalutamide 50mg tablet 28 tablets	4 440	Accord – R115.00 (2018) *not listed in 2020	Accord – 10 290 Cipla – 3 449 Litha – 2 145 Accord – 2 054 AstraZeneca – 618	Eurolab – R514.55 Accord – R515.70 Teva – R515.70 Zydus – R521.21 Specpharm – R582.17 Litha – R635.88 Cipla – R690.48 Sandoz – R706.75 AstraZeneca – R3 177.44
8	Bicalutamide 150mg tablet 28 tablets	330	Teva – R1 725.00 (2018) *not listed in 2020	Cipla – 2 291 Eurolab – 1 662 AstraZeneca – 749	Teva – R2 632.58 Specpharm – R2 644.61 AstraZeneca – R3 177.44

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
9	Bleomycin 15 IU injection	15 000 23 260	Teva – R322.66 (2018) Not awarded in 2020	Unbranded – 1 042	Teva – R410.79 Pharmachemie – R420.83 Bristol-Myers Squibb – R452.77
10	Buserelin 9,9mg injectable depot implant Single disposable applicator	55 332	Not awarded in 2018, no quote Not awarded in 2020	Sanofi – 2 792	Sanofi – R6 071.29
11	Busulfan 2mg tablet 100 tablets	100 277	Pharmacare – R1 171.28 (2018) Pharmacare – R1 201.23 (2020)	Aspen – 8	Pharmacare – R1 350.17
12	Calcium Folinate equivalent to Folinic Acid 15mg tablet 10 tablets	5 661 5 880	Teva – R218.50 (2018) Teva – R222.39 (2020)	Cipla – 1 768	Teva – R255.24
13	Calcium Folinate, equivalent to Folinic Acid 100mg injection	52 440	*not listed in 2018 Not awarded in 2020		Teva – R254.05
14	Calcium Folinate, equivalent to Folinic Acid 200mg injection	1 984	Not awarded in 2018, no quote Not awarded in 2020		Teva – R508.17

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
15	Calcium Folinate, equivalent to Folinic Acid 300mg injection	2 926 2 125	Not awarded in 2018, no quote Teva – R609.75		Teva – R762.19
16	Calcium Folinate, equivalent to Folinic Acid 50mg injection	34 072 19 970	Not awarded in 2018, no quote Not awarded in 2020		
17	Capecitabine 150mg tablet 60 tablets	4 962 14 680	Roche – R303.43 (2018) Accord – R191.16 (2020)	Ingwe – 2 331 Accord – 737 Roche – 735 Specpharm – 248	Cipla – R448.55 Ingwe – R468.73 Ingwe – R468.81 Specpharm – R473.63 Roche – R581.83
18	Capecitabine 500mg tablet 120 tablets	6 018 14 312	Roche – R1 437.31(2018) Accord – R905.50 (2020)	Ingwe – 5 850 Roche – 2 060 Accord – 1 553 Specpharm – 749	Cipla – R3 071.08 Ingwe – R3 209.27 Specpharm – R3 214.40 Ingwe – R3 244.45 Roche – R3 977.6
19	Carboplatin 150mg injection	8 544 7 020	Accord – R138.00 (2018) Teva – R159.81 (2020)	Cipla – 8 035 Aspen – 0	Bristol-Myers Squibb – R142.60 Teva – R319.62 Pharmachemie – R328.55 Aspen – R339.71
20	Carboplatin 450mg injection	18 859 20 840	Accord – R322.00 (2018) Teva – R383.64 (2020)	Aspen – 114 Cipla – 4	Pharmachemie – R847.34 Teva – R959.11 Aspen – R1 019.13 Teva – R1 214.35

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
21	Chlorambucil 2mg tablet 25 tablets	5 656 6 022	Pharmacare R401.58 (2018) Pharmacare R415.60 (2020)	Ethicare – 1 539	Pharmacare – R467.18
22	Ciclosporin 100mg capsule 50 capsules	15 422 15 270	Novartis – R760.73 (2018) Novartis – R760.73 (2020)	Novartis – 2 568	Sandoz – R3 685.44 Novartis – R4 505.21
23	Ciclosporin 25mg capsule 50 capsules	38 644 30 840	Novartis – R190.33 (2020) Novartis – R190.33 (2020)	Novartis – 10 814	Sandoz – R938.33 Novartis – R1 144.12
24	Ciclosporin 100mg/ml oral solution 50ml	406 1 265	Novartis – R909.53 (2018) Novartis – R909.53 (2020)	Novartis – 2 568	Sandoz – R2 153.12 Novartis – R4 688.83
25	Ciclosporin 50mg injection	16 450	Not awarded in 2018 Novartis – R60.08 (2020)	Novartis – 726	Novartis – R758.62
26	Cisplatin 10mg injection	2 312 1 815	Accord – R26.89 (2018) Not awarded in 2020	Accord – 14 140 Cipla – 692 Pfizer – 1 231	Accord – R29.17 Pfizer – R33.26 Sandoz – R40.46 Pharmachemie – R45.64 Pharmachemie – R64.36
27	Cisplatin 50mg injection	55 723 49 540	Accord – R100.05 (2018) Accord – R120.06 (2020)	Accord – 14 238 Cipla – 0	Sandoz – R103.27 Pharmachemie – R116.77 Accord – R145.89 Pfizer – R166.30 Pharmachemie – R322.05

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
28	Cyclophosphamide 1g injection	63 235 53 960	Baxter – R126.52 (2018) Baxter – R132.85 (2020)	Baxter – 17 021	Sanofi – R531.96
29	Cyclophosphamide 500mg injection	16 544 11 502	Baxter – R86.26 (2018) Baxter – R90.57 (2020)	Baxter – 11 714	Sanofi – R536.66
30	Cyclophosphamide 50mg tablet 50 tablets	7 933 5 080	Baxter – R210.49 (2018) Baxter – R221.01 (2020)	Baxter – 2 866	Sanofi – R272.21
31	Cytarabine 100mg injection	15 320	Not awarded in 2018, no quote Not awarded in 2020	Equity – 366 Pfizer – 317 Cipla – 0 Pharmaplan – 0	Teva – R34.71 Pfizer – R169.36 Pharmaplan – R637.47
32	Cytarabine 500mg injection	55 040	Not awarded in 2018, no quote Not awarded in 2020	Pfizer – 1 698 Equity – 786 Cipla – 0	Teva – R173.69 Pfizer – R551.76
33	Dacarbazine 200mg injection	28 790	Not awarded in 2018, no quote Key Oncologics – R698.87 (2020)	Key Oncologics – 5 546	Bayer – R225.46
34	Dactinomycin 0.5mg injection	12 492	Not awarded in 2018, no quote Not awarded in 2020	MSD – 97	
35	Dasatinib 20mg tablet 60 tablets	78	Not awarded in 2018, no quote Not awarded in 2020	Equity – 68	Equity – R8 758.94

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
36	Dasatinib 50mg tablet 60 tablets	264	Not awarded in 2018, no quote Not awarded in 2020	Equity – 234	Equity – R21 897.37
37	Dasatinib 70mg tablet 60 tablets	222	Not awarded in 2018, no quote Not awarded in 2020	Equity – 230	Equity – R30 607.26
38	Dasatinib 100mg tablet 30 tablets	770	Not awarded in 2018, no quote Not awarded in 2020	Equity – 1 155	
39	Daunorubicin 20mg injection	14 564 11 400	Pfizer – R107.66 (2018) Not awarded in 2020	Pfizer – 676	Pfizer – R571.01
40	Docetaxel 20mg injection	6 464 8 832	Accord – R172.50 (2018) Sanofi – R287.04 (2020)	Eurolab – 8 815 Sanofi – 3 047 Accord – 487	Accord – R708.17 Key Oncologics – R756.58 Zentiva – R764.78 Eurolab – R789.77 Accord – R789.89 Cipla – R903.12 Ranbaxy – R1 046.54 Winthrop – R1 265.00 Sanofi – R2 980.44

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
41	Docetaxel 80mg injection	28 412 38 780	Accord – R460.00 (2018) Sanofi – R681.72 (2020)	Eurolab – 4 068 Accord – 1 159	Accord – R2 832.71 Key Oncologics – R3 026.32 Zentiva – R3 059.08 Eurolab – R3 159.05 Accord – R3 159.18 Cipla – R3 612.46 Ranbaxy – R4 186.20 Winthrop – R4 427.50 Sanofi – R11 921.75
42	Doxorubicin 10mg injection	19 162 7 830	Accord – R36.80 (2018) Teva – R80.57 (2020)	Eurolab – 7 224 Cipla – 882	Cipla – R80.63 Accord –R81.02 Pharmachemie – R81.36 Accord – R84.38 Teva – R85.26 Key Oncologics – R90.83 Pharmachemie – R101.75 Sandoz – R106.28 Pfizer – R121.29 Pharmachemie – R126.76
44	Epirubicin 10mg injection	220 1 320	Accord – R89.70 (2018) Not awarded in 2020	Aspen – 3	Accord – R137.23 Accord – R138.14 Aspen – R144.31 Sandoz – R154.51 Teva – R172.95 Aspen – R186.00 Pfizer – R235.22 Pfizer – R246.47

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
45	Epirubicin 50mg injection	27 229 23 660	Accord – R224.25 (2018) Not awarded in 2020	Aspen – 17	Accord – R686.14 Accord – R690.77 Teva – R697.22 Aspen – R721.56 Sandoz – R772.94 Aspen – R785.78 Pfizer – R1 232.32
46	Etoposide 100mg injection	54 736 53 410	Not awarded in 2018 Not awarded in 2020		Sandoz – R193.88 Pharmachemie – R205.29 Aspen – R208.48 Bristol-Myers Squibb – R400.27 Bristol-Myers Squibb – R401.49 Pfizer – R2 761.63
47	Everolimus 0.25mg tablet 60 tablets	304 477	Novartis – R609.52 (2018) Novartis – R609.52 (2020)	Novartis – 1 552	Novartis – R1 940.48
48	Everolimus 0.75mg tablet 60 tablets	506 912	Novartis – R1 828.50 (2018) Novartis – R1 828.50 (2020)	Novartis – 2 140	Novartis – R5 821.46
49	Exemestane 25mg tablet 28 tablets	2 775 21 700	R205.29 (2018) Pfizer – R205.29 (2020) Pack size 30 tablets offered	Equity – 7 467	Equity – R1 210.26 Ranbaxy – R1 214.18 Aspen – R1 312.23 Pfizer – R1 785.32
50	Filgrastim 30 MU prefilled syringe	80 258 96 992	Amgen – R468.15 (2018) Teva – R327.70 (2020)	Cipla – 8 711 Amgen – 4 170 Sandoz – 122	Teva – R3 794.76 Amgen – R4 336.87

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
51	Filgrastim 48 MU prefilled syringe	15 250 11 280	Amgen – R723.67 (2018) Teva – R506.57 (2020)	Cipla – 447 Amgen – 478 Sandoz – 18	Teva – R6 071.60 Amgen – R6 703.99
52	Fludarabine Phosphate 10mg tablet 20 tablets	202 138	Not awarded in 2018, no quote Sanofi – R4 140.00 (2020)	Biopharma – 46	Sanofi – R8 412.68
53	Fludarabine Phosphate 50mg injection	3 621 2 207	Not awarded in 2018 Sanofi – R565.11 (2020)	Cipla/Teva – 907 Biopharma – 198	Teva – R2 318.50 Sanofi – R11 090.14
54	Fluorouracil 5% ointment 20g	6 912 12 791	Accord – R610.05 (2018) Mylan – R659.00 (2020)	Mylan – 17 775	Meda Pharma SA – R854.83
55	Fluorouracil 500mg injection	146 601 115 220	Accord – R22.43 (2018)	Cipla – 2	Pharmachemie – R31.98 Pharmachemie – R36.48 Pfizer – R439.39
56	Gemcitabine 1g injection	17 556 23 530	Accord – R155.25 (2018) Accord – R235.75 (2020)	Eurolab – 11 160 Accord – 8 511 Eli Lilly – 359 Mylan – 0 Novartis – 0 Ranbaxy – 0	Eurolab – R1 641.63 Accord – R1 644.00 Ranbaxy – R1 662.90 Sandoz – R1 664.76 Mylan – R1 664.83 Eli Lilly – R1 806.05

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
57	Gemcitabine 200mg injection	3 884 3 570	Accord – R46.00 (2018) Accord – R103.50 (2020)	Accord – 9 472 Eurolab – 8 651 Cipla – 318 Eli Lilly – 232 Mylan – 0 Novartis – 0 Ranbaxy – 0	Accord – R316.82 Eurolab – R328.33 Ranbaxy – R332.58 Sandoz – R332.89 Mylan – R332.96 Eli Lilly – R361.20
58	Goserelin 10.8mg injection	34 580 55 332	AstraZeneca – R740.03 (2018) AstraZeneca – R816.50 (2020)	AstraZeneca – 8 209	AstraZeneca – R6 130.94
59	Goserelin 3.6mg injection	10 134 11 353	AstraZeneca – R455.40 (2018) AstraZeneca – R455.40 (2020)	AstraZeneca – 1 929	AstraZeneca – R2 427.46
60	Granisetron 1mg injection	176 224 244 970	Not awarded in 2018, no samples offered in evaluation Not awarded in 2020	Ethicare – 42 592 Pharmaco – 19 539 Fresenius – 16 953 Adcock – 16 702 Mylan – 1 013	Fresenius Kabi – R110.18 Sandoz – R149.80 Teva – R171.98 Adcock – R260.76
61	Granisetron 1mg tablet 10 tablets	35 095 46 940	Cipla – R12.11 Not awarded in 2020	Cipla – 7 551 Ethicare – 1 842	Ranbaxy – R353.43 Cipla – R394.93 Aspen – R472.28 Roche – R1 076.09
62	Granisetron 3mg injection	221 834 9 700	Pharmacare – R50.20 (2018) Adcock Ingram – R48.48 (2020)	Ethicare – 6 630 Fresenius Kabi – 2 050 Pharmaco – 415	Brimpharm – R537.57 Adcock – R781.54

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
63	Hydroxyurea 500mg capsule 100 capsules	13 524 9 926	Not awarded in 2018, no quote Not awarded in 2020	Equity – 8 316	Equity – R273.51
64	Ibandronic acid 6mg injection	22 286 23 240	Not awarded in 2018, no quote Not awarded in 2020	Adcock – 1 139 Accord – 77	Accord – R2 867.49 Pharmacare – R3 318.06 Roche – R3 967.83
65	Idarubicin 10mg injection	1 677 1 550	Pfizer – R1 163.36 (2018) Pfizer – R1 163.36 (2018)	Pfizer – 676	Pfizer – R2 114.47
66	Ifosfamide 1g injection	7 982 6 196	Baxter – R540.22 (2018) Baxter – R567.23 (2020)	Baxter – 1 668	Sanofi – R866.25
67	Ifosfamide 2g injection	12 700 10 240	Baxter – R872.89 (2018) Baxter – R916.53 (2020)	Baxter – 2 847	Sanofi – R1 743.27
68	Ifosfamide 500mg injection	948 364	Baxter – R324.13 (2018) Baxter R340.34 (2020)	Baxter – 619	Sanofi – R524.15
69	Imatinib 100mg tablet/capsule 60 tablets/capsules	11 329 16 020	Accord – R224.25 (2018) Accord – R154.22 (2020)	Novartis – 2 008 Cipla – 1 882 Accord – 1 387 Ranbaxy – 0	Ranbaxy – R6 025.00 Cipla – R6 578.00 Accord – R6 578.00 Accord – R6 324.86 Novartis – R13 150.00 Novartis – R23 290.92

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
70	Imatinib 400mg tablet/capsule 30 tablets/capsules	1 396 3 823	Accord – R454.25 (2018) Ranbaxy – R330.63 (2020)	Accord – 1 670 Cipla – 705 Novartis – 475 Ranbaxy – 3	Accord – R10 432.93 Ranbaxy – R10 950.00 Accord – R11 503.00 Novartis – R12 524.08 Cipla – R12 648.85 Novartis – R46 581.87
71	Interferon alfa-2a 3 M IU prefilled syringe	15 010 10 366	Not awarded in 2018, no quote Not awarded in 2020		Roche – R307.09
72	Interferon alfa-2b 10 M IU injection	106 300	Not awarded in 2018, no quote Not awarded in 2020		MSD – R927.70 MSD – R5 681.80
73	Interferon alfa-2b 3 M IU injection	42 140	Not awarded in 2018, no quote Not awarded in 2020		MSD – R1 704.52
74	Interferon alfa-2b 5 M IU injection	150	Not awarded in 2018, no quote Not awarded in 2020		
75	Interferon beta-1a Injection containing 6 M IU per ml after reconstitution injection	38 366	Litha Pharma – R4 547.54 (2020) Litha Pharma – R4 547.54 (2020)		
76	Interferon beta-1b 8 M IU per ml after reconstitution injection	12 246 20 844	Bayer – R418.64 (2018) Bayer – R418.64 (2020)		Bayer – R7 599.99

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
77	Interferon beta-1a Prefilled syringe containing 6 M IU per ml	30	Not awarded in 2018, no quote *not listed in 2020		
78	Interferon beta-1a Prefilled syringe containing 12 M IU per ml	1 630	Not awarded in 2018, no quote *not listed in 2020		
79	Irinotecan 100mg injection	7 717 8 532	Mylan – R169.34 (2018) Not awarded in 2020		Safeline – R945.73 Cipla – R1 036.30 Accord – R1 056.05 Mylan – R1 059.76 Sandoz – R1 200.75 Pfizer – R3 539.99
80	Irinotecan 40mg injection	942 1 382	Accord – R74.75 (2018) Mylan – R175.24 (2020)		Safeline – R378.29 Accord – R404.11 Cipla – R414.52 Eurolab – R420.73 Mylan – R423.91 Sandoz – R480.28 Pfizer – R1 199.16
82	Letrozole 2.5mg tablet 28 tablets	31 550 107 140	Cipla – R32.79 (2018) Not awarded in 2020	Accord – 22 502 Eurolab – 14 053 Novartis – 6 915 Adcock – 3 156 Cipla – 2 Aspen – 0	Eurolab – R511.49 Adcock – R513.61 Cipla – R517.58 Accord – R517.71 Adcock – R533.03 Brimpharm – R1 002.89 Novartis – R1 190.44

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
83	Medroxyprogesterone Acetate 100mg tablet 100 tablets	363 580	Pfizer – R670.50 (2018) Pfizer – R744.26 (2020)		
84	Melphalan 2mg tablet 25 tablets	3 024 2 934	Pharmacare – R557.75 (2018) Not awarded in 2020	Aspen – 1 372	Pharmacare – R648.48
85	Melphalan 50mg injection	810	Not awarded in 2018, no quote Not awarded in 2020	Aspen – 2 523	
86	Mercaptopurine 50mg tablet 25 tablets	12 550 10 744	Pharmacare – R992.09 (2018) Pharmacare – R1065.58 (2020)	Ethicare – 4 153	Pharmacare – R1 282.15
87	Mesna 400mg injection	107 788 78 124	Baxter – R600.57 (2018) Baxter – R42.04 (2020)	Baxter – 12 683	Sanofi – R782.89
88	Methotrexate 1g injection	24 700	Teva – R281.78 (2018) Teva – R292.40 (2020)	Cipla – 1 058	Pharmachemie – R545.15 Pharmachemie – R615.16
89	Methotrexate 2.5mg tablet 100 tablets	150 992 157 299	Teva – R95.79 (2018) Teva – R95.80 (2020)	Pfizer – 91 029 Cipla – 10 698 Unknown Lab – 365	Pharmachemie – R157.26 Pfizer – R215.50
90	Methotrexate 500mg injection	803 2 040	Not awarded in 2018, no quote Not awarded in 2020	Cipla – 288	Pharmachemie – R157.79 Pharmachemie – R255.98 Pfizer – R449.58

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
91	Methotrexate 50mg injection	14 698 15 970	Teva – R25.93 (2018) Not awarded in 2020	Cipla – 27 088 Accord – 19 Pfizer – 0	Pharmachemie – R25.58 Pharmachemie – R42.77 Pfizer – R224.79
92	Methotrexate 5g injection	1 308 1 520	Teva – R1 138.50 (2018) Teva – R1 138.50 (2020)		Pharmachemie – R3 410.58
93	Mitoxantrone 20mg injection	1 260	Not awarded in 2018, no quote Sandoz – R2 564.33 (2020)	Sandoz – 649	Sandoz – R3 189.74
94	Mycophenolate mofetil 200mg/ml suspension 175ml	64 120	Roche – R1 265.80 (2018) Roche – R1624.58 (2020)	Roche – 141	Roche – R3 009.41
95	Mycophenolate mofetil 250mg capsule 100 capsules	31 565 41 800	Roche – R270.16 (2018) Sandoz – R230.00 (2020)	Roche – 4 449 Novartis – 1 255 Alkem – 888 Cipla –333 Abex – 1	Teva – R1 087.26 Alkem – R1 096.50 Sandoz – R1 106.96 Alkem – R1 146.17 Austell – R1 174.69 Sandoz – R1 532.49
96	Mycophenolate mofetil 500mg tablet 50 tablets	18 420 39 050	Roche – R270.16 (2018 Sandoz – R230.00 (2020)	Roche – 21 293 Novartis – 11 123 Cipla – 2 080 Accord – 239 Abex – 44 Alkem – 0	Teva – R1 087.26 Alkem – R1 096.50 Sandoz – R1 106.96 Roche – R1 153.22 Ingwe – R1 172.68 Austell – R1 174.69 Roche – R2 174.52 Zydus Healthcare – R2 624.83

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
97	Mycophenolic acid 180mg tablet 120 tablets	1 382 1 780	Novartis – R806.73 (2018) Novartis – R806.74 (2020)	Novartis – 555	Novartis – R2 770.88
98	Mycophenolic acid 360mg tablet 120 tablets	1 440 1 851	Novartis – R1 029.48 (2018) Novartis – R1 085.73 (2020)	Novartis – 1 144	Novartis – R5 541.75
99	Nilotinib 200mg capsule 112 capsules	821 2 160	Novartis – R2 176.28 (2018) Novartis – R2 265.22 (2020)	Novartis – 1 064	Novartis – R30 128.72
100	Ondansetron 4mg dispersible tablet 10 tablets	13 509 45 100	Cipla – R14.68 (2018) Ranbaxy – R6.15 (2020)	Sun Pharma – 96 654 Pharma Dynamics – 92 498 Zydus – 32 381 Cipla – 18 518 Sandoz – 12 008	Austell – R132.83 Sandoz – R163.12 Ranbaxy – R172.34 Cipla – R188.22 Austell – R265.67 Mylan – R295.20 Ranbaxy – R358.26 Zydus – R358.28 Novartis –R397.21 Novartis – R852.43

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
101	Ondansetron 4mg injection	176 257 168 370	Accord – R2.88 (2018) Biotech – R2.39 (2020)		Accord – R35.34 Pharma Dynamics – R37.20 Mylan – R38.50 Ranbaxy – R40.53 Zydus – R44.18 Brimpharm – R48.61 Fresenius – R49.71 Zydus – R50.80 Specpharm – R104.60 Mylan – R308.01 Adcock – R318.70 Aspen – R341.20
102	Ondansetron 8mg injection	229 314 244 970	Accord – R5.64 (2018) Biotech – R4.19 (2020)		Accord – R70.69 Zydus – R84.15 Pharma Dynamics – R85.22 Mylan – R88.18 Fresenius Kabi – R99.49 Brimpharm – R101.62 Specpharm – R209.21 Ranbaxy – R281.90 Zydus – R423.05 Novartis – R616.04 Adcock – R637.39 Aspen – R682.40

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
103	Ondansetron 8mg tablet 10 tablets	34 545 46 940	Not awarded in 2018, no quote Ranbaxy – R6.89 (2020)		Austell – R265.60 Ranbaxy – R344.72 Cipla – R376.44 Austell – R531.19 Mylan – R590.29 Ranbaxy – R716.44 Zydus – R716.50 Sandoz – R769.65 Novartis – R804.88 Novartis – R1 345.41
104	Oxaliplatin 100mg injection	11 758 15 820	Not awarded in 2018, end user to correct specification Teva – R248.86 (2020)	Eurolab – 8 916	Zentiva – R1 772.90 Pharmachemie – R1 780.17 Eurolab – R1 860.82 Sandoz – R1 860.84 Accord – R1 860.84 Key Oncologics – R2 118.42 Accord – R2 237.64 Ranbaxy – R2 501.78 Sanofi – R3 591.68
105	Oxaliplatin 50mg injection	3 831 10 382	Not awarded 2018, end user to correct specification Teva – R179.87 (2020)	Eurolab – 3 362	Zentiva – R886.75 Accord – R118.82 Pharmachemie – R890.08 Sandoz – R930.39 Eurolab – R930.41 Accord – R930.42 Key Oncologics – R1 059.21 Ranbaxy – R1 250.89 Sanofi – R1 795.87

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
106	Paclitaxel 10mg injection	39 678 59 600	Accord – R132.25 (2018) Cipla – R400.85 (2020)	Cipla – 21 271 Accord– 2 683 Bristol-Myers Squibb – 727 Mylan – 656 Eurolab – 2 Aspen – 0 Equity –0 Novartis – 0 Pfizer – 0	Sandoz – R414.61 Teva – R435.74 Accord – R445.65 Cipla – R452.22 Mylan – R460.03 Accord – R466.81 Equity – R591.53 Pharmacorp – R596.44 Aspen – R1 644.54 Teva – R2 187.85 Adcock – R3 042.18
107	Paclitaxel 30mg injection	1 786 23 805	Accord – R86.25 (2018) Accord – R133.09 (2020)	Cipla – 2 463 Accord – 3 494 Mylan – 557 Eurolab – 8 Aspen – 0 Equity – 0 Key Oncologics– 0 Novartis – 0 Pfizer – 0	Sandoz – R124.10 Teva – R130.45 Accord – R133.43 Cipla – R135.38 Mylan – R137.72 Accord – R139.76 Equity – R177.45 Aspen – R493.27 Teva – R655.06 Adcock – R916.32
108	Pamidronic acid 15mg injection	60	Not awarded in 2018, no quote *Not listed in 2020		
109	Ribavirin 200mg tablet 42 tablets	182 279	Not awarded in 2018, no quote Not awarded in 2020	Roche – 352	Roche – R391.62
110	Rituximab 100mg injection	5 759 8 660	Roche – R1 523.67 (2018) Roche – R1 987.40 (2020)	Roche – 10 251	Roche – R7 237.27

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
111	Rituximab 500mg injection	11 765 8 580	Roche – R7 618.76 (2018) Roche – R7 618.76 (2020)	Roche – 11 451	Roche – R18 093.29
112	Sirolimus 1mg tablet 30 tablets	6 750 6 940	Pfizer – R1 941.21 (2018) Pfizer – R2 163.18 (2020)	Wyeth – 3 907	Pfizer – R3 180.21
113	Tacrolimus 0.5mg capsules 30 capsules	3 051 8 240	Accord – R205.85 (2018) Astellas – R151.80 (2020)	Astellas – 1 320 Astellas – 2 335	Astellas – R646.04 Astellas – R663.22 Forrester – R907.80 Astellas – R1 076.73 Accord – R1 117.95
114	Tacrolimus 1mg capsule 30 capsules	19 123 51 375	Accord – R408.25 (2018) Astellas – R301.30 (2020)	Astellas– 27 727 Astellas – 15 398	Astellas – R1 208.53 Accord – R2 055.58 Forrester – R3 308.39
115	Tacrolimus 5mg capsule 30 capsules	6 387 10 180	Accord – R2 012.50 (2018) Astellas – R1 448.10 (2020)	Astellas – 7 164 Astellas – 1 591	Astellas – R5 880.53 Forrester – R8 049.05 Accord – R9 941.33
116	Tamoxifen 20mg tablet 28 tablets	187 532 159 324	Pharmacare – R37.93 (2018) AstraZeneca – R129.95 (2020)	Pfizer – 58 969 Aspen – 32 612 Cipla – 27 828 Novartis – 718 AstraZeneca – 644	Pharmachemie – R129.78 Pfizer – R141.76 Sandoz – R142.71 Pharmacare – R159.92 AstraZeneca – R659.53 Pharmachemie – R1 081.54
117	Thalidomide 50mg capsule 28 capsules	9 913 5 000	Not awarded in 2018, no quote Key Oncologics – R1 484.08 2020	Key Oncologics – 1 149	Key Oncologics – R4 022.56

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
118	Thioguanine 40mg tablet 25 tablets	1 358 1 555	Pharmacare – R2 219.84 (2018) Pharmacare – R2 304.31		Pharmacare – R2 589.99
119	Trastuzumab 440mg injection	990 1 952	Roche – R6 531.61 (2018) Mylan – R4 950.00 (2020)	Mylan – 4 903 Roche – 288	Mylan – R5 000.00 Roche – R8 500.00
120	Tretinoin 10mg capsule 100 capsules	2 244 1 236	Not awarded in 2018, no quote Pharmaco – R3 968.86	Pharmaco – 243	Roche – R5 166.02
121	Vinblastine 10mg injection	11 266 10 865	Teva – R227.70 (2018) Teva – R250.47 (2020)	Cipla – 3 058 Pharmaplan – 50	Cipla – R270.53 Pharmachemie – R289.80 Teva – R289.81
122	Vincristine 1mg injection	5 649 5 380	Teva – R79.69 (2018) Not awarded in 2020	Accord – 3 195 Cipla 1 876 Pfizer – 234	Pharmachemie – R96.95 Accord – R128.85 Pfizer – R400.25
123	Vincristine 2mg injection	35 402 143 010	Teva – R169.05 (2018) Accord – R97.75 (2020)	Cipla – 3 338 Pfizer – 232	Pharmachemie – R206.47 Pfizer – R836.74
124	Vinorelbine 10mg injection	3 638 3 010	Not awarded in 2018, no quote Sandoz – R151.27 (2020)	Sandoz – 1 315 Tema Medical – 159	Pharmaplan – R213.19 Sandoz – R221.58 Pierre Fabre – R228.93 Cipla – R257.21 Key Oncologics – R349.27 Teva – R389.25 Aspen – R3 481.17 Tema Medical – R3 335.00

Item Number	Description	Estimated Quantity	Tender Price and Supplier Awarded	Volume Private Sector	SEP Price in Private Sector
125	Vinorelbine 50mg injection	2 991 4 490	Not awarded in 2018, no quote Sandoz – R544.78 (2020)	Sandoz – 563 Tema Medical – 85	Sandoz – R1 108.07 Cipla – R1 286.03 Pierre Fabre – R1 216.71 Pharmaplan – R1 332.46 Teva – R1 430.63 Tema Medical – R1 667.50 Aspen – R1 740.58 Key Oncologics – R1 746.53 Pierre Fabre – R10 855.08
126	Zoledronic Acid 4mg injection	24 066 23 240	Not awarded in 2018, no quote Ranbaxy – R159.99 (2020)	Actor – 7 296 Adcock – 5 903 Cipla – 4 720 Novartis – 4 212 Sun Pharma – 613 Activo – 124 Camox – 23	Ranbaxy – R995.00 Actor Pharma R1 040.42 Activo Health – R1 058.77 Austell – R1 059.59 Cipla – R1 060.39

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