Utrecht University

South Africa's Single Exit Price Policy: *A step towards accessible and affordable medicines for all citizens of South Africa*

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Abbreviations

SEP	Single Exit Price
SEPA	Single Exit Price Adjustment
PMA	Pharmaceutical Manufacturers Association
NDoH	National Department of Health
SAPC	South African Pharmacy Council
APIs	Active Pharmaceutical Ingredients
MCC	Medicines Control Council
SAHPRA	South African Health Products Regulatory Authority
NDP	National Drug Policy
SADAP	South African Drug Action Programme
VAT	Value Added Tax
PSSA	Pharmaceutical Society of South Africa
TAC	Treatment Action Campaign
SKU	Stock-keeping unit
ERP	External reference price
ZAR	South African Rand
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
NEML	National Essential Medicines List
WHO EML	World Health Organization Model List of Essential Medicines

Abstract

To combat the high prices of medicines sold in the private healthcare sector, the National Health Department (NDoH) of South Africa developed a number of regulations pertaining to pricing and regulation of medicines. Of these, the Single Exit Price (SEP) policy had a confounding effect on the sale of medicines in the private sector. It was introduced along with several other related policies in 1997 and was met with strong opposition from stakeholders in the private pharmaceutical sector. It was eventually passed in 2004 after several court cases and revisions. The main goals of the SEP and related policies were (i) to introduce a transparent pricing system by introducing price caps at various points in the supply chain, (ii) to reduce the high prices of medicines, and (iii) to promote the use of generic alternatives to branded medicines. These aims were met to a certain degree – the average price of medicines was found to have decreased in the years following the SEP, and the standardization of the system increased, with all medicines and dispensaries being registered with the appropriate authority. However, there were some unintended consequences, such as the withdrawal of medicines from the market and the closure of local pharmacies due to insufficient profits. The SEP and related policies marked a strong step towards achieving affordable and accessible medicines for all citizens of South Africa. At the same time, the strong criticisms of the policies reveal key lessons to be kept in mind for the future, especially as South Africa moves towards establishing National Health Insurance (NHI) scheme.

Layman's summary

One of the greatest barriers to accessing medicine is affordability. When medicines are priced too high, a divide is automatically created between those who can pay for them, and those who cannot. In South Africa, this divide was compounded by apartheid-era regimes that discriminated access to resources on the basis of race. When the first democratically elected government came into power in 1994, they inherited a healthcare system that was strongly divided. The private sector catered to only a small percentage of the population, yet a disproportionately large amount of resources, personnel, and funding went into it. While the government covers medicines and healthcare services in the public sector, the private sector was largely ruled by big pharmaceutical companies. This left a lot of room across the supply chain for alterations in the price. For example, the manufacturers could sell their products at different prices depending on the buyer. Pharmacists and dispensing doctors would often push certain brands of medicines to consumers, not because of medical benefit, but because they were offered a discount by the distributor. In many cases, these benefits did not translate to the patients, who invariably ended up paying full price for the medicine anyway.

In 1996, the government established the National Drug Policy, which laid the groundwork for several monumental changes that would come in the following year. Through this, the government legally banned all incentive schemes (such as bonuses, rebates, discounts, and so on). Amongst the amendments introduced in 1997 was the single exit price (SEP), defined as the only price at which manufacturers could sell medicines at to buyers other than the government itself. The SEP, which is set by the manufacturer, comprises of the ex-manufacturer price, the logistics fee, and Value Added Tax (VAT). The government also introduced price caps on the dispensing fee (extra charge from pharmacists) and, later on, the logistics fee (extra charge by logistic service providers). Additionally, generic substitution was made mandatory, meaning that pharmacists and prescribing doctors were required to offer a generic alternative to expensive, branded medicines, so the patient could make an informed choice.

There was a lot of resistance to the policy, mainly from stakeholders in the private sector such as pharmaceutical manufactures, big pharmaceutical companies, and pharmacists. After a series of court cases and revisions to the amendments, the SEP and related regulations were implemented in 2004. Since then, the average price of medicines was found to have reduced. However, there were also several unintended consequences, such as the closure of local pharmacies due to insufficient profits, and the withdrawal of medicines from the market.

The SEP and related policies marked a strong step towards achieving affordable and accessible medicines for all citizens of South Africa. At the same time, the strong criticisms of the policies reveal key lessons to be kept in mind for the future, especially as South Africa moves towards establishing National Health Insurance (NHI) for all citizens of the country.

1. Introduction

1.1 What is the SEP Policy?

The discriminatory access to medicines and healthcare under apartheid left the healthcare system in South Africa heavily divided. In 1990, nearly 80% of the total medicine expenditure in South Africa came from the private sector[1], despite it catering to less than 20% of the population. When the first democratically elected government came into power in 1994, they saw a dire need for intervention. They sought to address low access to medicines due to unregulated and exorbitant pricing by introducing the National Drug Policy (NDP) in 1996[1]. The NDP served as a foundation for heavy reforms in terms of regulations and the introduction of a transparent pricing system. Following several years of further adjustments, revisions, and interventions, the Single Exit Pricy (SEP) policy was introduced in 2004 as a part of 'regulations relating to a transparent pricing system for medicines and scheduled substances'[2,3]. The main aim of the policy was to combat high market prices by establishing a fixed price at which medicines could be sold at by manufacturers to buyers other than the State[4]. The SEP is comprised of the ex-manufacturer price (set by the manufacturer), logistics fee (negotiated between the service providers), and 14% Value Added Tax (VAT)[5]. The value of the SEP is given in South African Rand (ZAR), the currency used in South Africa. Related policies introduced a cap on the logistics fee added by logistic service providers and the dispensing fee charged by pharmacists and dispensing doctors. A regulated annual increase of the SEP is allowed to account for economic factors such as inflation rates. The annual increase is called the single exit price adjustment (SEPA), which is determined by the Minister of Health. Box 1 shows an overview of how the initial SEP value was calculated for medicines in 2004, and the criteria upon which the SEPA is determined on a yearly basis.

Box 1: SEP and SEPA calculation[6]

SEP

The initial SEP was calculated in 2004 for all medicines and scheduled substances.

For medicines, this price could not be higher than the 'weighted average net selling price of the medicine." This was to be calculated using the formula:

S/N, where

S = the total ZAR value of net sales (being sales less discounts) for all packs of the same dosage strength of the medicine sold in the year, and

N = the total number of lowest units (eg. a tablet) for all of the packs of the same dosage strength of the medicine sold in the year 2003

SEPA

After 2004, any increase in SEP would have to be applied for. The SEPA is represented a percentage relative to the SEP of the previous year. The Minister of Health reviews the SEPA allowance upon consultation with the Pricing Committee and taking into consideration comments from interested persons. The SEPA is calculated on the basis of the following –

(i) the average Consumer Price Index (CPI) of the previous year

(ii) the average Producer Price Index (PPI) of the previous year

(iii) changes in the rates of foreign exchange and purchasing power parity

(iv) international pricing information relating to medicines and schedule substances

(v) comments received from interested persons

(vi) the need to ensure the availability, affordability, and quality of medicines and scheduled substances in the Republic.

The implementation of the SEP policy had several consequences. The overall price of medicines decreased by an average of 22%[7] - however, there were also several, unintended, consequences of the policy. This included the withdrawal of medicines from the market[8], and the closure of several local community pharmacies due to insufficient funds[5]. Additionally, the extensive bureaucratic processes involved in registering new medicines and their SEP, as well as

applying for SEPA, served as a huge deterrent to companies trying to get new medicines onto the market, and to companies who wished to keep their products available on the market while continuing to make a profit.

As a result, the reception of the policy was mixed. The Pharmaceutical Manufacturers Association (PMA), a local organization for pharmaceutical manufacturers in South Africa along with several prominent pharmaceutical companies strongly contended the stipulations of the policy, stating that under the new regulations, they would not have sufficient funds to sustain themselves. Pharmacists and licensed dispensers, under the Pharmaceutical Society of South Africa (PSSA) protested the cap on the dispensing fee that they could levy. When the cap on the logistics fee was introduced in later years, it too was met with significant contention[9]. The National Department of Health (NDoH), a government body, was strongly in favour of the reforms as a measure to close address the issues in the private healthcare and continued to make revisions and reforms as required to keep the legislations in place.

1.2 Objectives and methods of this review

The aim of this report is to review South Africa's SEP policy and its consequences. This includes background information about the healthcare system in South Africa, the events leading up to the implementation of policy, important precursors, and responses from various stakeholders. The outcomes and consequences of the policy will also be assessed – for example, price reduction, market withdrawal of medicines, overall access to medicines, and public response. Finally, the SEP will be analysed in context – could other countries have something to learn from South Africa's experience? Alternatively, what could South Africa have done differently? The review will conclude with future perspectives.

Several literary sources were used to collect information on the history and outcomes of the policy. This includes policy documents, academic articles, government Gazettes, and newspaper articles. The main databases used for the literature search were:

- Overton (for policy documents)
- Google Search (for news articles)
- Google Scholar (for academic articles)
- PubMed (for academic articles)
- The South African government archives (www.health.gov.za - for government Gazettes, bills and notices)
- SAFLII (South African Legal Information Institute – for court proceedings and legal documents)
- Mail & Guardian archives (one of the main news and journalism outlets in South Africa - for news articles and opinion pieces)

The key words used during a preliminary literature search in Overton and Google included the following terms: 'single exit price', 'medicine price South Africa', 'Pharmaceutical policy South Africa', 'Pharmaceutical pricing policies South Africa', 'National Drug Policy South Africa', 'SEP South Africa', and 'Medicine pricing policy South Africa'. All search terms were checked both in the singular and the plural and using 'South Africa' and 'SA'.

The key words used in a secondary literature search in Google, the South African government archives, SAFLII, and Mail & Guardian were as follows: 'Pharmaceutical society South Africa'. 'PMA court case 1998', 'pharmaceutical manufacturers' association South Africa', 'dispensing fees pharmacists', 'logistics fee pharmacists', 'SEP regulations', 'medicines and related substances act amendments', 'medicines and scheduled substances act', 'medicines and related substances act 101' and 'act 90 amendments.'

2. Main Body

2.1 Geopolitical Background

The apartheid era in South Africa saw a gross division in resources across society. While this spanned across various sectors - education, housing, employment, and so on - the healthcare sector saw the one of the largest disparities[10]. The protocols established to treat the White population differed highly from those used in the treatment of Black, Indian, and 'Coloured' (mixed-race) populations[10]. This was subsequently reflected in the epidemiology of diseases (eg. syphilis, tuberculosis, and childhood malnutrition) present in different demographics of the South African population during apartheid[10]. Localities with Black majority had significantly higher rates of disease and mortality than White majority areas. This was due to several reasons - access to facilities, preventive programs, restriction of education, and affordability of medicines and healthcare services. The private hospitals and healthcare facilities catered primarily to White people, while the public sector was for everyone else. Though it catered to only a small percentage of the overall population, the private sector, whose development was funded primarily by mining houses, received the majority of the funding and research. In the 1990s, over 60% of doctors and specialists were employed in the private sector. This was compounded by the increasing number of private hospitals, which is where these doctors and specialists primarily operated out of. Despite catering to less than 15% of the population, private sector medical schemes contributed to 46% of expenditure[11].

The effects of this were compounded by a shortage of medical staff in the public sector[10]. Medical training was also racially segregated, so most doctors and medical professionals were White. Black nurses were only trained during WWII when there was a shortage of nurses. However, they weren't allowed to treat White patients and were paid less than White nurses[10]. The funding difference between the private and public sectors also created a huge incentive for healthcare workers to migrate into the private sector[11]. This continued even after the official end of the apartheid, and is reflected by the percentage of medical professionals working in the

private health sector, which increased from 40% in the 80s to 79% in 2005[11]. Also many of them chose to leave South Africa entirely, and practice internationally. In more recent years, the pay gap between healthcare professionals in the private and public sectors has reduced, but there is still an imbalance favouring the private sector[12].

Additionally, healthcare schemes were only introduced after 1889, before which all private healthcare was paid for out-of-pocket[11]. Membership to these healthcare schemes was restricted to the White population until the 1970s. Often, they also required employment at certain firms or industries[4].

Black people were also restricted from higher education, such that they would only be qualified for menial jobs. This purposeful lack of education also had consequences for the health information received and understood by patients[10]. In addition to separation of education and healthcare, there were geographical separations in living space. 'Bantustans' were rural areas reserved for Black people[4], populated primarily by migrant workers. They were areas of low sanitation and high population density, contributing significantly to the spread of diseases[11]. Each Bantustan also had an individual department of health that made decisions about medicines (e.g. selection)[13].

The strong division between the private and public healthcare sectors continues to influence the situation today. When the first democratically elected government came into power in 1994, healthcare was on top of their priority list. Several reforms were required in order to bring balance to a highly separated and oppressive system, and the new government wasted no time in bringing reforms.

2.2 South Africa's Healthcare System

During the apartheid, South Africa had a highly fragmented healthcare system, with separation in developing and funding to care and medicine. At the time, there were fourteen provincial departments of health (each Bantustan had its own[11]). After 1994, when the democratic government came into power, this number was reduced to nine, united under a single National Department of Health (NDoH)[14]. The nine provincial departments are responsible for fifty-two health districts[12]. The system is quite complicated, as some aspects of health (mainly, promotive and preventive) are governed by the NDoH, while others (namely, curative) are still governed by the provincial health departments. An overview of the healthcare system can be seen in Figure 1. Additionally, while policies are determined by the NDoH, the responsibility of enforcement lies with the provincial departments[12].

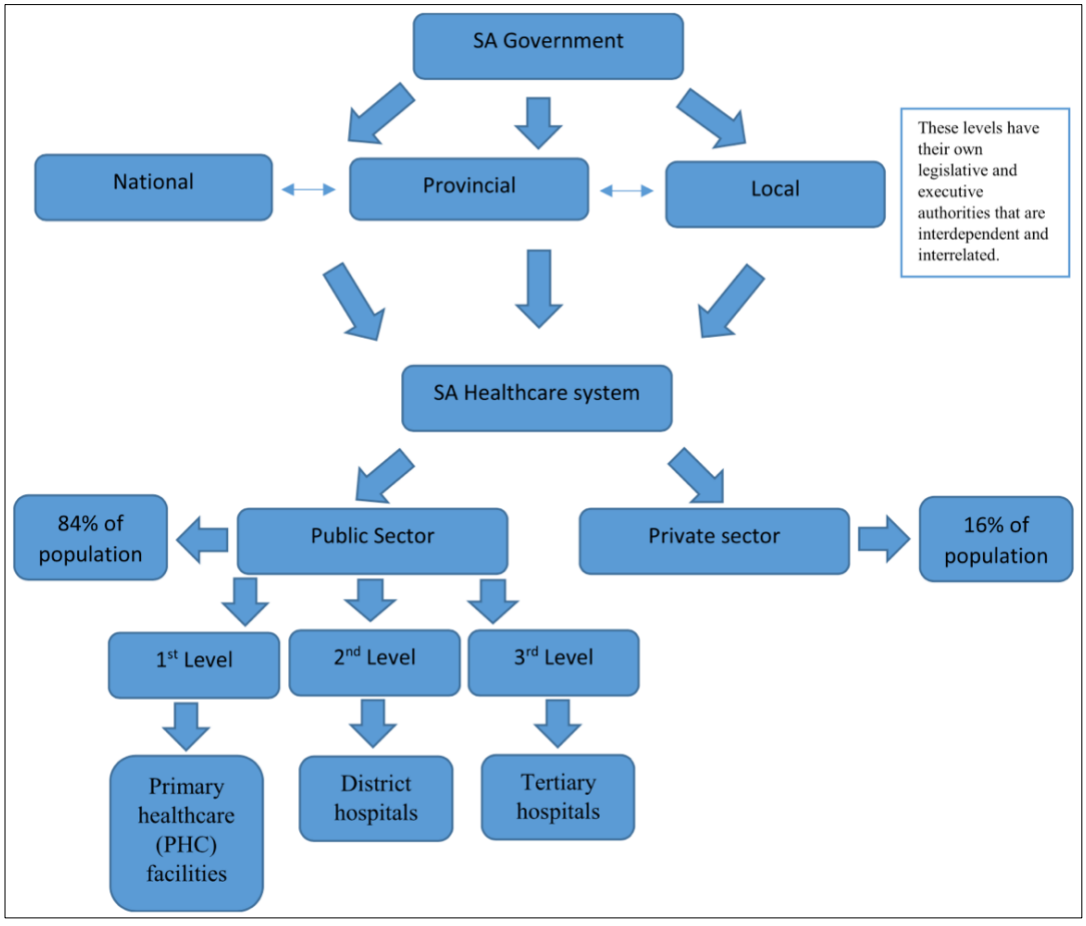

***Figure 1**. An overview of South Africa's healthcare system. Adapted from Moodley, Suleman & Perumal-Pillay 2021[15].*

All pharmaceutical institutions have to be registered with the South African Pharmacy Council (SAPC), which recognises six categories - community pharmacies, consultant pharmacies, private institutions, public institutions, manufacturing pharmacy, and wholesale pharmacy[16]. They also recognise academic institutions, including pharmacy students and interns[12]. The majority of pharmaceutical institutions are in the private sector – mainly community pharmacies, but also manufacturing pharmacies. A large percentage of wholesaler pharmacies and consultancy pharmacies (which do not dispense medicine but only advise) are also in the private sector[12]. For the public sector, public institutions and academic institutions are the main caterers. In fact, the majority of pharmacies in South Africa are either independently owned or part of a large pharmacy chain. They are primarily available in urban sectors and cater to people with insurance (i.e. the private sector)[12].

More recently, standard treatment guidelines have been integrated into the curriculum of study for health sciences, and this makes the prescribing process more transparent. This also encourages an evidence based approach to prescribing and dispensing medicines[13]. Prescription of medicine primarily occurs through medical practitioners. However, there are provisions through which prescribing power can be granted to other parties such as nurses, optometrists, and dental therapists[12] for certain medicines. There is no legislative allowance for pharmacists to adjust the patients' dose (after prescription by a medical practitioner) or conduct independent research[12].

Active pharmaceutical ingredients (APIs) are mostly imported[14]. South Africa does not have a large system for manufacturing APIs, but they do process finished pharmaceutical products[12]. All parties involved in the manufacturing, procurement, and distribution of medicines must be registered with the South African Health Products Regulatory Authority (SAHPRA). Additionally, all medicines have to be approved by and registered with SAHPRA to be on the market[12]. Prior to 2017, the main regulatory body was the Medicines Control Council (MCC), which was associated with the NDoH[17]. Although SAHPRA is the current body in charge, the MCC was the responsible regulatory body at the time of the SEP implementation, and will be referred to such

for the rest of this report. The distinction is important as the MCC was a government body, while the SAHPRA is an independent body created with the intent of separating important regulatory aspects of medicines from the work of the NDoH as a government department[17].

2.3 The need for price control regulations

There are several factors that contributed to the extremely high prices of medicines in South Africa. During the apartheid era, there were little to no checks on the pricing of medicines, and change in costs were often left to market forces[5]. Pharmaceutical companies had full freedom on the price at which they wished to sell their medicine. They would often sell at different prices, discriminating on the basis of buyer or volume of product bought[5]. The lack of regulation regarding transparency of pricing and transactions between different parties in the pharmaceutical supply chain contributed further to the overpricing of medicines. Offering various incentives, bonuses, rebates, discounts, and deals to purchasing clients was incredibly common, and wholly unchecked. This gave further power to the pharmaceutical companies, as they could, for example, push certain medicines that would yield higher profit, regardless of medical benefit to patients. It was not uncommon for samples to be offered to doctors and other medical professionals, complemented by bonuses as an incentive to increase purchase volumes of a particular medicine or from a specific company[5].

The lack of regulation gave room for price hikes at every step of the supply chain. These extra 'fees-for-service' payments – for example, the logistics fee charged by service providers, and the dispensing fee charged by pharmacists and dispensing doctors – contributed significantly to the cost increase in the private sector[11,5]. Importantly, more often than not, these discounts were not transferred to consumers, who continued to pay full price regardless of the price at which the supplier purchased the medicines[18].

There were several commissions even before 1994 that sought to investigate and tackle the high price of medicines[19]. The main three were the Snyman Commission (1961), the Steenkamp

Commission (1978), and the Browne Commission (1985). There was also the Gluckman Commission, which aimed to redirect the health system in 1942-44[11]. They identified the patent legislation as a key contributor to high prices and suggested government regulation of patents and licenses, but these were not approved. They also suggested promoting the use of generics, which was finally done in 2003[19]. Primarily, they identified the incentives, bonuses and rebates as a key contributor to high prices, which became an important point of reformation for more recently established drug policies. The Browne commission suggested a tender process for medicines in the public sector, which has since been implemented.

2.4 The National Drug Policy

When the new government was established in 1994, they inherited a highly fragmented and unequal healthcare system reminiscent of the strict apartheid policies. Affordable and accessible healthcare was a high priority, and the new Minister of Health set up eleven committees to advise on health related policies[20]. One of these was the National Drug Policy Committee. The tasks and aims of the committee, as outlined by the NDoH, are given below (Box 2)[1].

Box 2: Aims of the National Drug Policy Committee, 1994

- *Develop a pricing plan for drugs used in South Africa in the public and private sectors.*
- *Develop a plan to ensure that drugs are tested and evaluated for effectiveness in the South African context of treatment using epidemiological approaches.*
- *Develop an Essential Drugs List to be used in the public sector and prepare treatment guidelines for the health personnel.*
- *Develop specific strategies to increase the use of generic drugs in South Africa.*
- *Prepare a plan for effective procurement and distribution of drugs in South Africa, particularly in the rural areas.*
- *Investigate traditional medicines.*
- *Rationalise the structure for Pharmaceutical Services*

The National Drug Policy (NDP) was drafted to meet the aims of the NDP committee in 1994 and presented to the NDoH. A document was drafted later that year, and following a series of consultative workshops held in 1995, the NDP was finalised. It is interesting to note that while several relevant stakeholders were represented in the NDP committee – such as pharmacists, academics, consumer representatives, health and pharmaco-economists, and lawyers – there were no representatives from the pharmaceutical industry from the private sector (eg. pharmaceutical companies or manufacturers)[5]. They were included later during the workshops, along with officials from the provincial health departments, professional organisations, and representatives from the departments of Trade, Industry and Finance[5].

While the overarching aim of the NDP was to 'ensure the availability and accessibility of essential drugs to all citizens'[14,1], the scope of the policy addressed issues of health, economics, and national development. An overview of the main aims of the policy can be found in Box 3. A programme within the NDoH was set up to coordinate and supervise the implementation of the National Drug Policy, known as the South African Drug Action Programme (SADAP)[1].

Box 3: The National Drug Policy, 1996[1]

Health objectives

- *(a) To ensure the availability and accessibility of essential drugs to all citizens*
- *(b) To ensure the safety, efficacy and quality of drugs*
- *(c) To ensure good dispensing and prescribing practices*
- *(d) To promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information*
- *(e) To promote the concept of individual responsibility for health, preventive care and informed decision making.*

Economic objectives

- *(a) To lower the cost of drugs in both the private and public sectors*
- *(b) To promote the cost-effective and rational use of drugs*
- *(c) To establish a complementary partnership between Government bodies and private providers in the pharmaceutical sector*

(d) *To optimize the use of scarce resources through cooperation with international and regional agencies.*

National development objectives

- *To improve the knowledge, efficiency and management skills of pharmaceutical personnel*
- *To reorientate medical, paramedical and pharmaceutical education towards the principles underlying the National Drug Policy*
- *To support the development of the local pharmaceutical industry and the local production of essential drugs*
- *To promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational drug use, pharmacoeconomics and other areas of the pharmaceutical sector.*

The NDP therefore laid the foundation for several of the reforms that would occur in the private healthcare sector after 1994. It is important to note that these reforms were specific to the private sector, as the medicine prices in the public sector were and are regulated by a national competitive tender process, and majority of primary care services are free[14]. The MCC was tasked with reviewing 'legislations and regulations in order to support the objectives of the NDP'[1]. They also played an important role in connecting stakeholders such as the NDP consultative group, the SADAP, and other relevant organisations and agencies[1] towards achieving the goals of the NDP.

The first step towards implementing the goals of the NDP was to establish a legislative foundation for the intended reforms. An amendment bill to the Medicines and Related Substances Act 101 of 1965 was proposed in 1997 (Amendment Act 90)[14,1]. The Act 90 amendments proposed several reforms, which included the following points (Box 4) related to the pricing of medicines (paraphrased from the government Gazette)[21]:

Box 4: Overview of the key points in the Act 90 amendments (1997)[21]

- *to provide for measures for the supply of more affordable medicines in certain circumstances; (15C)*
- *to provide for the licensing of certain persons to compound, dispense or manufacture medicines; (15C)*
- *to prohibit bonusing and sampling of medicines; (18A, 18B)*
- *to provide for generic substitution of medicines; (22F(1))*
- *to provide for the establishment of a pricing committee: (22G(1))*
- *to promote a transparent pricing system; for which the pricing committee is to establish a single exit price for medicines; (22G(2) and (3))*
- *to regulate the purchase and sale of medicines by wholesalers; (22H(1))*

The Act 90 amendments lead to the establishment of a Pricing Committee and a 'transparent pricing system'. It was under this that the concept of a single exit price was introduced. It also introduced the significant change of banning all incentive schemes (e.g. bonuses, rebates, discounts, sampling offers, and so on). One of the key points of debate was the provision of compulsory licensing, which appeared to issues licenses without regard to the Patents Act[14]. This point was met with a lot of controversy, as many stakeholders in the pharmaceutical industry opposed it. Due to this, it wasn't until 2004 that the Act come into place. The details of the most relevant amendments as stated specifically in the official government Gazette[21] can be seen in Box 5.

Box 5: Act 90 Amendments to Medicines and Related Substances Act 101 of 1965[21]

Measures to ensure supply of more affordable medicines 15C

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may –

(a) notwithstanding anything to the contrary contained in the Patents Act 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicines under a patent granted in the Republic shall not extend to acts in the respect of such medicines which has been put onto the market by the owner of the medicines, or with his or her consent.

(b) Prescribe the conditions on which any medicine which is identical in compositions, meets the same quality standard and is intended to have the same proprietary name as that of another medicines already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicines already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported.

(c) Prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).

Bonusing 18A

No person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme.

Sampling of medicines 18B

(1) No person shall sample any medicine

(2) For the purposes of this section 'sample' means the free supply of medicines by a manufacturer or wholesaler or its agent to a pharmacist. medical practitioner. dentist. veterinarian. practitioner, nurse or other person registered under the Health Professions Act, 1974. but does not include the free supply of medicines for the purposes of clinical trials. donations of medicines to the State. tendering to the State and quality control by inspectors.

(3) The use of medicines or Scheduled substances for exhibition purposes shall be as prescribed.

Generic substitution 22F

(1) Subject to subsections (2),(3), and (4), a pharmacist shall -

(a) Inform all members of the public who visit his or her pharmacy with a prescription for dispensing, of the benefits of the substitution of a branded medicine of an interchangeable multi-source medicines; and

(b) dispense an interchangeable multi-source medicines instead of the medicines prescribed by a medical practitioner, dentist, practitioner, nurse, or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.

(2) If a pharmacist is forbidden as contemplated in subsection (1)(b), that fact shall be noted by the pharmacist on the prescription.

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.

(4) A pharmacist shall not sell an interchangeable multi-source medicine –

(a) If the person prescribing the medicine has written in his or her own hand on the prescription the words 'no substitution' next to the item prescribed;
(b) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or
(c) where the product has been declared not substitutable by the council

Pricing committee 22G
The Minister may. on the recommendation of the pricing committee, make regulations—
(2a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;
(2b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a).

(3a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed. and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State.
(3b) No pharmacist or person licensed in terms of section 22C(l)(a) shall sell a medicine at a price greater than the price contemplated in paragraph (a).
(3c) Paragraph (b) shall not be construed as preventing a pharmacist or person licensed in terms of this Act to charge a dispensing fee as contemplated in subsection (2)(b).

Purchase and sale of medicines by wholesalers 22H
(1a) No wholesaler shall purchase medicines from any source other than from the original manufacturer or from the primary importer of the finished product.
(1b) A wholesaler shall sell medicines only into the retail sector.

The concept of the single exit price was therefore introduced in 1997 under the Act 90 amendment bill, under the stipulation of a transparent pricing system. It defined the SEP as the 'only price at which manufacturers shall sell medicines and Scheduled substances to any person other than the State'[21]. The SEP includes the ex-manufacturer's price, logistics fee, and value added tax (VAT)[9]. The amendments also introduced a price cap on the dispensing fee charged by pharmacists. The Act 90 amendments tightened regulations on the activity of wholesalers, and regulated who they can buy from (original manufacturer or primary importer) and sell to (retail sector). Through this process, the logistics fee often charged by wholesalers were also capped.

All incentives schemes, including bonuses, rebates, discounts, and sampling offers, were banned. Additionally, the Act 90 clearly stated the requirement to mandatorily provide an offer of generic substitution[21,14]. The MCC (now SAHPRA) decides which medicines cannot be substituted, but for those that can, a generic offer is expected[14].

In South Africa, legislatives changes to Acts can only come into effect a year after they have been approved. The Act 90 amendments, though proposed in 1997, were only approved in 2003, and subsequently came into effect in 2004[14]. Figure 2 shows an overview of the key events from conceptualization to implementation, including the main court cases and revisions that are discussed in detail in the following section of this report.

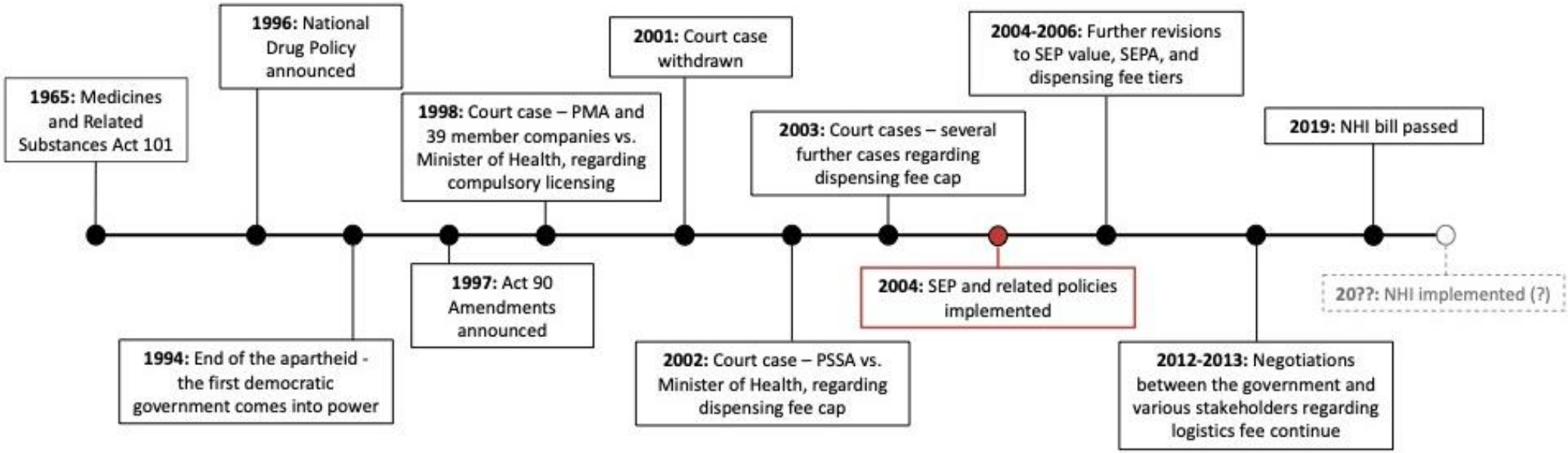

Figure 2. *Timeline of key milestones in the implementation of the SEP and related policies. PMA; Pharmaceutical Manufacturers Association, PSSA; Pharmaceutical Society of South Africa, SEP; single exit price, SEPA; single exit price adjustment, NHI; National Health Insurance.*

2.5 Court cases and revisions

The proposed legislative changes were contested at nearly every step, and there were a series of court cases between 1998-2003 before the Act 90 amendments could be implemented.

PMA and member companies vs. Minister of Health

In 1997, the Pharmaceutical Manufacturers Association (PMA), which represented majority of the pharmaceutical industry and thirty-nine member companies contested the implementation of the Act 90 amendments to the Medicines and Related Substances Control Act 101 of 1965[14]. These thirty-nine member companies included large, international pharmaceutical companies, such as GlaxoSmithKline, Merck and Co, and Bristol-Myers Squibb[22], who all made significant profit for medicine sales in South Africa in the years prior. The main point of contention was amendment 15(C), which allowed for compulsory licensing and parallel imports of medicines. The PMA and member companies claimed that the government had surpassed its jurisdiction, and did not have strong enough reasons to implement the restrictive policies[5]. They claimed that the regulation would violate intellectual property rights and patent laws as stipulated under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)[22]. The first appeal to court was made on February 18, 1998 – however, there were several delays and the actual court hearing was only scheduled for January 2001[14]. By that time, the Treatment Action Campaign (TAC), a newly-established AIDS advocacy group, joined the government's case as a 'friend of the court'[14,23]. This caused further delay, as the PMA and member companies requested additional time to prepare after the addition of TAC. The hearing was thus pushed to April 2001. The contribution of TAC highlighted the necessity and inaccessibility of HIV medicine, raising the international pressure on the PMA and associated pharmaceutical companies to an extreme. By the time the court hearing was due, the case was withdrawn[5,22]. So while the case was never officially heard in a court of law, it was considered a win for the NDoH, as the Act 90 amendments could finally be implemented – or so they thought.

PSSA and New Clicks Ltd. vs. Minister of Health

The Act 90 amendments were thus due to come into power in 2002. However, there were further objections against the cap on the dispensing fee that pharmacists were allowed to charge. The Pharmaceutical Society of South Africa (PSSA), a union for pharmacists, were joined by six other entities that own pharmacies[24] to contest the fee cap. A second application was placed by New Clicks SA (Pty) Ltd., the owner of eighty-six pharmacies[24], including both community pharmacies and private hospital arenas[14]. The respondents in both cases were the Minister of Health and the chairperson of the Pricing Committee[24].

The main point of contention for the PSSA, New Clicks Ltd. and associated parties was the cap on the dispensing fee[4,14,25]. The validity of the amendments was questioned, and an appeal to the Cape High Court was made[25]. A majority dismissed the challenges to the regulations, to which the applicants sought leave to appeal[25]. Following a delay in the judgement, the pharmacies went directly to the Supreme Court of Appeal (SCA) for a ruling. The SCA granted leave to appeal as well stating that the regulations proposed in the Act 90 amendments were invalid – essentially overturning the decisions made by the High Court[19,25]. A media statement put out on 20 December, 2004 summarised the view of the SCA[26]:

"The main findings were that (a) the dispensing fees, which have to be 'appropriate', are not appropriate because they did not take into account the viability of the dispensing industry and (b) regulations relating to the single exit price introduced a price control mechanism, which the Act did not envisage, and, in any event, were overboard."

Naturally, this was immediately contended by the Minister of Health and the chairperson of the Pricing Committee, who appealed to the Constitutional Court. There were several points of discussion and a complex trial ensued. Several changes were made to the wording of the new regulations[25]. The decision of the Supreme Court was overturned – the Constitutional Court ruled that the regulations need not be set aside in their entirety. However, critical revisions were necessary, especially to the dispensing fee tier system, in order to ensure that minimal damage was done to pharmacies (specifically rural, local, and community pharmacies)[19]. The

Court charged the Minister of Health with proving that the new regulation would not harm the pharmacies in this way[27]. As such, the tiers for the dispensing fee is revised annually. The Minister is required to take into account affordability and availability of medicines, inflation, and information supplied by pharmacists[26] when reviewing the regulations. Lastly, pharmacists must inform members of the public of the fee structure via a 'clearly displayed notice'[26], and also provide an invoice for each medicine, stating its SEP and the dispensing fee charged.

In the years following the implementation of the regulations, the Pricing Committee introduced a cap on the logistics fee (extra price paid by pharmaceutical manufacturers to wholesalers and distributors for their service)[9]. It was announced in 2012, but due to further contention from industry stakeholders, it was only implemented in 2013, thus coming into effect from 2014.

Summary

Since the Act 90 amendments were announced in 1997, there has been significant resistance to their implementation. At first, the major issue was the regulation pertaining to compulsory licensing (15C), under the claim that it did not comply with the TRIPS agreement. The second major issue was the cap on the dispensing fee, which affected profit margins for pharmacists. After that, it was the cap on the logistics fee charged by logistic service providers, implemented in 2012-2013. The annual increase in SEP (SEPA) allowed by the Minister of Health continues to be a point of contention, as some representatives from the private sector claim it does not always reflect the changing economic situation from year to year.

The SEP and related policies marked a monumental, and important step towards regulating medicine pricing in the private sector of South Africa. At the same time, the criticisms brought up by opposing stakeholders revealed certain areas that were perhaps overlooked in the broader scheme of making medicines more accessible and affordable.

2.6 Outcomes of the Policy

The implementation of the Act 90 amendments to the Medicines and Related Substances Control Act 101 of 1965 had several consequences. The SEP policy introduced as a part of the transparent pricing system regulation in particular changed the pharmaceutical market significantly.

Price reduction

At the time of implementation, the government proposed a 50% reduction in the manufacturer's price[5]. In practice, the average decrease in the price of medicines was observed at around 22% since the implementation of the SEP[7,5]. An in depth-analysis of a basket of medicines by Moodley and Suleman in 2019[8] observed a trend in which both generic and originator medicines showed an immediate decrease in price following the implementation of the SEP regulations, with a greater impact on generics.

Withdrawal of medicines from the market

An extensive study conducted by Naidoo and Suleman (2021)[3] investigated the impact of the SEP on medicine product withdrawal or discontinuation from the South African private healthcare market between 2001 and 2014. They found that 152 manufacturers withdrew at least one stock-keeping unit (SKU) over the fourteen year period[3]. They found that the largest number of withdrawals was in 2002, and discontinuations in 2003 and 2004. This is most likely a response to the court case between PMA and the Minister of Health being withdrawn in 2001. Naidoo & Suleman also found, counterintuitively to what the regulations intended, that it was generic manufacturers who withdrew the most[3]. They attribute this to the sensitivity of generic medicines to price fluctuations. Combined with the government regulated SEPA and cap on the dispensing fee, there was little scope left for pharmacies to increase revenues as they did in the past. In line with this, the year which had the least amount of withdrawals also had the highest SEPA (13.2% in 2009)[3], although Naidoo & Suleman suggest this could be also due to the value increase of the ZAR in comparison to the USD. On average, they found that as the SEPA increased, the number of SKU withdrawals decreased. For example, the SEPA value was 0% from

2004-2006, just after the SEP implementation, and these were the years in which they observed the highest number of withdrawals. In 2007, the SEPA value was 5.2%, and this was one of the years with the least number of withdrawals. Additionally, many companies stopped producing certain medicines or products as it stopped being economically viable to produce locally[3]. The conclusion of their study was that although the SEP policy may have led to an higher number of withdrawals, the limited SEPA increases did not affect availability of medicines as significantly as they were predicted to by manufacturers[3]. While this study provides valuable insights into the impact of the SEP policy, Naidoo & Suleman do acknowledge the potential other consequences that were not addressed in their study – such as increased transparency in the pricing system, decreased quality of service, or delayed market entry[3].

Closure of local pharmacies

The price control regulation regarding dispensing fees reduced profit margins for pharmacists on locally sold medicines greatly[28]. This was one of the major reasons that the PSSA and New Clicks Ltd. pharmacies protested the implementation of the regulation back in 2001. Several rural and community pharmacies were forced to close after going into bankruptcy[5]. This also lead to increased pressure on suppliers to reduce the cost per unit, to make up for the loss of profit when selling to consumers.

Cap on logistics fee

Initially, there was no cap on the logistics fee charged by service providers (i.e. wholesaler and distributors) – it was negotiated privately with no imposed regulation. However, this was not a transparent process, and in 2012, a legislation was implemented that would result in a cap on the logistics fee. The calculation of this component (as of 2012) can be seen in Box 6 below. While the dispensing fee tier is reassessed every year, the logistics fee tier does not seem to have been updated since its implementation in 2012.

Box 6: Logistics fee component of a transparent pricing system[29]

As stated in the government Gazette published on 18 September 2012, the tiers for the logistics fee are as follows -

i. *Where the ex-manufacturer price (ex VAT) of a medicine or scheduled substance is less than R100.00, the logistics fee must not exceed 8% of the ex-manufacturer price (ex VAT) + R3.00 in respect of that medicine or scheduled substance;*

ii. *Where the ex-manufacturer price (ex VAT) of a medicine or scheduled substance is equal to or greater than R100.00 but less than R500.00, the logistics fee must not exceed 6% of the ex-manufacturer price (ex VAT) + R4.00 in respect of that medicine or scheduled substance;*

iii. *Where the ex-manufacturer price (ex VAT) of a medicine or scheduled substance is equal to or greater than R500.00 but less than R1000.00, the logistics fee must not exceed 4% of the ex-manufacturer price (ex VAT) + R5.00 in respect of that medicine or scheduled substance;*

iv. *Where the ex-manufacturer price (ex VAT) of a medicine or scheduled substance is equal to or greater than R1000.00, the logistics fee must not exceed R54.00 in respect of that medicine or scheduled substance.*

Bangalee & Suleman conducted an extensive review in 2015 to assess the effects and outcomes of the logistics fee cap[9]. They studied a basket of 47 medicines, and found that only 16 showed a decrease in SEP following the logistics fee cap[9], with the others showing an increase. Those that had a decrease in SEP were, in general, medicines for which the logistics fee represented a higher percentage of the SEP before the cap. For those that had an increase in SEP, the logistics fee generally constituted a lower percentage of the final price before the fee cap was introduced. Bangalee & Suleman attribute this to pharmaceutical companies sometimes charging lower logistics fee as an incentive to sell more of their product[9]. However, they also observed that the largest reduction in SEP following the logistics fee cap could be seen in originator medicines without any generic alternative or strong competition. They suggest limiting the regulation to these medicines to get the most reduction in price with the least

consequences to other parties. Through their study it also became apparent that one of the main goals of the regulation – to increase transparency of the pricing system – was not entirely met, as there was still a lot of ambiguity surrounding the final fee paid, for all the services provided along the supply chain[9].

Higher priced generics

In addition to the establishment of the SEP, the Act 90 amendments also addressed the need for generic substitution of medicines. Pharmacists were required to offer generic alternatives for all medicines except those on a pre-determined, non-substitutable list (or if indicated so by the prescribing medical professional). Between 2003 and 2004, there was a 14% increase in the use of generic medicines[7]. However, it had been suggested that the SEP regulations encourage higher pricing of generics upon market entry[5]. This could be partially attributed to the dispensing fee being calculated as a percentage of the SEP, thus providing an incentive for generics entering the market to do so at a higher price than they may have before the regulations[5].

In summary, the SEP and related policies marked a monumental change for the pharmaceutical industry in South Africa. The regulations reformed what used to be a free market by introducing price control systems aimed at making medicines more affordable and accessible to patients. The average price of medicines reduced, and a significant step towards implementing a transparent pricing system was taken. With the introduction of the SEP, the SEPA, and the caps on the dispensing and logistics fee, nearly every step of the supply chain is monitored. Regular revisions to these regulations fosters an ongoing discussion on their continued benefit and relevance. Box 7 provides a review of the most recent updates of the SEPA and dispensing fee.

Box 7: Most recent updates to regulations[26,29–32]

SEPA 2023

Value: 3.28%; adjusted in July 2023 to include an additional 1.73% "top-up"
Application period: 11 January and 22 February; 18 August and 18 September for top-up
Approval period: 32 days; additional 32 days for top-up approval

SEPA 2024

Value: 6.76%
Application period: 12 January - 8 March
Approval period: 32 days

Dispensing fee 2023

i. *30% of SEP when SEP < R144.00*
ii. *R43.20 if SEP is greater than or equal to R144.01*

Logistics fee *(as of September 2012)*
Calculated as a percentage of the ex-manufacturer's price

Ex-manufacturer's price (excluding VAT)	*Maximum logistics fee (as a % of the ex-manufacturer's price)*
< R100.00	*8% + R3.00*
R100.00 – R500.00	*6% + R4.00*
R500.00 – R1000.00	*4% + R5.00*
> R1000.00	*R54.00*

3. Discussion

South Africa's healthcare system was characterized by inequitable division of resources, reminiscent of the apartheid era laws that governed the country until 1994. The newly elected democratic government was faced with a challenge and proposed several new regulations in order to address the disparity in the healthcare sector. These came in two initial steps – the National Drug Policy of 1996, and the Act 90 amendments to the Medicines and Related Substances Act in 1997. The SEP policy was introduced amongst regulations related to a transparent pricing system. The SEP was to be a single price, comprised of the ex-manufacturer's price, logistics fee and VAT, that a medicine or scheduled product could be sold at to any and all buyers other than the government. The largest component of the SEP, the ex-manufacturer's price, is determined by the manufacturer – yearly increases in the price are be determined by the Minister of Health (referred to as SEPA – single exit price adjustments) upon consultation with the Pricing Committee and taking into consideration a number of relevant factors (Box 1) as well as comments from interested persons.

3.1 Merits

One of the first steps taken was the banning of bonuses, rebates, discounts, and incentive schemes. This already had a major impact on the industry. It reduced the scope for discrimination between buyers and allowed for more flexibility in the market. Though the execution has had some issues, the intention behind introducing a transparent pricing scheme is positive. This includes the SEP policy as well as the pricing caps on the logistics and dispensing fees. Standardizing these has made medicines more affordable. In combination with the promotion and mandatory offer of generic substitution, it has done so without great detriment to accessibility of medicines. As a part of standardizing sale prices and legitimizing sales, every medicine (or scheduled substance) has to be registering with the MCC (now SAHPRA). Every pharmacy (or licensed dispenser) has to be registered as well (with the SAPC). In doing so, a more detailed overview of the demand and supply chain has emerged. In an interview in 2017,

Dr. Anban Pillay, the Deputy Director-General of the NDoH, addressed this in terms of dealing with stock-outs and medicine shortages. By having everything registered in a computer system, they are able to predict when pharmacies need a re-supply of a certain medicine, and in many cases prevent stock outs from occurring. In these ways, the SEP and related policies brought positive reforms and began the process of addressing the disparity and lack of equitability rampant in the private healthcare sector.

3.2 Criticisms

The reception of the SEP and related policies seems to be majorly negative, based on responses ranging from critical media reviews to complete court trials. It should be noted that these criticisms have come largely from representatives and stakeholders within the private pharmaceutical industry. Balancing the monumental task of making medicines accessible and affordable to all citizens of South Africa and the delicate factors influencing the pharmaceutical market is no easy task. The government of South Africa converted what was essentially a free market into one with regulations at nearly every step of the process. For example, in the first year of implementation of the SEP and related policies, pharmaceutical industry profit margins dropped by 44%[33].

While negative criticisms from those who profited from the market before regulations was perhaps inevitable, there are have been some key areas of critique that valuable lessons can be learnt from – not only for South Africa, but also for other countries looking to implement such pricing regulations.

Adaptability

During the initial stages it was mainly rural, community pharmacies that were under threat of insufficient funds due to lowered dispensing fee. In 2023, even big companies such as Adcock Ingram were facing pressure on their profit margins due to the strict regulations[34]. In January 2023, the SEPA was set at 3.8%, a decision that was opposed strongly by the pharmaceutical industry[30,35], under the claim that it did not accurately reflect the effect of inflation. Following

intense lobbying by the pharmaceutical industry, the Minister of Health conceded to an additional 'top-up' increase of up to 1.73% in July 2023 (so a total of 5.53% increase in SEP from the previous year)[36,37]. However, there were still concerns that the increase would not be enough to offset the effects of inflation, which came up to around 6% in the previous year[36]. The inconsistency of the SEPA has been a point of frustration for many in the industry.

Quality of service

One of the major criticisms of the SEP and related policies since their conception was that the they would de-incentivize pharmaceutical companies from i) expanding, and ii) providing quality services[5,36]. Due to the low profit margins, many multinational drug companies stopped paying a distribution fee to independent distributors of pharmaceutical products[38]. Amalgated Healthcare is one such company, which previously supplied medicines to around 5500 dispensing doctors in rural and township areas[38]. Distributing medicines into rural areas comes with its own challenges, ones that many multinational drug companies were not willing to deal with – at the same time, under the SEP regulations, they did not want to spend more money on an independent distributor, despite the local knowledge they may have[38]. In this way, reduced quality of service became an unintended consequence of the regulations.

Collaboration between stakeholders

A key lesson that can be learnt from South Africa's experience with its SEP and related policies is to include all potential stakeholders in the decision making as early as possible. One of the major critiques of the setting up of the policy was that representatives from the private pharmaceutical industrial sector were not involved in the initial committee which drafted the NDP[5]. Ideally, the terms and conditions of the policies and their effects on all relevant parties would be decided during the drafting of a new policy rather than after – which could save years of delay, court cases, and wasted time and resources. After advice from the Constitutional Court, the collaboration between the NDoH and pharmaceutical industry representatives has increased in that the Minister of Health is required to take comments into consideration when making annual updates to the SEPA, for example. The NDoH does this by publishing a

government notice a few months prior to the update inviting interested parties to submit their comments regarding the same.

Another related issue is regarding the regulations published along with the SEP policy in 2004 - the price cap on dispensing fee charged by pharmacists. An article published in the Mail & Guardian, one of South Africa's biggest news outlets, describes how pharmacists added several other services for which they claim compensation for, in order to bypass the cap on the dispensing fee[39]. An unfortunate consequence of this was that in these cases patients and consumers ended up paying more for their medicines, as these costs were not covered by medical schemes. The article attributes this to a lack of communication between the Council of Medical Schemes and the Pharmacy Council – where the latter established ways to make up their loss in profit due to the new rules, but the former did not recognize those services as reimbursable. As a result, the consumers and patients ended up paying even more out-of-pocket than before[39]. The government has since published a list of specific services that pharmacists are allowed to charge a fee for, which is updated regularly[40].

Bureaucracy

Before a medicine can be approved for sale, it needs to be registered and have an SEP. The time between the submission of the application for an SEP and its approval by the MCC (now SAHPRA) was initially stipulated to be one month – however, in practice it was not uncommon for this period to be extended or severely delayed[5]. Similarly, for companies wishing to increase their SEP, an application for the SEPA (introduced in 2010) must be made on a yearly basis. The approval period for the SEPA was originally set at 48 hours. However, quite often this was extended by several weeks. Currently, possibly due to the frequent delays, this approval period has been set at 32 days. Initially the application period was set a few months into the year; for example, in 2010, applications for SEPA could only be submitted from April 1st – assuming the applications were indeed approved by May 1st, that left only seven to eight months for companies to sell at the higher price[5]. This has been taking into consideration, and in 2023 and

2024 the initial application period for the SEPA was set between January and February of the respective year (Box 7)[31,32].

In summary, the SEP and related policies were well intentioned, and had several positive effects. They resulted in an overall decrease in the price of medicines and marked a strong step towards introducing a transparent pricing system. However, gaps in the execution, oversights, and lengthy bureaucratic processes resulting in unnecessary delays have invited several strong criticisms. Based on the numerous revisions and yearly updates, it does seem that the several of these criticisms are being learnt from, albeit slowly. In any case, there are important lessons to be learnt for South Africa in the future, and for other countries looking to introduce similar price control or transparency regulations.

4. SEP in an international context

4.1 Pricing policies in sub-Saharan Africa

A thorough review of pricing polices across sub-Saharan Africa was conducted and published by Koduah *et al.* in 2022[41]. They describe four main areas of medicine pricing policies –

- Targeted public subsidies
- Regulatory framework and direct price control policies
- Pricing polices targeting generic medicines
- Policies regarding purchasing

They describe the various policies in detail. Based on the results of their review, certain similarities and differences to the South African experience can be observed.

Similarities

The main similarities found pertained to the general facilitators and barriers faced, although naturally each country also had its individual obstacles to overcome. Issues seen commonly in the South African example such as lack of education about medicines and policies, frequent stock-outs, and low transparency in pricing systems were also reported in several sub-Saharan African countries. For example, Sudan also had difficulties with a lack of transparency and accessible information about the actual price at which medicines were being sold at[42].

There are also a few similarities in the choice of medicine pricing policy implemented South Africa and other sub-Saharan countries. For example, in Mali, the government introduced subsidies for generic medicines, promoting their use and reducing the price of medicines[41]. Sudan also regulated medicine prices through direct price controls, though it was not as successful[41] due to the aforementioned lack of transparency in the pricing system[42].

Differences

Koduah *et al.* 2022 found two main ways in which policies were implemented – one, via government regulatory frameworks to guide distribution (as seen in South Africa), and two, via

the usage of private distribution networks[41]. An example of the latter can be found in Tanzania, wherein the government incorporated pharmaceutical suppliers from the private sector in the distribution of medicines to public health facilities[41,43].

Ghana established a National Health Insurance (NHI) scheme in 2003[44], something that South Africa is working towards. Some issues they faced included delays in reimbursement of medicines and low participation of private sector providers. As South Africa heads toward the implementation of its own NHI, it would be wise to take note from other African countries in what worked and what did not. In the case of Ghana, they also used the National Essential Medicines List (NEML) as a guide for the reimbursement scheme included in its NHI – and it has been reported that, despite the issues, the scheme increased access to medicines for patients[44].

4.2 Comparison with other LMICs

BRICS (Brazil, Russia, India, China, and South Africa) have all committed to health system reforms, heading towards a Universal Health Coverage (UHC) scheme in the respective countries[45]. While each country has a unique policy and plan, some comparisons can be made on the basis of economic and financial status. Some similarities that were found in a 2018 comparative study include the presence of pricing regulations on selective lists of pharmaceutical products (for example, in the private sector, or on specific government lists)[45]. There are some systems present in BRICS that South Africa could learn from – for example, the promotion of locally produced products in Russia, achieved through pricing regulations.

There are also polices that have been implemented in South Africa that could be insightful for other countries. For example, the banning of bonuses, rebates, and incentives, which helped to increase the transparency of the pricing system in South Africa and has not yet been implemented in other BRICS countries[45]. Additionally, increased tracking and registering of products have helped in curtailing stock-outs, an issue India still struggles with[46].

5. Future perspectives

Demand side measures

An early critique of South Africa's pricing control polices was that it focused too heavily on supply side measures, and not enough on demand side measures[47]. Over the years however South Africa has introduced more such measures, for example via the promotion of generic alternatives. This has led to a significant growth in the generic medicine market[47]. However, there is still room for more demand side measures, such as patient and consumer education, to equip them to make the right choices when it comes to medicine and request generic substitutions themselves. There is also a need for incentivizing doctors and prescribing professionals to promote generics in the private healthcare sector[5]. Educating and encouraging both medical professionals and patients to make informed decisions about the medicines they prescribe or take would go a long way. Additionally, adapting the supply side measures in place to reduce the detrimental effect on relevant stakeholders could help improve the reception of such policies. For example, the cap on the logistics fee impacted both innovator brand medicines and generics medicines. However, only the innovator medicines without any generic alternative had a significant decrease in SEP following the new legislations[48]. As suggested by Bangalee & Suleman (2015)[9], the regulations could be adjusted such that only these companies and related products would be affected.

Alternative price control systems

Another suggestion for improving the pricing control system was to introduce a reference pricing scheme via an external reference pricing (ERP) system. This was done – as stipulated by the NDoH - by conducting an international benchmarking study, in which the prices of medicines in five countries – Australia, Canada, New Zealand, Spain, and South Africa – were compared, and the lowest price was considered as the reference price[47]. These countries were chosen based on the following criteria[47]:

- They have regulatory authorities that license medicines and ensure their quality
- They have systems for effective regulation of medicine prices

- They have accessible and regularly updated information regarding the prices at which medicines are sold
- They have rules on patents and intellectual property rights that are internationally accepted

An investigation into the value of the international benchmarking process was conducted recently by Cassar & Suleman (2019), and revealed that in majority of cases, the prices of medicines in the private sector of South Africa could be reduced[49]. They suggest that this could be because Spain, Australia, and New Zealand all use an internal reference pricing system for medicines. It was also found that 92% of the medicines that could be compared in the public sector had the South African tender price as the lowest available[49]. Cassar & Suleman also compared South African prices to those of BRICS, to assess if they would be a better basket of countries to conduct the ERP with. The cases for which they could find comparisons seemed promising, though information was not so easily available. Future collaboration between BRICS countries could facilitate information sharing and provide an opportunity for a more applicable ERP system to be put in place in South Africa, in which comparisons are made to countries that reflect a more similar socio-economic status that the original basket of countries. As ERP assessments are very time consuming, and require constant updating, it is recommended that such a system be introduced in combination with other policies[45].

Alternative reference pricing systems have been suggested as well, such as 'index pricing'. Bangalee & Suleman (2015)[9] suggest that reference pricing system could be more effective in lowering pricing than a price cap regulation, especially in the case of innovator brand medicines.

National Health Insurance scheme

The next step towards achieving the goal of accessible and affordable care to all South African citizens was to establish a NHI scheme. The NHI bill was introduced in August 2019[50], though it had been discussed for many years before. The NHI will be based on an NEML, which is curated in reference to the World Health Organization Model List of Essential Medicines (WHO EML).

The goal of the NEML is to highlight those medicines that should be prioritized and made accessible and affordable to all. The NDoH first published a document detailing the NHI policy in 2017[51], including a plan for its funding and implementation. More recently, they passed an update to the NHI Bill in June 2023[52], which marked a significant step towards the implementation of the policy. However, there have been significant contentions to the Bill, mainly that the funding plan and integration of the private and public sectors have not been outlined in enough detail to provide sufficient clarity to those who will be most affected[53,54]. There is still much to be done in terms of understanding and polishing the existing system before an NHI can be put into place. Considering that majority of the funding for the NHI will come from tax revenues[54], unifying the public and private sectors, and the socio-economic classes associated with them, will be paramount to the success of the NHI.

6. Conclusion

The SEP and related policies introduced in South Africa in the early 2000s had a ripple effect across the healthcare sector. Several of the court cases and hearings are considered landmark cases in the fight for accessible and affordable medicines for all citizens. The SEP and related policies mark a significant step towards bringing equality and equity into the healthcare sector and bridging the large gap between the private and public sectors. Introducing heavy regulations to an essentially free market is monumental task, which the NDoH has tackled over the last two and a half decades. The average price of medicines decreased as a result of the SEP and related policies, and the overall transparency in the pricing system is better than it was before. As can perhaps be expected from a policy change on this scale, there were strong criticisms of the policy from the beginning. Yet the criticisms highlight the areas that need improvement and adaptation. Some key points include making the policy process more inclusive, adjusting the guidelines in a way that ensures no stakeholder is left out of the discussion, and polishing the bureaucratic processes to limit delay and inefficiency. As South Africa heads towards establishing a NHI scheme, the lessons learnt from the journey of implementing the SEP and related policies will be invaluable to ensuring its success.

References

1. South African National Department of Health. National Drug Policy for South Africa. 1996; NDoH. sapc.za.org

2. Department of Health. *Medicines and Related Substances Act No.101 of 1965.*

3. Naidoo K, Suleman F. Evaluating the impact of single exit pricing (SEP) on medicine product withdrawal from the private healthcare market in South Africa. *S Afr Med J*. 2021;111(5):444. doi:10.7196/SAMJ.2021.v111i5.15297

4. WHO, Gray A, Suleman F, Patel A, Bannenberg W. South Africa: Implementation of reforms under the National Drug Policy. In: *South Africa: Implementation of Reforms under the National Drug Policy*. Vol WHO/HIS/HGF/CaseStudy/15.9. ; 2015.

5. Ngozwana S. Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries? In: Mackintosh M, Banda G, Tibandebage P, Wamae W, eds. *Making Medicines in Africa*. Palgrave Macmillan UK; 2016:203-223. doi:10.1007/978-1-137-54647-0_12

6. Department of Health. *Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances.* Vol 466, No. 7956.; 2004. https://www.gov.za/sites/default/files/gcis_document/201409/26304.pdf

7. McIntyre DI, Theide M. Health care financing and expenditure: pooling of resources and puscharing of health care. *South Afr Health Rev*. 2007;(1):35-46.

8. Moodley R, Suleman F. The impact of the single exit price policy on a basket of generic medicines in South Africa, using a time series analysis from 1999 to 2014. Schneider H, ed. *PLOS ONE*. 2019;14(7):e0219690. doi:10.1371/journal.pone.0219690

9. Bangalee V, Suleman F. Evaluating the effect of a proposed logistics fee cap on pharmaceuticals in South Africa - a pre and post analysis. *BMC Health Serv Res*. 2015;15(1):522. doi:10.1186/s12913-015-1184-6

10. Susser M, Cherry VP. Health and Health Care under Apartheid. *J Public Health Policy*. 1982;3(4):455. doi:10.2307/3342009

11. Coovadia H, Jewkes R, Barron P, Sanders D, McIntyre D. The health and health system of South Africa: historical roots of current public health challenges. *The Lancet*. 2009;374(9692):817-834. doi:10.1016/S0140-6736(09)60951-X

12. Gray A, Riddin J, Jugathpal J. Health Care and Pharmacy Practice in South Africa. *Can J Hosp Pharm*. 2016;69(1). doi:10.4212/cjhp.v69i1.1521

13. Fatima Suleman: making medicines more widely available. *Bull World Health Organ*. 2017;95(12):800-801. doi:10.2471/BLT.17.031217

14. Suleman F, Gray A. Pharmaceutical Policy in South Africa. In: *Pharmaceutical Policy in Countries with Developing Healthcare Systems*. ; 2015:285-302.

15. Moodley L, Suleman F, Perumal-Pillay VA. Perceptions from pharmaceutical stakeholders on how the pharmaceutical budget is allocated in South Africa. *J Pharm Policy Pract*. 2021;14(1):78. doi:10.1186/s40545-021-00362-3

16. South African Pharmacy Council, Registered Persons. https://sapc.za.org/registered-persons

17. Keyter A, Banoo S, Salek S, Walker S. The South African Regulatory System: Past, Present, and Future. *Front Pharmacol*. 2018;9:1407. doi:10.3389/fphar.2018.01407

18. Cut The Cost of Dispensed Drugs. *Mail & Guardian*. https://mg.co.za/article/1994-09-02-cut-the-cost-of-dispensed-drugs/. Published September 2, 1994.

19. Gray AL. Medicine pricing interventions – the South African experience. 2009;2(2).

20. Gray A, Matsebula T. Drug Pricing. In: South African Health Review; 2000:201-208. https://journals.co.za/doi/pdf/10.10520/AJA10251715_43

21. *No. 90 of 1997: Medicines and Related Substances Control Amendment Act, 1997.*; 1997. https://www.gov.za/sites/default/files/gcis_document/201409/a90-97.pdf

22. Oxfam. South Africa vs. The Drug Giants - A Challenge to Affordable Medicines. Published February 2001. https://oxfamilibrary.openrepository.com/bitstream/handle/10546/620381/bn-access-to-medicines-south-africa-010201-en.pdf?sequence=1&isAllowed=y#:~:text=The%2039%20companies%20involved%20in,%2C%20Roche%2C%20and%20Boehringer%20Ingelheim.

23. Sidley P. South African court battle damages drug industry's image. *BMJ*. 2001;332(7287):635.

24. *Pharmaceutical Society of South Africa and Others v Minister of Health and Another; New Clicks South Africa (Pty) Limited v Tshabalala-Msimang NO and Another (542/2004, 543/2004) [2004] ZASCA 122; 2005 (3) SA 238 (SCA); [2005] 1 All SA 326 (SCA); 2005 (6) BCLR 576 (SCA)*.(2004). https://www.saflii.org/za/cases/ZASCA/2004/122.html

25. *Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others (CCT 59/2004) [2005] ZACC 14; 2006 (2) SA 311 (CC); 2006 (1) BCLR 1 (CC)*.(2005). https://www.saflii.org/cgi-bin/disp.pl?file=za/cases/ZACC/2005/14.html&query=Minister%20of%20health

26. *Medicines and Related Substances Act: Dispensing Fee to Be Charged*.; 2023. https://www.gov.za/sites/default/files/gcis_document/202309/49309gon3875.pdf

27. Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others. The Constitutional Court of South Africa. Published September 30, 2005. https://collections.concourt.org.za/handle/20.500.12144/2222

28. Naudé C, Luiz J. An industry analysis of pharmaceutical production in South Africa. *44*. 2013;1(33-46). https://doi.org/10.4102/sajbm.v44i1.146

29. Department of Health. *Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances: Logistics Fee Component of a Transparent Pricing System*. Vol R. 770, No. 35699.; 2012. https://www.gov.za/sites/default/files/gcis_document/201409/35699rg9830gon770.pdf

30. Department of Health. *Medicines and Related Substances Act: Annual Single Exit Price Adjustment of Medicines and Scheduled Substances for the Year 2023*. Vol 2940, No. 47883.; 2023. https://www.gov.za/sites/default/files/gcis_document/202301/47883gon2940.pdf

31. Department of Health. *Second Single Exit Price Increase [SEPI] of Medicines and Scheduled Subtances for the Year 2023 [TOP-UP SEPI]*.; 2023. https://www.health.gov.za/nhi-pee/

32. Department of Health. *Annual Single Exit Price Adjustment [SEPA] of Medicines and Scheduled Substances for the Year 2024*.; 2024. https://www.health.gov.za/nhi-pee/

33. Bolin L. Clicks has faith in pharmacy model. *Mail & Guardian*. https://mg.co.za/article/2004-10-21-clicks-has-faith-in-pharmacy-model/. Published October 21, 2004.

34. Kahn T, Gous N. Adcock Ingram warns margins will remain under pressure despite latest SEP increase. *BusinessLive*. https://www.businesslive.co.za/bd/companies/healthcare/2023-08-23-adcock-ingram-raises-dividend-as-profit-grows-by-more-than-10/. Published August 23, 2023.

35. Ginindza B. Pharmaceutical industry disappointed at 3.28% price increase for medications. *IOL*. https://www.iol.co.za/business-report/companies/pharmaceutical-industry-disappointed-at-328-price-increase-for-medications-5f17aa4d-8367-4a72-bc3e-91379276e249. Published January 4, 2023.

36. Minister Phaahla must increase SEP fairly against market dynamics. *IOL*. https://www.iol.co.za/dailynews/opinion/minister-phaahla-must-increase-sep-fairly-against-market-dynamics-5e90e3bb-af0e-47d7-bb91-4784ba964c1d. Published August 19, 2023.

37. *Information and Instructions for the 2023 Top-up Single Exit Price Increase (TU-SEPI) Submissions*.; 2023. https://www.health.gov.za/wp-content/uploads/2023/08/2023-TU-SEPI-Instruction-Document-and-Guidelines-Final08_August_2023.pdf

38. Medicines less accessible for township, rural patients. *Mail & Guardian*. https://mg.co.za/article/2004-07-08-medicines-less-accessible-for-township-rural-patients/. Published July 8, 2004.

39. Villians through clumsiness. *Mail & Guardian*. https://mg.co.za/article/2004-10-27-villains-through-clumsiness/. Published October 27, 2004.

40. South African Pharmacy Council. *Rules Relating to the Services for Which a Pharmacist May Levy a Fee and Guidelines for Levying Such a Fee or Fees*. Vol 539, No. 49944.; 2023. https://www.gov.za/sites/default/files/gcis_document/202312/49944bn539.pdf

41. Koduah A, Baatiema L, De Chavez AC, et al. Implementation of medicines pricing policies in sub-Saharan Africa: systematic review. *Syst Rev*. 2022;11(1):257. doi:10.1186/s13643-022-02114-z

42. Ali G, Yahia A. Controlling medicine prices in Sudan: the challenge of the recently established medicines regulatory authority. *18*. 2012;8(811-20).

43. Wiedenmayer K, Mbwasi R, Mfuko W, et al. Jazia prime vendor system- a public-private partnership to improve medicine availability in Tanzania: from pilot to scale. *J Pharm Policy Pract*. 2019;12(1):4. doi:10.1186/s40545-019-0163-4

44. Ashigbie PG, Azameti D, Wirtz VJ. Challenges of medicines management in the public and private sector under Ghana's National Health Insurance Scheme – A qualitative study. *J Pharm Policy Pract*. 2016;9(1):6. doi:10.1186/s40545-016-0055-9

45. Bangalee V, Suleman F. A Comparative Study on Medicine Pricing in Brazil, Russia, India, China and South Africa (BRICS). *Glob J Health Sci*. 2018;10(10):152. doi:10.5539/gjhs.v10n10p152

46. Rao M. Interview: How South Africa pushed through major reforms to make medicines more affordable. Published November 23, 2017. https://scroll.in/pulse/858936/interview-how-south-africa-pushed-through-major-reforms-to-make-medicines-more-affordable

47. Bangalee V, Suleman F. Pseudo-Generics in South Africa: A Price Comparison. *Value Health Reg Issues*. 2019;19:87-91. doi:10.1016/j.vhri.2019.06.001

48. NHI - Home - National Health Insurance. https://www.health.gov.za/nhi/#:~:text=The%20National%20Health%20Insurance%20(NHI,the%20public%20and%20private%20sector

49. Cassar KL, Suleman F. The impact of international benchmarking on the price of immunosuppressive medicines for transplant recipients in South Africa. *S Afr Med J*. 2019;109(11):865. doi:10.7196/SAMJ.2019.v109i11.13944

50. Perumal-Pillay VA, Suleman F, Perumal-Pillay V. Drawing lessons from the standard treatment guidelines and essential medicines list concept in South Africa as the country moves towards national health insurance. *Open Access*.

51. *National Health Act: National Health Insurance Policy: Towards Universal Health Coverage*.; 2017. https://www.gov.za/sites/default/files/gcis_document/201707/40955gon627.pdf

52. *National Health Insurance Bill (B11B-2019)*. https://www.health.gov.za/wp-content/uploads/2023/07/NHI-Bill-2023.pdf

53. Prinsen L. South Africa's National Health Insurance bill has noble aims but leaves too much uncertain: it needs more work. *The Conversation*. https://theconversation.com/south-africas-national-health-insurance-bill-has-noble-aims-but-leaves-too-much-uncertain-it-needs-more-work-208604. Published June 29, 2023.

54. Steenkamp LA. South African taxpayers will bear the brunt of National Health Insurance. *The Conversation*. https://theconversation.com/south-african-taxpayers-will-bear-the-brunt-of-national-health-insurance-122409. Published August 29, 2019.

Appendix – Policy Brief

Policy title		Single Exit Price (SEP)
Administrative info		
Date of update		**Reviewer name**
6 February 2024		Sharanya Rao, Utrecht University
Information		
Domain		**[2023]**
Context	Population	62 million (2022) [1]
	Life expectancy at birth	62 (2021) [2]
	Total disease burden in DALYs	24.4-29.1 million (2019) [3]
	Per capita health expenditure (US$)	489.64 USD (2020) [2]
	Per capita pharmaceutical expenditure (US$)	
Policy design	Pricing intervention	The introduction of a single exit price (SEP), defined as the only price at which manufactures shall sell medicines to any person other than the State [4]. A SEP is mandatory for all medicines sold in the private sector.
	Pharmaceutical products concerned	All medicines and schedule substances sold in the private healthcare sector.
	Health service settings concerned	The South African Health Products Regulatory Authority (SAHPRA; previously Medicines Control Council MCC) is responsible for monitoring the registration and pricing of all medicines. The Minister of Health, acting on behalf of the National Department of Health (NDoH) is responsible for determining the single exit price adjustment (SEPA) and overseeing any revisions to the SEP and related policies.
	Supporting legislation or policy	The Act 90 Amendments (1997) to the Medicines and Related substances Act 101 of 1965 [4].
	Other relevant policies	National Drug Policy (1966) [5], banning of bonuses, rebates, and incentive schemes (1997; Act 90), cap on dispensing fees for pharmacists (1997; Act 90), mandatory generic substitution of medicines (1997; Act 90 [4]), cap on logistic fees (2012-2013) [6].
	Technical methods description	The SEP is determined by the manufacturer. It must be registered before the medicine can be sold. It includes the ex-manufacturer's price, the logistics fee, and 14% VAT. Companies can apply for an annual increase in the SEP price, which is determined by the Minister of Health (single exit price adjustment; SEPA). The SEPA is calculated based on (i) the average Consumer

		Price Index (CPI) of the previous year, (ii) the average Producer Price Index (PPI) of the previous year, (iii) the changes in the rates of foreign exchange and purchasing power parity, (iv) international pricing information relating to medicines and schedule substances, (v) comments received from interested persons, and (vi) the need to ensure the availability, affordability, and quality of medicines and scheduled substances in the Republic.
Rationale	What were the problems being solved?	Low affordability of medicines in the private sector due very high prices of medicines, lack of a transparent pricing system, discriminatory pricing based on buyer (e.g. using discounts, incentive schemes, bonuses, and rebates), low use of generics [7].
	What were the main policy changes?	The SEP policy was one of the several reforms proposed in the Act 90 Amendments and was introduced under 'regulations for a transparent pricing system.' The main aim was to introduce a price control mechanism to address the high prices of medicines in the private sector. The second aim was to increase transparency in the pricing system. The Act 90 amendments also introduced a cap on the dispensing fees, banned all incentive schemes, established a pricing committee, and established mandatory generic substitution of medicines. Subsequent regulations in 2012-13 introduced a cap in the logistic fees.
	What was the overall politico-legal environment?	The first post-apartheid, democratically elected government came into power in 1994. The healthcare system was strongly divided, with many apartheid-era regimes in place. The NDP was drawn up as early as 1996 as a first step to address the issues in the sector. There was strong contention to the SEP and related policies from pharmaceutical industry representatives.
Governance	Role of government	The government was the main driving force behind the policy. The National Department of Health spearheaded the policy and set up the MCC (now SAHPRA) as the main regulatory body of for the pricing and registration of medicines.
	Role of non-government actors, incl. private sector	Various stakeholders were involved in the initial drafting of NDP, which the SEP and related policies were built on. This included pharmacists, academics, consumer representatives, and lawyers. Representatives from the pharmaceutical industry were included at a later stage [7]. The PMA and PSSA (along with member companies and affiliated organisations) had major roles to play during the implementation process.
	Decision making process	There were several court cases before implementation due to strong opposition from stakeholders in the private sector (e.g. manufacturers, distributors, pharmacists, dispensing doctors). Several revisions were made upon court mandate. Due to the yearly increase allowance, discussions between the Minister of Health and stakeholders are continually in progress.
Implement	Main steps of policy roll out	1. The NDP was drafted and proposed in 1996. 2. The Act 90 amendments were introduced in 1997. 3. The first round of court cases (PMA and 39 major pharmaceutical companies vs. Minister of Health) contesting the compulsory licensing regulation in 1998.

		4. The court case was withdrawn in 2001 due to international pressure on the pharmaceutical companies. 5. A secondary court case was filed in 2002 (PSSA and New Clicks Ltd. vs. Minister of Health) regarding dispensing fee cap. 6. After several revisions, the SEP and related policies came into force in 2004. This was followed by more revisions, to the dispensing fee and annual increase allowance.
	Human resource	The SEP is determined by the manufacturer. The annual increase is determined by the Minister of Health upon consultation with the Pricing Committee.
	Financial resource	There is no publicly available data providing details of the financial resource funding the SEP or related policies.
	Infrastructure (e.g. IT)	All medicines and their SEPs must be registered with SAHPRA. Additionally, all pharmacists and dispensing practitioners must be licensed and registered with SAHPRA. All dispensaries must clearly state the SEP of their medicines so that patients are aware of the price they are paying.
Impacts	Policy uptake	The SEP and related policies were implemented in 2004.
	Price	The average price of medicines has reduced by 22% on average [8].
	Volume	
	Availability	All medicines sold in the private sector are subject to the SEP policy.
	Pharmaceutical expenditure	The overall reduction in costs of medicines has been significant. However, there is no easily available data stating the decrease in overall expenditure following the implementation of the SEP in numbers.
	Stakeholder acceptability	The SEP itself has not been very strongly opposed, but the related policies (cap on dispensing and logistics fees, ban of incentive schemes, mandatory generic substitution) have been points of strong contention. Opposing stakeholders include the PMA, the PSSA, and various stakeholders along the supply chain (e.g. manufacturers, wholesalers, and distributors). Supportive stakeholders include government bodies such as the National Department of Health and SAHPRA, and consumers experiencing an overall price reduction.
	Other impacts	Other impacts include the increased availability and use of generics, and higher levels of transparency in pricing systems across the supply chain. Unintended consequences also include the closure of local pharmacies due to insufficient profits [7], increased pricing of generics upon entering the market [9], and withdrawal of medicines from the market [9].

References - Appendix

[1] Department Statistics South Africa, Republic of South Africa. Mbalo brief – the missing piece of the puzzle. Census 2022 results. Published October 2023, retrieved from: https://www.statssa.gov.za/wp-content/uploads/2023/10/Mbalo-brief-October-2023-WEB-FINAL.pdf

[2] The World Bank. Life expectancy at birth, South Africa (2022). Retrieved from: https://data.worldbank.org/indicator/SP.DYN.LE00.IN?locations=ZA

[3] Achoki T, Sartorius B, Watkins D, et al. Health trends, inequalities and opportunities in South Africa's provinces, 1990-2019: findings from the Global Burden of Disease 2019 Study. *J Epidemiol Community Health*. Published online January 19, 2022. doi:10.1136/jech-2021-217480

[4] No. 90 of 1997: Medicines and Related Substances Control Amendment Act, 1997. (1997).

[5] South African National Department of Health. National Drug Policy for South Africa. NDoH, Pretoria, 1996.

[6] Bangalee, V. & Suleman, F. Evaluating the effect of a proposed logistics fee cap on pharmaceuticals in South Africa - a pre and post analysis. BMC Health Serv. Res. 15, 522 (2015).

[7] Ngozwana, S. Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries? in Making Medicines in Africa (eds. Mackintosh, M., Banda, G., Tibandebage, P. & Wamae, W.) 203–223 (Palgrave Macmillan UK, 2016). doi:10.1007/978-1-137-54647-0_12.

[8] McIntyre, D. I. & Theide, M. Health care financing and expenditure: pooling of resources and puscharing of health care. South Afr. Health Rev. 35–46 (2007).

[9] Moodley, R. & Suleman, F. The impact of the single exit price policy on a basket of generic medicines in South Africa, using a time series analysis from 1999 to 2014. PLOS ONE 14, e0219690 (2019).