# Transparency and South African medicines access - lessons from COVID-19 and beyond



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### Disclaimer

- I am a member of the South African National Essential Medicines List Committee (NEMLC) and co-chair of its Expert Review Committee (ERC)
- I serve on three Technical Advisory Committees at the South African Health Products Regulatory Authority (SAHPRA)
- I am co-chair of the WHO Technical Advisory Group on Pricing Policies for Medicines (TAG-PPM)

However, I am speaking here today as an independent academic and not on behalf of any structure or body



## **Outline**

- Background to South Africa's health system
  - Historical determinants; public and private sectors; plans for universal health coverage
- National Drug Policy 1996
  - Contested implementation
  - □ Single exit price
  - State tender price
- Lessons from COVID-19
  - ☐ Health Justice Initiative case
- Growing opposition to transparency
  - Vertex and access to treatment for cystic fibrosis
- Much more to do ....

Agenda item 11.7

28 May 2019

# Improving the transparency of markets for medicines, vaccines, and other health products<sup>1</sup>

- URGES Member States in accordance with their national and regional legal frameworks and contexts:
  - to take appropriate measures to publicly share information on the net prices<sup>2</sup> of health products;
  - (2) to take the necessary steps, as appropriate, to support dissemination and enhanced availability of, and access to, aggregated results data and, if already publicly available or voluntarily provided, costs from human subject clinical trials regardless of outcomes or whether the results will support an application for marketing approval, while ensuring patient confidentiality;
  - (3) to work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives;

<sup>&</sup>lt;sup>2</sup> For the purposes of this resolution, "net price," "effective price," "net transaction price" or "manufacturer selling price" are the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives.

#### 9 provinces; 52 health districts; 1.22 million km² (3 x Germany)



2024 mid-year estimate:

63 015 904

**Uninsured:** 

53 295 677

Gauteng the most populous province (15.9 m; 25.3%), followed by KwaZulu-Natal (12.3 m; 19.5%)

Black African 81.7% Coloured 8.5% White 7.2% Indian/Asian 2.6%

# The health and health system of South Africa: historical roots of current public health challenges

Hoosen Coovadia, Rachel Jewkes, Peter Barron, David Sanders, Diane McIntyre

The roots of a dysfunctional health system and the collision of the epidemics of communicable and non-communicable diseases in South Africa can be found in policies from periods of the country's history, from colonial subjugation, apartheid dispossession, to the post-apartheid period. Racial and gender discrimination, the migrant labour system, the destruction of family life, vast income inequalities, and extreme violence have all formed part of South Africa's troubled past, and all have inexorably affected health and health services. In 1994, when apartheid ended, the health system faced massive challenges, many of which still persist. Macroeconomic policies, fostering growth rather than redistribution, contributed to the persistence of economic disparities between races despite a large expansion in social grants. The public health system has been transformed into an integrated, comprehensive national service, but failures in leadership and stewardship and weak management have led to inadequate implementation of what are often good policies. Pivotal facets of primary health care are not in place and there is a substantial human resources crisis facing the health sector. The HIV epidemic has contributed to and accelerated these challenges. All of these factors need to be addressed by the new government if health is to be improved and the Millennium Development Goals achieved in South Africa.

Lancet 2009; 374: 817-34

Published Online August 25, 2009 DOI:10.1016/S0140-6736(09)60951-X

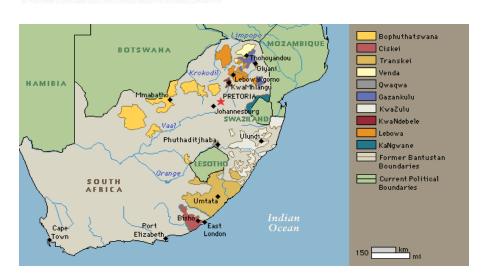
See Editorial page 757

See Comment pages 759 and 760

See Perspectives page 777

This is first in a Series of six papers on health in South Africa

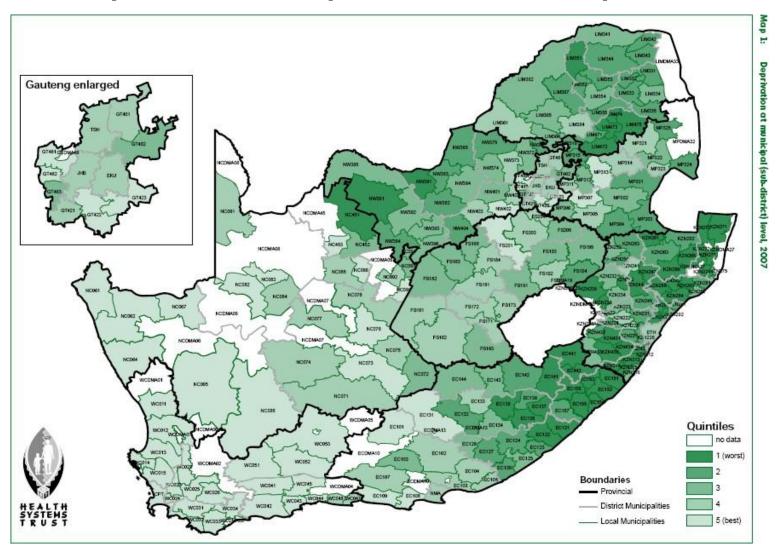
Nelson Mandela School of Medicine, University of KwaZulu-Natal, Durban, South



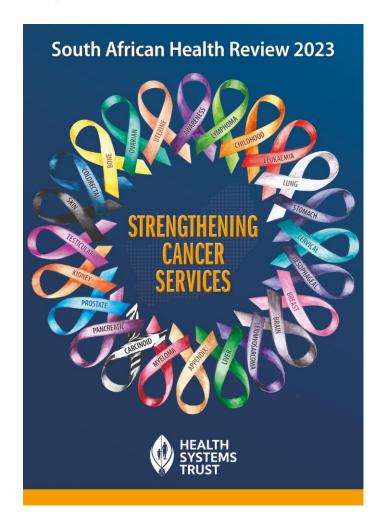
**Apartheid** era (1948-1994) - creation of the "homelands", formalizing the policies of segregation that had been in place since the 17<sup>th</sup> Century

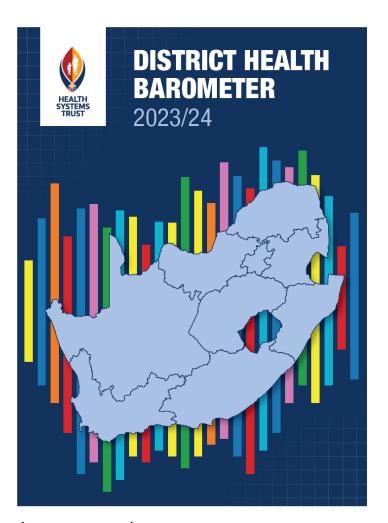
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# Consequences – persistent deprivation



# Key resources





https://www.hst.org.za/



# Public vs private health sector

- Public sector caters mainly for the uninsured population (~85%)
  - □ Funded from the fiscus (via provinces)
- Private sector caters mainly for the insured population (~15%), with some out-of-pocket procurement
  - □ Funded from employer and employee subscriptions
- Approximately EQUAL total expenditure (in total, ~8.5% of GDP)

# What about the private sector?

 Annual reports of the Council for Medical Schemes (https://www.medicalschemes.co.za/)







## Private sector - fragmented

Of the 71 medical schemes in 2022, 16 were open, and 55 were restricted.

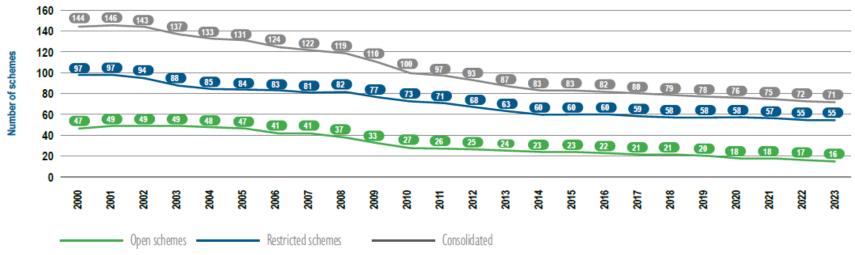


Figure 1: Number of medical schemes by scheme type (2000-2023)

In 2022, ten government-linked or funded medical schemes represented 72% of all restricted scheme beneficiaries and 33% of the total number of beneficiaries



#### https://pmg.org.za/bill/886/

#### ■ National Health Insurance Bill (B11-2019)

Section 76: Ordinary Bills affecting the provinces

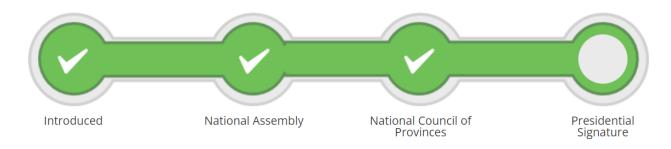
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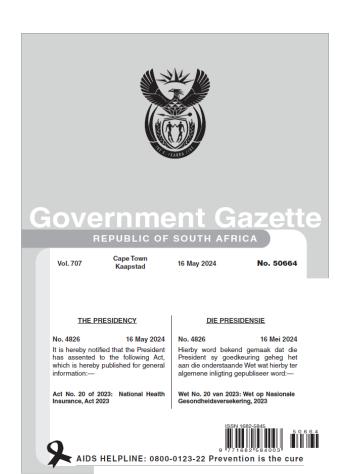








# National Health Insurance Act (Act 20 of 2023)



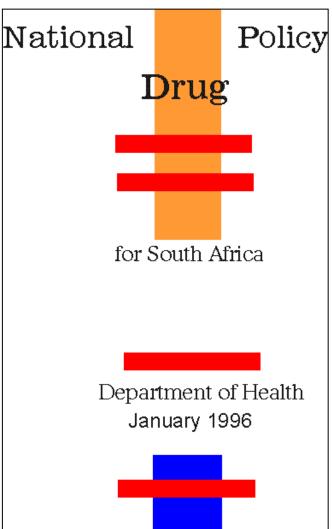
Assented to, but not yet promulgated.

SONA 2025: "This year, we will proceed with the preparatory work for the establishment of the NHI. This includes developing the first phase of a single electronic health record, preparatory work to establish Ministerial Advisory Committees on health technologies and health care benefits, and an accreditation framework for health service providers. The NHI will reduce inequalities in healthcare by ensuring everyone gets fair treatment. The NHI will save many lives by providing a package of services that include, for example, maternal and newborn care and services for people living with HIV, those with TB, and those suffering from non-communicable diseases such as heart disease, cancer and diabetes. Our most immediate priority is to strengthen the health system and improve the quality of care. A vital part of this is the modernisation, improvement and maintenance of existing health facilities and construction of new hospitals and clinics.



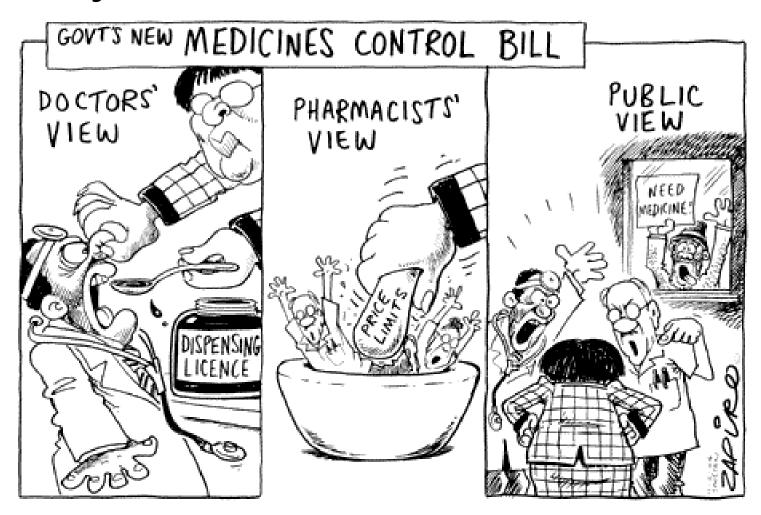
# The 7 key issues in 1994

- To develop a pricing plan for drugs (pub/pvt)
- To develop a plan to ensure all drugs are tested and evaluated for effectiveness
- To develop an Essential Drugs List and Standard Treatment Guidelines (pub)
- To develop a generics strategy
- To prepare a plan for effective procurement and distribution
- To investigate traditional medicines
- To rationalise the structure for Pharmaceutical Services





# Always contested ....

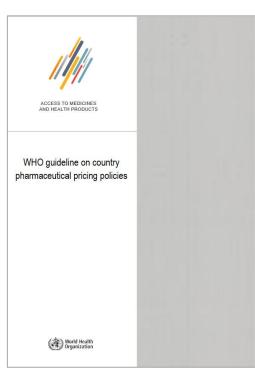




# NDP 1996 content - vague

- Chapter 4: Drug Pricing
  - □ AIM: To promote the availability of safe and effective drugs at the lowest possible cost
  - "This aim will be achieved by monitoring and negotiating drug prices and by rationalising the drug pricing system in the public and private sectors, and by promoting the use of generic drugs"

# In September 2020, WHO Guideline on country pharmaceutical pricing policies was published



#### Ten pricing policies

- 1. External reference pricing
- 2. Internal reference pricing
- 3. Value-based pricing
- Mark-up regulation across the pharmaceutical supply and distribution chain
- 5. Promoting price transparency
- 6. Tendering and negotiation
- Promoting the use of qualityassured generic and biosimilar medicines
- 8. Pooled procurement

- 9. Cost-plus pricing for setting the price of pharmaceutical products
- 10. Tax exemptions or tax reductions for pharmaceutical products

https://www.who.int/publications/i/item/9789240011878



## Recommendations

- External reference pricing
- Internal reference pricing
- Value-based pricing
- Mark-up regulation across the 4. pharmaceutical supply and distribution chain
- 5. Promoting price transparency
- Tendering and negotiation 6.

- 7. Promoting the use of quality-assured generic and biosimilar medicines
- 8. Pooled procurement
- 9. Cost-plus pricing for setting the price of pharmaceutical products
- Tax exemptions or tax reductions for pharmaceutical products

**Strong recommendations** for the policy

**Conditional recommendations** against the policy

**Conditional recommendations** for the policy

coherence, specificity, clear purpose, transparency, integrated framework, relevance, compliance, collaboration

**Eight principles for** developing and considering policies





# Drug pricing – the specifics

- A Pricing Committee with clearly defined functions to monitor and regulate drug prices will be established within the Ministry of Health
- There will be total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals
- A non-discriminatory pricing system will be introduced and, if necessary, enforced
  - s18A No person shall supply any medicine according to a bonus system, rebate system or any other incentive scheme
  - □ s18B No person shall sample any medicine
- The wholesale and retail percentage mark-up system will be replaced with a pricing system based on a fixed professional fee



# Legislated as follows:

- **18A. Bonusing**.—(1) No person shall supply any medicine, medical device or IVD according to a bonus system, rebate system or any other incentive scheme.
- (2) Notwithstanding subsection (1), the Minister may prescribe acceptable and prohibited acts in relation to subsection (1) in consultation with the Pricing Committee referred to in section 22G.
- **18B. Sampling of medicines, medical devices or IVDs.—(**1) No person shall sample any medicine, medical devices or IVD.



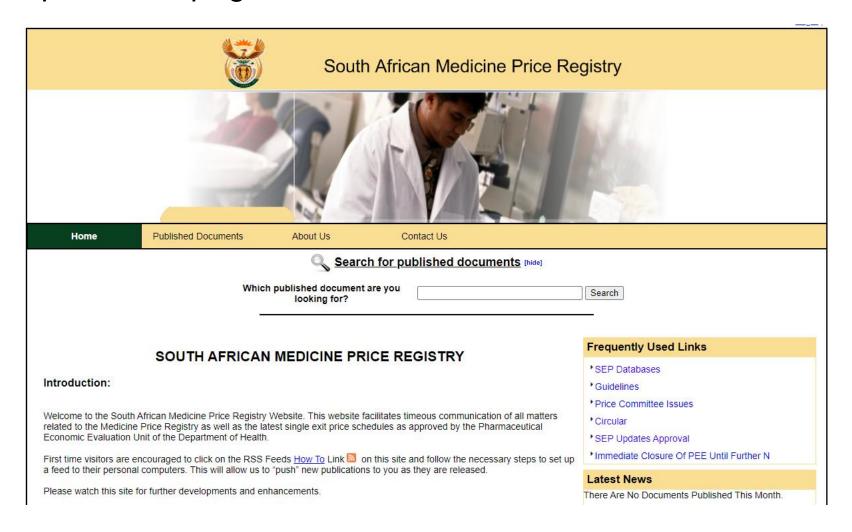
# The SEP provision

- **22G. Pricing committee.**—(1) The Minister shall appoint, for a period not exceeding five years, such persons as he or she may deem fit to be members of a committee to be known as the pricing committee.
- (2) The Minister may, on the recommendation of the pricing committee, make regulations—
- (a) on the introduction of a transparent pricing system for all medicines and Scheduled substances sold in the Republic;

...

(3)(a) 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.

#### http://www.mpr.gov.za/



#### https://www.health.gov.za/nhi-pee/



#### Pharmaceutical Economic Evaluation

Databases	Dispensing Fees	SEPU Documents	SEPA Documents	Other				
Contains information on prices of medicines sold in the private sector in South Africa, including the reference database for use during the Single Exit Price Adjustment (SEPA) implementation process. Information on Single Exit Prices (SEPS), Ex-manufacturer prices and Logistics Fees for each active and discontinued medicine is included. NB: Discontinued medicines shall always remain on the database as they are deemed registered at South African Regulatory Authority (SAHPRA), regardless of unavailability in the market. These may be re-introduced into the market at a later stage.								
Show 10 🗸	entries				Search:			
Database of I	Medicine Prices – 19 May	2025	_	_	DOWNLOAD			

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#### MEDICINE AND THE LAW

#### Is there transparency in the pricing of medicines in the South African private sector?

V Bangalee, 1 BPharm, MPharm, PhD; F Suleman, 1,2 BPharm, MPharm, PhD

Corresponding author: V Bangalee (bangalee@ukzn.ac.za)

Recent investigations by the Competition Commission of South Africa (SA) of suspected excessive pricing of cancer medicines in SA by three global pharmaceutical companies have once again drawn attention to increasing medicine pricing transparency and warrant further public debate.

S Afr Med J 2018;108(2):82-83. DOI:10.7196/SAMJ.2018.v108i2.12815

<sup>&</sup>lt;sup>1</sup> Discipline of Pharmaceutical Sciences, School of Health Sciences, Westville Campus, University of KwaZulu-Natal, Durban, South Africa

<sup>&</sup>lt;sup>2</sup> Prince Claus Chair of Development and Equity for the theme Affordable (Bio)Therapeutics for Public Health (September 2016 - September 2018), Faculty of Sciences, Utrecht University, Utrecht, The Netherlands



# Logistics fee not disclosed – varies between wholesalers/ distributors

Manufacturer Name	Nappi Code	Schedule	Proprietary Name	Generic name (APIs)	Qty of Each API
Pack Size	Dosage Form	Manufacturers	Logistics	Single Exit	
		Price	Fee	Price (VAT	
		(VAT incl.)	(VAT incl.)	Incl.)	







BOUTUSV TENDERS DOCUMENTSV MEDIAV VACANCIES NOTICESV OUTBREA

**Tenders** 

Select Tender Type

The National Department of Health always award BIDS in accordance with Treasury's procedures.

- . Tender documents can be collected at the Department of National Health's reception, 1112 Voortrekker Road, Dr. AB Xuma Building (previously EXXARO Building) in Thaba Tshwane, Pretoria and are free of charge.
- . Documents can be collected from 07:30am until 15:30pm from Mondays to Fridays.
- · Please remember to state the tender number as well as your postal address when requesting documents to be posted.



# NDoH Tenders Pharmaceutical Tenders Pharmaceutical Contracts Master Health Product List Expired Pharmaceutical Contracts NGO Funding Click here to see the Hottlist tab for the latest document. Show 10 v entries Contract No Contract Description Contract Starting Date Contract Circular Index Addendums HP05-2024DI/01 Supply and Delivery of Diagnostic Agents and Contract Media to 7 February 2025 Contract Circular Index February 2025 Add 1 Obsidian Price Clarification

_						
	Contract No	Contract Description	Contract Starting Date	Contract Circular	Index	Addendums
	HP05-2024DI/01	Supply and Delivery of Diagnostic Agents and Contrast Media to the Department of Health for the period ending 30 June 2027	7 February 2025	Contract Circular	Index February 2025	Add 1 Obsidian Price Clarification
		are Department of Fleatin for the period ending 30 June 2027		Successful Suppliers		
				Non-Awards		
	HP09-2023SD/02	Supply and Delivery of Solid Dosage Forms to the Department of Health for the period ending 30 April 2026	22 January 2025	Contract Circular		
		reality for the period ending 30 April 2020		Successful Suppliers		
				Non-Awards		

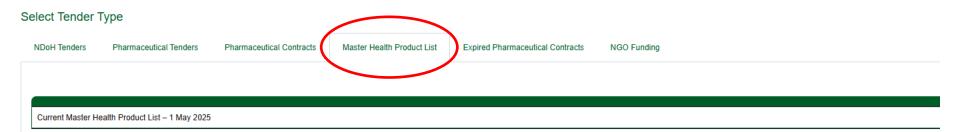




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# So – has transparency (almost) been achieved?

- Private sector SEP + ban on bonuses, rebates and discounts (and sampling)
- Public sector publicly-disclosed tender prices



# Problems – public sector

- Non-awards
  - Reluctance to respond to tenders, requiring procurement on quotation (sometimes exceeding private sector SEP)
- Failure to meet demand
  - When estimates are exceeded
  - When shortages occur



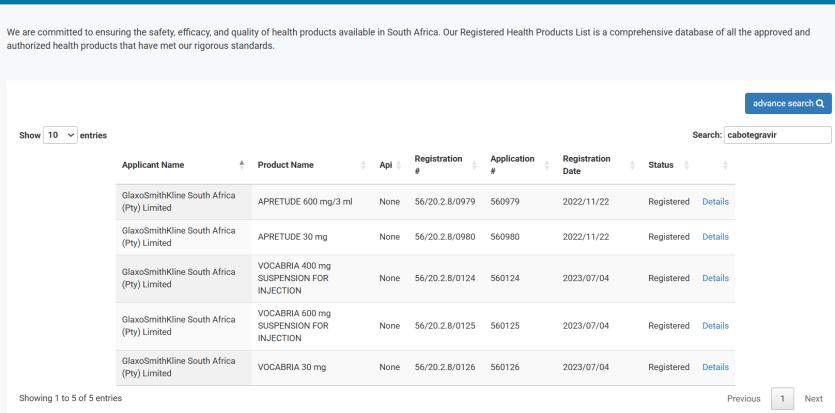
Failure to declare an SEP, despite registration with SAHPRA



SAHPRA Home

Medicines

Lot Release





# Problems – private sector

- Undisclosed bonusing, rebates and discounting
- Vertical integration of wholesalers and retailers
- Undisclosed prices for unregistered medicines imported for individual patients or groups (section 21)



## Lessons from COVID-19

- South Africa negotiated access to COVID-19 vaccines with a number of manufacturers, but was required to keep prices confidential.
- SA Constitution:
- 217. **Procurement.**—(1) When an organ of state in the national, provincial or local sphere of government, or any other institution identified in national legislation, contracts for goods or services, it must do so in accordance with a system which is fair, equitable, transparent, competitive and cost-effective.



AUGUST 30, 2023

# Judgment on contract transparency in the public procurement of Covid-19 vaccines

News & Opinions, Transparency

Health Justice Initiative v The Minister of Health and Information Officer, National Department of Health (Case No 10009/22).

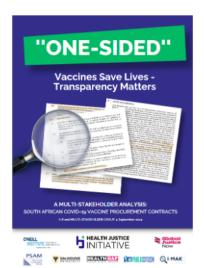
On Thursday 17 August 2023, the Pretoria High Court <u>ruled</u> in HJI's favour in our bid to compel the National Department of Health to provide access to the COVID-19 vaccine procurement contracts. The Court ordered (per Millar J) that all COVID-19 vaccine contracts (part 1) and negotiation related documents (part 2) must be made public within 10 court days of the Judgment (being 31 August 2023).



SEPTEMBER 5, 2023

#### Pandemic Transparency: Access the Vaccine Contracts and Analysis

#### **Download our Analysis**



"One-Sided": A multi-stakeholder analysis of South Africa's COVID-19 vaccine procurement contracts

Following the release of South Africa's COVID-19 vaccine procurement contracts, the Health Justice Initiative worked with a multi-stakeholder group to conduct this analysis of the four agreements. We found the terms and conditions are overwhelmingly one-sided and favour multinational corporations, placing governments in the Global South, and in turn, the people living in these countries, with unusually hefty demands and conditions, including a lack of transparency, and very little leverage against late or no delivery of supplies or inflated prices resulting in gross profiteering.

· Download here

#### **Download the the Vaccine Contracts**



# South Africans take on big pharma for access to 'miracle' cystic fibrosis drug

Cheri Nel cannot afford Vertex's Trikafta medicine, so she is suing to end 'patent abuse' and allow a generic version



**Kat Lay**, Global health correspondent

Mon 18 Mar 2024 05.00 GMT



• Cheri Nel's lawsuit argues that Vertex Pharmaceuticals needs to make its patented CF drug Trikafta available 'on reasonable terms' in South Africa. Photograph: Madelene Cronjé/Guardian

heri Nel has a blunt message for the multibillion-dollar pharmaceutical company Vertex: "Any person that dies from today - that's on you." Vertex makes a "miracle drug" called Trikafta that can transform the lives of people with cystic fibrosis.





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### CL case withdrawn

Spotlight
News - Provinces - Special Projects - Perspectives - About Us
In-depth, public interest health journalism

In May 2024, Vertex identified Equity Pharmaceuticals as the local company through which Trikafta could be imported into South Africa via Section 21 authorisations. These authorisations are granted by SAHPRA to enable importation of an unregistered medicine and are meant to be used in exceptional circumstances to remedy the need for an unregistered medicine, such as when there is a shortage of the registered product.

# Fight not yet over as case against Vertex is dropped after cystic fibrosis medicine price cut



Cystic fibrosis patient Cheri Nel dropped her legal challenge seeking to dramatically expand access to life-changing medicines for the condition. (Photo: Supplied)

News & Features

6th August 2024 | Catherine Tomlinson



Media Statement
For Immediate Release
11 December 2024

#### ACCESS TO CYSTIC FIBROSIS MEDICATION IN SOUTH AFRICA SECURED

In March 2022, the Competition Commission (Commission) initiated a complaint against Vertex Pharmaceutical Incorporated ("Vertex"), for allegedly engaging in exclusionary practices and excessive pricing in the provision of Kalydeco, Orkambi, Symdeko and Trikafta. These are drugs used to treat cystic fibrosis, a rare genetic disease that primarily affects the lungs and the pancreas.

Following the Commission's investigation and various engagements with Vertex, Vertex gave formal undertakings to the Commission to continue to make Trikafta available in South Africa through Section 21 of the Medicines and Related Substances Act ("Section 21"), which enables the sale of unregistered drugs within South Africa. The Commission welcomes Vertex's undertakings and as a result, it has non-referred all allegations against Vertex.



## "patient assistance programmes"

- If no discounting is allowed, how can "patient assistance programmes" operate? Except for medicines imported in terms of section 21?
- No public sector access?

To reduce the financial burden on eligible patients, Vertex started supplying Trikafta in April 2024 through a local distributor. This makes Trikafta available locally at prices that enable cystic fibrosis patients to access treatment. Separately, financial assistance is available through a patient assistance programme managed by a non-government organisation, and eligible cystic fibrosis patients who belong to certain medical schemes get Trikafta at no cost as they also receive some financial assistance from their medical aid schemes.



# National Health Insurance Series

#### **Issue Paper 1**

October 2022

South Africa's National Health
Insurance Bill and the Future of Medicine
Selection, Pricing and Procurement –
Some Critical Questions for Affordable



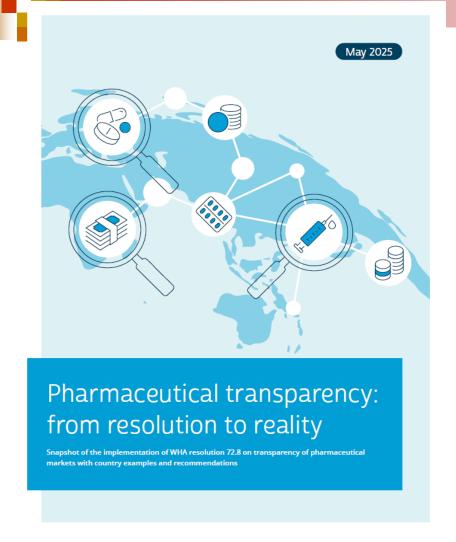
#### The Health Justice Initiative's 17 Questions

on the NHI and Medicine Access

- What specific measures are envisaged to enable and promote public transparency related to medicine selection, procurement and contracting processes under the NHI?
- 2 How will the deliberations of NHI ministerial advisory committees be made open to the public, and how (and how often) will this information be shared?
- Not everyone living in SA will be regarded as a 'user' of the NHI Fund. In these circumstances, will medicine manufacturers be permitted to sell medicines to health providers other than the State if so, how will this be done, and what will be the maximum price?
- Which medicines will automatically be covered under NHI benefits as part of the NHI Formulary? How will this information be communicated to the public, and how can the inclusion or exclusion of specific medicines be appealed?
- Which medicines will not be covered under NHI benefits as part of the NHI Formulary?
  On what basis will this exclusion be decided, how will poorer patients access life-saving medicines that are not included, and will humanitarian organisations be permitted to access medicines on individuals' behalf?
- 6 Will wealthier people be able to bypass NHI selection and purchase more expensive life-saving and other medicines on their own/with others where the State does not procure these itself?
- Many foreign migrants and South Africans without documentation will not be able to register as NHI Users. How will people who are not registered NHI Users (for any reason) be able to access basic health care services?
- 8 How will the price of medicines not included in or covered by the NHI be regulated? And what role will External Reference Pricing (ERP) methodology play in the NHI and beyond?
- 9 How will the NHI Fund (e.g., the Office of Health Products Procurement, the NHI Board) negotiate with global pharmaceutical manufacturers and suppliers in order to procure for the State, and how will that process be transparent and accountable?
- By when and how will the current Single Exit Price (SEP) system that governs private sector medicine acquisition be amended and/or extended, and in what phases of the implementation process will this occur? How will dispensing fees be charged, and how will Section 21 exemptions be managed?
- Why has the jurisdiction of the Competition Commission been excluded, and which other statutory body will be legally tasked with providing the necessary regulation of price and competition?
- How will the Minister determine that the NHI is 'fully implemented', and what will take place in terms of what medical schemes can and cannot offer members during the transition period, and after the (undefined) date?
- How will the current Imedical schemel provisions related to 'late-joiner penalties', 
  waiting periods' and top-up insurance products be managed or transitioned under 
  the NHI without prejudicing existing and also new members?
- Has consideration been given to designing a competitive and different single medicine pricing system for SA?
- What specific measures if any will the NHI Fund be permitted to take or recommend in respect of reducing medicine, to give effect to the intent of 'strategic purchasing' as referenced in the NHI Bill?
- How will SA's Intellectual Property strategy need to adapt to complement the NHI objectives of securing the 'best available medicines' in the most affordable way?
- What system will govern how the South African National Defence Force (SANDF) and State Security Agency (SSA) select, procure, and pay for medicines (they are exempt from the NHI), and how will pricing be monitored and regulated under that parallel procurement system?

# Global debates about external reference pricing

The WHITE HOUSE PRESIDENT DONALD J. TRUMP □ PRESIDENTIAL ACTIONS DELIVERING MOST-FAVORED-NATION PRESCRIPTION DRUG PRICING TO AMERICAN PATIENTS **Executive Orders** May 12, 2025



# OPACITY IN NET MEDICINES PRICING

FROM THE GLOBAL HEALTH ISSUE TO THE LOCAL EXPERIENCE: THE CASE OF NO ES SANO

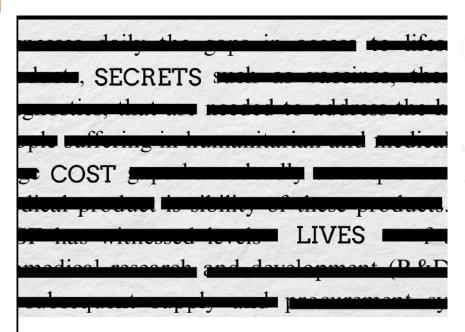




https://www.wemos.org/wp-content/uploads/2025/05/ Report-pharmaceutical-transparency-Wemos-HAI-2025-1.pdf



https://noessano.org/wp-content/uploads/2025/05/ Informe-Transp\_NES\_230425\_ENG.pdf



# TRANSPARENCY AND ACCESS TO MEDICAL PRODUCTS

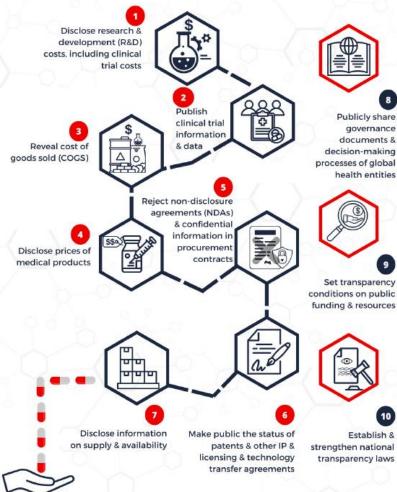
PROGRESS TOWARDS EQUITY IN ACCESS TO MEDICAL PRODUCTS CAN ONLY BE BUILT ON THE OPEN SHARING OF INFORMATION AND KNOWLEDGE, NOT ON SECRETS

**JUNE 2024** 



https://msfaccess.org/sites/default/files/2024-06/MSF-AC\_TransparencyReport\_June2024\_FINAL.pdf

#### TRANSPARENCY: 10 CRITICAL STEPS FOR ACCESS TO MEDICAL PRODUCTS





### Much more to do ....

- An enforceable marketing code of practice, with final regulations specifying which practices are "perverse"
- Clarity on the pricing of medicines to be reimbursed by the NHI Fund
- And more ...

