HEALTH JUSTICE INITIATIVE

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 Patient Access

The Health Justice Initiative's (HJI) focus on health equity includes analysing legislative tools that are proposed to provide access to affordable medicines for everyone who needs them, irrespective of income, race, or nationality. This is to ensure the most vulnerable in our communities are protected and are able to access life-saving medicines at the right time and in an affordable manner. For this reason, we examined specific policy proposals included in the National Health Insurance (NHI) Bill that involve and implicate the future of transparent and affordable medicine selection, access, and pricing.[1]

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For more information, please see: https://healthjusticeinitiative.org.za/about/#funders

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Useful links:

1. **HJI and CHESAI NHI e-Archive:** https://nhi.healthjusticeinitiative.org.za/
2. **Spotlight:** https://www.spotlightnsp.co.za/nhi/
3. **Parliamentary Monitoring Group (PMG):** https://pmg.org.za/bill/886/
4. **2019 National Health Insurance Bill:** https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf

> *The [NHI Bill's] proposed amendment to the Medicines and Related Substances Act has enormous implications for the procurement and supply of medicines in particular.*

Andrew Gray and Yousuf Vawda, 2018[2]

> *The entire shift of our medicine selection, procurement and reimbursement system to "NHI reimbursement" has not been adequately thought through, potentially posing a great risk for the future of medicine selection and access in the country for all people. This requires immediate attention at the highest levels of the executive and the legislature too – and likely needs a multi-department and stakeholder technical group to urgently determine the exact trajectory of this planned process.*

Health Justice Initiative, 2022

ABBREVIATIONS

ARV	Antiretroviral
CUPS	Contracting Units for Primary Healthcare Services
DG	Director-General
DDG	Deputy Director-General
DHMO	District Health Management Office
ERP	External Reference Pricing
GEMS	Government Employees Medical Scheme
HJI	Health Justice Initiative
HMI	Health Market Inquiry report, produced by the Competition Commission
IP	Intellectual Property
MAC	Ministerial Advisory Committee
NDoH	National Department of Health
NEMLC	National Essential Medicines List Committee
NHI	National Health Insurance
NDP	National Drug Policy
NPC	National Planning Commission
OHPP	Office of Health Products Procurement
OHSC	Office of Health Standards Compliance
PAIA	Promotion of Access to Information Act
PMB	Prescribed Minimum Benefits (as per the Medical Schemes Act)
PMG	Parliamentary Monitoring Group
SA	South Africa
SALDRU	Southern Africa Labour and Development Research Unit
SANDF	South African National Defence Force
SEP	Single Exit Price
SSA	State Security Agency
STG	Standard Treatment Guidelines
UHC	Universal Health Coverage
VMAC	Ministerial Advisory Committee on Covid-19 Vaccines
WHO	World Health Organization

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PREAMBLE TO THE NHI BILL

RECOGNISING

the socio-economic injustices, imbalances and inequities of the past;

the need to heal the divisions of the past and to establish a society based on democratic values, social justice and fundamental human rights; and

the need to improve the quality of life of all citizens and to free the potential of each person [...]

AND IN ORDER TO

achieve the progressive realisation of the right of access to quality personal health care services;

make progress towards achieving Universal Health Coverage;

ensure financial protection from the costs of health care and provide access to quality health care services by pooling public revenue in order to actively and strategically purchase health care services based on the principles of universality and social solidarity [defined in the NHI Bill as 'providing financial risk pooling to enable cross subsidisation between the young and the old, the rich and the poor and the healthy and the sick'];

create a single framework throughout the Republic for the public funding and public purchasing of health care services, medicines, health goods and health-related products, and to eliminate the fragmentation of health care funding in the Republic;

promote sustainable, equitable, appropriate, efficient, and effective public funding for the purchasing of health care services and the procurement of medicines, health goods and health-related products from service providers within the context of the national health system; and

ensure continuity and portability of financing and services throughout the Republic.[3]

KEY DEFINITIONS IN THE NHI BILL

Pooling of funds

means the aggregation of financial resources for the purpose of spreading the risk across the population so that individual users can access health services without financial risk;

Mandatory prepayment

means compulsory payment for health services before they are needed in accordance with income levels;

Complementary cover

means third party payment for personal health care service benefits not reimbursed by the Fund, including any top-up cover offered by medical schemes registered in terms of the Medical Schemes Act or any other voluntary private health insurance fund;

Medical scheme

means a medical scheme as defined in the Medical Schemes Act;

Comprehensive health care services

means health care services that are managed so as to ensure a continuum of health promotion, disease prevention, diagnosis, treatment and management, rehabilitation and palliative care services across the different levels and sites of care within the health system in accordance with the needs of users;

Emergency medical services

means services provided by any private or public entity dedicated, staffed and equipped to offer pre-hospital acute medical treatment and transport of the ill or injured;

Health care service

means—

(a) health care services, including reproductive health care and emergency medical treatment, contemplated in section 27 of the Constitution;

(b) basic nutrition and basic health care services contemplated in section 28(1)(c) of the Constitution;

(c) medical treatment contemplated in section 35(2)(e) of the Constitution; and

(d) where applicable, provincial, district and municipal health care services;

Health goods

in respect of the delivery of health care services, includes medical equipment, medical devices and supplies, health technology or health research intended for use or consumption by, application to, or for the promotion, preservation, diagnosis or improvement of, the health status of a human being;

Medicine

means medicine as defined in section 1 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

Primary health care

means addressing the main health problems in the community through providing promotive, preventive, curative and rehabilitative services and—

(a) is the first level of contact of individuals, the family and community with the national health system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process; and

(b) in the public health sector, is the clinic, and in the private health sector, is the general practitioner, primary care nursing professional, primary care dental professional and primary allied health professional, through multi-disciplinary practices;

Procurement

has the meaning ascribed to it in section 217(1) of the Constitution;

Contracting Unit for Primary Health Care

means a Contracting Unit for Primary Health Care referred to in section 37;

District Health Management Office

means a District Health Management Office referred to in section 36;

Permanent resident

means a person having permanent residence status in terms of the Immigration Act;

Refugee

has the meaning ascribed to it in section 1 of the Refugees Act.

EXECUTIVE SUMMARY

HJI Questions About Transparency and Transition to the NHI System

In order to move SA towards Universal Health Coverage, this Issue Paper asks the following questions to policy and law makers:

How will people in SA access life-saving medicines under the NHI system and how much will we have to pay?

SA should not perpetuate the current unequal two-tier health system and resultant inequity in medicine access where there is one system for the rich and one for the poor.

Based on our analysis of the provisions in the NHI Bill, the HJI has formulated **17 NHI Questions** about transparency and transition that lawmakers and government officials should grapple with, and ultimately answer, while they consider draft legislation for finalisation and adoption. This is against the background of government departments preparing to implement NHI.

The Issue Paper analyses some key provisions in the current NHI Bill and highlights potential enablers and challenges to medicines access. From this analysis, it distils questions and further areas for exploration that will serve as an entry point for future work and engagement.

The Health Justice Initiative's
17 Questions
on the NHI and Medicine Access[4]

1. 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?
3. 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?
4. **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?
5. **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?

7. 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?

10. 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?

11. **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?

12. **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?

13. How will the current [medical scheme] 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?

14. Has consideration been given to **designing a competitive and different single medicine pricing system for SA**?

15. 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?

16. 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?

17. 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?

SECTION 1:

Key Human Rights Principles

Health rights are meaningless without timely access to life-saving medicines. A key pillar of the HJI's strategy is to focus on the availability and accessibility of life-saving medicines for those who are most in need, and for all diseases. There is also a constitutional obligation on the State to give effect to meaningful access to health and human rights – which our courts have recognised as including the right to access life-saving medicines and treatment.

> *"The issue of access to medicines is a fundamental component of the full realization of the right to health. Medical care in the event of sickness and the prevention, and treatment and control of diseases, depends largely on timely and appropriate access to quality medicines."*[5]

South Africa's Constitution states:[6]

- That everyone has the right to have access to health care services, including reproductive health care (Section 27(1)(a)).
- The State is required to 'take reasonable legislative and other measures, within its available resources' to achieve the progressive realisation [of the right of access to health care services]. (Section 27(2))
- That no one may be refused emergency medical treatment. (Section 27(3))
- That every child has the right to basic health care services. (Section 28(1)(c))
- The right to bodily and psychological integrity is entrenched in section 12(2) of the Constitution.
- The rights to equality and human dignity are enshrined in the Constitution in sections 9 and 10.

In addition:

- Article 12 of the United Nations International Covenant on Economic, Social and Cultural Rights, adopted in 1966, provides for the right of everyone to the 'enjoyment of the highest attainable standard of physical and mental health'.
- Article 16 of the African Charter on Human and People's Rights (1981) provides for the 'right to enjoy the best attainable state of physical and mental health' and requires State Parties to 'take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick'.

SECTION 2:

South Africa's National Health Insurance (NHI) and Developments (October 2022)

1. According to the Department of Health (NDoH), National Health Insurance (NHI) is a 'health financing system that is designed to pool funds to provide access to quality affordable personal health services for all South Africans based on their health needs, irrespective of their socio-economic status.'[7]
2. At present (August 2022), the 2019 NHI Bill is being reviewed by the Parliamentary Portfolio Committee on Health (Portfolio Committee).
    a. Between 2019 and 2022 the Portfolio Committee conducted in-person hearings in all nine provinces, across 33 district municipalities, together with several virtual (online) public hearings.
    b. These hearings were attended by members of the public and various stakeholders, and some 1 075 oral submissions were received from NGOs, medical schemes, regulatory bodies, pharmaceutical companies, trade unions, political parties, professional bodies, members of the public and academics among others.
    c. In addition, the Portfolio Committee received 338 891 written submissions from the public.[8]
3. The Portfolio Committee voted in favour of a 'motion of desirability [on the NHI Bill]' on 18 May 2022.[9]
4. According to a news report produced by Bhekisisa in August 2022, the Minister of Public Service and Administration and the National Treasury recently approved the use of R30-million of the 2022 NHI budget for salaries for '44 NHI positions' that 'will be spread across five directorates, including user and service provider management; healthcare benefits and provider payment design; health product procurement; health systems digital information; and fraud management'[10].
    a. The report indicated these positions were likely to be appointed by January 2023. These positions are apparently intended for 'technical' people such as economists, public health medicine specialists, actuaries, and lawyers, who will draft operating procedures and regulations that will be gazetted for public comment after the NHI Bill has been signed into law.
    b. In addition to the 44 new positions the NHI Fund will also inherit at least 80 to 100 people and other posts from the NDoH to enable them to develop service benefit packages for all levels of care by March 2024.[11] National Treasury indicated in 2021 that 'ZAR121.3 million over the MTEF [medium-term economic framework] period is allocated in the NHI programme for strengthening the NHI unit, to be transferred to the entity when it is created'.[12]

NHI Summary Timeline: 1995 – 2022[13]

1995
A Commission of Inquiry into National Health Insurance was established (one of 11 committees set up at the time, with expedited reporting obligations). It confirmed principles of the 1994 ANC (African National Congress) National Health Plan and set out the future role of medical schemes.

1996
Publication of a National Drug Policy (NDP) for SA. The NDP called for the establishment of a Pricing Committee and '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'. It also called for the government to undertake a variety of actions to provide more affordable medicines such as the generic substitution of a branded drug.[14]

1997
A White Paper on the Transformation of the Health System in SA is released.

The Medicines and Related Substances Amendment Act of 1997 introduces an essential drug list, allows for parallel importation of medicines, and promotes the dispensing of generic medicine substitutes.[15]

The Social Health Insurance Working Group develops the regulatory framework that leads to the Medical Schemes Act of 1998, which in turn introduced the concept of Prescribed Minimum Benefits for scheme members.

2000
The Department of Social Development establishes the Taylor Committee of Inquiry into a Comprehensive Social Security System for SA. The commission recommends that the State should create a 'national health fund' and transform all aspects of social security, including healthcare reform (some recommendations have not been implemented to date).

2002
The National Department of Health establishes a Ministerial Task Team on Social Health Insurance. Its mandate is to draft an 'implementation plan' with proposals on how to move towards 'social health insurance and create supporting legislation and institutional mechanisms that will in the long term result in the realisation of National Health Insurance in SA.'[16]

The Medicines and Related Substances Amendment Act 59 of 2002[17] makes amendments to the Medicines and Related Substances Act of 1965. These amendments provide inter alia for a term of office of members of the Pricing Committee and create mechanisms to operationalise provisions related to licensing for dispensing or manufacturing medicines and for generic substitution. Note: Medicine pricing interventions that dealt with transparent pricing of medicines in the private sector only came into effect in 2004.

2003
The National Health Act is passed, creating a national health system with plans to establish district health systems to implement primary health care throughout SA. Certain sections of this Act have not yet been promulgated (see Chapter 6 of the Act for example).

2007
The ANC Policy Conference commits to implementing a National Health Insurance system in SA.

2009
A Ministerial Advisory Committee is appointed to provide the Minister and Department of Health with 'recommendations regarding the relevant health system reforms and matters relating to the design and roll out of National Health Insurance'.[18]

2011
Department of Health releases a National Health Insurance in SA Policy Paper.[19]

2012-2017
Implementation phase of the NHI pilot roll-out begins in 2012, piloting 'health system strengthening (HSS) initiatives; the establishment of the NHI Fund and key institutions; and the moving of central hospitals to the national sphere'.[20]

2015
Department of Health publishes the White Paper on National Health Insurance.[21]

2018
Release of Draft National Health Insurance Bill.[22]

2019
Release of National Health Insurance Bill.[23]

Portfolio Committee on Health invites stakeholders and interested parties to submit written submissions about the NHI. It also conducts visits to several municipalities and holds provincial hearings. Over 300 000 written submissions were received.

2021-2022
Due to the COVID-19 pandemic, the Portfolio Committee invites select stakeholders to make virtual e-presentations.

2022 (as at October 2022)
Virtual stakeholder parliamentary presentations are concluded and deliberations on the NHI Bill by the Portfolio Committee on Health have commenced.

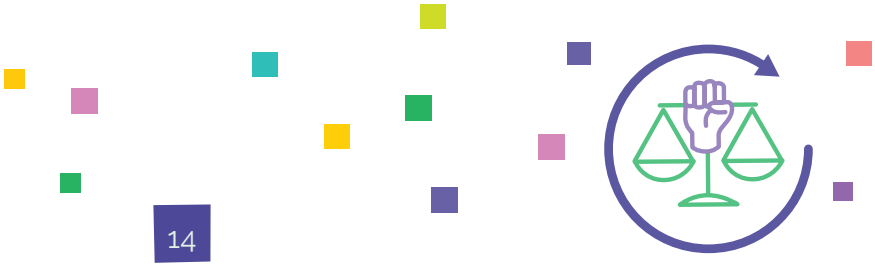
The NHI Bill is currently under consideration by the Portfolio Committee in the National Assembly, and it is tagged as a 'Section 76' Bill (a Section 76 Bill is an ordinary bill that affects the provinces, and it must be considered by both the National Assembly and the National Council of Provinces in Parliament).

SECTION 3:

Inequality and Medical Scheme Coverage in South Africa

> *"The notable difference between us [South Africa] and other countries is that the share of income captured by our top 10% and especially the top 5% is excessive."*[24]
>
> *Southern Africa Labour and Development Research Unit (SALDRU), 2018*

1. In 2022 the World Bank ranked SA as the most unequal country in the world, adding that it also ranked first among 164 countries in the World Bank's global poverty database.[25]
2. In 2018 the Southern Africa Labour and Development Research Unit at the University of Cape Town (SALDRU) found that: [26]
   a. 50% of South Africans are chronically poor;
   b. The chronically poor and vulnerable poor are predominantly Black African;
   c. Only about 20% of the South African population can be considered as 'middle class';
   d. Race is still one of the strongest predictors of poverty in SA; and
   e. Members of larger, female-headed, or rural households face a higher risk of poverty, and are less likely to enter the ranks of the middle class.' (See Figure 1 below).
3. Statistics South Africa's mid-year population estimates for 2021 estimate SA's population at 60.14 million people.[27]
4. Data from the World Health Organization (WHO) and World Bank estimate that more than 58% of total healthcare spend in SA is financed by government revenue; 33.9% by private medical schemes; and just under 6% through out-of-pocket payments.[28]
5. Private healthcare funding is primarily provided via medical scheme membership in SA.
6. In 2021, approximately 9.7 million people in SA were beneficiaries of a private medical scheme[29] (16% of the population). About 80% of the population rely on the public sector ('health care provided by tax-financed public sector institutions'[30]) – that is, more than 50 million people, across nine provinces.



a. South Africa's 2021 General Household Survey[31] shows that medical scheme coverage is also uneven between provinces. For example, it is about 8.2% in Limpopo and 9.1% in Mpumalanga, while in Gauteng it is approximately 24%, and is about 23.7% in the Western Cape.

b. The gender distribution of medical scheme members in 2020 was almost equal across all medical schemes. The average age of women members was slightly higher at 34.1 years compared to 31.9 years for men.[32]

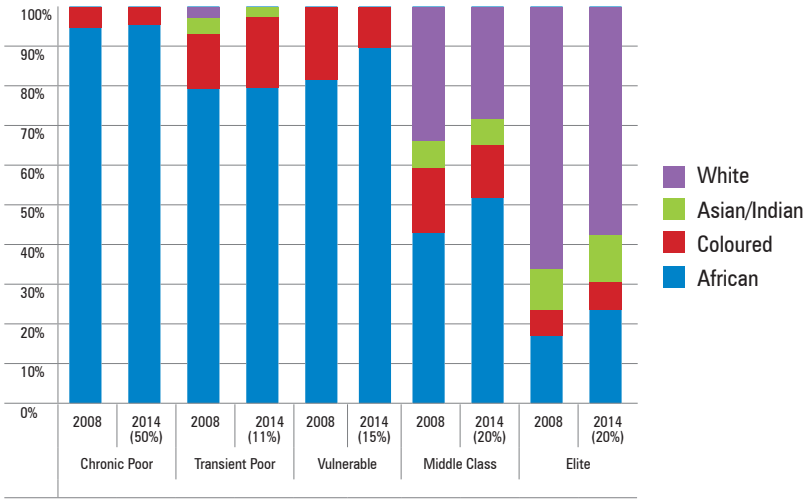
c. The Competition Commission's Health Market Inquiry (HMI) report (2019) previously found that at that time about "70% of medical scheme members were concentrated in two medical schemes (Discovery Health, and Government Employees Medical Scheme (GEMS)), and that 76% of insured lives were administered by just two companies (Discovery Health and Medscheme)".[33]

7 The legacy of apartheid also created an unequal health system.

a. About 77.7% of whites are medical scheme beneficiaries as reported in the 2021 General Household Survey. In contrast, 9.3% of black Africans are medical scheme beneficiaries, including government employees on GEMS.[34]

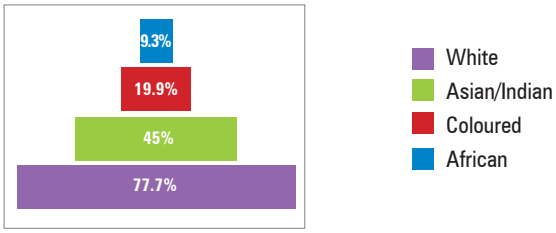
b. Non-beneficiaries are dependent on State health care services and patients also fund their own medical expenses through out-of-pocket payments using a network of private practitioners. (See Figure 2 below).

Figure 1: Racial composition and social class in South Africa[35]



Source: Social stratification, life chances and vulnerability to poverty in South Africa

Figure 2: Percentage of individuals who are members of medical schemes by population group[36]



SECTION 4:

WHO Guidelines on Country Pharmaceutical Pricing Policies (2020)

Before we set out key provisions in the NHI Bill that affect medicine selection and pricing as well as procurement, it is useful to summarise some of the key WHO Recommendations on medicine pricing policies for national systems.

The WHO states that 'pharmaceutical pricing policies need to be carefully planned, carried out, and regularly checked and revised according to changing conditions. Strong, well-thought-out policies can guide well-informed and balanced decisions to achieve affordable access to essential health products.'[37]

It also suggests considering the following measures at country level in respect of pricing transparency[38]:

1. **External reference pricing** (also known as international reference pricing or benchmarking) – uses the price of a pharmaceutical product in one or several jurisdictions to derive a benchmark or reference price.

   Status: Not yet implemented in SA[39]

2. **Internal reference pricing** uses a set of pharmaceutical products that are therapeutically comparable and interchangeable, to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement rate of a product.

   Status: Implemented by private sector and to an extent by the State

3. **Value-based pricing** is an approach that aims to set prices for pharmaceutical products based on the measured and quantified 'value' or worth that patients and health systems attribute to pharmaceutical products.

   Status: Not implemented[40]

4. **Price transparency** – the sharing, disclosure and dissemination of information related to prices of pharmaceutical products to relevant parties and the public to ensure accountability. Full price transparency includes the publication of prices at all price types (e.g., ex-factory prices, pharmacy retail prices), the disclosure of the net transaction prices between suppliers (e.g., manufacturers, service providers) and payers/purchasers (governments, consumers).[41]

   Status: Not fully implemented (notably with regard to private sector logistics fees)[42]

SECTION 5:

The NHI Bill – Rationale and Some Learnings From COVID-19 Implicating Intellectual Property Law

In introducing the NHI Bill, the South African government has stated that it wants to ensure that:

a. No one is deprived of their right to access healthcare because of their socio-economic status;

b. A single public health fund is created that has enough resources to plan for and effectively meet the health needs of the entire population, not just a select few; and

c. Universal Health Coverage (UHC) is achieved.

Early Lessons from COVID-19

The COVID-19 pandemic provided many lessons for health systems preparedness and strengthening, including the importance of access to life-saving interventions. It also showed that the South African government in partnership with the private health sector and others can design and implement a programme that relies on national or single procurement and joint implementation.

For example:

1. The NDoH contracted with vaccine manufacturers (at their request and based on their 'demands') to purchase vaccines for all SA, which were then allocated to provincial health departments and private health sector stakeholders (medical schemes, pharmacies, faith-based organisations) for administration.
2. This allowed for a somewhat coordinated response to addressing the initial scarcity of supplies, and the demands of certain pharmaceutical manufacturers that, at the time, were only willing to sell to the State.
3. As a result, the country relied on a single procurement system and at the same time sought to ensure equity in allocation and access.[43]
4. During a Bhekisisa webinar on COVID-19 and its lessons for NHI, the DDG responsible for implementing NHI in SA and the national COVID-19 vaccine roll-out commented that 'the pandemic proved that collaboration is possible, and not as difficult as had previously been imagined'.[44]

5. But this 'joint' or national approach was not universally welcomed and was initially met with legal challenge[45], and requests for 'secrecy', where private manufacturers have demanded 'non-disclosure' and high levels of confidentiality from governments.[46] As such, several groups, including the HJI, have argued that transparency has not been prioritised in vaccine procurement in the COVID-19 pandemic as a result.[47]

A key concern, as highlighted by the pandemic, is that access to life-saving interventions (here medicines) is not just about selection or procurement, but also about existing Intellectual Property (IP) barriers to timely access.[48]

1. For example, much-needed amendments to SA's patent laws require finalisation – further delays may prejudice 'strategic purchasing' as envisaged in the NHI Bill.
2. At the very least, in addition to introducing pre-grant opposition procedures in our patent laws, lawmakers should consider the inclusion of public interest and public health grounds for compulsory licences, and a streamlined administrative process for hearing compulsory licence applications.

In order to reduce the costs of medicine procurement and increase government and others negotiating power, IP reform is critical and goes hand in hand with the aims and objectives of the NHI.

SECTION 6:

The NHI Bill – Health and Income Inequality and Health Xenophobia in South Africa

The publication of the NHI Bill in 2019 was the culmination of extensive policy and executive deliberations that had been under way since 1994, and which were intended to address glaring inequities in access to affordable health care services, with the aim of unifying SA's two-tier health system.[49]

Who will the NHI Fund cover and for what services?

The NHI Bill provides that anyone seeking health care services under the NHI must be registered as a user of the [NHI] Fund and 'present proof of such registration to the health care service provider or health establishment in order to secure the health care service benefits to which he or she is entitled.'

The NHI Bill (Section 4(1)) provides that the NHI Fund, in consultation with the Minister, must purchase health care services, determined by the Benefits Advisory Committee, on behalf of:

(a) South African citizens;

(b) permanent residents;

(c) refugees;

(d) inmates; and

(e) certain categories of individual foreigners as determined by the Minister of Home Affairs (after consultation with the Minister and the Minister of Finance).

All children, including children of asylum seekers or 'illegal migrants' (see note below), will be entitled to basic health care services. An asylum seeker or 'illegal foreigner' (see note below) is only entitled to:

(a) emergency medical services; and

(b) services for notifiable conditions of public health concern.

NOTE: The HJI does not believe that any human being should be called or declared 'illegal', especially in a context of repeated and documented failures by the South African government in addressing documentation requests and applications from asylum seekers, migrants, and even from people born in SA. Where that derogatory language is used, it is because it is a direct quote from the NHI Bill and the drafters who chose to use that language.

The NHI Bill also states that a foreigner visiting for any purpose must have travel insurance to receive health care services. It states that if they do not have travel insurance, then they only have the right to emergency medical services and services for notifiable conditions of public health concern.

Several civil society organisations have strongly rejected the exclusion of asylum seekers, exemption permit holders and other migrants from basic health care provisions in the NHI Bill.[50] They have pointed out that this exclusion does not make sense in terms of public health, is not backed by scientific evidence, and conflicts with the South African Constitution. The dysfunctional asylum system and other components of documentation overseen by the Department of Home Affairs mean that many people (including South Africans) are not documented and will thus will not be able to access health care in terms of NHI.[51]

Finally, members of the South African National Defence Force (SANDF) and the State Security Agency (SSA) are excluded from the NHI Bill (section 3(1) and 3(2)). It is unclear what requirements will govern how they access medicines – and select, tender, negotiate and procure medicines in parallel to NHI, and at what maximum price.

SECTION 7:

The NHI Bill – The Role of Medical Schemes

A new regulatory framework for medical schemes and 'top-up' health insurance products that will offer 'complementary cover'

The NHI Bill provides that medical schemes registered in terms of the Medical Schemes Act (MSA) of 1998 or any other voluntary private health insurance scheme will be permitted, but at the same time restricted to only providing complementary cover for healthcare services once NHI is determined to be 'fully implemented' by the Minister.

One of the shortest sections (Section 33) of the NHI Bill states:

> Role of medical schemes:
>
> 'Once National Health Insurance has been fully implemented as determined by the Minister through regulations in the Gazette, medical schemes may only offer complementary cover to services not reimbursable by the (NHI) Fund.'

'Complementary cover' is defined in the NHI Bill as:

> a: '[...] third party payment for personal health care service benefits not reimbursed by the [NHI] Fund, including any top-up cover offered by medical schemes registered in terms of the Medical Schemes Act or any other voluntary private health insurance fund.'

Specific amendments to the MSA in the NHI Bill include the following:

> A 'medical scheme shall apply to the Registrar for the approval of any benefit option [if such a medical scheme provides members with more than one benefit option] that constitutes complementary or top-up cover and that does not overlap with the personal health care service benefits purchased by the National Health Insurance Fund on behalf of users...'. [p. 37]

What takes place during this 'transition period', in respect of Medical Schemes, until the day/date that the Minister 'determines' that the NHI is 'fully implemented' is unclear from the NHI Bill's provisions. It is not clear what notice periods will be applicable to manage the transition in the best interests of all patients.

Thus, once NHI is declared 'fully implemented' medical schemes may be restricted to only providing approved complementary cover which includes (see above) reimbursement for services not covered by the NHI and top-up cover. For patients excluded from the NHI or who do not qualify or have not (or cannot) register per the procedures set out for registration as a 'user' (for e.g., a foreign national working in SA on a work permit, including foreign embassy staff, MNC staff, academics, artists, etc.) it is unclear how and where they will access basic health services if schemes and top-up companies are restricted in what they can cover and offer outside of NHI approved services.

SECTION 8:

Access to Medicines

The Status Quo and the Proposed Mechanics of Medicine Selection and Procurement

Currently the public accesses medicines from the State or from private providers such as pharmacies (prescribed by a doctor) where some or all the costs are underwritten by medical schemes. Alternatively, where a patient has no medical scheme cover or has exhausted their benefits, they pay for medicines in full (out-of-pocket expenses).

Medicines procurement is governed by the Public Finance Management Act (1999), the Preferential Procurement Policy Framework Act (2005), the Constitution (1996), and the Medicines and Related Substances Act, 101 of 1965. In particular the Public Finance Management Act provides that government departments (here Health) must maintain an 'appropriate procurement and provisioning system that is fair, equitable, transparent, competitive and cost-effective'.[52] Section 217 of the Constitution provides that 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'.[53]

Currently, medicines selected for use by the public sector are available at all levels of care (primary, secondary, tertiary, and quaternary). They are selected by the National Essential Medicines List Committee (NEMLC).[54] The NEMLC is backed by three expert review committees.[55] The NDoH ordinarily enters public procurement contracts through a tender process and at times engages in single provider negotiation, where there is only one manufacturer/supplier. Emergency procurement for national and/or provincial purposes is possible but involves a different process. Health facilities that wish to procure medicines that are not included on the National Essential Medicines List must submit a 'motivation submission' to (for now) provincial Pharmaceutical and Therapeutics Committees.[56] Private providers buy medicines from wholesalers, distributors, or manufacturers, where the price is governed by national legislation related to the SEP system. Medical schemes have numerous medicine lists (known as drug formularies) available for various benefit options. These lists are subject to annual review, and can be updated due to price changes, safety warnings, improved medicines entering the market or changes in disease specific treatment guidelines, among others.[57]

While the implementation of the SEP system in SA was meant to be the first phase of addressing pricing concerns in our country (for ex-manufacturer price), the second phase[58] required the Minister of Health to publish a methodology for 'conforming' to international benchmarks – commonly referred to as the ERP methodology.

The ERP Methodology and current outstanding regulations

In December 2006, a draft ERP methodology was published for comment, and then again in 2014.[59] By 2019, the ERP had still not been finalised or adopted because the pharmaceutical industry repeatedly challenged[60] its implementation by questioning the basket of comparison countries (the selected countries included Australia, Canada, New Zealand, Spain, and SA) and the use of the 'lowest', instead of the 'average' price.[61]

For this and other reasons, SA's international benchmarking regulations for medicines have to date not been finalised. This affects many patients and their access to affordable medicines as patients in SA are likely to be paying more for the same medicines than people in selected benchmark countries.

The price of medicines can also be inflated by a lack of proper regulation of bonuses, discounts, rebates, and other incentive schemes. Regulating these aspects under the NHI will therefore be critical.[62]

In 2019, Cassar and Suleman published results from an 'international benchmarking exercise' using the 2014 ERP methodology to assess the price of immunosuppressive medicines for transplant recipients in SA over a three-year period. They found that the private sector prices were higher in SA when compared to Spain, Canada, New Zealand, and Australia.

Limitations of current two-tier medicine pricing system

The current dual system of medicine purchasing and pricing in SA has been criticised for failing to adequately protect patients.[63] This was also highlighted by the South African National Planning Commission in 2020 and the HMI carried out by the Competition Commission which was finalised in 2019.

South African National Planning Commission Report on Pharmaceutical Pricing Policies (2020)

In early 2020 the National Planning Commission (NPC) published a research report on Pharmaceutical Pricing Policies[64]:

The NPC report highlighted that:

1. The 'dispensing fee' in the private or non-state sector adds to the cost of certain lower-priced medicines onto patients, and as a result increases the price of medicines.
2. While India and SA may have the lowest prices for antiretrovirals (ARVs) in the world they had different pricing approaches. The 'Indian government issued a compulsory licence for ARV drugs [...]' and this increased access to generic medicines in the market. In SA, the government relied on its purchasing power and negotiated significant discounts on the unit price of ARVs.

3. The price of medicines to treat non-communicable diseases such as diabetes and cardiac diseases remain high when compared to countries such as Brazil, India, Spain, and New Zealand.[65]
4. The massive price differentials between ARVs and medicines for non-communicable diseases is the result of the lack of a proper price referencing system.

Below we set out what the NPC recommended in its Report and the implementation status:

Table 1: National Planning Commission Recommendations and Status

NPC Recommended	Implemented / Not Implemented[66]
Enhance the regulatory powers of the Pricing Committee to allow them to interrogate and negotiate prices of originator and generic drugs with manufacturers.	Not done
Strengthen the disclosure obligations of manufacturers to provide information on costs, volumes and the actual (not just planned) logistics fees to the Pricing Committee.	Not done – could be expedited if the DG (Director-General) of Health requests this information
Conduct a regulatory impact assessment on the current regulations relating to dispensing fees to determine how its regressive nature impacts on the affordability of medicines (especially lower-priced ones) across the income quintiles.	Under review
The NDoH to build capacity within government to implement the ERP and, over the medium to long term, government should consider adopting a value-based pricing methodology.	Not finalised
The NDoH should establish a real-time medicine inventory monitoring system that provides the information it needs to better forecast demand for drugs on the Essential Medicines List.	Dashboard is in place
The NDoH should develop and implement a monitoring system that collects consistent and longitudinal data on the prices, volumes, and costs of medicines across therapeutic categories, and by generic and originator across public and private sectors.	Appears that medical schemes are providing this information to the NDoH

Competition Commission Health Market Inquiry (HMI) Report (2019)

The Competition Commission initiated the HMI in 2013 and issued its Report in 2019.[67] The following key health role players were identified by the HMI in the public and private health sectors:

1. Public health sector;
2. Regulatory bodies;
3. Medical product suppliers;
4. Private healthcare providers (practitioners, facilities, emergency services and pharmacies);
5. Private healthcare funders; and
6. Industry bodies.

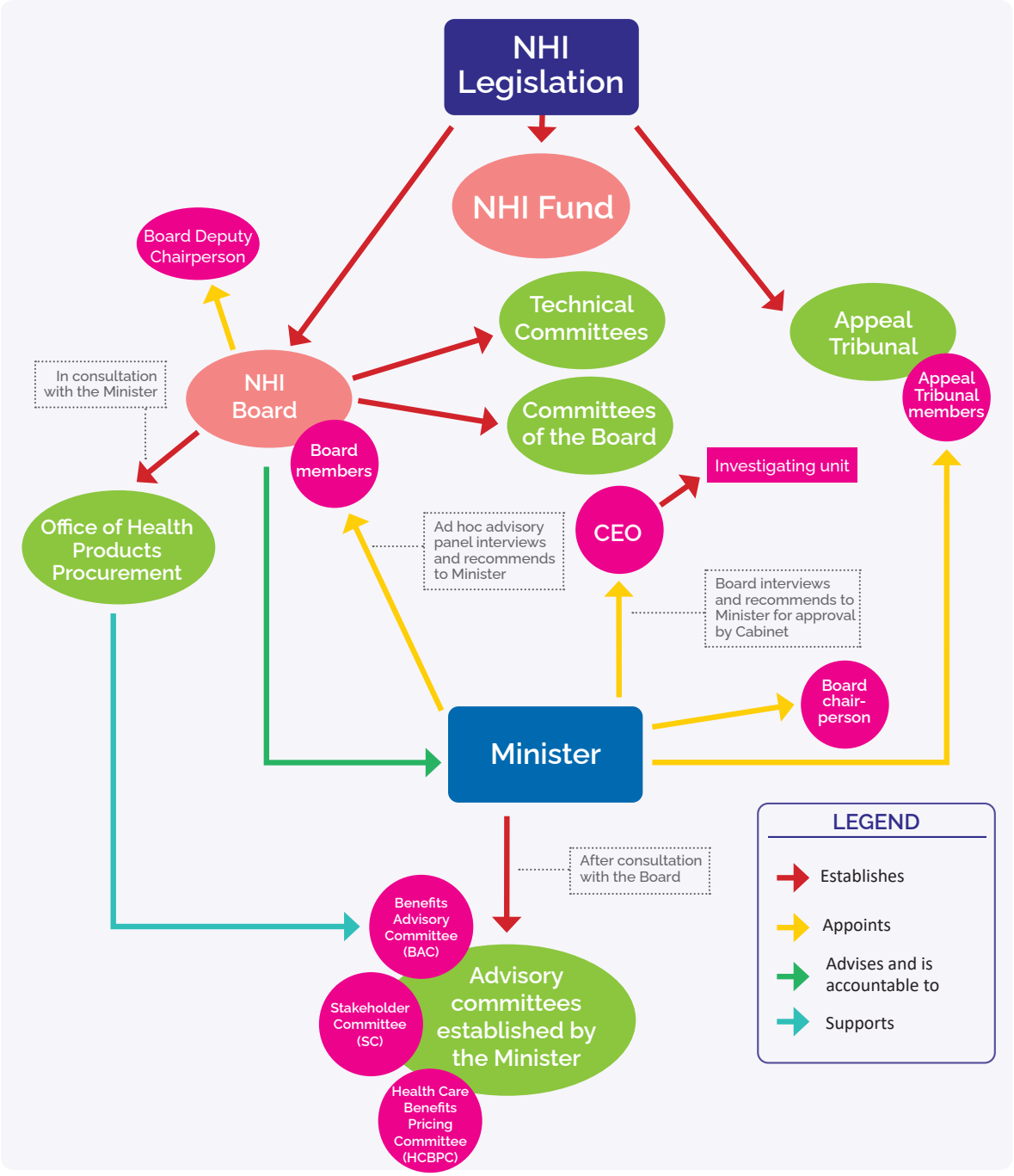
The HMI Report discussed at the interplay between private financers, providers, practitioners and the role of regulation and regulatory bodies governing that interaction (the HMI did not include medicine pricing in its ambit).[68] The HMI Report found significant market failures and a worrying lack of proper regulation, that impede market competition. Among others, it recommended the establishment of a dedicated healthcare regulatory authority.

SECTION 9:

Structure and Mechanics of Medicine Selection and Procurement in the NHI Bill

The NHI Bill is 60 pages in length and includes provisions to operationalise the NHI in phases. Below we focus on some of the key provisions that may affect the selection, procurement and provision of life-saving medicines and vaccines.

Figure 3: Summary Diagram of Power and Decision-making under the NHI Bill



Establishment of the National Health Insurance Fund

Chapter 3 of the NHI Bill establishes a NHI Fund as an 'autonomous public entity' overseen by the Minister [of Health] and governed by the NHI Board.[69]

According to the NHI Bill:

1. The NHI Fund will 'pool' allocated financial resources to purchase medicines, health services and health products from accredited providers (healthcare service providers, establishments, and suppliers) and determine the payment rates annually for providers.
2. The NHI Fund will have the power to enter into contracts for the procurement and supply of specific medicines, health-related products, and healthcare service providers with accredited suppliers, to meet the healthcare needs of its users.
3. The NHI Fund will be responsible for contracts for the 'procurement and supply of specific health care services, medicines, health goods and health-related products with an accredited health care service provider, health establishment or supplier', and must negotiate the lowest possible price for goods and health care services.[70]

Establishment of the National Health Insurance Board

Chapter 4 of the NHI Bill establishes a NHI Board that is accountable to the Minister, to govern the NHI Fund (see below). The Minister must appoint members to the NHI Board, and it will be one of the most important exercises of Ministerial discretion and power under the NHI scheme. Chapters 6 and 7 also reference the role of the NHI Board.[71]

According to the NHI Bill the NHI Board must work closely with the Minister, and it will also oversee the 'transition' until the NHI Fund is fully implemented and in certain instances it must be consulted on certain decisions by the Minister.

1. The Minister will appoint 11 persons who are not employed by the NHI Fund (see below) to the NHI Board, and at least one of the NHI Board members will act as a 'representative' of the Minister (Section 13).
2. Sections 23 and 24 of the NHI Bill also provide that the NHI Board will be permitted to establish Technical Committees that are necessary to achieve the purpose of the Act.
3. Sections 25 to 27 provide that the Minister must, after consultation with the NHI Board, establish a:
    a. Benefits Advisory Committee;
    b. Health Care Benefits Pricing Committee and
    c. Stakeholder Advisory Committee.
4. As set out in Section 15, the NHI Board must also advise the Minister, inter alia, on:
    a. the management and administration of the NHI Fund;
    b. the development of comprehensive health care services to be funded by the NHI Fund through the Benefits Advisory Committee;
    c. the pricing of health care services to be purchased by the NHI Fund through the Health Care Benefits Pricing Committee;

5. The NHI Board will have broad discretion and power and will determine its own procedures in consultation with the Minister (Section 17). It will also be responsible for:
    a. Governance of the NHI Fund as the accounting authority (Section 15).
    b. Appointing the Office of Health Products Procurement (OHPP). And in turn, the OHPP (see below) will advise the NHI Board on 'any matter pertinent to the procurement of health-related products' (Section 38).
    c. Interviewing and recommending the Chief Executive Officer of the NHI Fund (Section 19).
    d. It may also evaluate and advise on any 'practices and decisions of the NHI Fund or the Chief Executive Officer' and 'must inform the Minister of any advice it gives to the CEO' (Section 15).
    e. Appointing the Deputy Chairperson of the NHI Board (Section 14).

Establishment of the Office of Health Products Procurement (OHPP)

Chapter 8 of the NHI Bill includes the establishment of the Office of Health Products Procurement (OHPP).[72]

1. Section 38 provides that the NHI Board, in consultation with the Minister, must establish an OHPP which will set the parameters for the public procurement of health-related products.
2. The OHPP will be a departmental unit appointed by the NHI Board with a legislative mandate that, among other things, permits it to negotiate procurement contracts and prices.
3. The OHPP will be located within the NHI Fund and is responsible for the 'centralised facilitation and coordination of functions related to the public procurement of health-related products, [including medicines]'.
    a. It is unclear what proportion of current NDoH staff that deal with medicine selection and procurement will be transferred in the transition and post transition phases (to the OHPP), by when and under what HR conditions.
    b. The number of people that will staff the OHPP is not stated in the NHI Bill.
4. The OHPP will determine, with the Benefits Advisory Committee, the National Health Council and the NHI Fund, the selection of health-related products to be procured and develop a 'national health products list.'
5. The OHPP is required to support the Benefits Advisory Committee (see below) in the development and maintenance of the NHI Formulary.[73]
    a. Accredited healthcare service providers and health establishments are required to procure medicines according to the NHI Formulary.
    b. A review of the NHI Formulary will be conducted at least annually.

OHPP and Procurement

For any patient who wishes to secure affordable and timely access to life-saving medicines, the OHPP is likely to become one of the most important offices in and for SA's planned unified health system under the NHI. Because the OHPP is tasked with developing and updating the NHI Formulary and national health products list it must also manage all aspects of procurement.

The NHI Bill provides that the OHPP is required to:

1. Coordinate supply chain management processes and price negotiations;
2. Facilitate cost-effective, equitable and appropriate public procurement;
3. Support the processes of ordering and distribution of health-related products nationally and at district level;
4. Support the District Health Management Office in concluding and managing contracts with suppliers and vendors;
5. Establish mechanisms to monitor and evaluate the risks inherent in the public procurement process; and
6. Facilitate the procurement of high-cost devices and equipment. The NHI Bill also refers to the concept of 'strategic purchasing' – vaguely defined as the 'active purchasing of health care services by the pooling of funds and the purchasing of comprehensive health care services from accredited and contracted providers on behalf of the population'. No further details are provided in the NHI Bill on this aspect.

The OHPP (in addition to supporting the Benefits Advisory Committee and undertaking the procurement aspects) must also advise the NHI Board on 'any matter pertinent to the procurement of health-related products'.

Establishment of the NHI Technical and Advisory Committees (Responsible for Medicine Selection and Procurement)

Chapter 6 of the NHI Bill provides that the NHI Board will be permitted to establish Technical Committees that are necessary to achieve the purpose of the Act.[74] Chapter 7 provides for three key Ministerial Advisory Committees that must be established by the Minister. They are the:

1. Benefits Advisory Committee;
2. Health Care Benefits Pricing Committee; and
3. Stakeholder Committee.

The key membership and other features (roles) of these three committees are summarised below:

Benefits Advisory Committee

Section 25 of the NHI Bill provides that the Minister must, after consultation with the NHI Board, establish a Benefits Advisory Committee and the Minister must appoint the Chairperson.

1. The minimum/maximum number of committee members is not stated. But members must be persons with 'technical expertise in medicine, public health, health economics, epidemiology, and the rights of patients,' and 'one member must represent the Minister'.
2. Members will serve for a period of five years and be reappointed for one term only.
3. Members will determine cost-effective treatment guidelines and consider emerging technologies and recommend health care benefits to the NHI Fund.

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Health Care Benefits Pricing Committee

Section 26 provides that the Minister must, after consultation with the NHI Board, establish a Health Care Benefits Pricing Committee and the Minister must appoint the Chairperson.

1. The committee will consist of not less than 16 and not more than 24 members. Members must be persons with 'expertise in actuarial science, medicines, epidemiology, health management, health economics, health financing, labour and rights of patients,' and 'one member must represent the Minister'.
2. The term or duration of service for committee members is not stated.
3. The Health Care Benefits Pricing Committee must recommend the prices of health service benefits to the NHI Fund. The frequency of price reviews is not mentioned in this section of the NHI Bill.

Stakeholder Advisory Committee

Section 27 of the NHI Bill provides that the Minister must, after consultation with the NHI Board, establish a Stakeholder Advisory Committee.

1. The minimum/maximum number of committee members is not stated. It is not clear who must appoint the Chairperson.
2. The term or duration of service for committee members and role is not specified/stated.
3. Members must include 'representatives from the statutory health professions councils, health public entities, organised labour, civil society organisations, associations of health professionals and providers, and patient advocacy groups'.

Given the important role that these Advisory Committees will play in the broader NHI scheme, we looked at whether there is any explicit provisions in the NHI Bill related to:

a. Transparency of the Advisory Committees with a focus on provisions for the timely publication of formal advice

We found none. This is a concern because in a current Promotion of Access to Information matter [in which the HJI is requesting the timely and automatic disclosure of all expert advisers details and their advice in the COVID-19 pandemic] the Deputy Director-General of Health (DDG) stated that, notwithstanding that the Department has since uploaded several MAC Advisories, the Minister still has a 'broad discretion' in relation to advice given by such Advisory Committees and is 'not obliged' to publish any or all expert advice received from any and especially the Ministerial Advisory Committees on COVID-19 and Vaccines (MAC and VMAC) nor within a set time period.[75]

b. Nomination or opposition to appointments of individuals to Advisory Committees

We found none. This is a concern because in the COVID-19 pandemic in 2020, the then-Minister of Health controversially removed and replaced several members of the COVID-19 Ministerial Advisory Committee (MAC), for which it was subsequently heavily criticised.[76]

The then-Minister did not share the full reasons for their removal and did so without adequate notification according to media reports.[77] For some time, the NDoH did not publicly share the details of all the individuals it appointed to various Advisory Committees in the pandemic, nor has it disclosed all the names of other expert advisers to the Minister who may offer advice in parallel to the MACs.

At that time, News24 filed two PAIA (Promotion of Access to Information Act) requests, in May and June 2020, for approximately 70 MAC Advisories to be disclosed/published.[78] During a press briefing on 13 July 2020 the then-Minister of Health explicitly stated that the MAC Advisories would not be published. After pressure by civil society, the media and health care personnel and MAC members, the NDoH finally shared these on the Coronavirus portal during August 2020.[79]

Access to information and transparency in health sector decision-making and contracting

The HJI requested the proactive and timely disclosure of, inter alia, all Covid-19 pandemic-related expert advice. This request was not responded to and so the HJI filed PAIA requests in 2021 for the disclosure of the names of all local and international expert advisers to the NDoH/ Minister, and for the release of all MAC Advisories (specifically related to the advice on prioritisation for people with comorbidities, and the expert advice that led to the pausing of the AstraZeneca/ Covishield/Serum II vaccine roll-out and details related to its onward sale/ donation). These were refused.

Fortunately, because of pressure from media houses and civic groups as well as some scientists/researchers, several MAC advisories were eventually made public including on the SACoronavirus portal on the NDoH website from August 2020 to June 2022. News24's and HJI's PAIA requests activated, at least in part, the bulk upload of several MAC advisories in 2021.

The HJI's analysis of MAC Advisories published between August 2020 and August 2021 showed that on average there was a delay of 68 days between the submission and publishing of MAC Advisories, and 111 days for the VMAC.

The rest of the information requested by the HJI was not provided. Following what is called a 'deemed refusal', in March 2022 the HJI filed a court application to compel disclosure of all outstanding information and details and, for future purposes, disclosure of expert advice within 72 hours in a pandemic in the interests of pandemic transparency.

The NDoH belatedly filed its answering affidavit in July 2022.

The NDoH did not disclose all the expert names and details, nor the expert opinion and advice related to the pausing of the AstraZeneca/Covishield/Serum II vaccine roll-out which influenced vaccine selection and procurement for SA in 2021, nor the comorbidity prioritisation framework, nor the national vaccine strategy.

In respect of the AstraZeneca/Covishield/Serum II roll-out that was paused, the NDoH stated that this decision was made by Cabinet and that 'the minutes of Cabinet are protected from disclosure in terms of PAIA' (paragraph 30 of answering affidavit). It did not disclose the names of all the international experts advising the Minister because it argued that the 'list of experts is also a moving target, as and when one expert becomes unavailable, advice is sought from another expert' (paragraph 59).

In response to the HJI's application, the NDoH stated in court papers and also to the media that:

a. *In addition to the MACs, the Minister is/was advised by multiple other experts including the President of the SA Medical Research Council (professor Glenda Gray) and the former MAC Chairperson, Professor Salim Abdool Karim (Epidemiologist, University of KwaZulu Natal) and individuals from the World Health Organization.*

b. *The onward sale agreement details for the AstraZeneca/Covishield/Serum II vaccine is with the National Treasury, not the NDoH.*

c. *There is no constitutional obligation on the Minister of Health to make any of the advice of the MACs publicly available.*

Note: Only a single Social and Behavioural Change Advisory has been published to date.

Based on how the NDoH managed the issue of the disclosure of expert advice in a pandemic, the HJI recommends there should be explicit provisions that create legal obligations for the timely publication of not just the names of members of all and any of the Ministers Advisers but of all expert advisories too. This not only helps to build public trust in scientific and expert decision-making, but it will also avoid a situation where a minister's 'executive discretion' is invoked to only share information when he/she deems it appropriate – making it difficult for the public to establish what is not in the public domain and why. Not doing so creates a negative precedent for proactive disclosure of information in an open and democratic society.

c. Managing conflicts of interest for Advisory Committee members

The NHI Bill's provisions on declaring and managing conflicts of interest are very general in nature. It simply provides that committee members who have a 'personal or financial interest in any matter on which such committee gives advice, must disclose that interest when that matter is discussed and be recused during the discussion'. The NHI Bill thus does not provide for mandatory public disclosure (like a parliamentary declaration register).

Because medicine selection will also be tied to substantial procurement using public funds, these provisions require substantial strengthening. This is also because the risk of vested interests or even perceived conflicts of interest (for example, experts who run clinical trials for a medical product, should have no direct or indirect role in its selection for national use) in shaping medicine selection, and in turn procurement, is high, and should be managed accordingly – also with proactive measures.

The next version of the NHI Bill needs to include explicit provisions for the automatic public declaration of all members' interests, processes for managing these and how the public and patient advocacy groups could request the non-appointment or removal of a committee member related to a conflict of interest.

d. Roles and qualifications of Advisory Committee members

The NHI Bill's provisions are very general. Advisory committees are however required to perform their functions 'impartially and without fear, favour or prejudice'.

The NHI Bill does state that individuals appointed to Advisory Committees are required to (a) be fit and proper; (b) have appropriate expertise or experience; and (c) have the ability to perform effectively as a member of that committee.

In very general terms, the NHI Bill states that Advisory Committee members must not expose themselves to:

(a) '... any situation in which the risk of a conflict between his or her official responsibilities and private interests may arise; or

(b) use his or her position, or any information entrusted to him or her, for self-enrichment or to improperly benefit any other person.'

It is unclear who will assess this risk and manage it accordingly. Presumably the Chairperson of the relevant Advisory Committee will decide and rule on ordinary members' conflicts of interest. It is unclear who will be tasked with managing any of the Minister-appointed Chairpersons' conflicts.

The NHI Appeal Tribunal

Section 43 of the NHI Bill provides that anyone may appeal against any decision of the NHI Fund within 60 days, to a newly created NHI Appeal Tribunal, which will have the same powers as a High Court. However, while establishing the Appeal Tribunal, the NHI Bill does not preclude the public from seeking relief in an ordinary court of law.

Section 44 provides that the Minister will appoint the NHI Appeal Tribunal.

It will be made up of five persons who will serve for three years (with a single renewable term), of which:

1. One person must have a legal background, who will also serve as the Chairperson of the Appeal Tribunal.
2. Two people must have a medical background; and
3. Two people must have a financial background.

(We assume here that no appeals for 'non-selection' of medicines will be permitted unless clinical efficacy through regulatory approval has been proven.)

SECTION 10:

Moving from a Two-Tiered Health System to a Single Health System

The NHI Bill proposes a single medicine pricing system for the entire country, and the conversion of the existing private sector SEP system for use by the NHI Fund. This will require a carefully thought-out transition process. The NHI Bill also mentions a phased-in implementation of NHI in the country using 'a progressive and programmatic approach based on financial resource availability'. The transitional arrangements are set out in Section 57 of the NHI Bill and refer to two key phases:

Phase 1, for a period of five years from 2017 to 2022:

To continue implementing 'health system strengthening initiatives', including the alignment of human resources; develop NHI legislation and required legislative amendments; establish institutions for the NHI Fund to function; and include the 'purchasing of personal health care services for vulnerable groups such as children, women, people with disabilities and the elderly'.

Phase 2, for a period of four years from 2022 to 2026:

To continue 'health system strengthening initiatives on an on-going basis; the mobilisation of additional resources; and selective contracting of health care services from private providers'. Recently the DDG of Health in charge of NHI stated that while the second phase would ideally run between the period 2022-2026, there was doubt whether the NHI Fund would be functional by 2026, mainly due to delays and challenges created by the COVID-19 pandemic, and suggested that it could take decades for the NHI to fully come into effect.[80] The speed at which NHI may be expected to be rolled out against the backdrop of upcoming national elections [in 2024] is something to monitor. At its National Policy Conference in 2022 the ANC (the ruling party in SA, with a majority in the National Assembly) reaffirmed prior resolutions on NHI and called for the 'expedition of the NHI Bill [in] Parliament'.[81]

Pricing Mechanisms Conversion and the NHI

a. Amending the status quo on medicine pricing

One of the most critical aspects in the NHI Bill affecting future access to medicine is the proposed amendment of Section 22 of the Medicines and Related Substances Act, 1965, related to the current private sector SEP (medicine pricing system) in SA.

Section 22 of the Medicines Act reads:

> G(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.

Section 58 of the NHI Bill and the accompanying Schedule set out the proposed amendments. Section 58 includes the amendment of Section 22 of the Medicines Act in the following way *(amendments are underlined; words in **bold** type in [square brackets] indicate omissions from existing legislation):*

> Section 58 of the NHI Bill:
>
> (a) The transparent pricing system contemplated in subsection (2)(a) shall include a single exit price which shall be published as prescribed by the Office of Health Products Procurement contemplated in subsection (1), and such price shall be the only price at which manufacturers shall sell medicines and Scheduled substances to **[any person other than the State]** the National Health Insurance Fund established by section 9 of the National Health Insurance Act, 2019, or any other person.

This means that, with the proposed transitional arrangements (which are uncertain in duration as they have not been specifically set out in the NHI Bill), the entire country's medicine pricing system could be governed by the current SEP mechanism as the contradictory portion of the NHI Bill states that the SEP (issued by the OHPP) shall be the only price at which manufacturers shall sell to the NHI Fund or any other person (amendment to the Medicines Act).

If there is going to be a market for non-users of the NHI Fund, or for medicines that are not procured by the NHI Fund, then the danger is it may be unregulated. Therefore, the jurisdiction of competition authorities is even more important (see below).

At the level of providers, it is also difficult to understand who is contracting whom. The Contracting Units for Primary Healthcare Services (CUPS) are made up of providers, so they cannot contract themselves and yet the District Health Management Offices (DHMOs) will struggle to contract especially if they cannot contract a public sector provider (if the latter fails to get Office of Health Standards Compliance (OHSC) accreditation).

Several medicine pricing experts have warned that the current SEP mechanism cannot simply be shifted from the private sector (covering all medicines, apart from Schedule 0 medicines, and covering about 25% of people) to NHI (for everyone), leaving the non-NHI market unregulated.

1. The implementation of a SEP could take years (transitional plans need to be carefully thought through).
2. The SEP is also linked with dispensing fees and SEPA (annual single price *adjustment*) processes, and those have not been addressed in the NHI Bill.
3. The transitional period to carry out this proposed migration is likely to be protracted, when the NHI benefit package is slowly expanded from primary healthcare to more sophisticated services. While that happens, the State will still need to provide central hospital services.
4. The private sector, likewise, will not stop providing services across the board. Experts also warn that a prohibition on providing services that are within the benefit package to those who choose to buy them elsewhere is not likely to survive a constitutional challenge.

SECTION 11:

Other Stakeholders (Concerns and Questions)

Issues Raised by Regulatory Stakeholders (Role of Competition Law)

> *"Any exemption should be based on a careful consideration of the potential consequences [...] what is unusual, if not unheard of, is the blanket exemption of entire social healthcare systems from competition law enforcement."*
>
> *Competition Commission Submission to Parliament, 2022*[82]

Section 3(5) of the NHI Bill provides that:

> '...the Competition Act, 1998 (Act No. 89 of 1998), is not applicable to any transactions concluded in terms of this Act'.

The NHI Bill thus seeks to exclude the NHI scheme from the jurisdiction of competition authorities and applicable competition laws. This is a key concern for medicine pricing practices and risks preventing the proper redress of collusion and other anti-competitive pricing practices among private providers.

In its presentation to Parliament, the Competition Commission stated that such an exemption would create unintended consequences potentially affecting patient access because, in its view:[83]

1. The Competition Act (1998) as it stands does offer mechanisms to protect the NHI's activities as Section 3 of the Competition Act would apply to the work of the NHI.[84]
2. If the Competition Act is not applicable, it would exclude the Competition Commission from investigating collusion, excessive pricing, gouging, abusive practices, and other anti-competitive practices (including in merger negotiations) on the part of private healthcare providers and monopolies. And this is a critical safeguard for patients, highlighted by the anti-gouging work of the Commission during the COVID-19 pandemic.[85]

Specifically, the Competition Commission warned that the proposed exemption could have the effect of undermining the purpose of the Fund to 'negotiate the lowest possible price for goods and healthcare services' when entering contracts with accredited healthcare service providers and health establishments at primary health care and hospital levels.

It will similarly undermine the Fund's ability to negotiate low prices with other service providers not in the healthcare industry. Other service providers may even be in a stronger bargaining position relative to the Fund compared with healthcare service providers, as many will be able sell to other parties besides the Fund (the Fund will not have monopoly power in those circumstances). The Competition Commission also raised several other areas where it felt that the NHI Bill was unclear.[86]

Issues Raised by Some Private Health Sector Stakeholders During Public Hearings

(See also Annexure A)

The HJI analysed meeting minutes and presentations by several private health sector stakeholders who made submissions to the Portfolio Committee [on Health] between 18 May 2021 and 29 March 2022. We looked at these submissions because of the risk of future legal challenges by the [private health industry].

Below we summarise some of the issues raised by five private health organisations/groups/companies (the Self-Care Association of SA, Health Products Association of SA, Johnson & Johnson[87], Black Business Council, and the Pharmaceutical Task Group).

The private healthcare organisations asked the following (in summary):

1. The NHI Bill is unclear on how medicines that are not covered in the NHI Fund would be priced or accessible for patients or individuals who wish to buy or use them privately – as prescribed by a doctor (the 'Office of Health Procurement Products' will procure medicines recommended by a 'Benefit Advisory Committee' under the NHI) and will individuals have to make out-of-pocket or co-payments to access those medicines (where not on top-up insurance)?
2. How will the market for medicines outside of the NHI Fund be regulated?
3. The NHI Bill lacks detail on how the medicines will be priced.
4. The NHI Bill is not specific on how low to medium risk medicines will be priced.

SECTION 12:

Key Questions from the Health Justice Initiative (October 2022)

The medicine selection process in the NHI Bill is complex and proposes several parallel advisory structures – at times in a contradictory manner. The HJI analysed the limited provisions in the NHI Bill specifically focusing on the selection, procurement, and pricing of medicines under the proposed NHI scheme for SA. Because there is little information included in the NHI Bill on the exact mechanics, and there are still many unanswered questions that should not simply be left to regulations (for example, migration to a single procurement medicine system will be complex and time-consuming) we list some key questions below:

Note: At the time when public submissions were invited in 2019 the HJI was not yet established, and the Portfolio Committee on Health was unable to accept a submission from the HJI upon our establishment in 2020. As a result, the HJI has developed a set of questions that hopefully will support the legislature and even the executive in this process. We also hope that journalists focusing on this area of work will help elevate these questions for proper discussion among relevant policy and law makers for adequate resolution.

The Health Justice Initiative's 17 Questions on the NHI and Medicine Access

Note: This is an expanded version of the questions that appears at the front of this Issue Paper.

1. Given the planned use of public resources through user contributions, and the constitutional imperative for transparency in contracting, all medicine selection, procurement, and contracting processes under the NHI require transparency and accountability. What specific proactive and public transparency measures are envisaged under the NHI?
2. Will deliberations of the NHI ministerial advisory committees and in particular the Health Care Benefits Pricing Committee be open to the public?
    a. Will the recommendations from advisory committees, including on medicine selection, be made public via legislative obligation or only by ministerial 'choice' and by when?
    b. When and how will this information be shared with the public (if at all) and how often will it be shared?
3. Given that not everyone living in SA will be regarded by the state as a 'user' of the NHI Fund, will medicine manufacturers (suppliers, licensees etc) be permitted to sell medicines to any other health provider, other than the state? If so, under what circumstances and at what maximum price?

4. Which medicines will automatically be covered under NHI benefits as part of the NHI Formulary?

   a. Will the NHI Formulary automatically be drawn from current national health protocols and the prescribed minimum benefits (PMB) list?

   b. On which public/government communications site will this information be available?

   c. Can the inclusion and exclusion of specific medicines in the NHI Formulary be appealed on non-clinical grounds, and by whom?

5. Which medicines will not be covered to begin with under NHI benefits as part of the NHI Formulary – and, over time, on what basis (criteria) will this exclusion be decided?

   a. How exactly will poorer patients access certain lifesaving (prevention and treatment) medicines that may not immediately be included in and covered by the NHI due to the state's budgetary limitations and cost considerations, and from who will these patients be able to access the necessary treatment or medicines?

   b. Will humanitarian organisations be permitted to do so on their behalf and how?

6. Will wealthier people who are also required to be registered users of the NHI fund, be able to bypass state (NHI) medicine selection and purchase more expensive life-saving and other medicines on their own or with others, where the state is not a position to procure these itself? Will this be a temporary situation only or indefinitely permitted?

7. 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? Because medicines will be sold to certified and accredited providers at prices determined by the Health Care Benefits Pricing Committee and provided to patients covered by the NHI Fund, public sector health facilities will need to procure medicines – but they too will have to be certified and accredited providers.

   a. What role, if any, will the External Reference Pricing (ERP) methodology play in the NHI and potentially beyond it?

9. Who in the NHI Fund (e.g., the Office of Health Products Procurement, the NHI Board) will negotiate with global pharmaceutical manufacturers and suppliers on behalf of the NHI Fund in order to procure for the state, and how will that process be transparent and accountable?

   a. Will there be a high-level dedicated procurement team conversant in complex contract negotiations? Who will this procurement team consist of, and which departments will be represented?

   b. How will the envisaged procurement system achieve transparent and open decision making?

   c. What provisions need to be included in the NHI framework to achieve this?

   d. Will all procurement bids and contractual agreements be made public automatically to encourage proactive disclosure?

10 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?

a. What contingency plans are there, should there be any legal challenges by private providers to changing or extending the SEP system?

b. When and how will a unified medicine selection and procurement system come into effect?

c. Will dispensing fees be charged or will there be another provider payment mechanism implemented to replace them?

d. The SEP system does not cover Section 21 medicines. How will these exceptions be managed?

11 Why has the jurisdiction of the Competition Commission been excluded? Regulation is vital for enforcement of anti-competitive practices such as price gouging/excessive pricing, collusion, and abuse of dominance by private providers to the NHI Fund and those outside of the ambit of the NHI Fund.

a. Other than the Competition Commission, which other statutory body will be legally tasked with providing the necessary regulation of price and competition?

12 What takes place in the transition period in respect of medical schemes until the 'day' that the Minister determines that the NHI is 'fully implemented' - as that Ministerial determination will restrict what medical schemes can offer by way of coverage to medical scheme members after that day/date (per the NHI Bill - only 'complementary cover' will be permitted after that date (not defined as yet).

13 How will NHI regulate private providers/schemes and insurance products and transition to a fully implemented NHI system without prejudicing existing or even newer members? Given the socio-economic context of the country and growing unemployment, mandatory NHI contributions are likely to be based on uncertain employment trends. Medical scheme and 'top-up' insurance benefits and products may not be widely affordable and available to more people, unless there is proper regulation of premiums and entry requirements.

a. Will provisions related to 'late-joiner penalties' and' waiting periods' under the Medical Schemes Act be repealed. If yes, by when?

b. What conditions and rules will govern top-up products or new joiners of medical schemes, given a policy preference to move away from 'risk rating' and to give effect to the objectives of the NHI?

14 Has consideration been given to designing a competitive and different single medicine pricing system for SA instead?

a. Is there a technical multi-department expert task team working on this aspect in particular?

15 Aside from clinical effectiveness, if cost is going to be a key factor for selection and inclusion – what measures if any will the NHI Fund be permitted to take or recommend in respect of reducing costs to ensure inclusion, to give effect to the intent of 'strategic purchasing' as referenced in the NHI Bill?

16 How would SA's Intellectual Property strategy need to adapt in the short to long term to complement the NHI's objectives of securing the 'best available medicines' in the most affordable way, and by when will this happen?

17 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?

CONCLUSION

This Issue Paper is intended serve as an entry point for further analysis of several complex issues related to medicine selection, procurement, and access under the planned NHI system, and to raise questions for deliberation and debate. The prospective provisions and changes of the NHI will affect all patients, including those who are not registered users of the NHI Fund.

Part 2 of the HJI's NHI Series will include the outcome of deliberations from a series of workshops and consultative meetings that we will convene between late 2022 and early 2023, with a view to developing a set of technical recommendations for consideration by our lawmakers and Cabinet.

We trust that these questions and ultimately the recommendations will support securing and protecting affordable medicine access for all patients in SA.

ANNEXURE A:

Summaries of submissions by private stakeholder groups on medicine pricing and procurement

1. Self-Care Association of South Africa (SCASA)[88]

The NHI Bill proposes in its Schedule that the SEP will apply to the NHI. The SEP is currently only applicable to private sector and the public sector is governed by tenders as required by Constitution, Public Finance Management Act (and the envisaged new Procurement Bill).

[SCASA] is not in favour of proposed changes in pricing because:

- Self-care Schedule 0 products are already excluded from the SEP system
- Competitive bidding is a constitutional requirement
- In the case of S0 medicines:
  - Market forces work very well in the supply of self-care products
  - Many self-care products would be unavailable in NHI and therefore not fall under its control
  - A price regulatory regime would severely limit the ability of manufacturers, traders, and wholesalers to be responsive to the irrespective markets.

If the new NHI-proposed SEP is applied to Schedule 0 medicines SCASA argued that:

- The variety of market conditions which provide medicine access to patients, cannot be accommodated in a 'single' price system.
- Traders may decide to no longer stock these products as they would not be able to do so profitably, thereby decreasing access to healthcare. Some of the rules for logistics and wholesaling fees would have to apply, which would mean that the logistics would have to be paid off the SEP (as is the case at present), further eroding the profit margin of these traders.
- Only a fixed, maximum dispensing fee would have to be levied, and not a mark-up, making the stocking of, for example, a small two-pack paracetamol unviable.
- A prohibition on bonuses (e.g., buy one get one free), rebates (a discount of sort) and incentive schemes (e.g., marketing and advertising campaigns) would be similarly detrimental in the Schedule 0 market and its traders.

2. Health Products Association (HPA)[89]

On the role of the SEP and its applicability to complementary medicines such as herbal medicines:

- The HPA believed the current exemption on complementary medicines would cease to exist, and its members would be expected to sell such products including S0, Category A, and Category D medicines at SEP.
- The unintended consequences for S0, Category A, and Category D medicines could be extensive. As a result, access to S0 category products would be severely restricted.

3. Johnson & Johnson[90]

According to Johnson & Johnson, the NHI Bill has at least 'five different, and contradictory, proposals in relation to the pricing of medicines and medical devices in the NHI system', namely:

a. 'A set, or regulated, single price as "the only" price of sale into any market in South Africa (section 58 and the Schedule to the Bill), only applicable to medicines.

b. A bid price, under the Public Finance Management Act (PFMA) and National Treasury regulations (clause 38(7)).

c. A negotiated price, to be negotiated with the Fund at the "lowest possible price" (clause 11(2)(e)).

d. Inclusion in the "all-inclusive fee" payable to specialists and hospital services based on performance of, amongst others, the "health goods" (clause 41(3)(b)).

e. A "rate" for, amongst others, suppliers, determined annually by the NHI Fund (clause 10(1)(g)).'

Johnson & Johnson stated:

'The NHI cannot create a procurement system that is contradictory to the Constitution. Section 217 of the Constitution, recognised in clause38(7), states that procurement by any organ of state must be fair, equitable, transparent, competitive, and cost-effective. SEP is no longer suited for the introduction of innovative technologies in the various South African markets. J&J, along with other companies, has proposed risk-sharing-, managed entry-, patient access and other such programmes to facilitate access in the South African market. Further engagements are required with the NDoH on these proposals.'

Proposed changes to the NHI Bill per Johnson & Johnson:

- 'The removal of all references to the SEP in the Schedule to the NHI Bill.
- The possibility of negotiations with the NDoH on the suitability of the current SEP in an evolving market should not be excluded, but the correct place to do so is under the Medicines Act and within the broader framework of the Supply Side Regulator for Health discussions, as recommended by the HMI.
- Allow for negotiations with specialists and hospitals that are not organs of state, to participate in all-inclusive fee negotiations, based on health outcomes and health good performance (clause 41(3)(b)).
- Allow price negotiations with the NHI Fund Office of Health Products and Procurement based on alternative reimbursement models, risk-sharing programmes, portfolio trade-offs, health outcomes, patient assistance programmes, training- and other product support, etc., to be added as a new sub-clause under clause 38(5), within the framework of the PFMA and the Preferential Procurement Policy Framework Act (PPPFA).
- Allow for differential pricing in non-NHI markets.'

4. Black Business Council [91]

The Black Business Council argued that:

- 'The NHI Bill requires clarity on how prices of medicines and Scheduled substances will be determined for purchase by the Fund.
- There is no clear indication of how the "setting of prices" by the Office of Health Products Procurement (OHPP) will work in relation to the "negotiation of prices" by the Fund and the SEP which will apply to the purchases by the Fund.
- There is also no clarity on whether a procurement process will be followed by the Fund to procure medicines and scheduled substances as required by the legislation applicable to public sector procurement.
- The NHI Bill does not adequately delineate the relationship between the SEP system created by the Medicines and Related Substances Act 101 of 1965 ("Medicines Act") and the procurement of medicines at the "lowest possible price" as contemplated in section 11(2)(e) of the NHI Bill.
  - In terms of section 11(2)(e) of the Bill, the Fund may enter into a contract for the procurement and supply of specific healthcare services, medicines, health goods and health-related products with an accredited health care service provider, health establishment or supplier, and must (i.e. is under an obligation), to inter alia "negotiate the lowest possible price for goods and health care services without compromising the interests of users or violating the provisions of this Act or other applicable law."

5. Pharmaceutical Task Group (PTG)[92]

PTG argued that amendments to section 22G of the Medicines Act should be removed from the Schedule to the NHI Bill and that:

- 'A single pricing dispensation is not appropriate for medicines to be procured by the Fund
- A flexible pricing framework that allows differentiated pricing is proposed. This allows responsiveness to the needs of geographical areas, levels of care and negotiations directly with providers, as envisaged by section 38(6) of the Bill.'

Endnotes

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53 Constitution of the Republic of South Africa. 1996. https://www.justice.gov.za/legislation/constitution/saconstitution-web-eng.pdf

54 The Committee is composed of experts in internal medicine, clinical specialities, public health, pharmacology, evidence-based medicine, health economics and bioethics.

55 For primary and hospital care, there are Standard Treatment Guidelines (STGs) for each condition, and the Essential Medicines List is extracted from those. For tertiary/quaternary level, there are no STGs, but medicines are 'recommended 'or 'not recommended'. The Master Health Products List is the actual list of procured medicines across levels of care for the public sector in South Africa. See: 'Master Health Product List (1 August 2022)'. 2022. https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.health.gov.za%2Fwp-content%2Fuploads%2F2022%2F07%2FCurrent-Master-Health-Product-List-1-July-2022.xlsx&wdOrigin=BROWSELINK[Accessed 1 September 2022].

56 Meyer, S., Nqabeni, G. and Tsotetsi, N., 2021. 'Access to Cancer Medicines in SA'. [online] Cancer Alliance, pp.21, 24. Available at: https://canceralliance.co.za/wp-content/uploads/2021/06/Access-to-Cancer-Medicines-SA-April-2021-v3.pdf [Accessed 7 September 2022].

57 Perumal-Pillay, V., & Suleman, F. 2017. 'Selection of essential medicines for South Africa - an analysis of in-depth interviews with national essential medicines list committee members'. BMC Health Services Research, 17(1). doi: 10.1186/s12913-016-1946-9. The lists are drawn up by Clinical and Therapeutics Committees (other than for Discovery, this is outsourced). Apart from clinical and therapeutic considerations, cost is a key factor in selection (IP rules also create additional barriers to affordable access). All medical schemes have to offer Prescribed Minimum Benefits (PMBs) – these are a set of defined benefits to ensure that all medical scheme members have access to certain minimum health services, regardless of the benefit option or the scheme they belong to. But, for the 26 conditions included on the Chronic Disease List (issued by the Council for Medical Schemes (CMS)) there are CMS-specific algorithms. These have rarely been updated, and are not subject to a transparent development process, and do not necessarily match the STGs in the public sector. For patients living with HIV, medical schemes have to offer at least what the state does (ARV regimens).

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59 Medicines and Related Substances Act (Act No. 101 of 1965) www.gov.za/sites/default/files/gcis_document/201409/37625rg10189gon354.pdf [Accessed 8 June 2022].

60 The Constitutional Court of South Africa. 2005.'Minister of Health and Another v New Clicks South Africa (Pty) Ltd and Others'. https://collections.concourt.org.za/handle/20.500.12144/2222 [Accessed 1 September 2022].

61 Wadee, H., Marawa, N., Reddy, L., Sherif, S. and Jitsing, A. 2020. 'Research on Pharmaceutical Pricing Policies Final Report'. National Planning Commission, p.46. https://www.nationalplanningcommission.org.za/assets/Documents/Pharmaceutical%20Pricing%20Policy%20Report%20February%202020.pdf [Accessed 11 May 2022].

62 To date, the Minister has not yet finalised regulations on 'marketing' (per section 18C of the Medicines Act).

63 See also: Gray AL. 2009. 'Medicine pricing interventions – the South African experience'. Southern Med Review. 2009; 2(2): 15-19; and Gray A, Suleman F. 2015. 'Pharmaceutical pricing in South Africa'. In: Babar Z (ed). Pharmaceutical Prices in the 21st Century. Springer International Publishing, Cham, 2015 (pp 251-265); and Gray AL. 2015. 'Pharmaceutical pricing and reimbursement policies: perspectives for the future'. Journal of Pharmaceutical Policy and Practice 2015; 8(Suppl. 1): K3; and Gray A, Suleman F, Patel A, Bannenberg W. 2015. 'South Africa: Implementation of reforms under the National Drug Policy'. World Health Organisation. https://www.who.int/publications/i/item/WHO-HIS-HGF-CaseStudy-15.9 and Yip, Winnie & Hafez, and Reem. 2015. 'Improving health system efficiency: reforms for improving the efficiency of health systems: lessons from 10 country cases'. World Health Organization (WHO). https://apps.who.int/iris/handle/10665/185989

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65 National Planning Commission. 2020. p.48

66 based on information available to HJI (September 2022)

67 Solanki, G.C., Cornell, J. E., Besada, D., Morar, R.L., & Wilkinson, T. 2020. 'The Competition Commission Health Market Inquiry Report: An overview and key imperatives'. SAMJ: South African Medical Journal, 110(2), 88-91. https://dx.doi.org/10.7196/samj.2020.v110i2.14455

68 Competition Commission. 'Health Market Inquiry Report'. 2019. Retrieved 12 May 2022, from https://www.compcom.co.za/wp-content/uploads/2020/01/Final-Findings-and-recommendations-report-Health-Market-Inquiry.pdf

69 National Health Insurance Bill, 2019.

70 The National Health Insurance Bill, Section 10 states that the fund must also: (a)... purchase such services of sufficient quantity and quality to meet the needs of users; (b) take all reasonable measures to ensure that there may be no interruption to supply for the duration of the contract; (c) conduct its business in a manner that is consistent with the best interests of users; (d) not conduct itself in a manner that contravenes (the NHI) Act.

71 Chapter 6, Section 23: the Board may establish a committee and, subject to conditions as it may impose, delegate or assign any of its powers or duties to a committee so established. Section 24: The Board may also establish a technical committee. Chapter 7: Section 25 - 27: The Minister must, after consultation with the Board and by notice in the gazette, establish the advisory committees (Benefits Advisory, Health Care Benefits Pricing and Stakeholder Advisory Committees).

72 National Health Insurance Bill 2019.

73 National Health Insurance Bill 2019, Section 38. It is comprised of the 'Essential Medicine List and Essential Equipment List as well as a list of health-related products used in the delivery of health care services as approved by the Minister in consultation with the National Health Council and the NHI Fund'.

74 National Health Insurance Bill, 2019.

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81 ANC '6th National Policy Conference Report, 28-31 July 2022, NASREC, Gauteng. https://cisp.cachefly.net/assets/articles/attachments/88865_6th_npc_report.pdf

82 Competition Commission SA, 2022 - NHI Library | Health Justice Initiative. https://nhi.healthjusticeinitiative.org.za/document/competition-commission-2022/ [Accessed 22 September 2022].

83 See: HJI NHI Library. 'Competition Commission SA, 2022'. NHI Power point presentation. https://nhi.healthjusticeinitiative.org.za/document/competition-commission-2022/ [Accessed 1 September 2022].The Competition Commission also stated: 'For activities that warrant exemption, but which fall within the ambit of the Competition Act, there is scope to make use of Section 10 exemption processes, including block exemptions. This is a more measured approach which ensures that exemptions and their implications are carefully thought through prior to being granted and removes the risks of large unintended consequences. Secondly, undertakings are exempted if they are entrusted with the operation of a service of general economic interest ("SGEI")'.

84 The Competition Commission said that 'some of the activities may not constitute "economic activity" or is conduct "designed for a socio-economic objective" and which therefore is excluded based on section 3 of the Competition Act'.

85 See: Competition Commission. 2021. 'Competition Commission publishes final report of its COVID-19 impact study'. https://www.compcom.co.za/wp-content/uploads/2021/04/COMPETITION-COMMISSION-PUBLISHES-FINAL-REPORT-OF-ITS-COVID-19-IMPACT-STUDY-1.pdf [Accessed 1 September 2022]; and Bulbulia, T. 09 October 2021. 'Competition Commission advances efforts to mitigate price gouging during pandemic'. Engineering News. https://www.engineeringnews.co.za/article/competition-commission-advances-efforts-to-mitigate-price-gouging-during-pandemic-2021-09-10 [Accessed 1 September 2022].

86 In its submission the Competition Commission also had the following questions:

What will be the ability of users to choose the healthcare providers at which they are registered.

What will be the ability of users to use services other than those for which they have registered.

How active and strategic purchasing will be performed and selective contracting.
Decision making powers of Contracting Units.

What will be the ability of Contracting Units to contract with providers outside the sub-district.

Whether the NHI Fund will contract with only Contracting Units at the primary health level. The role of collective bargaining.

The role of medical schemes under the NHI.

The way in which providers will be reimbursed.

Process for price setting and negotiation.

Whether private and public providers will compete.

How health-related innovations will be incorporated timeously under the NHI.

What will be the authority of the NHI Fund to purchase or 'otherwise acquire' goods, equipment, land, buildings, and any other kinds of movable and immovable property.

From: Competition Commission. 28 January 2022. 'Competition Commission comments on the National Health Insurance Bill' Power point presentation (downloaded from https://pmg.org.za/page/National%20Health%20Insurance%20(NHI)%20Bill:%20public%20hearings%20day%2024)

87 In its submission Johnson & Johnson also stated that: 'The NHI cannot create a procurement system that is contradictory to the constitution. Section 217 of the Constitution, recognised in clause38(7), states that procurement by any organ of state must be fair, equitable, transparent, competitive, and cost-effective. The SEP (system) is no longer suited for the introduction of innovative technologies in the various South African markets. J&J, along with other companies, has proposed risk-sharing, managed entry, patient access and other such programmes to facilitate access in the South African market. Further engagements are required with the Department of Health on these proposals.' Johnson & Johnson. 2022. 'Presentation to the Portfolio Committee on Health'. Power point presentation. Downloaded from https://static.pmg.org.za/210720JJ_PRESENTATION.pdf [Accessed 17 September 2022]

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89 Parliamentary Monitoring Group (PMG). 2021. 'National Health Insurance (NHI) Bill: public hearings day 8'

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92 Parliamentary Monitoring Group (PMG). 2021.

In order to move SA towards Universal Health Coverage, this Issue Paper asks the following questions to policy and law makers:

How will people in SA access life-saving medicines under the NHI system and how much will we have to pay?

SA should not perpetuate the current unequal two-tier health system and resultant inequity in medicine access where there is one system for the rich and one for the poor.

Based on our analysis of the provisions in the NHI Bill, the HJI has formulated **17 NHI Questions** about transparency and transition that lawmakers and government officials should grapple with, and ultimately answer, while they consider draft legislation for finalisation and adoption. This is against the background of government departments preparing to implement NHI.

The Issue Paper analyses some key provisions in the current NHI Bill and highlights potential enablers and challenges to medicines access. From this analysis, it distils questions and further areas for exploration that will serve as an entry point for future work and engagement.

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