

Pharmaceutical Task Group (PTG)

Presentation to the:

**Portfolio Committee on Health on the National
Health Insurance Bill [B11-2019]**

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An association of pharmaceutical manufacturers operating in South Africa

About the Pharmaceutical Task Group



*THE PHARMACEUTICAL TASK GROUP (PTG) IS AN ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS
OPERATING IN SOUTH AFRICA*

- Established in 2004 to respond to the Transparent Pricing Regulations
- PTG is an umbrella body which represents pharmaceutical associations on issues of common interest.
- Members of associations are involved in the manufacturing and or sale, and distribution of health products within South Africa.
- The purpose of the PTG is to consider and to respond to issues of common interest to the member associations and the South African pharmaceutical industry.

Members

Represent more than 80% of the pharmaceutical market

- ✓ Generic and Biosimilar Medicines of Southern Africa (GBMSA)



- ✓ Innovative Pharmaceutical Association South Africa (IPASA)



- ✓ Pharmaceuticals Made in South Africa (PHARMISA)



- ✓ Self-Care Association of South Africa (SCA)



The members of the PTG strive to contribute to an environment that promotes growth and investment in the South African pharmaceutical industry while aspiring through their actions to broaden access to medicines for people living in South Africa.

The PTG believes Medicines are a Healthcare System Enabler

Medicines are not another mere commodity item

Without medicines, healthcare systems cannot achieve their stated health goals or improved patient healthcare outcomes

COVID-19 has shown us that medicines are a healthcare solution for patients and nations when collaborative partnerships for change are agreed

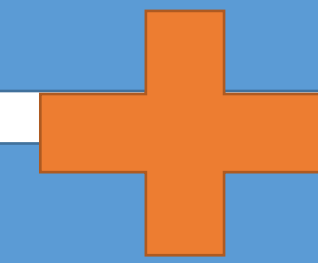
The PTG supports a universal healthcare system for South Africa, however ...



The NHI challenge is about finding the right balance between access, equity, affordability and sustainability

- The current levels of healthcare financing inequality are unsustainable and undesirable
- A more equitable healthcare system is supported
- A more equitable distribution of healthcare resources to achieve the constitutional mandates that underpin this goal, are supported
- The strengths of the public and private sectors should be leveraged to address the inequality that currently exists

Improved access to health care and medicine is needed for all South African patients



While ensuring the sustainability of existing and viable healthcare businesses that contribute to economic growth and job creation

It is essential that the NHI scheme is backed by a sustainable healthcare sector in order to ensure security of healthcare provision and medicine supply

The Pharmaceutical Industry is one of the only healthcare players that currently provides healthcare solutions for both the Public and Private Sector Patient

Key
Submissions

PTG's 4 Key NHI Positions :

1. The PTG respectfully submits that a **Single Payer / single purchaser model will not meet the medicines treatment needs** of all South African patients.
2. The PTG calls for the adoption of a **flexible hybrid pricing framework for medicines** to improve South African patient access and health outcomes.
3. **Rationing of the NHI medicine benefits** to lower than the current patient benefits available **will compromise patient care and health outcomes.**
4. PTG support for **complementary health insurance** will ensure: **sustainable patient access to treatment; a sustainable healthcare sector; improved health outcomes and lower patient out of pocket payments**

GB 1. The PTG submits that a Single Payer / single purchaser model will not meet the medicines treatment needs of all South African patients

A view of the South African Medicines Market: Public and Private Sectors



	Public Sector Medicines	Private Sector Medicines
Annual sector value • *Doh Master Product List Value Annualized/Overstated • ^IQVIA • ~Assuming 50 million patients reliant on Public Sector	~R15 billion*	R45.7 billion^ R29 billion prescription medicines
Top 3 Therapeutic areas by value Proxy for the SA disease burden	<ul style="list-style-type: none"> ▪ HIV R8.5 billion ▪ Vaccines R4 billion ▪ Antibiotics R1.1 billion 	<ul style="list-style-type: none"> ▪ Antidepressants ▪ Anti-ulcerants ▪ HIV
Number of molecules available	512	1020
No of manufacturers / suppliers	81	178

Implications for NHI

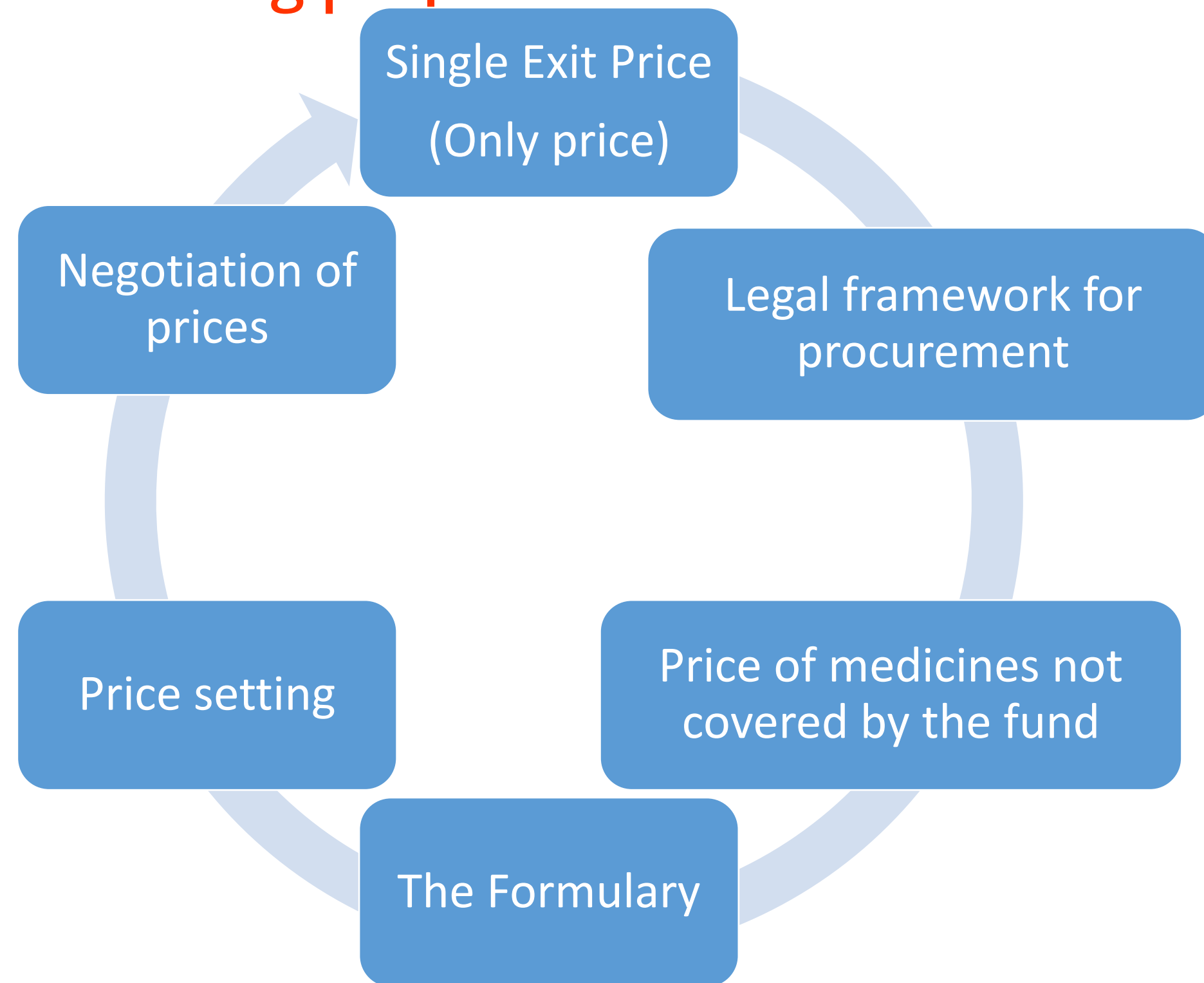
1. A single payer/purchaser model does not mean that >R60 billion will be spent on NHI medicines
2. NHI needs to procure more than 500 medicine molecules to address the SA patient disease burden
3. A single payer, winner takes all procurement system will not improve health outcomes, economic growth or job creation
4. Industry Sustainability is key to NHI success

The interdependence of the public and private sectors to deliver a secure and sustainable supply of affordable medicines, should be acknowledged by the NHI

2. The PTG calls for the adoption of a flexible hybrid pricing framework for medicines

To improve South African patient access and health outcomes

These conflicting proposals cannot work in harmony



The proposed flexible hybrid model for medicines pricing should be based on these principles:

- patient access to medicines;
- security of supply of medicines;
- the ongoing sustainability of the pharmaceutical industry.

A flexible hybrid pricing framework, that allows differentiated | responsive pricing, effectively reduces inequality as it leads to a sustainable medicines supply chain

2. The PTG calls for the adoption of a flexible hybrid pricing framework for medicines to improve South African patient access and health outcomes.

Pricing

Recommendations: The pricing of NHI medicines

- A single pricing dispensation is not appropriate for medicines to be procured by the Fund
- **A flexible pricing framework that allows differentiated/responsive 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

Amendments to Section 22G of the Medicines Act should be removed from the Schedule to the Bill

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^{GB} 2. The PTG calls for the adoption of a flexible hybrid pricing framework for medicines to improve South African patient access and health outcomes.

Sustainability

Recommendations: Ensuring a sustainable medicines industry

While retaining a competitive procurement system in order to obtain 'value for money':

- The Fund will be bound by the procurement processes as set out in the PFMA and the PPPFA
- Review the intention for an SEP system as envisaged in the proposed amendments to S22G of the Medicines Act
- Consider a differentiated and responsive pricing system within a flexible framework for discussion between the medicines industry and the NDoH

• Ensuring **industry sustainability** is essential in whatever medicine pricing system is contemplated.

This will directly affect:

- **Security of supply of medicines and patient access considerations**

The medicines industry cannot remain sustainable on a 'winner takes all' procurement system

3. Rationing of the NHI medicine benefits to lower than the current patient benefits available will compromise patient care and outcomes

Appropriate
Medicines

The Formulary and Essential Medicines List must be set on the basis of evidence-based medicine, ensuring access for patients to appropriate medicines

Access must be progressive and not regressive, in line with constitutional principles:

- Current access to medicines and molecules by patients prior to the implementation of the Bill, must not be reduced or limited post implementation of the NHI Scheme
- Post implementation of the NHI scheme, patients who are stable and well controlled on existing medicines should continue to have access to such medicines in line with these constitutional principles

Proposed principles applying to Formulary development and the EML:

- Procurement should **not be based** exclusively on the Formulary. Patients who are **unresponsive to treatment or experience treatment failure** must have access to medicines to address their needs
- The Formulary should **include innovative medicines and a sustainable choice of generics**

Patients should have access to appropriate medicines including innovative medicines and patients should not be worse off than they were before NHI

3. Rationing of the NHI medicine benefits to lower than the current patient benefits available will compromise patient care and outcomes

Appropriate Medicines

Recommendations: **Formulary and Essential Medicine List**

The Formulary and Essential Medicines List must be set on the basis of evidence-based medicine, ensuring access for patients to appropriate medicines

Proposed actions:

- Procurement outside of the formularies should remain possible in the NHI system in the interests of patient access to appropriate medicines and optimal patient care
- The Bill should facilitate a multiplicity of suppliers by allowing procurement to address the needs of all patients

Proposed actions:

- Formularies should be set on the basis of **evidence-based medicine**
- Reference is made to the National Drug Policy 1995, which provides for the Formulary and its envisaged complementary list (section 7(4)(c))
- There should be **appropriate exceptions** for patients who have **failed formulary treatments**, or who experience adverse effects

Patient medicine access must be progressive and not regressive, in line with constitutional principles

3. Rationing of the NHI medicine benefits to lower than the current patient benefits available will compromise patient care and outcomes

Benefits covered by the Fund: Benefits Advisory Committee (BAC)

Proposed principles to guide the decision-making:

- Access should be allowed to new technologies and innovations, based on value assessments
- Access should be allowed to a sustainable choice of generic medicines
- The Benefits package should ensure continuing patient access to the kind of benefits to which there was prior access

- The Bill must specify the factors that the BAC and the Fund must consider when determining what healthcare services and medicines should be included in the benefits package
- Potential confusion between 'comprehensive benefits' and 'medically necessary' should be explicitly resolved

The absence of explicit governance, process and guidance could result in a benefits package that is arbitrary and negatively impacts the ability of suppliers to satisfy requirements

3. Rationing of the NHI medicine benefits to lower than the current patient benefits available will compromise patient care and outcomes

Recommendations: Office of Health Products Procurement

The Bill states that:

- The OHPP will facilitate and coordinate procurement while providers will procure
- The OHPP will coordinate price negotiations

Proposed principles for the OHPP:

- No provisions of the Bill relating to the OHPP should limit or restrict the required pricing flexibility at the early stage

Proposal:

- It is proposed that stakeholders are invited to participate in discussions with the NDoH on **possible pricing models as per negotiations mandated by section 38(3) and procurement under section 38(6), within the context of delivering responsive care**
- **A hybrid flexible pricing framework is proposed that allows differentiated/responsive pricing**

The role, powers and functions of the Office of Health Products Procurement needs to be clarified in respect of price setting and procurement

3. Rationing of the NHI medicine benefits to lower than the existing patient benefits available will compromise patient care and outcomes

Prescribers' right to prescribe medicines not on the NHI Formulary

Situation:

- The Bill permits the user to access treatment not set out in the Formulary, but included in the complementary list



Conflicts with:

- A healthcare services practitioner must prescribe medicines set out in the Formulary



- The Bill must make it express that a practitioner can, without losing his/her accreditation, prescribe medicines not set out in the Formulary where justifiable circumstances exist
(Sections 39(2)(iv) and 39(8)(d))

It must be made clear in the Bill that a healthcare practitioner will prescribe medicines outside the NHI Formulary under justifiable circumstances

4. PTG Support for complementary health insurance:

The business case: Ensuring a sustainable medicines industry

- Where the NHI benefit is unable to provide the kinds or quality of healthcare services required to improve patient outcomes, South Africans **should not be deprived of the right to access healthcare services in the private sector**
- The **interdependence of the public and private sectors** to deliver a secure and sustainable supply of affordable medicines, **should be acknowledged by the NHI**
- Investment and overheads are **covered largely by revenue from the private sector**, which allows lower prices to the State. Economic growth and investment will reduce if this dynamic is disrupted.

- Medicine supply at the 'lowest price' as envisaged in the Bill or at the price level currently supplied to the State alone, **is not sustainable, even if volumes increase**
- Unless innovative medicines are procured by the NHI Fund:
 - the pharma industry will not be sustainable and
 - the availability of generics in the future will be diminished

Generics follow on after innovative medicines are registered in South Africa; launched and used in the local market

Allowing patients to purchase voluntary complementary health insurance will ensure a sustainable medicines sector to support NHI

Implementation of the Bill

Implementation should be dependent on the achievement of concrete milestones – rather than the lapse of the time-period

Implementation of the NHI is envisaged in two phases

Strengthen the health system first:

- The underlying health system strengthening initiatives need to be completed before full implementation of the NHI scheme

Don't take away rights:

- The Bill of Rights gives the State an obligation not to limit, diminish or take away people's existing access to healthcare services

Ensure continuity of access:

- Nine million people make use of medical schemes to access quality healthcare. Until the NHI scheme is fully implemented, there is a risk these nine million people could lack continuity in access to these services, constituting a regressive measure

- A milestone approach rather than a date-based approach to the implementation of NHI should be followed
- The interventions set out in the Presidential Health Compact for each Pillar should be pre-conditions for full implementation of the NHI scheme
- The Fund should be sufficiently liquid before full implementation

Where the NHI is unable to provide specific healthcare services required to improve patient outcomes, South Africans should not be deprived of the right to access healthcare services in the private sector

Conclusion:

As COVID-19 has demonstrated, medicines are a healthcare system enabler

Key
Submissions

1. The PTG respectfully submits that a Single Payer / single purchaser model will **not meet the medicines treatment needs** of all South African patients.
2. The PTG calls for the adoption of a **flexible hybrid pricing framework for medicines** to improve South African patient access and health outcomes
3. Rationing of the NHI medicine benefits to **lower than the existing patient benefits** available **will compromise patient care and outcomes**
4. **PTG Support for complementary** health insurance will ensure : **sustainable patient access to treatment, a sustainable healthcare sector, improved health outcomes and lower out of pocket payments**

The PTG will constructively engage with the NHI process with the goal of ensuring that patients have sustainable access to medicines



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