Presentation to the Portfolio Committee on Health

National Health Insurance Bill No: 11 of 2019

Johnson & Johnson

Serving our customers through 3 sectors

Pharmaceuticals

Medical Devices

Consumer Health

- Our first responsibility is to doctors, nurses and patients, to mothers and fathers, and to everyone who uses our products. Every day, our products touch over a billion people worldwide.
- That's why we are the world's most comprehensive and broadly based provider of healthcare products, in Pharmaceuticals, in Medical Devices and in Consumer Health.

Our footprint in SA

Johnson & Johnson South Africa has a proud history of more than **90 years** in South Africa (SA).

Consumer Health is the oldest Johnson & Johnson business in SA – first incorporated in **1930,** with two manufacturing sites.

More than **R360 million** has been invested in both consumer plants to ensure that the **growth demands of the business are met**.

Our Medical Devices business has **four local sites** which are working to expand patient access, improve outcomes, reduce health system costs and drive value.

Manufacturing operations started in **East London** in the early **1950s** where we continue to have one of our manufacturing plants which focuses on personal care products. Our **second plant**, a state of the art pharmaceutical facility, is located, along with our Commercial Head Office, in **Cape Town**.

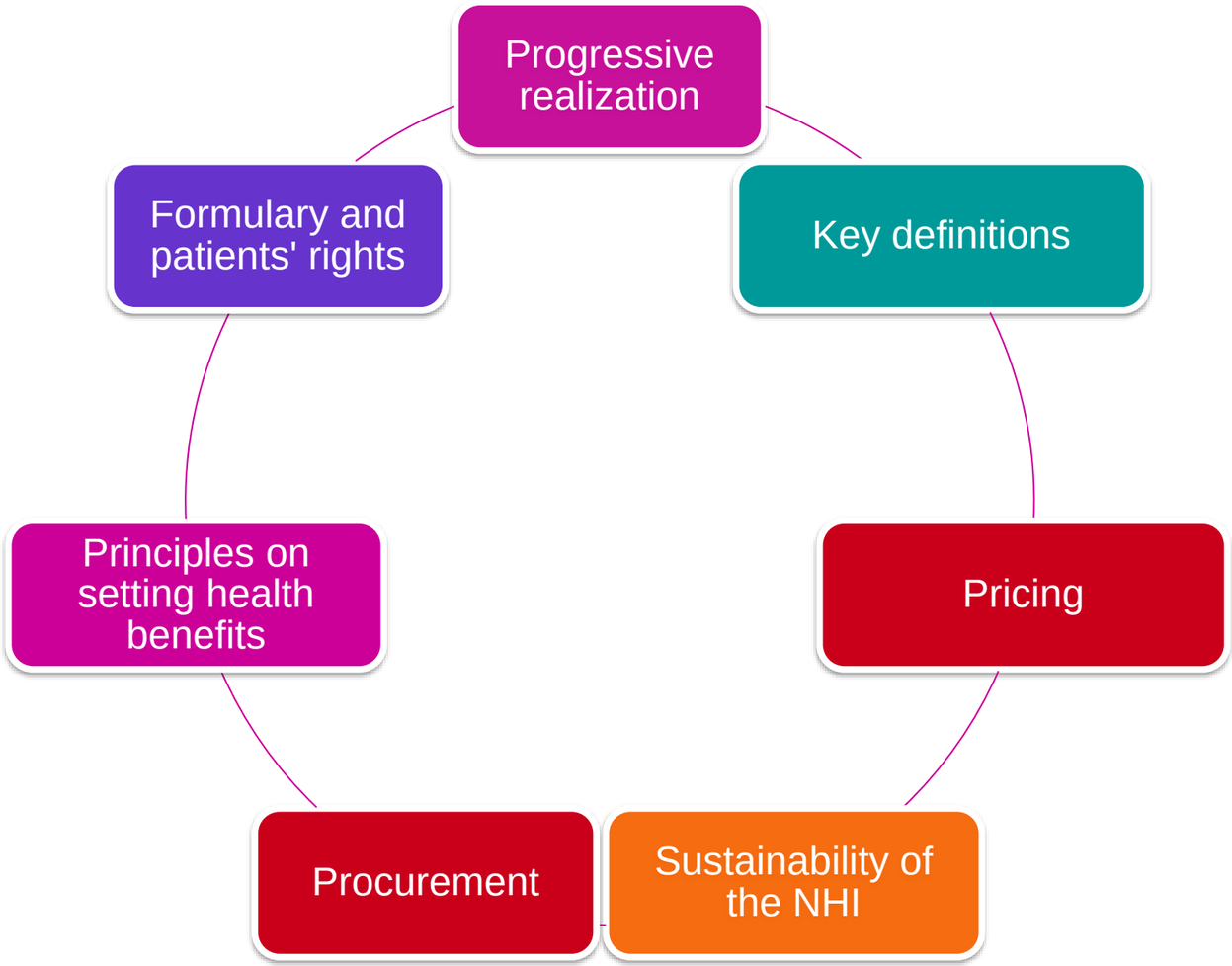
The South African team is comprised of approximately 1,000 employees – across the spectrum of functional areas. They are a passionate group of people who work hard to ensure that our products and services proudly meet our high quality standards and best serve the needs of consumers.

Introduction

- At Johnson & Johnson, we believe that good health is at the heart of human progress—it enables children to thrive, women to succeed, families and communities to prosper, and countries to rise from poverty and achieve economic security. That is why we have a promise to relentlessly drive better health for all.

- Ensuring universal health care does not mean that provision of care must be free or that a single-payer system is the best or only solution, but it does require **sustainable financing for both suppliers and providers, and those needing care.**

- The presentation will focus on the patients' perspective, and the industry perspective, in particular, medical devices, pharmaceuticals and consumer health sectors.



1. Progressive realization of health rights

Section 27 of the constitution:

Talks about progressive realization

NHI proposes a narrow system:

Limitations on medical schemes (clause 33),

Only “necessary "care (clauses 6(a), 7(2)(c), 8(2)(c)),

Strict formulary adherence

Clause 7(4)(c)

NHI Bill challenges:

- Patients who have had cover for care, such as through discretionary funds at academic facilities or through their medical schemes, would no longer have this cover;
- Patients who had care that might now be deemed more than what would be “necessary” care under the NHI would no longer receive this care.
- Academic facilities where sophisticated training and care must take place.

Proposed changes to the bill: formularies & rights

The wording in the NHI Bill be amended to not exclude or limit social security mechanisms and the care it covers, such as that provided for by medical schemes (clause 33), or through the Road Accident Fund or Compensation Fund (as RAF & COID benefits limitations are being proposed in the Schedule to the Bill.)

Where “comprehensive”(1) or “necessary”(2) care is listed, as well as the benefits associated with it, it be made clear according to which principles benefits will be set (see for example the principles outlined according to which the PMBs are determined and reviewed & updated).

Any existing rights afforded to patients will not be removed.

The “progressive” realisation be entrenched in the Bill by, for example, outlining the use of information relating to health outcomes, epidemiology, human- and other resource availability, etc. in a programmatic expansion of health care rights, along the lines of how the Constitutional Court has ruled on such matters.

1. Clauses 1, 15(3)(b), 39(8)(a).
2. Clauses 6(a), 7(2)(b), 8(2)(c).
3. Clauses 20(3)(b), 38,

2. Formularies & HTA: limitations to patient rights

The EML and EEL are only the “essential” medicines & devices – currently in public sector a lot more than what is on the EML is available on tender & buy-outs
The content of the EML and EEL, as well as an HTA MACs are set in another law – the National Health Act

Clause 35(4) states that OHPP formulary will only “comprise the EML and the EEL” (no options for anything but these); and there may be a complementary list “approved by the MoH: (clause 7(4)(c); providers will be penalized if they do not adhere to the formulary (clauses 7(4) and 39(8)(d)).

Clause 7(4)(b) assumes that all medical devices would have ndergone an HTA or they would not be funded.

Clause 57(4)(d) refers to a Ministerial Advisory Committee (MAC) to conduct HTA. This should be a separate independent statutory body, and not an advisory body to the Minister.

J&J’s medical devices are widely used in emergency care (trauma) in both the public and private sectors:

- Healthcare professional training
- Timely availability of the products including theatre sets
- Patient need: Medical devices are not necessarily interchangeable

The rights of the patients could be impacted by the strictly enforced formulary, the HTA and procurement systems (training and theatre sets)

Proposed changes to the bill: patient rights & suppliers

Emergency care be included in the setting of the NHI benefit package[3] as an absolute right, that the wording relating to compliance with the rules of the NHI Fund to ensure that emergency care is not delayed or limited[4] and that suppliers are measured against relevant criteria such as (a) appropriateness of care in relation to the injury, (b) healthcare professional training and (c) ability to deliver to sites when required.

Reproductive care must be included in the benefit package as a result of its specific listing in section 27(1)(a) of the Constitution, and given effect to in line with the principles of appropriateness of care and evidence-based medicine.

The procurement of- and linkage between ambulance services, which must, constitutionally so, be provided by provinces, to establishments and providers where healthcare services are rendered, must be clear.

3. Clause 38 – BAC
4. See Oppelt case in the Constitutional Court

Formularies / lists of medicines & devices

One size does not fit all… The clauses, what they say and the challenges:

Clauses in the Bill	What the clauses say	Challenges
38(6), 39(2)(b)(iii) and 8(2)(d)	Provider must procure according to the Formulary	If not, provider will be excluded from being an NHI provider
38(4), 38	Formulary comprises only the EML and EEL	EML and EEL set under the National Health Act (no regulations and no participatory process), no principles on how these lists are to be set
7(4)(c)	Complementary list “approved by the MoH”	No provision for complementary list in clauses 28, 39 or 8. No principles on how this is to be determined

Case study

Examples of patient healthcare rights that that could be affected if the NHI Bill is passed and implemented in its current form – unintended consequences of mandated adherence to formularies:

In the field of mental healthcare, patients with schizophrenia are vulnerable, and unless adequately treated, suffer relapses that permanently deteriorate their condition. These relapses are also costly, as it leads to increasing incidences of hospitalization, for longer periods of time. The high levels hospitalization of patients living with mental health conditions have recently been cited in a report as increasing healthcare spend. Part of this vulnerability related to the administration of oral medication, where patients are non-compliant. Injectables, and in particular injectables with research showing speedy treatment effects and lower hospitalization rates, should be available. Although not on tender, various public mental health facilities do use these products. **Under the NHI Bill, where there is no possibility to deviate from medicines that are on the Essential Medicines List (EML),** these patients would no longer have access to this treatment option, and patients who are at crisis points as known defaulters on oral medication, won't have access.

3. Principles on setting benefits

1. As per the NHI Whitepaper, that benefits are determined on the basis of “evidence-based medicine”

2. That every patient is entitled to “appropriate care”, irrespective of what the most patients, or the average patient needs (which is the function of an “essential … list)

3. What is evidence-based and appropriate is determined by persons who are professionals in that specific field, e.g.:
   - for mental health it would be psychiatrists, occupational therapists and psychologists,
   - for broken bones, it would be orthopaedic surgeons, orthotists & prosthetists and physiotherapists:

The BAC can therefore not advise without the input of the specific professionals registered (i.e. legally authorized) in a particular field

This means that the determination of benefits, and the formularies that flow from them, are always evidence-based, appropriate and set in consultation with the right professionals

Case study

Examples of patient healthcare which will be impacted with the use of formularies in procurement decisions:

An example of applying the principle of evidence-based medicine, and deviations from formularies, is in prostate cancer. Although chemotherapy may be adequate for some patients in the treatment of prostate cancer, many men cannot tolerate the side-effects and would need access to hormone blockers, such as abiraterone or enzalutamide outside of protocol/formulary and the EML. These products therefore have to be available in order to ensure appropriate treatment for these men who do not react well on other treatments - this group of patients also has the right to be appropriately treated.

4. Pricing of medicines

The NHI Bill appears to have at least five different, and contradictory, proposals in relation to medicines and medical devices pricing in the NHI system, namely:

- 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;
- A bid price, under the PFMA and NT regulations (clause 38(7));
- A negotiated price, to be negotiated with the Fund at the “lowest possible price” (clause 11(2)(e));
- Possible 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));
- A “rate” for, amongst others, suppliers, determined annually by the NHI Fund (clause 10(1)(g)).

The NHI cannot create a procurement system that is contradictory to the constitution. Section 217 of the Constitution, recognised in clause 38(7), states that procurement by any organ of state must be fair, equitable, transparent, competitive and cost-effective. The exclusion of competition law from the Act is therefore problematic.

The SEP is no longer suited for the introduction of innovative technologies in the various South African markets. J&J, as have other companies, have 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.

Proposed changes to the bill: pricing

The removal of all references to the SEP in the Schedule to the NHI Bill. The possibility of negotiations with the National Department of Health on the suitability of the current SEP in an evolving market should not be excluded, however the correct place to do so, is under the Medicines Act and within the broader framework of Supply Side Regulator for Health discussions, as recommended by the HMI.

The removal of “suppliers” in all clauses referring to price / rates / fee determination, which refers to providers and not suppliers.

Allowing 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));

Allowing price negotiations with the NHIF (OHPP) on the basis of 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 PPPFA;

Allowing differential pricing in non-NHI markets.

5. Definitions

The definitions of the various types of goods that could be procured as part of the NHI system, would create confusion, in that it does not align with definitions of health products as found in legislation such as the Medicines and Related Substances Act, 1965 (“Medicines Act”); the Hazardous Substances Act, 1973; the Foodstuffs, Cosmetics and Disinfectants Act, 1972; the National Regulator for Compulsory Specifications Act, 2008; and the Standards Act, 2008.

The Medicines Act governs three types of products, of which only one, medicines, is defined in the NHI Bill. “Medical devices” is listed separately from “supplies” and “medical equipment”, as well as “health technology” is attached.

New definition being created through the NHI Bill that might lead to contradictory provisions for suppliers and have implications for criteria of accreditation and licensing, set by the NHI Bill and other laws.

The definition of “medical devices” in the Medicines Act covers supplies, medical equipment and health technology.

The inclusion of “health research” as a form of “health good” commodifies research. Health research is defined in the National Health Act and the 2014 Research Regulations. Similarly, a health good, is not a “service” as defined under “health goods”.

Proposed changes to the bill: definitions

The definition of “health good” be redrafted as referring to “products regulated in terms of, and as defined by the Medicines and Related Substances Act, 1965,the Hazardous Substances Act, 1973; the Foodstuffs, Cosmetics and Disinfectants Act, 1972; the National Regulator for Compulsory Specifications Act, 2008; and the Standards Act, 2008; and any other law regulating and/or controlling the manufacturing and/or importing and supply of goods used in the diagnosis and/or treatment of users”.

The definition of “health related product” be redrafted as “products that are not health goods, but which are used as part of the delivery of healthcare services, or which are used by the NHI Fund in the execution of its powers and functions.”

That where investigations and complaints are concerned (clauses 6, 11 and 42ff) and suppliers are at stake, the fallowing wording be inserted to replace current powers of investigation: “The Fund must refer allegations of fraud, corruption, theft or any other crime to the appropriate authority” and “complaints in relation to health goods must be referred to the relevant authority with jurisdiction over the specific health good”.

Clause 10 1 (l) to be amended by the underlined addition: “monitor the registration, license or accreditation status, as the case may be, of health care service providers, health establishments and suppliers and, where applicable, to verify the requisite registration or accreditation of any specific health good, where so required by legislation”

Proposed changes to the bill

The definition of “health good” be redrafted as referring to “products regulated in terms of, and as defined by the Medicines and Related Substances Act, 1965,the Hazardous Substances Act, 1973; the Foodstuffs, Cosmetics and Disinfectants Act, 1972; the National Regulator for Compulsory Specifications Act, 2008; and the Standards Act, 2008; and any other law regulating and/or controlling the manufacturing and/or importing and supply of goods used in the diagnosis and/or treatment of users”.

Clause 41(3)(b) be amended to read: “In the case of specialist and hospital services, payments must be all-inclusive and based on the performance of the health care service provider and/or health establishment, including all input costs associated with the provision of such services” and the phrase “or supplier of health goods, as the case may be” can be removed.

Allowing private sector providers and private sector health establishments to procure independently from the NHI, subject to the services being evaluated on patient outcomes;

6. Procurement

Based on the strict adherence requirements to the NHI Formulary for medicines and medical devices, the emphasis on the lowest possible price.

While the Essential Medicines List (EML) is important for prioritizing medicines and managing budgetary constraints, there is a need to have a pathway for integrating innovative medicines in the healthcare system.

In its current form, the draft NHI Bill does not address how innovative medicines or medical devices will be adopted into the health system.

Under the NHI, it will become extremely difficult to introduce innovative medicines and medical devices.

The availability of a broad range of medicines and medical devices provides healthcare professionals with the necessary options to treat diverse patient populations with differing medical histories and clinical needs using the principle of evidence-based medicine.

In the United Kingdom, the NHS has prioritized the integration of innovative medicines through the Accelerated Access Review, which “aims to speed up access to innovative medicines, devices and diagnostics for NHS patients

Procurement

There are also obligations placed on suppliers of health goods, such as J&J, which it cannot fulfil, because such fulfilment would contravene other laws. For example, the regulations (clause 55(1)(d) and (e)) supply of personal and health information to the NHIF (e.g. on adverse events).

The setting of “best practices” in relation to the payment of suppliers (clause 11(1)(i)(ii)) could also potentially contradict the payment rules set under the PFMA and NT Regulations, which requires payment within 30 days from date of invoice. Similarly, procurement must (and not “may” as per clause 11(2)) be underpinned by a contract, and the conditions of supply listed in subclause (2) are in any event part of the GCC and SCC as set under the PFMA for supply to organs of state.

The NHLS, as a provider of pathology services to the public sector, is, in itself a schedule 3 entity under the PFMA, and would undertake its own procurement of health goods and other products. Private or public hospitals and private providers would already have acquired capital equipment (classified as medical devices) that form part of the goods used.

These could contravene the POPI Act and the constitutional right to privacy, where such information is generated outside of the NHI system and is expected to be entered into or provided into the system by suppliers.

There are also contradictions to the PFMA and NT regulations. Portfolio Committee should also consider the draft Procurement Bill currently being proposed.

To require of laboratories, establishments and providers to procure, as clause 38(6) say only from the “supplier listed” and in accordance with the Formulary, would not be feasible, in particular, if the goods would not be appropriate for use with existing capital equipment, medical devices, or if the medicine, for example, require specific devices to be administered, etc.

Procurement

Furthermore, if an “all-inclusive fee” (clause 41(3)(b)) is to be paid, establishments and providers should be free to determine the inputs that go into the provision of that service, also as such establishments and providers will be paid on performance and should be accountable for all aspects of the care delivered.

Clause 38(6) also refers to the Formulary as being inclusive of “suppliers”. We believe this is a drafting error.

There are circumstances, in line with the principle of evidence-based medicine, which was firmly entrenched in the NHI White Paper, 2017 and that requires deviations from formularies in order to ensure appropriate care for a particular patient, and most importantly, to protect vulnerable patients in line with the constitutional principles as set out above under paragraph 3.1.

Establishments should be free to determine their inputs.

A formulary normally does not include the names of the suppliers, and these may differ from one tender to the next.

The absolute exclusion of non-formulary products will not be in the interest of patients or progressing public health objectives and will mean that only “average” patients will be able to access care funded by the NHI. Patients who clinically require alternatives will not be able to access it,

Proposed changes to the bill: Procument

Clause 38(6) be split into two separate sections: one dealing with the basis of procurement, and the other dealing with suppliers and the supply chain The definition of “health related product” be redrafted as “products that are not health goods, but which are used as part of the delivery of healthcare services, or which are used by the NHI Fund in the execution of its powers and functions.”

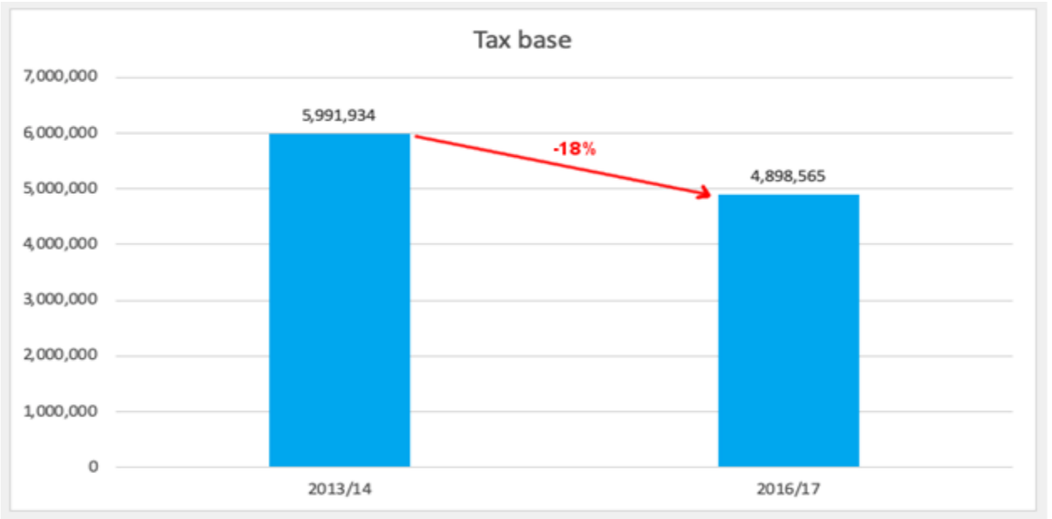
Exceptions, similar to those included in the medical schemes’ legislation, be added to the wording in the NHI Bill, so as to protect the rights of a-typical patient. Clauses 7(4)(c) and 8(2)(d) be amended to include the underline phrase: “the health care product or treatment is not included in the Formulary, except in circumstances where a complementary list has been approved by the Minister, or where the circumstances listed in clause 38(6) are present” and seeks treatment that is not included in the Formulary unless the circumstances listed in clause 38(6) are present, and where clause 38(6), adds the following underlined phrase: “must procure according to the Formulary unless the prescriber identifies circumstances of potential harm or adverse events; harm or adverse events and/or treatment failure in the care of a patient which care is generally covered by the NHI Fund.”

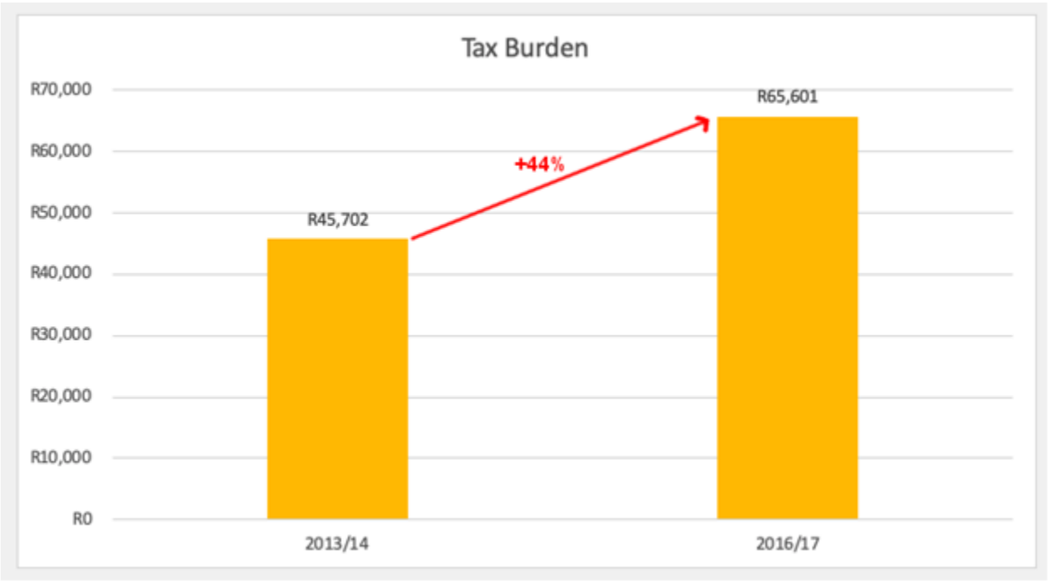
Allow price negotiations with the OHPP on the basis of alternative reimbursement models, risk-sharing programmes, portfolio trade-offs, health outcomes, patient assistance programmes, training- and other product support, etc., to be added as a new sub-clause under clause 38(5), within the framework of the PFMA and PPPFA;

7. Sustainability of the NHI

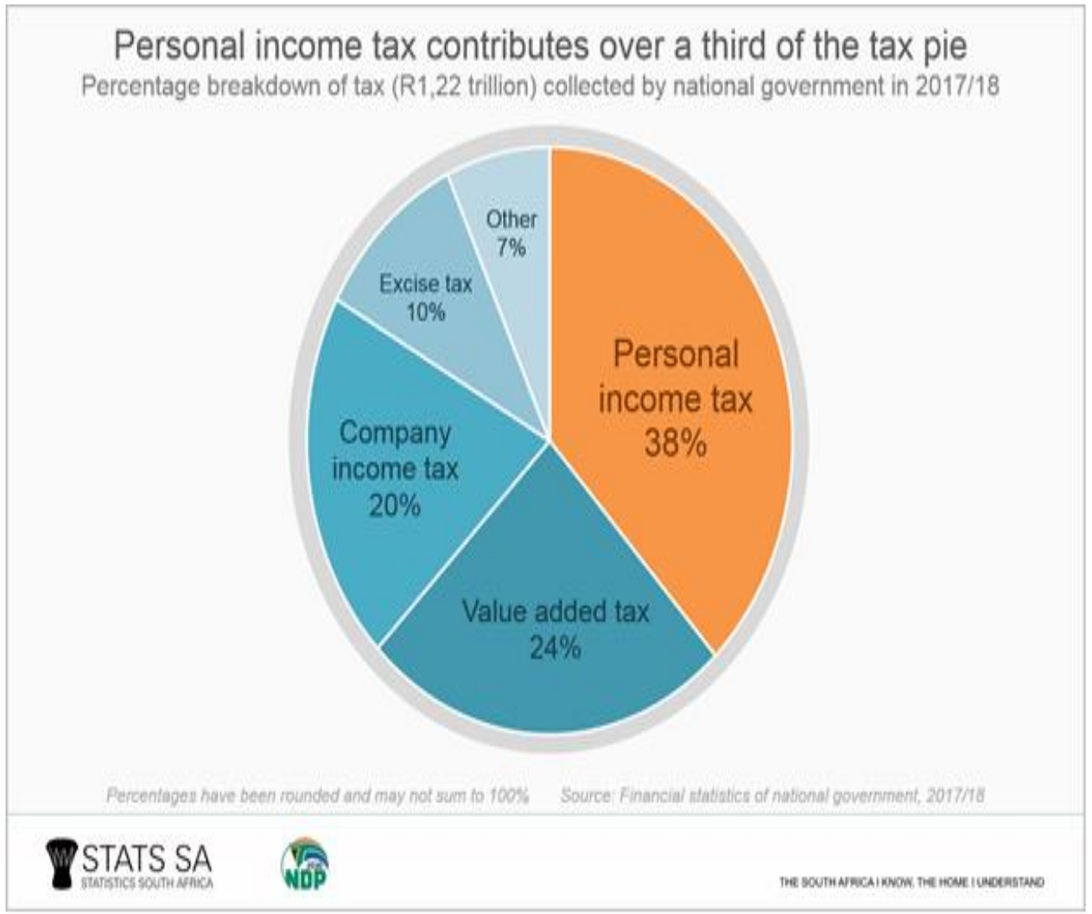
The finalization of this Bill on the NHI should be done concurrently with a funding proposal to ensure that sustainability questions are addressed in the design process of the NHI. In its recommendations to the Finance Minister on the NHI, the Davies Tax Committee noted: “Given the large [fiscal resources] … at stake, it would be critical to manage the fiscal risk by linking expenditure outlays to available fiscal resources. Here credible cost scenarios play a pivotal role and their absence could compromise the goals of the NHI.”

The finalization of this Bill on the NHI should be done concurrently with a funding proposal to ensure that sustainability questions are addressed in the design process of the NHI.





Sustainability of the NHI



Case study

Examples cited by the Davis Tax Commission on the NHI

“A case in point is that of Ireland, where the White Paper on Universal Health Insurance in 2011 promised implementation by 2016, without providing either costings or details of the service package.

In November 2015, after an Economic and Social Research Institute study indicated it was unaffordable, given that total public health spending would have to increase by between €666 million and €2 billion (3.5 to 11%), the Irish government abandoned its plan. ”

Case study

Consideration of financial sustainability of the NHI is important as even well-established universal health systems face financial challenges. In its 2016 report, the UK's National Audit Office highlighted the financial challenges faced by the National Health System (NHS) by noting:

"The messages in our two previous reports on NHS financial sustainability have been consistent and clear in stating that the trend in NHS trusts' and NHS foundation trusts' declining financial performance was not sustainable. In 2015-16 trusts' financial performance worsened considerably. Efforts to get NHS finances on track, such as large savings and efficiency targets, have damaged trusts' financial positions and contributed to the current situation. With more than two-thirds of trusts in deficit in 2015-16, we repeat our view that financial problems are endemic, and this is not sustainable . . "

Proposed way forward: financial impact assessment of the Bill

Increasing spending on health should consider long-term fiscal space and not threaten the government's long-term solvency or be to the detriment of investments in other sectors that are critical for comprehensive progress towards the SDGs.

The implementation of the NHI should be preceded by a full fiscal impact assessment and the impact on the individual taxpayers. Due consideration should also be made for the loss of benefits medical schemes members would forgo, while there is an increase in the tax for the NHI.

Thank you


Johnson & Johnson