MSD
INVENTING FOR LIFE

PRESENTATION TO THE PARLIAMENTARY PORTFOLIO COMMITTEE ON HEALTH | THE DRAFT NHI BILL

14 July 2021

Zweli Bashman, Managing Director: Sub-Saharan Africa

MSD has a demonstrated commitment to patients and strengthening of healthcare systems across sub-Saharan Africa

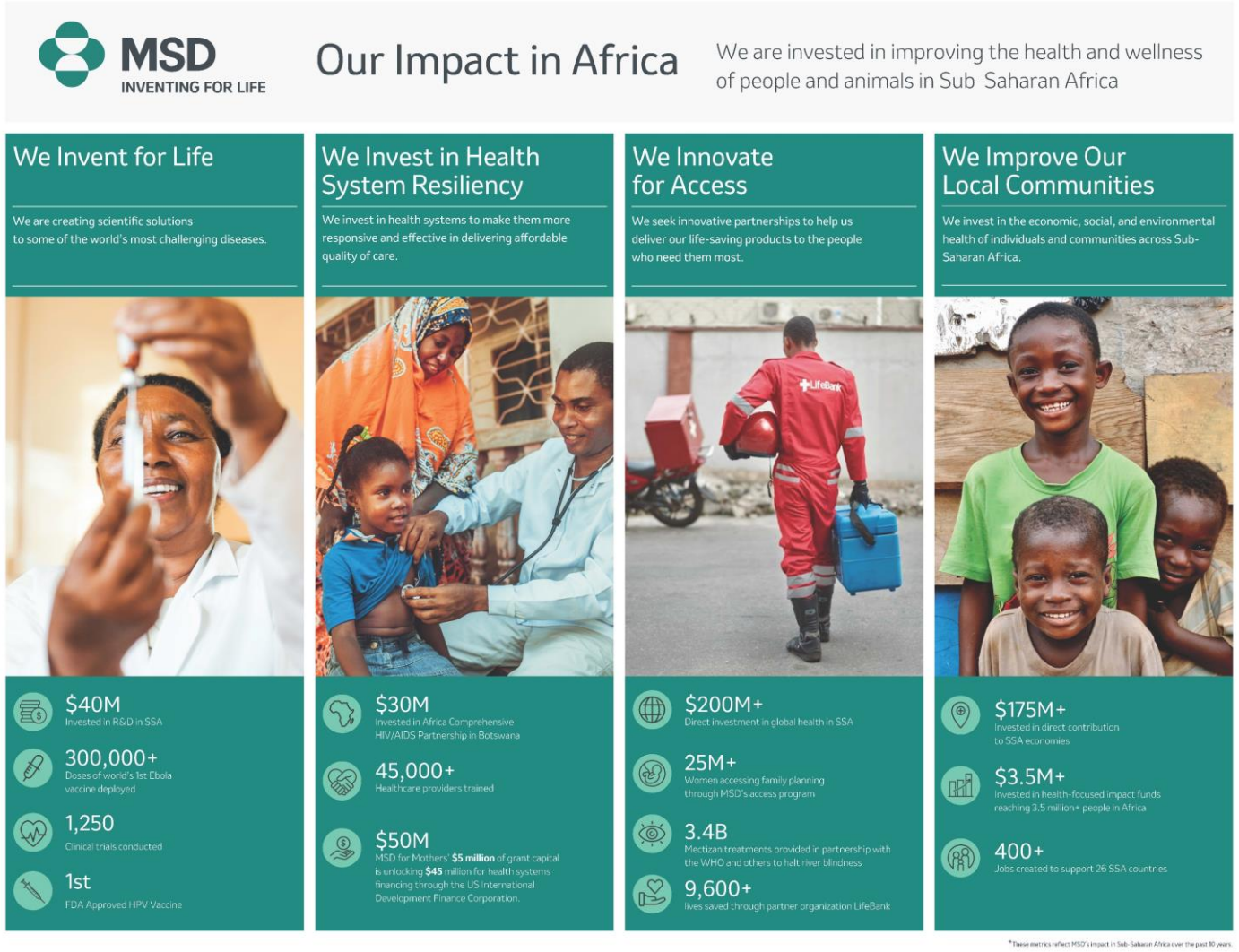
- **For over 130 years** MSD has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives
- **Since our launch in South Africa more than 50 years ago**, we have served South African patients' by providing therapeutics in the areas of HIV, oncology, infectious diseases and vaccines.
- In 1976 MSD established a **local medicines packaging plant** contributing to local manufacturing
- We have conducted **over 1200 clinical trials in South Africa**, significantly contributing to SA's R&D capacity and the knowledge economy
- In 2020 we entered into a **landmark R12 million partnership with Unjani Clinics** Network, a nurse-owned and operated model providing quality, affordable private primary health care to underserved communities across the country

Provides an **affordable alternative** to primary healthcare services

UNJANI CLINIC

Takes healthcare **to** our **communities**

Empowers black women Professional Nurses



The NHI represents a singular opportunity to realise quality healthcare for all on a progressive basis

Specificity and certainty critical to achieving this

- MSD supports the intention of the NHI Bill to expand access to quality healthcare services to all patients, regardless of socio-economic status
- We believe that to realise its intent, the NHI must give rise to a health system which invests in and incentivises health outcomes, ensuring that the right medical intervention can be administered to the right patient, at the right time.
- We see the introduction of the NHI Bill is a singular opportunity to reflect on the health system that we have, create a vision of what we need and enact the measures that will make it a reality
- To achieve this we believe that the NHI Bill must be specific and create certainty to ensure citizens can hold relevant bodies accountable
- We believe that there are a number of areas where the current Bill falls short of certainty and specificity

Against the test of certainty, it is our view that the Bill falls short in key areas

The right medical intervention for the right patient

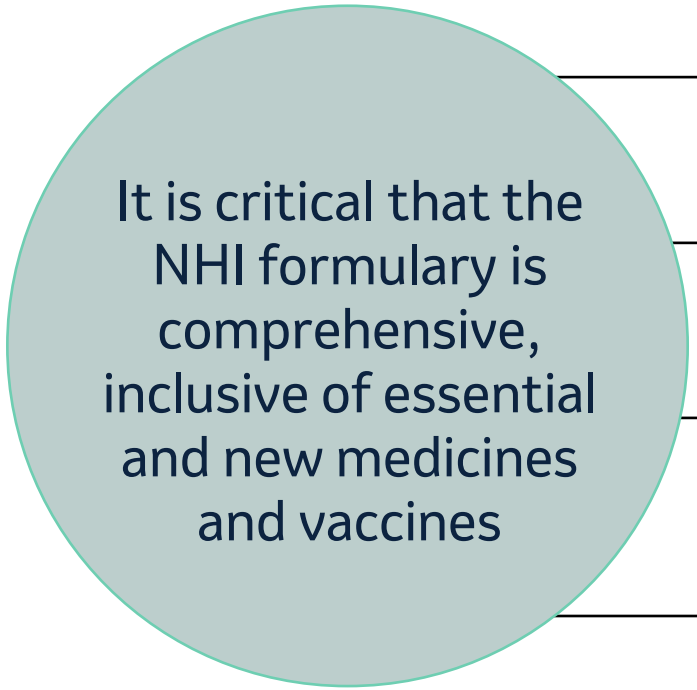
- The Bill remains unclear regarding benefits design – the principles informing the development thereof and where final decision-making lies
- There is no clear pathway for introducing innovative medicines into the NHI system – HTAs as described in the Bill remains unclear in terms of principles informing decision making and how it would practically work given some of the realities in our healthcare system
- "Progressive realisation" precludes removing existing access to medicines.
- EMLs, by definition, provide for the treatment of the most common diseases of the majority of patients. However it could leave the most vulnerable at risk, i.e.:
  - People living with rare diseases; and
  - Patients who do not respond to standard care
- Clear provision must be made for managing exceptions for vulnerable patient groups
- The Bill's requirement of strict adherence by prescribers to the formulary could lead to inappropriate care, leading to sub-optimal patient outcomes, increased overall costs and unsustainable industries

At the right time

- The Bill emphasises the cost of medicine rather than the value of evidence-based care for the patient and health system as a whole
- Restricted formularies, specifically at local level, could cause treatment delays, unnecessary costs and poor patient outcomes – Similarly, health establishments should be enabled to procure medicines based on local patient needs
- Unclear funding could jeopardise the sustainability of the NHI and healthcare system
- The Bill's implementation timeline does not account for achieving critical goals or milestones

The right medical intervention for the right patient:
Evidence-based medicines save lives and promote sustainability

South Africa needs a formulary reflecting the needs of all patients



- EMLs, by definition, provide for the treatment of the most common diseases of the majority of patients. However the EML can leave the most vulnerable at risk
- Price sensitivity drives the EML's emphasis on generics and limited inclusion of innovative molecules
- The NHI formulary must be inclusive of an EML and must also make provision for new medicines. This requires that the complementary list development process be informed by evidence-based medicines in collaboration with medical societies and patient groups
- HCPs must be empowered to prescribe medicines to help patients meet their health goals and ensure that the most appropriate interventions are enacted at the individual patient level

The NHI represents an opportunity to ensure a comprehensive and evidence-based formulary consisting of vaccines and therapies in keeping with the pace of scientific innovation

At the right time:
Multiple important but unclear steps before patients can access new medicines

For patients with complex conditions, access delayed may be access denied

Inclusion in the NHI Benefits

The NHI Bill does not define or set criteria for determining the benefits package. There are no clear inclusion or exclusion criteria:

- The meaning and intent of phrases alluding to benefits, such as 'medically necessary' or 'comprehensive' are unclear.
- There are no principles in accordance with which the BAC must fulfil their functions (e.g. evidence-based medicine & taking into consideration vulnerable populations, and existing rights and entitlements)
- The BAC determines benefits, but only advises the Fund, which then develops the benefits, in consultation with (meaning together with) the Minister.

Inclusion in Treatment Guidelines

- Benefits must be based on Treatment Guidelines that reflect "evidence-based medicine", as stated in the NHI White Paper.
- It would be impossible for all members of the BAC to comply with healthcare professional legislation on all health care disciplines. We recommend that Treatment Guidelines be set in conjunction with relevant healthcare professional groups or clinical experts in relevant fields or under the auspices of the independent Supply Side Regulator for Health as the HMI recommends.

Health Technology Assessment

- The implementation of HTA would be challenging due to factors including a shortage of epidemiological and cost data; the absence and impracticalities of thresholds; a shortage of experts to conduct assessments; the cost and time HTAs take.
- MSD supports value-based pricing. In the lead up to the NHI implementation, there is an opportunity for the private and public sectors to work in partnership towards an appropriate value assessment framework for the NHI.
- Furthermore, an effective value assessment framework should be managed independently of the NHI fund and its decisions should have a direct bearing on patient access.

Inclusion in the Essential Medicines List (EML)

- The concept of an EML also does not align with a set of "comprehensive" benefits: medicines available on EML programs are not the only medicines that should be available in the public health systems, instead they are the "most needed".
- If the provisions of clause 38(4) are to be adopted by Parliament, many patients who currently have access to non-EML, and also to non-tender medicines in the public health sector, may no longer have access to these.

Inclusion in the NHI Formulary

- The NHI medicines access- and supply system must cover medicines not included in the EML, but which have been available on state tender and/or as discretionary spend; medicines required, in line with the principles of evidence-based medicine, by populations that are vulnerable, have unique features of their conditions and/or where treatment for an NHI-covered condition has failed, for example, including medicines required by academia or used to treat orphan diseases.

MSD

Evidence-based medicine can contribute to a more cost-efficient health system

South Africa spends 8.1% of GDP on healthcare, which is equivalent to other OECD countries, however its life expectancy is 64,2 years compared to 72,6 for the world -

- Presidential Health Compact, 2018

- MSD is mindful of the economic and budget constraints the country faces
- These circumstances make it more critical to focus resources on paying for outcomes rather than just products
- Evidence-based medicine could meaningfully contribute to the viability of the NHI by:
  - Cutting overall treatment costs at a whole system & economy level
  - Avoiding costly treatment failures, loss to follow-up and rescue therapies

Negotiations on the basis of outcomes favour payors and the health system as a whole

As MSD we believe that a negotiated price with options of alternative reimbursement, risk sharing, value-based pricing and similar agreements as appropriate, will enable greater patient access to innovative treatments

Pricing frameworks in the current Bill appear contradictory and unlikely to expand patient access to innovation

- The current Bill prescribes four, contradictory pricing frameworks (as per below);
- These models may be impossible to implement in the manner and order prescribed;
- Some of these may challenge the innovative pharmaceutical industry's viability, creating uncertainty; and
- Most importantly we do not believe these alone can expand patient access to innovative treatments

Fixed price	Pre-determined price	Negotiated lowest price	Bid price
• Set in terms of as of yet unknown regulations to be determined by the Pricing Committee in terms of s22G • *Clause 58 and schedule amending s22G, Medicines Act*	• Payment rate for suppliers determined annually by the Fund • *Clause 10(1)(g)*	• Price negotiated to the lowest possible by the NHIF • *Clause 11(2)(e)*	• Based on free pricing and competition with possible NHIF transversal tender • *Clause 38(7)*

In Summary

1. **Rule of Law, enshrined in the Constitution, demands that the NHI Bill must be specific to create certainty and ensure accountability. To this effect clarity is required in a number of areas including:**
   - Criteria for determining the benefits package as well as decision-making in this regard; and
   - Ability of all Health Establishments (public & private hospitals and contracting units for primary health) to procure medicines based on their local and patient needs and in alignment with the National Treasury ruled and guidelines

2. **The NHI represents an opportunity to ensure a comprehensive and evidence-based formulary consisting of vaccines and therapies in keeping with the pace of scientific innovation, and to service all patients**
   - It is critical that the NHI formulary is comprehensive, inclusive of essential and new medicines and vaccines;
   - This requires that the complementary list development process be informed by evidence-based medicines in collaboration with medical societies and patient groups informed by the principles of (a) evidence-based medicine, (b) considering the right of access to healthcare and progressive realization thereof, (c) taking into consideration vulnerable populations, and (d) existing rights and entitlements.
   - HCPs must not be penalised but rather be empowered to prescribe medicines to help patients meet their health goals; and
   - There must be a suitable pathway for patient access to medicines and vaccines not included in the formulary.

3. **Given the country's limited resources, it is critical to focus resources on paying for outcomes rather than products**
   - Government, in collaboration with the private sector should develop an appropriate value assessment framework for the NHI which prioritises value and cost-effectiveness versus 'the lowest price'; and
   - Based on an appropriate value assessment, the NHI should adopt a flexible pricing framework can support cost-effectiveness whilst enabling improved patient access to innovation

Recommendations (1/2)

Recommendation	Current Bill	Proposed Amendment/s
Improved certainty and specificity for patients and industry, including: • **Benefits**: The NHI must spell out a benefits package. Furthermore, the BAC's recommendations should be binding and there must be clear principles and criteria informing the benefits design process. • **Role of Provinces:** Provinces have a constitutional right to deliver healthcare AND be funded for it. It is critical for Provinces to continue to have procuring ability to enable responsiveness to local needs • **Procurement:** Procurement should be flexible enabling individual institutions to procure based on local patient needs in line with Public Procurement Bill. • **Supplier accreditation:** Pharmaceutical companies which are suppliers are registered with SAHPRA and their products are registered with same – we do not see a role for NHI in accreditation	• There are no principles in accordance with which the BAC must fulfil their functions (clause 25). • For example, they must 'DETERMINE" the benefits (clause 25(5)), but they are only an ADVISORY Committee (clause 25(1)). • Bill states that Provinces do not have a role anymore – only two levels will exist – districts and national. • The NHIF procures (clauses 10(1)(b), 11(1)(g) & 11(1)(i)(i), 11(2)) – NHIF- and clause 20(3) – procurement unit established by the CEO. However there is an Office of Health Products Procurement (OHPP) established (clause 38), but its relationship to the procurement unit in clause 20 is unclear. • Clause 55(1)(h) refers to the accreditation of "suppliers" as does clause 10(1)(l) – the NHI monitoring supplier accreditation.	**Benefits:** • The BAC should make recommendations that are bearing on the NHI versus advise • Add principles that must inform decision-making, including (a) evidence-based medicine, (b) considering the right of access to healthcare and progressive realization thereof, (c) taking into consideration vulnerable populations, and (d) existing rights and entitlements. **Role of Provinces:** • Provinces have a constitutional right to deliver healthcare AND be funded for it (Constitution, sections 104 + Schedule 4; s133, s227 (each province entitled to equitable share to fulfil its functions) **Supplier Accreditation:** • SAHPRA licences suppliers and also registers their products, no requirement for NHIF to accredit medicines, medical device or IVD suppliers **Procurement:** • The OHPP cannot set any procurement system that goes against the PFMA and National Treasury Regulations. • Procurement should be permitted by entities within their budgets, which budgets (for public sector) or reimbursement (for private sector) will be set also on health outcomes, which means that there should be control over what "tools" to use to obtain optimal outcomes

Recommendations (2/2)

Recommendation	Current Bill	Proposed Amendment/s
Ensuring a comprehensive and evidence-based formulary consisting of vaccines and therapies that keep pace with science and global best practice	• No clear path to introduce new medicines • Unclear and unworkable HTA provisions. • The role of BAC and development of the benefits package is unclear. • Insufficient provision of medicines for rare diseases, patients who do not respond to standard care, academia. • Patients might lose access to current regimens.	• Include a definition of "evidence-based medicine" and make a the criterion for decision-making as in the NHI White Paper • Section 25(5) add new phrase: "…in accordance with the principles of evidence-based medicine." • Amend references to formulary to provide for treatment failure, adverse events, harm or potential harm, and the requirements of academia. • Include measures to ensure continued access to all medicines that are currently available. • Clarify definition of complementary list and define process of development thereof including principle of evidence-based medicine and consultation with medical societies and patient groups.
Investing in and incentivising outcomes in the health system	• Over emphasis on lowest cost versus value and cost-effectiveness • Unclear and unworkable HTA provisions. • Pricing frameworks appear contradictory and unworkable in the manner prescribed.	• Include a definition of "value-based care" • Section 35 (1): Add "…in accordance with value-based care." • Section 41(1): Add "…in accordance with value-based care." • Include measures to allow negotiated prices with options of alternative reimbursement, risk sharing, value-based pricing and similar agreements and a level of confidentiality