INNOVATION IN SERVICE OF THE NHI

Presentation to the Portfolio Committee on Health

June 29, 2021

IPASA
Innovative Pharmaceutical Association
South Africa

About the Innovative Pharmaceutical Association South Africa (IPASA)

The Innovative Pharmaceutical Association of South Africa (IPASA) is a voluntary association of leading international companies dedicated to researching and developing novel medications, medical devices and diagnostic tools. Spanning the entire pharmaceutical value chain – from development, to manufacturing and distribution – IPASA supports initiatives in both the public and private healthcare sectors to help develop practical solutions to address the country's most pressing healthcare challenges. IPASA's philosophy is one of collaboration with other role players in the healthcare sector to achieve maximum benefit from the latest discoveries and technologies in the field of pharmaceuticals.

Our economic contribution to South Africa

Research
Innovative pharmaceutical companies in South Africa will have spent over R3-billion on clinical research of new treatments between 2016 and 2021. Their research and development (R&D) and clinical trials covered 100,000 patients, representing an investment of more than R1-billion.

Jobs
The innovative pharmaceutical companies present in South Africa represent a total of 14,000 direct and indirect jobs.

Local production
Local production is valued at R17.9-billion and growing. The innovative pharmaceutical companies in South Africa have invested R1.3-billion in local manufacturing capacity.

Essential Requirements for achieving sustainable universal health coverage

- Progressive realisation of health rights
- Value-based healthcare improving access to evidence based formularies
- Innovative pricing, novel access solutions and alternative reimbursement models
- Procurement models that contribute to sustainability of the private sector and security of supply
- An independent Health Technology Assessment entity that undertakes assessments on the value-based nature of healthcare
- Economic growth must drive step-wise implementation

THE INNOIVATIVE PHARMACEUTICAL INDUSTRY IS COMMITTED TO CONTRIBUTE TO UHC

Our commitment to Universal Health Coverage (UHC)

The innovative biopharmaceutical industry stands together with the global health community to support all countries in accelerating efforts to achieve UHC. In South Africa, IPASA's members fully support Government's ambition to enact legislation progressively to realise people's health rights.

The value of innovative medicines and vaccines

IPASA members research and develop innovative medicines and vaccines that help people to live longer and more fulfilled lives. Innovative medicines and vaccines also cut overall healthcare costs by speeding up recovery times. They often reduce the need for surgery and hospitalisation.

COVID-19 highlighted the importance of investment in innovation. Thanks to new technologies, which had been developed over the past decade, our industry developed multiple candidate vaccines within months after the pandemic's outbreak – a process that would previously had taken several years

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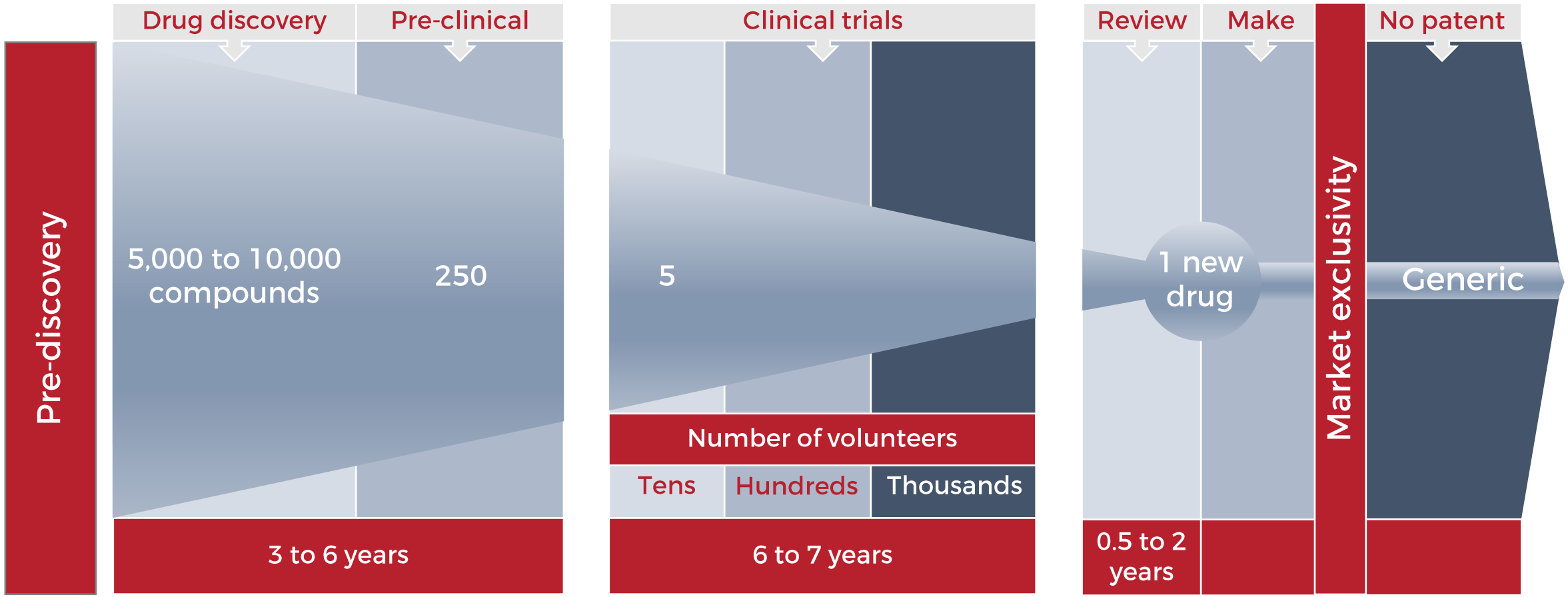
The need for innovative social partnerships

COVID-19 confirmed our longstanding commitment to match our scientific innovations with equally innovative social partnerships to ensure equitable access to life saving medicines and vaccines. We recognise the current inefficiencies and inequities of South Africa's dual healthcare systems and share Government's ambition to achieve UHC in our country. We are committed to bring the same spirit of collaboration that drove our search for COVID-19 vaccines to the challenge of ensuring the realisation of all South Africans' health rights.

Life of a medicine



Developing a new medicine takes an average 10 to 15 years.
For every 5,000 to 10,000 compounds in the pipeline, only one is approved.

References:
- DiMasi et al, Journal of Health Economics, January 2016
- The Pharmaceutical Industry in Figures. European Federation of Pharmaceutical Industries. Key Data 2018 https://www.efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf

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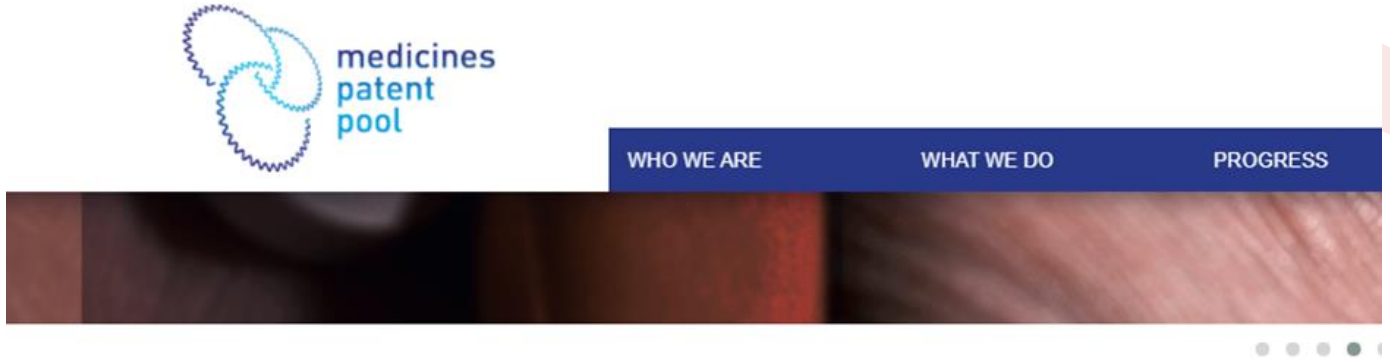
Advancement of Access to Innovations in Collaborations with Generic Companies



About Us

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries.

Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups and other stakeholders, to prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations.

To date, MPP has signed agreements with ten patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals and a tuberculosis treatment. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC).

www.medicinespatentpool.org

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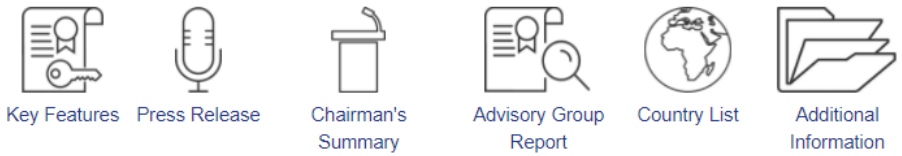
Emtricitabine that is on State Tender is Available through Four Local Generic Firms



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Our principles and promises

We are committed to support the Government of South Africa in achieving UHC

UHC is a direction, not a destination

Principle

The Constitution calls for "progressive" realisation of healthcare rights. This demands a gradual expansion of coverage as more resources become available.

Promise

We use science to change lives

Our most important contribution is to bring innovative medicines and vaccines to South Africa. Appropriate novel treatments extend and improve the quality of patients' lives and strengthen the healthcare system.

Health is an investment, not a cost

Principle

Investment in healthcare improves patients' quality of life, increases productivity and prevents catastrophic expenditure. This demands a "whole-economy" and "all-government" approach.

Promise

We will tackle affordability and access head on

We are open to participating in the development of new tools, including alternative reimbursement models (ARMs), that are aimed at high value outcomes while improving affordability. reimbursement models

Innovation is the engine of progress

Principle

Innovation in healthcare must be supported across the continuum of prevention, diagnostics and care. Innovative financing and service delivery models help build sustainable systems and improve patients' quality of life.

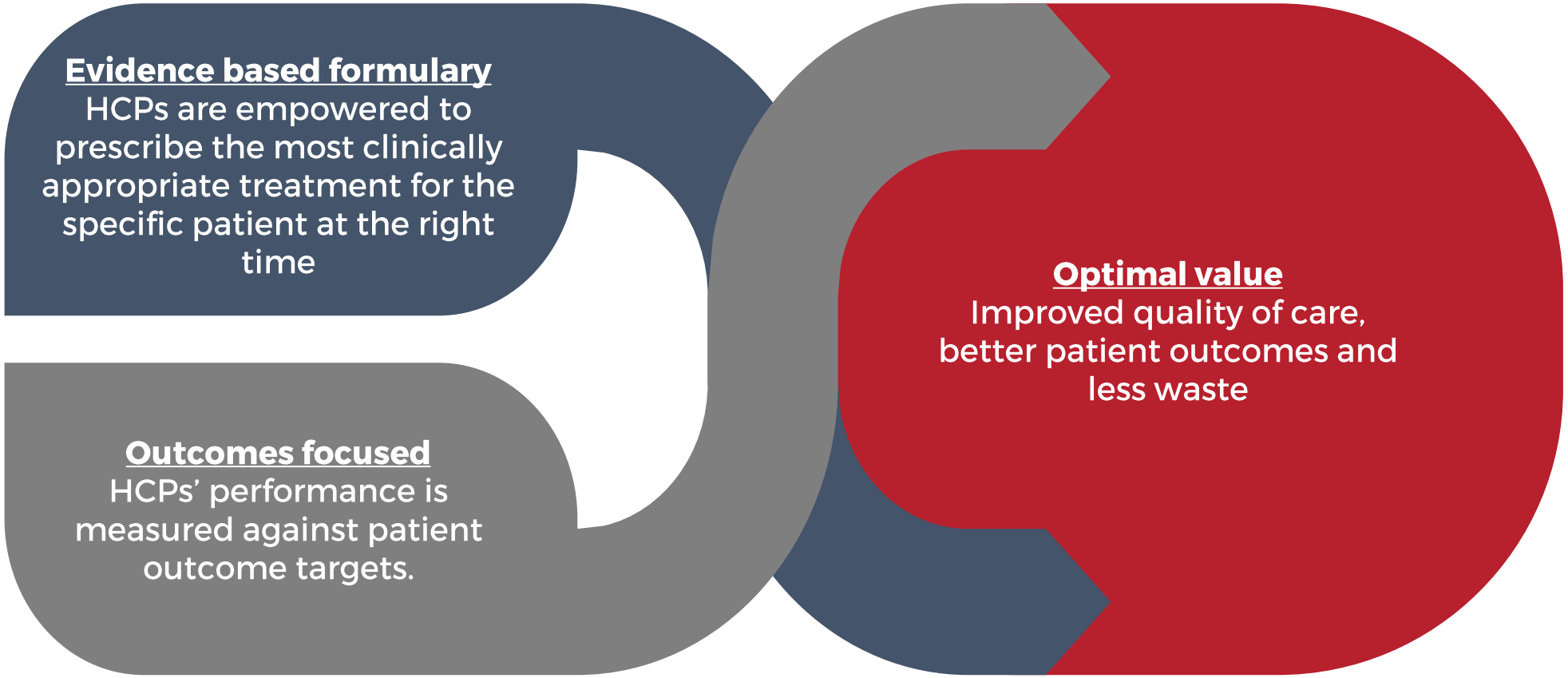
Promise

We will make a positive contribution to the process

IPASA is committed to collaborating with a broad range of stakeholders, to bring fresh ideas to the table, and to be open to constructive feedback and debate.

THE RIGHT MEDICINE AT THE RIGHT TIME FOR THE RIGHT PATIENT SAVES PRECIOUS RESOURCES

Empowering HCPs to prescribe the most appropriate treatments from an evidence-based formulary that includes new medicines and vaccines that will improve patient outcomes and can limit avoidable costs



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CHALLENGES AND RECOMMENDATIONS

To achieve sustainable UHC, the NHI Bill needs to be amended in six key respects:

1. The Bill does not provide adequate reassurance that health rights will be realised **progressively**.
   - The current Bill prevents the private private healthcare sector from providing its current services.
   - This constitutes **regressive** legislation that is not aligned with the Constitution

2. The NHI need to motivate providers to exceed outcome targets. To achieve this, the Bill needs to be amended to ensure:
   - Value-based care
   - Access to evidence-based medicine

3. Specific provision needs to be made for alternative reimbursement models and the proposed extension of the single exit price (SEP) to the public sector needs to be removed.

4. We call for procurement models that will contribute to the sustainability of the private sector, including funders, service providers and treatment developers. Such models would also contribute to security of supply.

5. The current Bill places health technology assessments under control of the NHI and over-emphasis the role costs should play in adjudicating new medicines. Instead, the Bill needs to provide for the establishment by legislation of an independent Health Technology Assessment entity that undertakes assessments on the value-based nature of healthcare.

6. The current Bill dictates that the NHI will be implemented according to fixed timelines, rather than when the system has shown that it is ready. The Bill needs to determine that the NHI will be phased in according to benefits that are set, and comprehensively provided, in line with the principles of evidence-based medicine and value-based care. This phased-in approach must be subject to processes of public participation prior to being recommended.

We thank you for your time and wish you well for your deliberations.

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Addendum:
Proposed amendments to the National Health Insurance Bill

NOTE for following pages:

Underlined text = proposed additions to existing sections in the Bill
Strike-it-through = proposed deletion from the NHI Bill text

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Progressive realisation of health rights

The Constitution calls on Government to enact legislation that progressively realise people's health rights. Implementation of the NHI Bill, in its current form, might lead to an unconstitutional regression of access to health if patients lose access to the treatments they currently rely on, or if future NHI benefits need to be cut back due to economic decline. Thus:

1. The NHI can only be implemented lawfully if it will be sustainable. The NHI must therefore be established at a pace that national economic challenge should it prevent access to services and treatments that are currently available in the multi-payer systegrowth can support, and in phases that are linked to the achievement of predetermined goals.
2. A single payer system would be at risk of Constitutional m.

Proposed amendments

Section 1 amendment to definition: "private health ~~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"
Section 6(o): "to purchase health care services ~~that are not covered by the Fund~~ through a ~~complementary~~ voluntary medical ~~insurance~~ scheme registered in terms of the Medical Schemes Act, any other private health insurance scheme or out of pocket payments, as the case may be."
Section 33: IPASA propose that this section be deleted. There are powers under the Medical Schemes Act as it stands to determine the scope and nature of benefits.

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Value-based healthcare

Higher standards of treatment and care improve patient outcomes, reduce waste and raise health system efficiency. Ambitious provider standards must be set and monitored. The NHI need to motivate providers to exceed outcome targets. To achieve this, they need access to innovative medicines and technology, as well as broad prescription freedom.

Proposed amendments

Section 1: insert definition of "evidence-based medicine", as internationally agreed, and as set in the NHI Green- and White Papers: "'**evidence-based medicine**' means the conscientious, explicit and judicious use of current best evidence in making decisions about the care of beneficiaries whereby individual clinical experience is integrated with the best available external clinical evidence from systematic research"

Section 1: Insert definition of "value-based care": "'**value-based care**' means care and reimbursement models that obtains value through the measurement of patient outcomes"

Section 25(5) add new phrase: "The Benefits Advisory Committee must determine and review, in accordance with the principles of evidence-based medicine—"

Section 35 (1): "The Fund must actively and strategically purchase health care services on behalf of users in accordance with need and in accordance with value-based care."

Section 41(1): "The Fund, in consultation with the Minister, must determine the nature of provider payment mechanisms and adopt additional mechanisms in accordance with the principles of value-based care".

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Evidence-based formulary and treatment approval under exceptional circumstances

Delays in providing patients with the most appropriate treatment often cause disease progression and the development of comorbidities that require hospitalisation and rapidly raise costs. Early, effective treatment can stop or delay disease progression, save money and hospital resources, and improve the quality of patients' lives. Medicines must be available, and such availability must go beyond what is deemed "essential". Access to innovative treatments cannot be restricted to specialist levels of care if they are to achieve their full potential to maximise resources while improving outcomes. Not all patients are adequately treated, reach treatment targets or respond positively to formulary medicine. Some patients experience adverse effects, or could even suffer harm on medicines generally used. What is available would go beyond what is included in the Essential Medicines List, as is envisaged in the National Drug Policy. These patients are particularly vulnerable, and are equally entitled to care. HCPs should therefore be empowered to prescribe the most appropriate medicine from an evidence-based formulary. Digital technology and specialist consultations could reduce the need for referrals and allow for rapid approval of treatments that fall outside the local HCPs prescription mandate.

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Proposed amendments

Section 1: Insert definition of "evidence-based medicine" as proposed on previous slide

Section 1: amend definition of formulary: "'**Formulary**' means a medicine list compiled on the basis of evidence-based medicine, considering appropriate alternatives in cases of treatment failure, adverse events, harm or potential harm, with a view of ensuring access to medicines for all ~~the Formulary and its composition referred to~~ and as set out in section 38(4);

Section 7(4)(c): "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~~ due to the prevalence and nature of the condition, and/or where not providing treatment to a patient would unreasonably limit the right of access to healthcare.

Section 8(2)(d): "seeks treatment that is not included in the Formulary and/or that does not fall under circumstances set out in section 7(4)(c)."

Section 38(3) develop a national health products list, with due consideration of the principles of evidence-based medicines, and value-based assessment;

Section 38(4): "... development and maintenance of the Formulary, whilst considering the total cost of care, comprised of:

(a) the Essential Medicine List and Essential Equipment List;
(b) all medicines available in the public sector at the time of the Act coming into effect;
(c) other medicines included in the Formulary pursuant to the principles of evidence-based medicine and value-based care;
(d) additional medicines required by patients in the circumstances set out in section 7(4) (c) including what is required by academic medicine, used in the delivery of health care services as set by the Fund after consultation with professional associations, patients and other stakeholders ~~approved by the Minister in consultation with the National Health Council and the Fund~~.

Innovative pricing, novel access solutions and ARMs

The innovative pharmaceutical industry is working with governments around the world to develop pricing and market access- and alternative reimbursement models that support innovation while improving affordability. While single exit pricing (SEP) has the potential to lower prices to an extent, it is often too rigid to allow social partnerships that improve access to medicines through innovative pricing and market access models. The SEP and other legislation that could obstruct novel pricing and access models need to be reconsidered. In this regard we would support broadening of the Pricing Committee's mandate to consider pricing and market access comprehensively. Scientifically informed, holistic health technology assessments in an independent multi-stakeholder forum should consider both the clinical and pharmaco-economic value of medicines.

Proposed amendments

Section 1: Add new definition: "'medicines, medical device or IVD pricing- and access models' mean outcomes-guarantees, managed entry agreements, risk-sharing agreements, price-volume agreements, bundled payments and other models in terms of which medicines could become accessible and available within the NHI"
Section 15(3)(d) add: "the improvement of efficiency and performance of the Fund in terms of strategic purchasing and provision of health care services and the negotiation and implementation of NHI medicines pricing- and access models;"
Section 26(5) add: "The Healthcare Benefits Pricing Committee shall exercise its mandate with due consideration of the principles of value-based care and evidence-based medicine."
Remove in Schedule to the NHI Bill (table) with reference to section 58, the proposed amendment to Act 101 of 1965 that proposes to extend the single exit price (SEP) to the public sector, on basis of section 217 of the Constitution that requires procurement to be "fair, equitable, transparent, competitive and cost-effective" (as set by legislation, therefore requiring consideration of the Draft Procurement Bill). Price-setting as per the SEP would therefore not align with the Constitution. Such prices also hamper innovation and participation on value-based care projects, and therefore access and availability.

Value-based pricing informed by HTA and other tools

IPASA is supportive of the use of good scientific and economic practice when assessing health technologies leading to an objective opinion on value, rather than cost, that encourages innovation. HTA's should be undertaken by an independent body that takes an holistic and. system-wide perspective on value, as opposed to only a narrow approach based on cost. Such a system must be uniform, transparent, have clear timelines and involve stakeholders. Countries with developed HTA systems have access to data that assesses value. South Africa has no such national or regional data sources, although the passing of the NaPHISA Act and its implementation will assist in generating such data. IPASA supports the implementation of an HTA model, and an Outcomes Measurement Regulatory Organisation (OMRO), as recommended by the Health Market Inquiry, in order to ensure enhanced decision-making in the provision and funding of health care.

Proposed amendments

Section 1 add this definition: (propose IPASA adds to what Prof Valodia states): "value-based pricing means novel ways of setting prices for innovative medicines in terms of improving access by considering the costs, benefits, budget impact and future return on investment in a transparent manner, which could use health technology assessment'

'Health technology assessment' means a form of value-based assessments that comprises a systematic evaluation of properties, effects and/or impacts of health technologies and interventions, covering the direct, intended consequences of technologies and interventions, and their indirect, unintended consequences, as established by an independent body established by statute;

Section 7(4) Treatment must not be funded if a health care service provider demonstrates –

(c) no value-based ~~cost-effective~~ intervention exists for the health care service as determined by a such a system ~~health technology~~ assessment.

Section 57(3)(d) (considering amendments to the whole of section 57 by removing policy objectives from legislation) be amended and replaced with: "The establishment by legislation of an independent Health Technology- or Value Assessment entity that undertakes assessments on the value-based nature of healthcare"

Sustainable procurement models

Rigid, centralised procurement systems and tender processes where the winner takes all come with the risk of interruptions in availability from single source suppliers. It could also threaten the viability of the national pharmaceutical industry. Importantly, centralised procurement often delays the introduction of valuable innovative treatments. We propose that sole-supplier tenders should be avoided in the interest of continuity. We also support that academic hospitals and regional centres of excellence should be free to procure specialised treatments that are specific to their needs, as well as new medicines that show a significant improvement on the standard of care before they are introduced in the generally available NHI formulary. Academic complexes (central and tertiary facilities`) require access to medicines for teaching and research / scientific purposes and be permitted to procure as "trading entities" for these purposes. Consideration must be had for the new proposed procurement legislation, as the NHI Fund could, constitutionally-speaking, not deviate from that system.

Proposed amendments

It is important that the NHI Bill and the new Procurement Bill (on which IPASA commented in its draft format earlier this year) align. The Procurement Bill is constitutionally-mandated by section 217 and should facilitate flexible procurement, as the NHI Fund could not be exempted from its operation.

Section 11(2): "Any entity authorised by the Act to deliver health services in terms of sections 7(2)(f), 32(2), and 37~~, the Fund~~ may enter into a contract ~~for the procurement and~~ supply of specific health care services, medicines …"

Section 38 (1) The Board, in consultation with the Minister, must establish an Office of Health Products Procurement which sets parameters for the public procurement of health related products, in line with national procurement legislation

Section 38(2) The Office of Health Products Procurement must be located within the Fund and is responsible for the centralised facilitation and coordination of functions related to the public procurement of health related products, including but not limited to medicines, medical devices and equipment, within the powers afforded to health establishments to procure in response to the health needs of the populations it serve, and to enter into'medicines, medical device or IVD pricing- and access models

Reliable forecasting to ensure security of supply

Reliable forecasting impacts directly on the availability and price of medicines. Unreliable forecasting poses a significant threat to the sustainability of the local pharmaceutical industry. We welcome the reported progress by the DoH in implementing digital- and data systems that could support accurate forecasting.

Proposed amendments

Sections 10(1)(i): "… collate utilisation data and implement information management systems to assist in forecasting, monitoring the quality and standard of health care services, medicines, health goods and health related products purchased by the Fund"
Section 10(1)(q): "… maintain a national database on the demographic and epidemiological profile of the population to ensure accurate forecasting, and to utilize data generated by the National Public Health Institute to ensure responsiveness to the access to healthcare requirements of the population;

Economic growth must drive step-wise implementation

Sustainable universal healthcare precludes the introduction of treatments and services that would later have to be withdrawn when the country comes under economic pressure. It is therefore imperative that the NHI should be introduced at a pace no faster than what our economic growth can support. A phased introduction, linked to negotiated economic targets could avoid austerity driven regression of health rights that could potentially face Constitutional challenge.

Proposed amendments

To effect the above, IPASA proposes:
The HMI Recommendations are aimed at preparing the private sector for the NHI – IPASA highly recommends that those recommendations, such as the Outcomes Measurement Regulatory Authority, be implemented as necessary precursors to successful contracting of the private sector as providers to the NHI Fund.
Section 57: IPASA proposes that section 57 be redrafted in its totality – it currently lists past policy interventions by the NDOH< and not how the NHI will be implemented to progressively realise healthcare rights. A logical (and tested) way that could be done is per level of care care, which phased-in approach will be subject to processes of public participation prior to being recommended and per disease entities, e.g. PHC with vaccines, preventative care and key chronic conditions that are the major burden of disease.
Section 57(1): The NHI shall be phased in according to benefits that are set, and comprehensively provided, in line with the principles of evidence-based medicine and value-based

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