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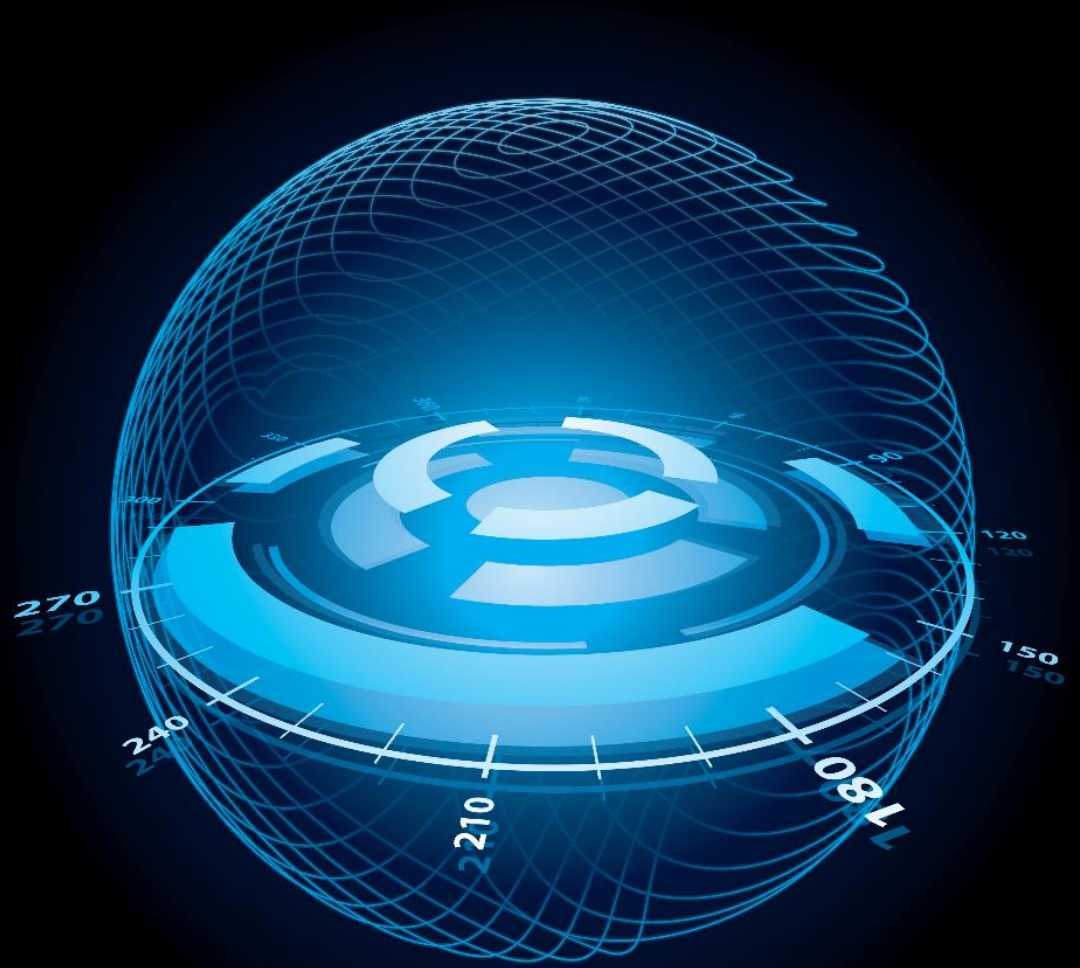

Deloitte Digital Dialogue powered by J&J

Enabling innovation in the NHI

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Opening remarks

The South African government aims to achieve universal health coverage for its citizens through the National Health Insurance (NHI) by 2025.However, several challenges in South Africa such as the lack of health care personnel, bureaucratic difficulties, inefficiencies and limited access to health care for the poor, and inconsistent access to health care in rural areas have impacted the implementation of the NHI. The National Planning Commission has stated that full implementation of the scheme could take up to 25 years given this background.

The NHI bill was introduced to Parliament in August 2019 and is currently under consideration with the National Assembly Portfolio Committee on Health. In the medium-term expenditure framework for 2021-2023, the government allocated R7.5 billion to the NHI programme to strengthen the system and contract accredited service providers. Government seeks to ensure availability of essential medicine and other medical supplies in all health facilities. A single national benefits package was developed in preparation of the NHI bill which specifies all medicines listed on the national Essential Medical List (EML.). “Like other African countries, South Africa’s EML consists of low-cost , low value drugs, with high value innovative drugs being limited”, explains Ashleigh Theophanides, Deloitte Africa’s Life Sciences and Health Care Industry leader.

In partnership with Johnson & Johnson, Deloitte and it’s invited guests from across the ecosystem discuss how the NHI can enable sustainable innovation in health and value-based health care. The focus is on how pharmaceutical companies can align more closely to the NHI to improve outcomes and create an environment that enables innovative pharmaceuticals to have a strong presence in the NHI going forward.

Facilitator

Ashleigh Theophanides
Africa Life Sciences and Health Care Industry Leader
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Panellists

Dr Anban Pillay
Deputy Director General, Health Regulation and Compliance
Department of Health

Aluwani Museisi
Director: Government Affairs & Policy
Johnson & Johnson

Bada Pharasi
CEO
The Innovative Pharmaceutical Association of South Africa (IPASA)

Lauren Pretorius
CEO
Campaigning for Cancer

"pharmaceutical manufacturers need to adopt an approach that explains the clinical benefits of the product, demonstrating its superiority against others when introducing a new innovative medicine in the market"

- Dr Anban Pillay, Deputy Director General, Health Regulation & Compliance
Department of Health

Department of Health: View on the role of innovative Pharma in NHI

Health care discussions between government and pharmaceutical manufacturers tend to be polarised regarding access to medicine. According to Dr Anban Pillay, Deputy Director General of Health Regulation and Compliance in the Department of Health, the COVID-19 vaccine manufacturing process has shown the possibility of developing innovative products and bringing them to market in a short period of time. Not only were regulatory barriers dealt with effectively in this regard, but governments have shown commitment to procuring COVID-19 related medical products in large volumes from across the globe.

Dr Pillay adds that it is, however, crucial to have a clear distinction between innovative medicines and medicine that provides significant therapeutic advantage. Health systems across the world and purchasers are demanding that pharmaceutical manufacturers demonstrate the clinical benefit that innovative medicines provide. "One of the challenges the industry faces, is the lack of documentation of the clinical benefits that would support the pricing approach", he explains.

The EU study on 'Innovative Payment Models for High-Cost Innovative Medicines',[1] reported that 9 in 10 'so called innovative' medicines provide marginal clinical benefits. Dr Pillay states that "pharmaceutical manufacturers need to adopt an approach that explains the clinical benefits of the product demonstrating its superiority against others when introducing a new innovative medicine in the market". He further adds that it would also be beneficial to explore the products in real life situations outside of clinical trials. Like the COVID-19 vaccine approach, proper documentation should be performed to measure how effective the products are performing in preventing infections.

To support the innovative medicine market, procurement systems in government need to be reformed. The Public Finance Management Act (PFMA) assumes that products are equivalent to each other and largely operates on a competitive basis, not considering that the innovative market is very different. The EU has reported that it is willing to take a joint risk approach with the pharmaceutical industry to identify potential benefits of products, assess them and roll them out into the market. In the same manner, Dr Pillay believes that locally a partnership between government and industry in a cost sharing approach is beneficial towards the Research and Development (R&D) of innovative medicines.

Alternatively, pharmaceutical manufacturers that decide to take the risk on their own, should commit to transparency regarding the cost of R&D and production of the innovative medication. This will assist in informing the price and benefit associated with the medicine especially considering the health systems tight budget.

[1]European Commission. 2018." Innovative Payment Models for High-Cost Innovative Medicines".

"The draft NHI bill imposes more limitations on innovation and on innovative medicines and is very vague on how innovation will be included"

- Aluwani Museisi, Director: Government Affairs & Policy Johnson & Johnson

Pharma perspective on NHI

The value of innovation in pharma has shown clear evidence in improving life expectancy. In the United States (US), pharmaceuticals have contributed 35 per cent to life expectancy gains between 1990 and 2015. Furthermore, biopharmaceutical innovation accounts for a 76 per cent reduction in mortality in patients with HIV, 60 per cent reduction in mortality for patients with breast cancer, and 52 per cent for those with heart disease.[2]

Innovation and R&D are core to pharmaceutical manufacturing businesses. Success in the cycle of innovation depends on key components being met including a successful health care system, an open market to ensure procurement, effective use of intellectual property (IP), and predictable regulatory outcomes. According to Aluwani Museisi, Johnson & Johnson's Director for Government Affairs and Policy "the draft NHI bill imposes more limitations on innovation and on innovative medicine". He further expands that "the bill is vague regarding how to introduce innovative products into the market. It is clear on the reimbursement of medicine on the Essential Medicines List (EML); however, the EML does not include all products available for patients' needs. A clear example being the COVID-19 vaccine that is not on the EML but is being accessed by the public". The bill also poses a challenge for prescribers who do not prescribe in line with the EML, the potential risk of losing accreditation with the NHI.

In addition, historically the EML has been unpredictable regarding timelines of reviewing either the current list or applications made for new products to be included on the list. Reviewing the procurement process of the NHI, Museisi notes the current bill is not geared towards procuring innovative medicine. The focus is on the lowest possible price model. "This poses a challenge to competing companies if they are not awarded a tender by the NHI-as they could potentially have spent four to five years without business and face the risk of not operating".

Delivery and financing models for pharma to consider for NHI

The Innovative Pharmaceuticals Association of South Africa (IPASA), a voluntary association of international companies dedicated to researching novel medications, medical devices, and diagnostic tools, emphasises the role that private healthcare and innovative pharma can play in the country's health care delivery system under NHI. "

Considering the South African economy and outlook, IPASA is of the view that the NHI funding is likely to be unsustainable in absence of sustained economic growth. "IPASA advocates that financing must be based on sound and realistic costing", explains Pharasi, the CEO of IPASA. The current proposal suggests that funding for NHI will be raised through a combination of pre-payment sources, but will be primarily based on general taxes.[3]

[2] Buxbaum, J. Chernew, M. Fendrick, M. Culter, D. 2020. "Contributions of public health, pharmaceuticals, and other medical care to US life expectancy changes, 1990-2015". Health Affairs

[3] The White paper on National Health Insurance. 2015. South African government. https://www.gov.za/about-government/government-programmes/national-health-insurance-0

"IPASA advocates for a pricing system that considers and facilitates patient access to all medicines including innovative molecules"

- Bada Pharasi, *CEO,* The Innovative Pharmaceutical Association of South Africa

"the advancement of medicine means nothing to patients if they cannot access them"

- Lauren Pretorius, CEO, Campaigning for Cancer

Medical pricing is another challenge the current NHI bill imposes on innovation. Pharasi adds that "IPASA advocates for a pricing system that considers and facilitates patient access to all medicines including innovative molecules. It recommends an Alternative Reimbursement Model (ARM), and the proposed extension of the Structural Adjustment Programme (SAP) be removed". Pillay adds that initial discussions by the Department of Health with Treasury advised for a separate fund to be established outside the EML to cater for innovative medicine.

As it stands government plans to establish a centralised function that will facilitate and coordinate the procurement of medical products. IPASA urges the pricing regime to look at ARMs that provide risk sharing and engagement between government and suppliers. Through the Health Technology Assessment (HTA), the pricing regime needs to consider the value the medicine delivers to patients. The NHI bill, however, does not define or indicate which entity will execute these assessments. Thus, IPASA recommends an independent body to be tasked with this assignment and conduct marginal value assessments.

Making provision for value-based health care in the NHI

Lauren Pretorius, CEO and co-founder of Campaigning for Cancer, has spent over 10 years advocating for the promotion and protection of patients' rights with regards to policy, healthcare costs and healthcare delivery. She states that "the advancement of medicine means nothing to patients if they cannot access them". Pretorius further expands that there is a significant skew of focus on disease areas in South Africa where the health system focuses on one disease area at a time. This results in regress in improving other rare disease. Museisi also argues that the NHI does not sufficiently cater for rare disease cases but is rather geared more towards broad public health needs in key high burden areas. "It has been proven that ignored disease will be future diseases that will cripple GDP and the value of life for patients", says Pretorius.

In 2010 the economic cost of productivity losses together with treatment costs for cancer in the US were estimated at US$1.6 trillion which equates to approximately two per cent of its GDP. In South Africa's context, it is crucial to acknowledge that there are not enough resources available, and government does not have enough funding to implement the NHI on its own.

Studies show that 40 per cent of cancer affects woman during their prime working and child raising years between ages 30 to 54. Clinical benefit should thus not only be assessed in isolation when reviewing innovative medicine but should be seen together with the benefit in terms of quality of life it gives to patients, economic productivity, and ensuring inclusiveness. Pretorius emphasises that "the value of medicine should not be measured by its cost alone, but by the benefit it brings to individual patients and to society".

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Recommendation for Alternative Reimbursement Models (ARMs)

It is beneficial for various actors including government, pharmaceutical companies, and patient cohorts to co-develop a practical ARM framework. A steering committee is already formed to agree on principles to guide on developing such ARM proposals. The committee has selected several frameworks to run pilots on the ARM initiatives to inform the NHI bill. Pharmaceutical companies have asked for clear guidelines on risk sharing models to be set. In addition, government has called for clear guidelines on how to assess the value of innovative medicine and for documentation of data to prove the clinical benefits which will motivate the command of higher procurement prices.

Conclusion

The pandemic has shown the power of partnerships between government and the private sector, with further collaboration essential to fulfilling the NHI goals. Partnerships and rewards for higher therapeutic value for innovative medicines is required to create incentives for the pharmaceutical industry to innovate. In this regard, clinical benefit should not be assessed in isolation when reviewing innovative medicine but should be seen together with the benefit in terms of quality of life it gives to patients, economic productivity, and ensuring inclusiveness. However, uncertainty of clinical effectiveness, pricing and regulatory requirements remain barriers that need to be addressed to allow better access to innovative medicines- these are areas which would benefit through multistakeholder dialogue and legal certainty on the inclusion of innovation within the NHI framework.

Thus, increased dialogue among all stakeholders to explore suggestions, to engage and to build capacity will be essential.

South Africa needs leadership to drive change, devote resources and expand its appetite to risk, to enable innovation in the NHI.

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