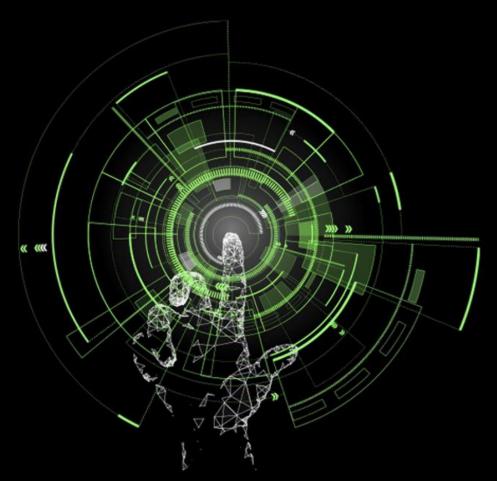
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Deloitte Dialogue powered by J&J Sustainability of the pharmaceutical industry under the NHI 6 May 2022



Setting the scene

In highly unequal countries like South Africa, equal access to health care is often a key challenge. This is not only a social issue, but also an economic issue given that a healthy country is also more likely to be a productive country.

The planned introduction of a national health insurance (NHI) system in South Africa aims at addressing crucial access issues. The aspect of how the system will be financed often overshadows the discourse; however, the key premise of universal access is fundamental.

Facilitator



Ashleigh Theophanides Africa Life Sciences and Health Care Industry Leader Chief Sustainability Officer Deloitte

Panellists



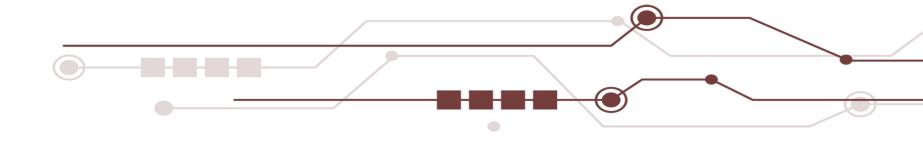
Dr Mark Blecher *Chief Director, Health and Social Development* **National Treasury**



Rashmee Ragaven Senior Manager, Invest SA The Department of Trade, Industry and Competition (DTIC)



Aluwani Museisi Senior Director, Government Affairs & Policy, Sub-Saharan Africa Johnson & Johnson



"Innovative pharma companies are dependent on the private sector for between 95% and 40% depending on the company you look at. NHI creates uncertainty about how they will operate going forward?"

- Aluwani Museisi, Senior Director: Government Affairs & Policy, Sub-Saharan Africa, Johnson & Johnson

Overcoming uncertainties

While there is consensus among most public and private stakeholders that the introduction of a national health insurance system could increase access to care and pharmaceuticals significantly, the current proposed bill still requires ongoing consultations and debate among affected parties.

Due to the uncertainty regarding the final version of the bill, the pharmaceutical industry voiced several concerns regarding the NHI. Industry representatives are concerned that should the bill be passed in the current form, in which it had been introduced in parliament, it would compromise the viability and sustainability of the pharmaceutical industry in South Africa.

Among the factors that cause uncertainty are a lack of clarity about:

- the role of private healthcare providers and medical schemes
- the definition of 'necessary care'
- the Essential Medicines List (EML)
- the source of financing
- timeframes of implementation

The role of private healthcare providers and medical schemes

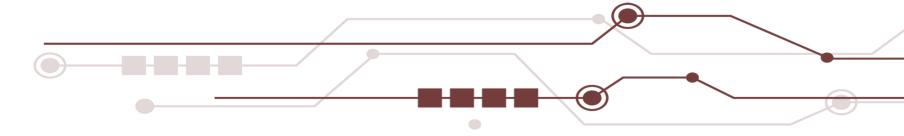
Examples from other countries that provide universal access to healthcare, show that the private sector plays an important role in the provision of healthcare. However, at present, the private sector is concerned that the current NHI proposal does not provide enough clarity about the role of the private sector or defines its role too narrowly. Further, there are many elements of the current proposal that limit private sector involvement.

The definition of 'necessary care'

While the proposed bill refers to the provision of 'necessary care', there seems to be ambiguity about what this entails. The private sector voiced its concern that there is not enough clarity about what happens to patients if the specific care they require is not deemed necessary.

The Essential Medicines List (EML)

Currently, most of the public sector's pharmaceutical spending is allocated towards the procurement of HIV and TB drugs as well as vaccines. The allocation towards therapeutic pharmaceuticals is limited. Furthermore, the public sector tends to procure old medicines and rarely considers innovative drugs and by doing so reduces the access to more efficient and effective medicines.



"Universal health coverage requires sustainable financing, otherwise the system will not be sustainable for suppliers and providers."

- Aluwani Museisi, Senior Director: Government Affairs & Policy, Sub-Saharan Africa, Johnson & Johnson Currently, innovative pharmaceutical companies depend on the private healthcare sector for between 95% and 40% depending on the company you look at in South Africa.

The proposed NHI bill will include a essential medicines list (EML), which will stipulate what medicine will be procured. Pharmaceutical companies are concerned that the scope of the EML will be limited and will most likely exclude innovative medicines due to their higher costs, as the EML is likely to focus on the lowest possible price. Furthermore, there is a lack of clarity and detail about the process of how new and innovative medicines might be added to the EML. The narrow scope and potential rigidity of this list potentially renders pharmaceutical manufacturing unstainable in South Africa and might prevent patients from accessing the best possible treatment. This is especially concerning in the context of rare diseases and for patients that require so-called orphan drugs.

The source of financing

To ensure universal health coverage, there should be no payment at the point of treatment, according to Aluwani Museisi. However, for this to work, it will require sustainable financing that creates sustainability for suppliers and providers. Currently, pharmaceutical companies struggle to collect payments on time from certain provincial health departments and this affects the cashflows and sustainability of these companies. The industry cautions, that once a single-payer system is introduced and the payment practices do not improve, it could lead to serious financial issues for pharmaceutical companies.

Furthermore, the pharmaceutical industry is concerned about the sustainability of its industry should a tender-based system for all medicines be introduced. Under such a system pharmaceutical companies would only be able to sell their products including therapeutic medicines every few years. Such infrequent purchases would exclude unsuccessful bidders from the market for the period the tender is valid for and hence pose a threat to cashflows and ultimately the sustainability of the industry.

Timeframe of implementation

While the pharmaceutical industry appreciates that the NHI will most likely follow a phased approached when introduced, it is concerned, that the proposed bill sets a fixed implementation date of 1 January 2026 and does not make clear provision for a phased approach. This fixed implementation date might not leave enough time for finding workable solutions to address the number of yet to be clarified issues. The industry acknowledges that further dialogue will be necessary to arrive at a bill that will ensure universal access and at the same time the sustainability of the pharmaceutical industry in the country.

Treasury view

The Treasury is aware that the proposed bill in its current state does not answer all the questions of the pharmaceutical industry and still requires consultations and dialogue with the private sector. In this context, it is important to understand that the NHI, like universal health systems in other countries, makes provision for the involvement of the private sector alongside the public sector. The rollout of the COVID-19 vaccines and the treatment of multi-drug resistant tuberculosis (MDR-TB) in South Africa provide valuable lessons on how a mixed provision model can work. Private pharmacies, as part of the mix of sites, administered free of charge COVID-19 vaccines even to those without insurance cover. In the case of MDR-TB, strong collaboration between the public and the private sector significantly enhanced the treatment of the disease and has ultimately led to a change in the World Health Organisation's guidelines on how to treat MDR-TB globally.

The Treasury assures the industry that the primary goal of the NHI system is the expansion of access, which should ultimately benefit the pharmaceutical industry as it will create volume effects. This was, for example, the case in Croatia when an electronic prescription system was introduced that allowed patients to receive their medicines at any private or public pharmacy in the country.

While a centralised procurement system might be viewed sceptically by the private sector, it can also create efficiencies that create benefits for patients and pharmaceutical companies alike. Centralised procurement and EMLs do not automatically exclude innovative drugs. Indonesia's National Health Insurance (JKN) serves as an example for how access to innovative drugs can be ensured under a national health insurance scheme. Indonesia uses an e-catalogue in combination with an electronic tendering and negotiations process that treats innovative drugs differently to standard drugs and hence ensures access to these type of drugs to patients.

An important element for the success of the NHI will be the creation and empowerment of strong agencies to carry out the assessment of pharmaceuticals. In the past, this function was sometimes carried out by the Treasury. Instead of carrying out this function, Treasury would prefer to finance an independent agency that carries out the Health Technology Assessment (HTA) and would welcome the capacitation of the South African Health Products Regulatory Authority (SAHPRA) to conduct rapid reviews.

Further, the NHI system is not meant to be introduced overnight, but rather in a phased manner that will allow for adjustments and will be aligned to current financial limitations. In this context, there are still several practical questions to be answered. The gradual introduction would include the onboarding of 2000-3000 general practitioners (GPs) over a multi-year period and during this transition period there will be room for engagement to get the practicalities right.

"Lot of the details are not finally developed and there is still room for negotiations. The overall goal is the expansion of access to care and medicines."

- Dr Mark Blecher, Chief Director: Health and Social Development, National Treasury

"We are aware of the challenges, but we should not be defined by these challenges; hence we encourage private sector dialogue to develop programmes to assist the private sector to overcome these challenges."

- Rashmee Ragaven, Senior Manager: Invest SA, The Department of Trade, Industry and Competition (DTIC)

Creating a conducive environment to ensure sustainability

Given the DTIC's mandate to facilitate investment in and industrialisation of the economy, it aims at creating a conducive environment for pharmaceutical manufacturers. The sector has been identified as a strategic priority for the department and it is looking at developing a healthcare masterplan through a consultative process that involves public and private sector stakeholders.

Recent global supply chain disruptions and subsequent stock outs, reinforce the need to create a resilient healthcare system and to increase local manufacturing capacity and capabilities. Factors including the rising burden from lifestyle diseases is expected to increase the demand for innovative pharmaceuticals. Increased demand as well as the country's positioning and trackrecord in pharmaceutical manufacturing bode well for South Africa for strengthening its role as a key gateway for manufacturers to tap into the regional market. According to the DTIC, improving and expanding local production capacity will also reduce the country's dependency on imports and hence enhance the resilience of the healthcare system. The department has adopted a holistic view towards the industry and has a number of instruments that it uses to attract investment into South Africa. It sees itself a vital link between the government and the private sector as it is well positioned to facilitate introductions among various stakeholders and act as an advocate and conduit for investors to engage robustly on a number of matters that affect their investment and the climate of investment

Finding compromise

Given the current state of the proposed bill and the shared understanding of the benefits of the NHI, ongoing consultations and dialogue between the government and the private sector remain critical. There is a need to find the balanced approach with a win win for all parties concerned and government continues to take the consultative approach when developing policy for the country.

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