Demant

PRESENTATION TO THE PORTFOLIO COMMITTEE ON HEALTH NHI Bill

13 July 2021

15h45

Virtual

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ABOUT OTICON SOUTH AFRICA - NOW DEMANT SOUTH AFRICA

- The Offices of Oticon South Africa (Oticon) were opened in 1997 and the business employs 46 full time employees.
- Our products are currently on tender with government, and government hospitals nationally are supplied with Oticon hearing aids. Oticon prides itself on the projects that it has co-run with the government, including patient advocacy days, training seminars to government audiologists and Ear, Nose & Throat Surgeons.
- Oticon also donates a significant number of hearing aids every year to patients that cannot access government services and cannot afford to pay for private services.
- Oticon South Africa also distributes bone-anchored implant systems and cochlear implants under the banner of Oticon Medical, and balance and audiological equipment through Interacoustics and MedRx in South Africa
- Oticon is now named Demant South Africa (Demant), with effect from 24 March 2020. The name change was in line with a global decision, out of our headquarters in Denmark. The product offering and expertise remain the same as before, but now under the name of Demant.

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Discussion Points

1. Background
2. Inclusion of audiology in the Bill and Prescribed Minimum Benefits
3. Submission Summary
    - Pricing
    - Innovation
    - Formulary
    - Treatment Guidelines
    - Payment of providers
    - Medicines Act
    - Supply Chain
    - SAHPRA
    - BBBEE
    - Benefit Package
    - Governance
4. Conclusion

Background

- Demant fully supports the concept of NHI and its ideal to accomplish the progressive realisation of the right of access to healthcare services as set out under section 27 of the Constitution.
- The Bill’s attempt to bridge the gap between privately funded individuals and individuals accessing healthcare in the public sector is well appreciated, if done in a way that there is progression on both ends.
- We do believe however that the implementation of the NHI must be subject to the recognition of the gaps and implementation of the recommendations highlighted by the Health Market Inquiry, the Davies Committee and recommendations made by industry and those contained in our submission of 29 November 2019.

Audiology as a Prescribed Minimum Benefit PMBs - Prevalence

- Over 5% of the world's population **require rehabilitation** to address their 'disabling' hearing loss (432 million adults and 34 million children).
- It is estimated that by 2050 over 700 million people – or one in every ten people – will have disabling hearing loss.
- Over 1 billion young adults are at risk of permanent, avoidable hearing loss due to unsafe listening practices
- Nearly 80% of people with disabling hearing loss live in low- and middle-income countries *(including Sub-Saharan Africa).*

WHO, 2021

Audiology as a Prescribed Minimum Benefit PMBs – Individual Impact

- **Cognition, Education and Employment**
  - Delays in communication and speech… *WHO, 2021*
  - Slow learning and poor schooling… *Peer, 2015*
  - Problems with employment and societal integration in the long term … *Peer, 2015*
  - Increased mental load – decline in memory…. *Rönnberg et al. (2013).*
- **Psycho-social impact**
  - People with hearing loss have larger risk of mental health issues such as **depression and dementia**… Barnett et al, 2016
  - Social isolation, loneliness and stigma …. *WHO, 2021*
- **Physical**
  - Poor balance and fall-related injuries…. Lin et al. (2012).

Audiology as a Prescribed Minimum Benefit PMBs – National Impact

- Hearing loss has a negative impact on overall health and is associated with increased use of healthcare.
- Societies can gain large social and economic benefits by investing in proper hearing care.

Barnett et al, 2016

- WHO estimates that unaddressed hearing loss poses an annual global cost of US$ 980 billion. This includes health sector costs (excluding the cost of hearing devices), costs of educational support, loss of productivity, and societal costs. 57% of these costs are attributed to low- and middle-income countries.

WHO, 2021

- Hearing aid fitting especially in older adults thus will prevent social withdrawal and diminishes the risk of cognitive decline and depression.

Lawrence, 2019

Audiology as a Prescribed Minimum Benefit PMBs

- People with hearing impairment are disabled and therefore vulnerable. However, some of these people can be provided, the opportunity to hear, or improved hearing. Further, detection and treatment at an early age will prevent deterioration and assist with speech. If missed, at the early age, it may result in permanent hearing loss.
- Being provided with the ability to hear through hearing aid devices, such as the ones produced by Oticon, provides quality of life, dignity and opportunity to be independent and to participate in their communities.
- People with this disability can the be empowered to participate in the community, which includes seeking jobs, and doing jobs not previously being able to be done due to the disability. Two-thirds of adults with hearing loss are in the economic prime of their life. Economic participation is very important in South Africa.
- Despite these factors, audiology currently has no place in the NHI/the Bill and the Medical Schemes Act 131 of 1998 and it is still considered by both as an optional treatment. **Oticon believes that audiology should be included in the NHI and the current PMB's as a minimum benefit to provide the hearing impaired the opportunity to hear and have a good quality of life and job opportunities.**

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Oticon submission summary

- **Inclusive approach:** Our belief is that having one funder can cripple the health industry of the country and create barriers to access, the very barriers that the NHI is attempting to breach. The exclusive approach will also limit users' right to choose. We therefore propose there be a multiple funder system in place, which will allow for flexibility and ensure broader and better coverage. It will also provide some level of a risk- equalization mechanism and appropriate care in higher risk pools.
- **Funding:** Prior to the implementation of the NHIF, there must be a guarantee that there is capacity to fund the NHI. From the available literature, the evidence is pointing to the fact that the funding the NHI is no longer affordable, this was part of the the including the findings by the Davies Tax Committee in 2017. Without financial stability and sustainability, the NHI will fail. The failure will leave 100% of the population without funding and therefore no treatment, particularly if it is a single funder system as proposed in the Bill, which we disagree with precisely for this and other reasons. This will be a contravention of section 27 of the Constitution.

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Oticon submission summary - Pricing

- **Product Pricing:** We propose alternative reimbursement models, as have been proposed by industry over the years be implemented. These models will encourage competition and innovation which will ensure better pricing and outcomes for patients, and this will ultimately breach the access gap.
- It must also be recognized there is a huge difference between the business model for medicines and devices, which includes differences in training support, post-sale training and support, maintenance etc., and therefore, separate pricing measures must be created for each, considering these differences and more.

Oticon submission summary - Pricing

- **Procurement through tender:** Oticon is currently on tender to government for the supply of hearing aid devices and consumables and is in support of the tender system being part of the pricing mechanism, provided the measures to ensure that the system is *"…fair, equitable, transparent and cost-effective…"* and are reinforced and processes are reviewed to eliminate any contravention of section 217 of the Constitution.
- The is currently no EEL (Essential Equipment List), whilst there is a list for essential medicines (EML), and requisite processes to review same. The Bill proposes the development of a formulary for EML and EEL under clause 38(4), however the EEL must be developed and approved prior to such formulary and prior to the Bill being passed.
- We therefore propose that EEL be developed as soon as possible as it is not only a requirement under NHI but there is even now a current need for it. The NHI must also provide adequate resources and structures to review these two lists from time to time.

Oticon submission summary - Pricing

- **Multiple pricing mechanisms**
- **Single Exit Price (SEP):** is also another pricing mechanism envisaged under the Bill in addition to the tender system.
- **Negotiated Pricing:** Clause 38 proposes another pricing mechanism,.
- **Supplier rates:** The Bill also provides under clause 41(3) that there will be a rate for suppliers that will be determined annually.
- Oticon foresees that these multiple pricing mechanisms will cause confusion, and require costly systems and infrastructure to implement, and transparency may be an issue.
- Oticon strongly proposes that the tender system remain the pricing system and that price negotiation take into consideration innovative products and the benefit they provide the patient.
- In general, Oticon urges that the tender procurement system must be clear, simple and efficient

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Oticon submission summary - Innovation

- Oticon prides itself in being an innovative company that strives to find solution to suit individual with hearing loss. Innovative products such as the ones introduced by Oticon, e.g.:
  - The first discreet in-the-ear-hearing device (1977)
  - The first fully digital hearing device (1996)
  - In 2014 Oticon announced that its devices now support the brain making sense of sounds by giving it the conditions it need to create meaning from sound, instead of overloading it by turning up the volume
- While these innovative and beneficial, value adding devices are accessible to privately funded patients, they are not available to state patients, due to underfunding, leaving patients with outdated devices. Resulting in deprivation of a quality of life for a majority of our patients. The devices that are provided to most patients in the public sector are outdated.

Oticon submission summary - Innovation

- Negotiating *"…the lowest price possible…"* as envisaged in clause 11(2) of the Bill *"…without compromising the interests of the user."* It is unclear to what extent the interest will be protected and whether it includes access to innovative products, or only access to the bare minimum even if the innovative product is indicated and necessary for some patients. This provision is an indication that innovation and new technology are not priority in the Bill.
- Innovative products are more expensive due to the research and development and the technology that most of them use. They provide quality of life and ensure that previously untreated conditions are treated, and they have the ability to reach a wider and more diverse group of patients due to ease of administration and patient compliance.
- **The Bill must make provision for funding of innovative products to ensure inclusivity and to give effect to the principle of Constitutional equality.**

Oticon submission summary - Formulary

- Formularies and lists (EML and EEL) are accepted as a way to create certainty. However these formularies and lists may cause more harm than good if they are finite, i.e. no room for exceptions and alternatives, if what is in the formulary and/or the list is not suitable for a patient, or if what the patient requires is not covered.
- The Medicines Act Regulations 15H and 15I provide patients with alternatives and exceptions in the abovementioned instances. Clause 38(4) of the Bill does not cover these instances. The result will be that those patients not covered by the formulary and the lists will be left without treatment and the ones currently covered under the Medicines Act Regulations who are on non-formulary, non-EML and non-tender products will no longer be covered resulting in no treatment or out of pocket treatment.
- It is important that the Bill provide for these circumstances, including continued treatment on clinical trial products.

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Oticon submission summary – Treatment Guidelines

- The Benefits Advisory Committee, (“BAC”) will determine and review cost effective treatment guidelines that take into account the emergence of new technologies in terms of clause 25(5)(b).

- Oticon strongly recommends that BAC consult with or involve healthcare professionals and their respective associations or groups in developing these guidelines based on evidence-based medicine. This requirement must be included in clause 25(5)(b), in order for the guidelines to be clinically appropriate and relevant to the patient.

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Oticon submission summary – Payment of Providers and Suppliers

- The Bill proposes that, *"…payment to specialists and hospital services be all-inclusive and based on the performance of the health care service provider, health establishment or supplier of health goods, as the case may be."*
- Oticon is in full support of this approach, however, fee for outcomes cannot be effected without an effective system in place. This approach has proven to be complex and has not been implemented over the years as a result.
- To this end, Oticon support the recommendation made by the Health Market Inquiry, (HMI), for the establishment of an Outcomes Measurement and Reporting Organisation (OMRO).
- OMRO must be stablished and be up and running prior to the NHI being in effect, in order to avoid uncertainties and unpaid providers and suppliers as a result.
- "All-inclusive" must be defined.

Oticon submission summary – Payment of Providers and Suppliers

- We propose further that:
  - The term “All-inclusive” be defined.
  - Time-lines for payment of suppliers must be set as is done with any contract.
  - Consequences for non-timeous payments or recourses available to providers that have not been reimbursed must be established in the Bill
  - Payment to providers must not be benchmarked with what the medical schemes are currently doing, as we believe the payment is insufficient, due to the fact that these provider have to work in private and public, rely on medical device profits and professionals fees to cross-subsidize offering in their businesses. This is currently possible for them to achieve due to multiple funder system, it can however not be achieved with a single funder system, as envisaged under the Bill, which is not supported.

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Oticon submission summary – The Medicines Act

- Sections 18A and 18B of the Medicines and Related Substances Act 101 of 1965, (“Medicines Act”), prohibit the donation of and placement of devices. If the Device Regulations are passed with this prohibition still in tact, the government in tertiary and academic hospitals, will no longer benefit financially from such placements and donations which will result in increased cost to the Fund and ultimately the user.

- Oticon proposes that the the Bill provides for the placement and donations to tertiary hospitals to alleviate the financial burden on the Fund.

Oticon submission summary – Supply Chain and Delivery

- Delivery direct to health facilities in terms of clause 38(6) of the Bill and listing of suppliers in formulary. The following must be considered and addressed:
- There are currently depots with employees around the country who take delivery from suppliers, what will happen to the infrastructure and employees.
- The direct delivery (52 health districts, 227 district hospitals and over 4200 clinics) will be at additional costs to the supplier and which cost will be added to the price of the product, costing the fund more.
- Listing of suppliers under formulary- if the listing results in non-listed bidders not being allowed to bid, then the listing will be unfair and anti-competitive in contravention of section 27 of the Constitution.
- What will happen to data currently on the database of the Central Supplier Database.

Oticon submission summary – SAHPRA

- Approval of medicines /products takes between 6 to 10 years by the time an innovative product is registered, it is no longer innovative as there would be a new and better product meaning our people have to use outdated products. The delays are a contravention of section 27 of the Constitution that promotes the progressive realization of access to healthcare.
- **Oticon proposes that:**
- the cause of the delays be investigated and corrected
- The decision-makers in the registration of new products, be qualified to do so and must include clinicians.
- The accreditation of service providers be left to SAHPRA and the PFMA.

Oticon submission summary – BBBEE

- The procurement systems proposed in the Bill are supported, except where otherwise indicated. Oticon proposes that:
  - Tender splitting be allowed to allow smaller suppliers without national footprint to participate and and this will increase competition and ultimately benefit the Fund.
  - In order to prevent exclusion of certain products from being supplied to the country by multinational suppliers who struggle to achieve required BBBEE scores in order to participate in tenders, there must be open engagement with these companies by government in order to reach a practical consensus in the interest of the public.

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Oticon submission summary – Benefit Package Development

- The composition of BAC and other bodies listed under the Bill to develop, benefit packages, Formulary EML and EEL should be people who are qualified to make appropriate determination on these items, e.g., people in the health sector, clinicians, in order to ensure credibility of the processes and appropriate determination of benefit to users.
- In addition to clinical efficacies and others, a holistic Health Technology Assessment must be applied to consider the product benefit and not just the cost aspect, as is currently often the case.
- We propose that HTA be applied prior to implementation of the NHI to determine upfront what will be provided and what will not, so that there is no gap or mismatch between what has been promised as free, comprehensive benefit package and what is actually delivered.

Oticon submission summary – Governance

- The various consultations with the Minister by the Fund in a lot of the operational functions e.g., purchasing of health care services, benefit design and development of formulary, etc.
- These consultations are not encouraged by Oticon on the following bases:
  - The extent and process according to which the Minister will input is not defined.
  - The issues are highly operational, and the Board should be qualified and equipped, skilled to deal with without the Minister
  - Consultation will create red tape and potentially bottlenecks and unnecessary delays due to the Minister's numerous other commitments.
- Oticon proposes that principles of good corporate governance be implemented and the board deal with these issues without the Minister. We cannot afford any unnecessary delays to delivery of healthcare to our people.

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CONCLUSION

- The National Health Insurance is supported by Oticon. It must be implemented in line with section 27 of the Constitution. The progressive realization of everyone's right to access to health care will be achieved if we, among others:
  - Implement a multi-funder system and choice by users;
  - Ensure sustainable funding to the NHIF prior to implementation of NHI;
  - Implement fair and transparent procurement processes;
  - Incorporate and fund innovative products and utilize Health Technology Assessment in our healthcare;
  - Provide for a system to support fee for outcomes and pay suppliers timeously;
  - Ensure that SAHPRA is supported, and product approval is efficient;
  - Negotiate with multinational suppliers on entry barriers to promote access to product;
  - Promote accountability and good governance and avoid delays to access.