OTICON NHI SUBMISSION 2019

DR SM DHLOMO MP
CHAIRPERSON
PORTFOLIO COMMITTEE ON HEALTH
3RD FLOOR
90 PLEIN STREET
CAPE TOWN
8000

By email: vmajalamba@parliament.gov.za
29 November 2019

Dear Dr Dhlomo,

RE: COMMENTS ON THE NATIONAL HEALTH INSURANCE BILL

1. WHO IS OTICON

Oticon South Africa (Pty) Ltd belongs to Demant A/S, a leading multinational company based in Denmark. Demant A/S is the parent company of hearing healthcare companies such as Oticon, Bernafon, Sonic, Philips, Interacoustics, GSI, Oticon Medical, Maico and a few others. Demant A/S is the original manufacturer of products such as hearing aids, bone-anchored implant systems, cochlear implants and diagnostic audiological and balance equipment.

Oticon A/S is a company that provides hearing aids to people who suffer from hearing loss. Our mission is to help people with hearing loss fulfil their potential while living with the life they choose with the hearing they have.

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Registration No: 1997/020137/07

Oticon was founded in 1904 in Denmark and opened its offices in South Africa in 1997.
In order to achieve our mission, Oticon strives to be the leader in high performance hearing solutions, and to supply the most sophisticated technology and audiology possible. But helping people fulfil their potential includes much more than delivering on the most advanced hearing science and innovative cutting edge designs. Through the People First promise, Oticon has placed a deep appreciation and understanding of what people need, desire and are driven by, as the core of all our innovation. Quite simply, we put the individual needs and wishes of people with hearing loss first in our development of new.

Oticon is a global company located in over 20 countries, and employs approx. 13 000 globally.

Oticon South Africa

The Offices of Oticon South Africa were opened on 1997 and Oticon South Africa employs 46 full time employees.

Our products are currently on tender with government, and are supplied to government hospitals all over the country with hearing aids. Oticon South Africa prides itself on the projects that it has co-run with the government of including patient advocacy days and training seminars to government audiologists and Ear, Nose, Throat Surgeons.

We also donate a significant number of hearing aids every year to patients that cannot access government services and cannot afford to pay for private services.

Currently Oticon South Africa is also the distributor of Oticon Medical, our surgical implant division, responsible for bone-anchored implant systems and cochlear implants, as well as Interacoustics / MedRx – our balance disorders and audiological equipment division.

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2. LOSS OF HEARING

One out of six adults suffer from some degree of hearing loss and an estimated 80% of people who suffer from tinnitus also experience some degree of hearing loss, though they may be unaware of it.

Hearing loss can be age -related or noise induced, and can occur in the outer and middle ear or in the inner ear.

2.1. PEDIATRIC HEARING SOLUTIONS

In 2012 the Continued Medical Education Journal[1] ("CMEJ") published that a review estimated that the prevalence of hearing loss in children aged 5 - 14 years in sub-Saharan Africa is 1.9%. South Africa has a population of 10.6 million children in this age bracket, and a further 5.2 million below 5 years of age. Using a conservative prevalence of 1% for the combined group one can estimate that 1.5 million children under the age of 15 years in South Africa have some form of hearing impairment.

Oticon's paediatric philosophy reflects an ongoing commitment to make it easier for healthcare providers to help children with hearing loss achieve their full potential.

Years of experience working with paediatric professionals and families have taught us that the best solutions aren't shaped by what technology can do – but rather by what it can do to meet the needs of the individual user. It's not just the children we strive to support; it's also the caregivers responsible for their development.

Insights from audiologists, children, parents and teachers have resulted in our holistic approach to paediatric hearing care – from audiology and technology to counselling, fitting and service. This is how we aim to provide the most child-friendly hearing care available.

Our mission "a better future for every child with hearing loss" is based on three defining dimensions: Individualisation – Performance – Living.

1 http://www.cmej.org.za/index.php/cmej/article/view/2448/2536

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We assist children with hearing loss in realising their full potential with instruments capable of meeting their individual needs on their journey towards adulthood.

2.2. DANGERS OF NOT TREATING HEARING LOSS

Untreated, hearing loss can cause one to withdraw from socialising because conversations take so much more mental energy. Left untreated, hearing loss can lead to feelings of isolation, depression and permanent disability.

Early diagnosis and treatment is therefore of utmost important. In children diagnosis and treatment must happen within the first 6 months of life, failing which the risk of permanent damage escalates. The CMEJ states that "*A lack of infantile and early childhood auditory stimulation will result in a permanent functional communication handicap with associated learning difficulties, impaired cognitive development, and emotional/psychological issues.*"[2]The CMEJ also confirmed that the childhood hearing loss has a high prevalence in South Africa.

Adults with untreated hearing loss avoid social engagements and experience social isolation since they cannot hear their communication partners and follow the conversation. Social isolation and withdrawal from society are known factors for decline in cognition which leads to dementia in the aging population (Shafiro & Sheft, 2017).[3] Therefore it is proven that untreated hearing loss leads to a higher rate of cognitive decline, dementia as well as depression (Lawrence, 2019).[4]

Hearing aid fitting especially in older adults thus will prevent social withdrawal and diminishes the risk of cognitive decline and depression(Lawrence, 2019).

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2 CMEJ above at 1

[3] Shafiro, V., & Sheft, S. (2017). Hearing Loss and Ethnicity in Age-related Cognitive Decline. *Hearing Journal, 71*(1), 8–9. https://doi.org/10.1097/01.HJ.0000529842.91837.39

[4] Lawrence, B. J. (2019). Is hearing loss associated with depression in older adults? *Hearing Journal, 72*(7), 8–11. https://doi.org/10.1097/01.HJ.0000575352.06069.0e

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2.3. PEOPLE AND CHILDREN WITH DISABILITY

Deaf people and people with hearing impairment are regarded as people with disability and Oticon devices cater for such people and enable them to restore dignity into their everyday lives. The Constitution of South Africa provides that the state must never be discriminated against people on the basis of disability.

Persons living with a disability and children are deemed to be vulnerable, and require substantive equality to ensure equitable access to rights, such as healthcare rights.

The UN Convention on the Rights of Persons with Disabilities, ("the Convention"), are *"to promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities, and to promote respect for their inherent dignity"*

Section 28 of the Protection of Equality and Prevention of Unfair Discrimination Act 4 of 2000 ("PEPUDA"), provides special measures to promote equality with regard to race, gender and disability. Section 9 of PEPUDA provides:

> ***"Prohibition of unfair discrimination on ground of disability.***—*Subject to section 6 no person may unfairly discriminate against any person on the ground of disability, including—*
>
> 5. *(a) denying or removing from any person who has a disability, any supporting or enabling facility necessary for their functioning in society;"*

Children's' rights are protected under the Children's' Act 38 of 2005, and children with disabilities are specifically protected under section 11, which provides that due consideration must be given to provide the child with conditions that ensure dignity, promote self-reliance and facilitate active participation in the community.

Oticon devices ensure that people and children with disability are provided dignity and an opportunity to be independent and to participate in their communities.

The Bill recognises vulnerable groups, as it specifically refers to purchasing of personal health care services for vulnerable groups such as children, women, people with disabilities and the elderly under the transitional arrangements.

In keeping with the aforementioned rights of children and people with disabilities, we therefore propose that the Bill make provisions for a process that will fast-track the provision of healthcare services including hearing devices / implants and consumables to this vulnerable group.

3. BACKGROUND

The Bill is an attempt by government to accomplish the protection and progressive realisation of the right of access to healthcare services as set out under section 27 of the Constitution. Oticon is therefore in full support of this concept. It must be borne in mind that the Bill, once an Act will affect all South Africans and that for the Bill to benefit all South Africans the gaps identified by Health Market[5] Inquiry both in the public and private must be addressed.

The proposal in the Bill that the NHIF be the *end all be all*, is however not supported, this approach simply leaves citizens with very little choice and no alternative if they are unhappy with the "service provider". We therefore propose that there be multiple funder system in place which allow for flexibility and will ensure broader and better coverage than in a single provider system. However, in order to ensure that resources are utilised efficiently, measures should be put in place across the various funders to ensure that citizens do not to utilise more than one fund for the same benefit.

Multiple funds will also provide the opportunity for risk-equalisation mechanisms, in order to effect appropriate care also in higher risk pools such as rare diseases which more often than not are not treated due to the high cost of treatment.

5 http://www.compcom.co.za/wp-content/uploads/2014/09/Health-Market-Inquiry-Report.pdf

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There are a few jurisdictions we can refer to as a country who have implemented the multiple funder system and are experiencing success, such as the UK, where 11,5% of the its population have some sort of private cover,[6] Germany, France, Japan and China.

This multiple funder system must include private medical schemes, where users can exercise their choice to use either the NHI or private funding, not both. This limitation or exclusion may be regarded as unconstitutional. (See 4below)

The multiple funder system will better achieve the goal of ensuring the right to access to healthcare services and the progressive realisation thereof than a single fund system.

4. COMMENTS

3.1. ULTRA VIRES

In addition to the Bill limiting the applicability of medical schemes, clause 4(5) of the Bill provides that the Competition Act is not applicable to the transactions envisaged under the Bill, and, by stating that any provision of any other legislation that contradicts provisions of Bill save for the PFMA and the Constitution, will not be applicable, also by implication excludes provisions of the legislation such as the Consumer Protection Act. The Bill also limits the applicability and or amends certain provisions under other legislations such as the RAF and the Compensation Fund Act. These exclusions and limitations by the Bill are ultra vires. If there is a limitation it should be provided in those very same Acts, not in the Bill. These exclusions and limitations must not become applicable until the relevant Acts are accordingly amended.

3.2. FUNDING THE NHI

There are a few opinions that regard the proposals made for the funding of the NHI, as not feasible, this includes the findings made by the Davies Tax Committee[7] in 2017.

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6 http://www.euro.who.int/__data/assets/pdf_file/0007/98422/Private_Medical_Insurance_UK.pdf.

7 https://www.taxcom.org.za/docs/20171113%20Financing%20a%20NHI%20for%20SA%20-%20on%20website.pdf.

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It was also stated in the Medium Term Policy Statement 2019[8] that *"...given the macroeconomic and fiscal outlook, the estimates to roll out NHI that were published in the NHI Green Paper in 2011 and White Paper in 2017 are no longer affordable."*

While Oticon supports the NHI, it would be reckless for the Bill to be passed for implementation with the knowledge that the funding is not feasible. This will result in the contravention by the government of its constitutional duty to provide the progressive realisation of the right of access to healthcare as set out under section 27. The lack of funding will result in regress in the realisation of this right. The funding model must simply precede the NHI and must be sustainable. The Davies Tax Committee[9] gave the Irish government as an example, where the equivalent of the NHI was abandoned due to the fact that it would have resulted in exponential and unaffordable increase in public health spending.

Financial sustainability will therefore ensure that the NHI does not fail. Should this exercise not be done, and the NHI is implemented without same, and without implementing the multiple funder system, citizens will be left without medical cover. To demonstrate how critical sustainability of funding is; in 2016, the UK reported an unsustainable declining financial performance in the NHS trust and NHS Foundation trust, which resulted in the trusts being in a deficit in 2015-2016[10].

Oticon proposes that that the funding for the NHI be concrete before THE Bill is passed as an Act of parliament.

3.3. PRICING

The Bill proposes multiple pricing mechanisms, which we are not in favour of, including the existing single price as set out under the Medicines and Related Substances Act 101 of 1965.

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[8] http://www.treasury.gov.za/documents/mtbps/2019/mtbps/FullMTBPS.pdf.

[9] Davies Tax Committee, 2017, 30 Report on Financing A National Health Insurance for South Africa for The Minister Of Finance, March 2017.

[10] National Audit Office UK. 2016. The financial stability of the NHS. 22 November 2016.

We propose that alternative reimbursement models be implemented as proposed by industry over the years which will ensure a healthy competitive environment, encourage innovation resulting in improved clinical outcomes for patients, create space for risk sharing.

Separate pricing measures for medicines vs medical devices needs to be considered as the business model and level of support and training, including support and training post-sale, differs vastly between medicines and medical devices and the same formula cannot be applied. We propose further that NHI must allow for the after care of medical devices such as consumables and repairs. In our experience repairable hearing instruments are currently being scrapped and new instruments fitted to the patient in the absence of funds for out-of-warranty repairs. This has increased the cost of care significantly. The NHS in the UK for example work on a "external repair loop" system. The hospital has refurbished hearing instrumentsn site and a patient with a broken hearing aid is immediately refitted with a refurbished unit of the same model and make and the broken units send in bulk to the manufacturer for refurbishment and returned to the hospital in working condition. The cost is worked on a weighted average cost of repairs (regardless of the fault found) and comes at a significant saving compared to a new instrument.

3.3.1. Procurement through tender

The tender system also remains part of the pricing mechanisms proposed by the Bill under clause 38(7) largely due to the requirements set by section 217 of the constitution. Oticon is in full support of this process in the procurement of medical devices and IVD's as it provides for procurement *"...in accordance with a system which is fair, equitable, transparent, competitive and cost-effective"*, section 217.

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Oticon are currently on tender, for the supply of hearing aid devices and consumables to government.

In South Africa there is currently an EML(Essential Medicines List) in place, together with processes and structures that support its development, update and review. There is currently no EEL (Essential Equipment List). Clause 38(4) of the Bill provides that Formulary comprising of EML and EEL will be developed. However, in the absence of the EEL, a Formulary can therefore not be developed, or it should not be developed without the inclusion of an EEL as this will then leave patients without devices, who required them for treatment, especially given the fact that there are will be no alternative funding as proposed under the Bill.
Section 90(1)(d) of the National Health Act provides that the Minister may in consultation with the National Health Council, make regulations regarding the development of EEL. The EEL must therefore be developed prior to developing the Formulary and certainly, prior to the Bill being passed. There must be sufficient public engagement in the development of the EEL and the structures and systems that will support it.

The structures must also allow for adequate resources so that regular updates to the formulary is possible, as and when new cost-effective technology (that will elevate the level of patient care) becomes available. The hearing instrument specifications on the current government tender system inadvertently encouragesthe submission of very old technology. The specifications requires a serious overhaul to create access to the newest technology with proven improved patient outcomes at affordable prices.

3.3.2. SEP

The Bill provides in addition to tender and SEP, negotiated pricing under clause 38, an all-inclusive fee under section 41(3) and a rate for suppliers that will be

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determined annually by the NHI under clause 10. The existence of these multiple pricing mechanisms, in the bill will not only cause confusion, but the implementation of all of them may require varying infrastructure which will definitely be costly.

In general, Oticon urges that the tender procurement system must be clear, simple and efficient and must, to accomplish this the prices negotiated and must cover costs of innovative products that will benefit patients. Therefore, references to "lowest possible price" under the Bill must be scrapped. The tender system must have effective contract management systems with regular volume reviews and price reviews to guarantee continued customer access to healthcare services.

Clause 38(6) stipulates that a *"provider and ... establishment"* must procure. This leaves the possibility, in particular in light of the (semi-) autonomous nature of public hospitals under the NHI, could issue their own tenders. Given the reducing role of provinces (having no control anymore over health service provision),[11] there would be no provincial tenders. Which affect a number of products available on provincial tenders, and would, insofar as discretionary spend in academic hospitals are concerned, severely affect such facilities and the patients served at such facilities.

3.4. INNOVATION

Oticon prides itself in being an innovative company that strives to find solutions to suit individuals with hearing loss. Just a few examples; in 1977 Oticon introduced the first discreet in-the-ear-hearing device and in 1996 launched the first fully digital hearing device. In 2014 Oticon announced that its devices now support the brain makes sense of sounds by giving it the conditions it need to create meaning from sound, instead of overloading it by turning up the volume.

[11] Clause 7(2)(f).

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It is however our experience that the patients in the public sector currently do not have access to the latest technology or hearing implants (either bone-anchored systems or cochlear implants) due to the procedure not being well funded in state. The benefits according to WebMD[12] include being able to hear speech at a near normal level without lip reading, it becomes easier to speak on the phone and hearing music better than before. Although the results are not the same for everyone, this is a clear indication of the deprivation of a quality of life for a majority of our patients. In addition the devices that are provided to most patients in the public sector are outdated.

Clause 11(2)(e) of the Bill provides that the fund will negotiate the lowest price possible for goods and services. This provision is an indication that innovation and new technology are not priority in the Bill. Although the clause does go on to say *"...without compromising the interest of the user..."*, it is not clear if these interests will be protected to what extent, by providing innovative products or old outdated technologies?. Innovation comes at a price and history has shown that lowest price possible will ensure only the bare minimum even in cases where more innovative solutions are required by some patients.

Innovative medicines and devices are will ensure compliance with treatment as they provide ease in administration, and therefore adverse effects are reduced and treatment is improved, thereby reducing a particular disease burden.

The Bill must therefore make room for more innovation. Supporting innovation will ensure that first and foremost, our society has the best quality of life and that previously untreated conditions and a widely diverse groups of patients will be

12 https://www.webmd.com/healthy-aging/qa/what-are-the-advantages-of-a-cochlear-implant

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treated through new solutions. This approach ensures inclusivity instead of exclusivity and gives effect to the principle of Constitutional equality.[13]

3.5. DEVELOPMENT OF FORMULARY

3.5.1. While we recognize the need for these lists in order to create certainty and to prioritize certain medicines and devices. Clause 38(4) of the Bill provides that the Benefits Advisory Committee, ("BAC") will develop and maintain of the Formulary, comprised of the Essential Medicine List and Essential Equipment List as well as a list of health related products used in the delivery of health care services as approved by the Minister in consultation with the National Health Council and the Fund. However, the following is not addressed under the Bill:

3.5.1.1. What recourse patients and providers have if the medicines or devices listed under the Formulary are ineffective or cause harm to patients. The implementation of clause 38(4) as is will leave patients who currently have access to non-EML and non-tender medicines without treatment. The current legislative framework allows for exceptions and alternatives to the listed items. This will also leave patients who require the continued treatment of clinical trial drugs, for example, without treatment if those drugs or devices are not on the Formulary.

3.5.1.2. What is the recourse for the population whose needs are not covered by medicines or equipment on the list?

3.5.1.3. The composition of the BAC in the development of the Formulary as aforementioned.

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[13] *Minister of Finance and Other v Van Heerden* (CCT 63/03) [2004] ZACC 3; 2004 (6) SA 121 (CC) at par 27: *"This substantive notion of equality recognises that besides uneven race, class and gender attributes of our society, there are other levels and forms of social differentiation and systematic under-privilege, which still persist. The Constitution enjoins us to dismantle them and to prevent the creation of new patterns of disadvantage."*

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3.5.1.4. The drugs or equipment on the list should not be all that is available to users, they must be lists because they are the most needed, but provision should be made for medicines that do not form part of the list, this is supported by the WHO[14] and the National Drug Policy.[15]

- **We propose that clarity be provided as to what role the NHI will play in the funding of research and/ or clinical trials.**
- **We propose further that the definition of evidence based medicine be included in the Bill and a provision be made along the lines of what is contained under the Medical Schemes Act Regulations 15H and 15I, i.e. exceptions and alternatives need to be provided for products not on the list where the listed products do not benefit the patient or they cause harm even after being utilised. In our area of therapy, one ear-piece, for example will certainly not fit all patients. All benefits provided by the NHI Fund and other funds must be clinically appropriate and evidence based, irrespective of the option.**
- **The development of the Formulary, (EML and EEL) be done on consultation with clinicians and health professional associations and bodies that deal with the relevant diseases and conditions daily and can positively contribute to the list that will benefit the citizens of the country.**

3.6. TREATMENT GUIDELINES

The Bill proposes under clause 25(5)(b) that the BAC must determine and review cost effective treatment guidelines that take into account the emergence of new technologies. The Bill is silent with regards to type and level of engagement of healthcare professionals and their respective associations or groups in developing these guidelines as they

[14] https://www.who.int/medicines/services/essmedicines_def/en/
[15] http://apps.who.int/medicinedocs/documents/s17744en/s17744en.pdf

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currently do. It is only fitting the clinicians and healthcare professionals be involved in the determination hereof, after all they are the ones who deliver the heath care and are bound by the healthcare legislation and regulations and unlike the BAC they are *au fait* with the various disciplines applicable and the treatments thereunder.

We propose that the treatment guidelines as envisaged under Clause 25 be developed with the involvement of clinicians and healthcare professionals or health professional associations or groups based on evidence based medicine.

3.7. PAYMENT OF PROVIDERS AND SUPPLIERS

3.7.1. Clause 41(3)(b) of the Bill provides that:

> *"(b) In the case of specialist and hospital services, payments must 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. "*

While the principle of performance/outcome-based payment is ideal and fully supported by Oticon, we also appreciate how difficult implementing this system has been and has not been implemented due to its complexity. In order to cater for this reimbursement, model the HMI made recommendations for the establishment of an Outcomes Measurement and Reporting Organisation ("OMRO"), which is supported.

We propose that the Bill provide clarity on the meaning of "all-inclusive" whether this includes payment to the facility, the provider and the supplier. Further that a determination be made beforehand on how providers will be paid.

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3.7.2. The Bill also provides that the Fund must establish mechanisms and issue directives for the regular, appropriate and timeous payment of health care service providers, health establishments and suppliers. There are however no timelines set with regards to the payment terms to providers in the Bill and further, no consequences are established in the Bill as to what disincentive is there for the Fund if there is no timeous payment, alternatively what recourse providers have should they not be paid on time or at all.

Although this is not a proposal under the Bill, we propose and caution that the current payment to providers by medical schemes must not be used as a benchmark for the rates for providers by the Fund. What is currently being reimbursed to providers by schemes is undoubtedly not sufficient and there is currently heavy reliance on the cross-subsidization in their businesses between private and public payments, as well as significant cross-subsidization between medical device profits and professional fees. However, with the proposed single funder system there will be one source of income.

Regarding the recourse for non-payment, we propose that timeframes be established by the Bill e.g. within 30 days of the service being provided and should payment not be made on time, someone other than the fund must be held personally accountable, considering the fact that holding the Fund accountable will be shooting ourselves in the foot.

3.7.3. The Bill has not addressed how the debt currently owed to providers prior to the implementation of the NHI will be dealt with. This is a critical conversation that must be held. Oticon proposes that the providers be settled prior to implementation, this is part of the issues that exist and must be eliminated.

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3.8. SECTIONS 18A AND 18B OF THE MEDICINES ACT

The suspension of the implementation of the Device Regulations is coming to an end in 2021. We envisage that once into effect, the donations and placements of devices will come to an end. This will mean that any benefits derived financially by such placements and donations will cease (by government in tertiary and academic hospitals), resulting in increased costs to the Fund.

We propose that suppliers be allowed to continue placements and donations to tertiary hospitals in order to ease the potential financial burden on the Fund, which will be passed on the to the users in some way or other.

3.9. SUPPLY CHAIN AND DELIVERY

Although Oticon already delivers directly to health facilities and establishments and will not be affected by the requirement of clause 38(6) of the Bill that requires suppliers to do so, further, the clause provides that suppliers will be listed in the Formulary. There three issues that we foresee as inevitable which are not addressed in the Bill:

3.9.1. What does the NHI intend to do with the current infrastructure of the depots that exist around the country, in addition, if it is envisaged or implied that the depots will become redundant, what will happen to the employees in those depots.

3.9.2. The direct delivery to 52 health districts, 227 district hospitals and over 4200 clinics will add to the expenses of the suppliers who will no doubt increase their prices in order to cover this increased costs. This is in additional to the cost suppliers already incur for supplying to the private health facilities.

3.9.3. The listing of suppliers under the Formulary will be in contravention of section 217 of the Constitution, i.e. the listing will result in the prevention of non-listed bidders from bidding, this position will be grossly unfair and anti-competitive.

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We propose that a plan with regard to what will happen to the depots and the employees employed there. Further, how the NHI intends to cater for the increased costs related to the direct delivery. We also propose that the listing of suppliers under Formulary be amended to indicate that only suppliers successful during the procurement process set out under clause 36(7) be listed under Formulary.

3.9.4. Procurement in the public health care sector together with the Central Supplier Database) are managed and controlled by National Treasury. It is Oticon's experience that the CSD has been well-managed, however the Bill is silent on what will happen to the data that is currently on the database and how new suppliers will get on there. We recommend that this be addressed.

3.10. SAHPRA

3.10.1. The efficiencies in SAHPRA have always been less that desired, even in the MCC days. Approval of medicines in a country like ours takes between 6 to 10 years. While a drug or a device may have been launched and brought to South Africa as innovative, by the time the drugs are registered, they are no longer innovative as there would be a new and better product in the market which means that our health services are lagging or outdated and our people do not and will not benefit from innovative healthcare if these delays are allowed to persist. This is a real issue of access and should be looked into by among others, improving the systems and employing qualified and skilled personnel.

Oticon also proposes that that the decision-making in SAHPRA with regards to the approvals of medicines and the companies who provide same be made by people who are qualified to make such decisions, i.e. people who have clinical backgrounds and understand the needs in the healthcare sector in general. It must be

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a diverse group of health professionals, with specific knowledge of the clinical applications of the medicine / medical device.

3.10.2. The Bill also provides for accreditation of service providers and health establishment by the Fund under clause 39(1). While accreditation is necessary and supported, the process of accreditation is already in place and is currently been performed by SAHPRA and the PFMA procurement process will ensure that providers are duly certified and licensed, and therefore it is not necessary to add this function to the Fund.

3.11. BBBEE

Oticon as stated above supports the procurement system as established by clause 38(7) of the bill and giving effect to section 217 of the Constitution. This system will allow for local business to participate in the procurement, which will encourage economic growth and job creation. However, the process must support the spirit of section 217 of fairness and transparency. Suppliers must also have the autonomy to procure what their patients require, especially healthcare providers, as they are responsible personally for the outcomes of their patients. Restricting procurement at this level will effectively hinder the autonomy of the healthcare providers and contravene the provisions of the Healthcare Professions Act.

It must however be borne in mind that due to the size some of the smaller suppliers, they may not be have a national footprint, which entrenches the idea of splitting tenders among suppliers in order to allow access throughout the country and to increase competition.

Further number of suppliers in South Africa are multinational companies who are owned by international shareholder. While these global companies have demonstrated their support for BBEEE and transformation, the conditions of qualifying for a bid e.g. BBBEE

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scores, have an impact of increasing product prices, some of the companies are reluctant to part with ownership or sub-contract in order to achieve these scores, in most cases due to the fear of losing control of the quality and efficiencies in their products. In certain instances, some have attempted to engage in Equity Equivalent structures that would help them improve their BBBEE rating and to demonstrate their willingness to invest in South Africa, however, this process is not easy, it is time-consuming, costly and it is riddled with red tape. Some companies may not achieve these scores and it may result in the exclusion of certain medicines from South Africa. In some of these cases, public interest should come first.

There is a great need for engagement between government and multinational companies in the health sector with regards to the issues that are experienced in respect of BBBEE, particularly ownership. There should be a solution that works for both parties, which will ensure the sustainability of these companies in the country and guarantee job security, but most importantly the sustained supply of health products to the South African population.

3.12. DEVELOPMENT OF THE BENEFIT PACKAGE AND THE BAC

The Benefits Advisory Committee ("BAC"), is tasked under clause 25 of the Bill to develop and review *"...the health care service benefits and types of services to be reimbursed..."*

It is proposed that bodies such as the BAC, are listed under the Bill who are tasked with the determination of benefits, formulary and guidelines among others, must in general comprise of people in the health industry who deal with and understand the needs in the health sector. Clinicians should be engaged in any of these processes whether as individuals or through health professional associates. This will ensure the credibility of the processes and provide come

comfort that the benefits have been considered from a clinical benefit perspective as well as other factors.

In addition to the determination of clinical efficacies, a comprehensive, wholistic Health Technology Assessment (HTA) must be applied in the process of determining the benefits and not just consideration of the cost of a specific treatment, as is currently often the case. This approach of engaging a rigorous HTA as opposed to benchmarking or applying what government can afford, for example, when developing benefits prior to the implementation of the Bill will prevent a gap or a mismatch between what has been promised as a free, comprehensive benefit package and what is actually delivered, as is seen in most developing countries, according to the Davies Tax Committee.[16]

3.13. GOVERNANCE

The Bill makes reference to the Fund having to consult with the Minister in a lot of their operational functions, for example, clauses 4(1) and 7(1) provides that the purchasing of healthcare services must be done in consultation with the Minister and clause 11(1)(i)(viii) provides that benefit design must also be done in consultation with the Minister, the Minister is also involved in developing the formulary the determination of information required to measure health outcomes, to list a few. These requirements amount to unnecessary political interference, and do not provide the process, in respect of the influence the minister will have in such decision making, if the decisions will be up to him or not, which is not encouraged. In addition, these issues are highly operational, which the board of the fund should be skilled and qualified to perform or be able to engage qualified people to deliberate on them. This is also burdensome on the Minister and the level of consultation creates red tape that will definitely cause a delay in the delivery of healthcare services.

[16]Davies Tax Committee, 2017, 30 Report on Financing A National Health Insurance for South Africa for The Minister of Finance, March 2017.

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We propose that the Minister not be involved in such operational matters and that the principles of good corporate governance must be respected.

CONCLUSION

Oticon is grateful to have had the opportunity to comment on this critical piece of legislation, and we encourage an ongoing dialog on the issues identified hereunder and we are available for any consultation that may be required in order to clarify the contents of this document or any matter relating thereto.

Yours faithfully

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