The South African Medical Technology Industry Association (SAMED)

Submission

ON THE DRAFT GOVERNANCE REGULATIONS PERTAINING TO THE ESTABLISHMENT OF THE STRUCTURE OF THE NHI FUND

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Comments to: regcomments@health.gov.za

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1. About SAMED

SAMED is a not-for-gain voluntary trade association that represents the medical technology industry in South Africa, including manufacturers, distributors, and wholesalers, ranging from micro enterprises to large multinational companies, supplying medical devices, medical equipment and in-vitro diagnostics. SAMED's members play a critical role in supplying essential medical devices and technologies to healthcare providers and, by extension, the public in South Africa. For details, please see: https://samed.org.za/.

2. Overlaps in definitions remain unresolved

SAMED (hereinafter "we") wish to also use this opportunity to make clear that the definitional issues pertaining to our members' products, in the NHI Act, Act No 20 of 2023 ("NHI Act") remain, and therefore also have an impact on the proposed draft regulations. This is as issues of pricing, and benefits (and thereby the HTA and procurement of our members' products are affected by where these products are based in the NHI Act and the regulations).

For the sake of clarity, we reiterate the issue here:
"health goods", in respect of the delivery of health care services, includes medical equipment, medical devices and supplies, health technology or health research intended for use or consumption by, application to, or for the promotion, preservation, diagnosis or improvement of, the health status of a human being;

And

"health product" means a product regulated in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), the Hazardous Substances Act, 1973 (Act No. 15 of 1973), the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), or any other product regulated by a law governing its quality, efficacy or performance and used in the provision of health care services.

Medical devices, as defined and understood, and regulated by SAHPRA includes products in both the definitions of “health product” and “health goods”. It includes capital equipment, implants and the supportive sets thereto, consumables, disposables, assistive devices, etc.
An "in vitro diagnostic (IVD) medical device" is a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring, or compatibility purposes. In simpler terms, it's a test performed on a sample taken from the body (like blood or tissue) to help diagnose or monitor a condition, or to determine if a blood transfusion will be compatible.

“Health goods” are to be “strategically procured” by the NHI Fund, and therefore under the control of the Board and CEO, set up by these draft regulations. However, “health products” procurement is one of the Units of the NHI Fund.

As the NHI structures start fulfilling their functions, most notably those in relation to –

- engagements on equity and efficiency in “health goods” procurement (draft reg 13(1)(c); and
- the finalisation by Ministerial decree, of decisions by the Benefits- and Benefits Pricing Committee (draft reg 25(7)),

these definitional inconsistencies will lead to conflicting applications of the law.

For example, health products will be included in the formularies, but that, by definition, include health goods, such as “medical equipment” and “supplies”. When contracting in healthcare professionals as part of phase 1 of the NHI Act, such contracted parties would already be owning such “health goods” and “health products”, and would have established systems of supply based on bilateral supply agreements. The exclusion of certain “supplies” (this is assumed to refer to consumable and disposables) would have far-reaching implications for the capital equipment, or even the medicines used, as part of a patient’s care.

Medical devices, as defined in the Medicines Act cannot be in two different definitions in the NHI Act. We propose that there is only one definition for the products supplied by SAMED’s members, which definition should align with the Medicines Act and the regulations thereto. Also see section 4 of the SAMED submission to the Health Portfolio Committee, dated 29 November 2019, attached hereto as Annexure “A” (hereinafter “the SAMED NHI Bill Submission”)

3. Linkages to the NHI Act

As the regulations relate to the NHI Act, and should be directly empowered by the NHI Act, SAMED’s previous commentary of the governance structures relating to the NHI Fund, remain relevant (see section 13 of the SAMED NHI Bill Submission), namely:

- A sufficiently independent and accountable Board should be appointed;
- the Board of the NHI Fund must have the power to establish committees that are required for the fulfilment of its key functions, i.e. purchasing of health care services and payment of such services (and not be Committees under the auspices of the Minister of Health);
- The Board must be responsible for all decisions regarding the strategic positioning and operationalisation of the NHI Fund, including the appointment of the chief executive officer and key committees;

- The board must also be duty-bound to ensure that the Fund is conducted in a financially sustainable manner. Should the reserves fall below the statutory specified minimum (as contemplated to be stipulated in Regulations), provision must be made for obligatory remedial action.

We note that the NHI Act, in terms of the sections relating to the Board and the CEO have changed since initially commented on, however the sections relating to the Benefits-, Benefits Pricing- and Stakeholder Advisory Committees have not changed.

The changes notably relate to the involvement of cabinet in the appointment of the NHI Fund's Board, and the CEO. These changes are welcomed. However, there is some uncertainty introduced in the Draft Regulations as to who actually approves an appointment of a Board member: draft regulation 3(1)(d) states that "if the Minister or cabinet" does not approve, indicating a veto power by the Minister, which is contrary to the NHI Act's section 13(3)(b). The definitive nature of the power of the cabinet in sections 13(9) (dissolution of the Board) and section 14(1) (appointment of the CEO) is also not clearly stated in the regulations. This means that the regulations must align with the Act and not create a situation where the Minister pre-assessess and pre-determines approvals.

The Proposed Governance Regulations are made pursuant to sections 55(1)(x), (z) and (zA) of the NHI Act. These sections as included in the NHI Act, and to which the NHI regulations must align, read as follows:

(x) the proceedings of the meetings of committees appointed in terms of this Act and a code of conduct for members of those committees;
…
(z) any matter that may or must be prescribed in terms of this Act; and
(zA) any ancillary or incidental administrative or procedural matter that may be necessary for the proper implementation or administration of this Act.

The draft regulations are not in line with section 55(a) which does not afford any powers relating to corporate governance, functions or powers of the structure set up by the Governance Regulations. We also note that the regulations (on the basis of draft regulation 13) give effect to section 10(1)(p) of the NHI Act, which section however is not a procedural matter, but rather one of substance., The same applies to draft regulation 25(7) which gives effect to section 56 (on the Directives by the Minister), and is also not procedural, but rather substantive in nature, namely allows price-setting to take place, even in the absence of a procurement and HTA framework, and without involvement of the NHI Fund and its Board.

Two concerns in relation to the NHI Fund, as raised previously by SAMED, remain:

- The NHI structures are not independent as is required by the PFMA. Even if the appointment process is transparent and has built-in protections to prevent conflicts of interests, many of their powers must be approved by the Minister of Health or exercised in concurrence with the Minister of Health.
    - For example, the Essential Medicine List (EML) and the Essential Equipment List (EEL) must be approved by the Minister of Health, in consultation with the Fund and the National Health Council. This means that, insofar as our members' products are concerned, the NHI Fund will not be an independent entity and accountable under the Public Finance Management Act (PFMA).

- Other examples where the NHI Fund cannot act independently, are found in section 25(5)(c) (on benefits), on Board procedure (section 17(3)), or the mandatory reporting of advice given to the CEO by the Board (section 18)).

- Decisions that should be made in legislation, are deferred to the Minister of Health. For example, the policy in relation to performance of the Advisory Committees is left to the Minister (draft regulation 24(1)). That would typically be the role of the Board of a public entity, as is set in the Public Finance Management Act (PFMA).

4. The NHI Fund's Board

Appointment processes

We note that the process of establishing the NHI Fund's Board is quite cumbersome, with various entities or officials involved. There is a Nominations Committee, an Ad Hoc Advisory (in effect an Interview-) Panel, the Director-General of Health and an Inquiry Committee. This is apart from the involvement of the Minister and cabinet, as the case may be.

The process starts with a call for nominations for the Board on the NHI Fund's website. However, without the Board being in effect, and without their being a CEO and staff, the NHI Fund is not in existence and cannot have a website. Draft regulations 2(4)(c) and 4(1)(a)) can therefore not apply for the first appointment of the Board.

It is unclear why a nomination must be supported by five entities or persons (draft regulation 4(4)(b)). We also note that there is a Board Committee nomination form (Annexure 1.2) – however, committees of a Board are internally appointed by the Board, and not through an external process. Given that the Board has the power to determine its own workings (draft regulation 14), the appointment of Board Committees under draft regulation 4 is problematic.

The Panel to conduct public interviews is supported, however, the nominations are filtered by the DG (draft regulation 5), and therefore, if a nominee does not make it through the political process of short-listing, the Panel would not be of assistance in ensuring a truly independent Board. We note that the composition of the Panel (draft regulation 2) excludes a person from the legal profession, which is important as the Board is to include members with such skills, given that such skills are required in the NHI Act (section 13(5)(b)). Draft regulation 2 refers to the "Statutory Health Professional Councils", but the only such entity we are aware of, is the "Forum of Statutory Health Professional Councils" established in terms of the National Health Act.

We referred above to the veto power of the Minister in draft regulation 3(1)(d), which means that the short-listed candidates must be pre-approved by the Minister before the public interview process can start. There are, therefore, two points where the Minister can veto the names of nominees– once at short-listing, and then on appointment. It is also not clear how conflicts between the Minister, and the cabinet, will be handled. We submit that this process should be empowered by section 13(3)(b) of the NHI Act, namely that the appointments are made by cabinet, and not the Minister of Health.

The "task requirements" and "responsibilities" of the Board, which are to be set by the Minister in terms of draft regulation 4(3)(a)(i)) is also problematic: these tasks and responsibilities must be the powers of the Board, as set out in section 15, and not be a ministerial discretion empowered by regulation. As setting up the process of establishing the Board, the draft Regulations must align with the Act, and not create, through ministerial powers, tasks and responsibilities. Under the PFMA the NHI Fund's Board would have to exercise its statutory powers and functions only.

Similarly, the DG-established "nomination committee" is also not empowered by section 13(2) of the NHI Act. This Committee, solely comprised by government employees, will have significant decision-making powers, namely on which nominees "do not quality" or "qualify but [are] not included" (draft regulation 5(3)(e)). As such decisions, especially relating to those who qualify, but are not included, can be legally challenged, the issue would be which entity would be the respondent in such a case, as the staff members would come from various government departments.

There is a contradiction between draft regulation 14(1), and section 17(3) of the Act – the last-mentioned states that the Board determines its own procedures, but "in consultation with the Minister". This hampers the independence of the NHI Board, and its accountability under the PFMA.

The experiences in South Africa of government entities' Board member names forwarded, approvals, and disputes thereunder, and the involvement of various officials and government entities in the process would create significant room for disputes and possible legal challenges. For example, although the NHI Board is appointed by the cabinet, a list is first forwarded "to the Minister" for cabinet approval (section 13(3)(b) and (4)).

Removals / dissolution

The removal of an individual Board member is in the sole discretion of the Minister (section 13(8)) – again meaning that where the Minister views a Board member unfavourably, even if appointed by cabinet, the Minister can remove such a person. In contrast, Board dissolution must be approved by the cabinet (section 13(9)). But, then, the draft regulations provides for the removal of a Board member "on the recommendation of the majority of the Board" (draft regulation 8(1)(b)). Both instances of removal are subject to an inquiry, and if such an Inquiry so "recommends". This raises a further question – can the Minister refuse such a "recommendation" by an Inquiry, given the power in section 13(8)?

Draft regulation 18 on Board dissolution is at odds with section 13. This regulation is also not clear, stating that the inquiry must be done "quickly", that it can only be on "substantial merits" and is to be done "with a minimum of legal formalities" – given the enormous responsibility of the NHI Fund's Board under the PFMA, we submit that such a process must indeed be formal, as if not managed with appropriate governance and legal considerations it could lead to criminal investigation.

We note that the above Board dissolution process is in contrast to the process for the removal of individual Board members as set out in draft regulation 8 and the process for the removal of the CEO (draft regulation 17). SAMED recommend that the regulations align with the specifics as contained in the NHI Act in relation to *dissolution* (of a *whole* Board) (section 13(9) and the *removal* of an individual Board member (section 13(8)).

The sequencing of the draft regulations include Board dissolution (draft regulation 18) is after the part on the CEO, and we propose Board dissolution be included under the parts of the regulations dealing with the Board.

There appears to be confusion between dissolution (which normally would involve the whole board) and the implication of draft regulation 18(7), namely that the Minister is to "ensure" that a "whole" or "balance" of a new Board be appointed. We recommend that the matters pertaining to dissolution of the whole Board and removal of a member or certain members of the Board, be clarified in the regulations.

SAMED supports draft regulations 11 (standards of conduct) add 12 (performance policy and scoring tools) – however, Board independence would mean that these aspects are not prescribed in

regulations, as is included in Annexure 5. It also means that, when matters are not included in that Annexure, it may be argued that it would not be a ground to, for example, remove a Board member or dissolve the Board. Standards of conduct and undertaking performance reviews should be included in the regulations itself, and become grounds for removal of Board members and/ or the CEO. It must therefore be the principles, that the Inquiry, as set up in the draft regulations, apply.

Powers granted

Draft regulation 13 gives a much wider power than section 10(1)(p), referring to "entities" (much wider than what is listed in the NHI Act). Furthermore, it is the NHI *Fund* and not only the Board which is to undertake the section 10-function to "liaise and exchange information" with the NDoH. This draft regulation also has to be limited by the provisions of the Promotion of Access to Information Act, 2000, and the grounds on which commercially- and/or competitively sensitive information should not be disclosed.

We note that the above (i.e. that is a power of the NHI Fund is being referred to in the draft Regulations) means that the whole of chapter 3 of the NHI Act would also have to be brought into effect, and not only the "governance sections" (i.e. chapters 4, 5 and 6), as well as section 55 and 56. Therefore, nearly all sections of the NHI Act will be in effect and not in the politically stated ten to fifteen years only.. We argue that the provisions on benefits, for example, would necessitate sections 7 and 8 would also have to be brought into effect. Public statements that the NHI Act will be brought into effect incrementally, can therefore not practically be undertaken.

The role of the NHI Fund's Board in draft regulation 13(1) insofar as it relates to "equity and efficiency … in the strategic purchasing of medicines and health goods" means that the Board, and not the Fund or the Health Products Procurement Unit, will be determining how procurement is to work. Apart from the NHI Fund's powers, there are also powers that will affect the supply of products by SAMED's members in the Benefits Advisory Committee and the Benefits Pricing Committee. The draft Regulations now also includes the power of the Minister to set a price under draft regulation 25(7). This is of concern to SAMED's members, as the mechanics of procurement, whether to private sector contractors (such as private laboratories, hospitals or practices) or a part of public procurement (by the NHLS or provincial health departments, or transversal tenders) are far from clear.

Also still absent, and without which the draft regulations 13 and 27 cannot be in effect, is the set of regulations envisaged by section 55(1)(a) of the NHI Act on "the legal relationship between the Fund and the various categories of health establishments, health care service providers or suppliers as provided for in the National Health Act".

5. The CEO

Section 19(4) explicitly states that a renewal of the CEO's terms is only possible once. This is however not clear from draft regulation 15(8)(b) and we proposed that this draft regulation be reworded.

Usually, it is a Board that has oversight and control over the CEO, but section 19(4)(b) of the NHI Act subjects the CEO to the recommendations, directives and determinations of the Board, but only "in consultation with the Minister". It is unclear how, under the PFMA, the Board can be the accounting authority, if it is itself, and its accounting officer, the CEO, under the control of the Minister.

Draft regulation 16 also incorrectly states that the CEO is appointed by the Minister – the CEO is appointed by cabinet, in terms of section 19(2)(b) of the NHI Act.

6. The Advisory Committees

There are inconsistencies in the NHI Act, which now also affects the Draft Regulations. There are no powers and functions described for the Benefits Pricing Committee, but there are for the Benefits Advisory Committee (section 25(5)). There are no numbers of members described for the Benefits Advisory Committee, but there are for the Benefits Pricing Committee (section 26(1)), which in light of draft regulation 25(7) could have a profound impact on SAMED's members and the pricing of the medical devices and IVDs they supply, whether into the private sector, or into the public sector. The absence of describing the number of members means that a stakeholder committee could be severely underrepresented of the broader health sector constituencies that are relevant, and leaves the number, and composition, to the discretion of the Minister.

We also note that the Stakeholder Advisory Committee are excluded from the draft Regulations – it not being clear why this is the case, especially as section 55(1)(x) refers to all Committees. SAMED stresses as per previous submissions that the exclusion of all suppliers (i.e. medicines, medical devices, IVDs and other products) from this Committee is problematic.

The Committees appear to be accountable to, and directly interacting with the Minister. Indeed, in draft regulation 24(1), the Minister sets the policies for performance of these Committees. The powers now solidified in the draft Regulations (e.g. on benefits and pricing) would lead to conflicts between the roles of the NHI Fund and its functionaries with the Committees on the same topics.
It also signals an unacceptable involvement of the Minister in operational matters of the NHI Fund, again in contravention of the PFMA.

Apart from the operationalisation of the recommendations of the above Committees, the NHI Act awards various operational powers[1] to the Minister, which means that, unlike in other Schedule 3 PFMA entities, the Board and the Fund are unable to act independently (PFMA, section 49).

7. Ministerial powers in NHI Act, proposed governance regulations and still to be exercised

SAMED does not take issue with the right of the Minister to appoint Board members, it is indeed a power that resides, rightly so, also in other schedule 3 PFMA entities, such as the Council for Medical Schemes (CMS), the National Health Laboratory Services (NHLS), Medical Research Council (MRC) and Office of Health Standards Compliance (OHSC).

However, in some, but not all, of the above and similar entities does the Minister appoint the CEO, and in none of them does the Minister get operationally involved. All these entities have powers to *advise* the Minister and there are reports to the Minister (and Parliament), but in none of them are operational decisions left to the concurrence of the Minister, as is the case in the NHI Act. The NHI uses the phrase "in consultation with the Minister" in relation to the powers and functions of the NHI Fund and its structures several times.

Some of these powers are now also included in the proposed Governance Regulations, such as that the Minister develop and maintain policies (draft regulation 24(1)) on "researching and benchmarking practice" and performance management, amongst others.
SAMED proposes that the role of the Minister of Health be limited, as is the case in the schedule 3 PFMA entities listed above, and that the Minister not be involved in operational matters, such as policies and performance management.

8. **Conclusion**

SAMED supports the general concept of a process that is open to public scrutiny, but remain concerned about the powers of the Minister, the uncertainty in some of the proposed regulations as set out above and the practicality of implementing processes of appointments and removals relating to the various structures i.e. board and committees referred to in the regulations.

SAMED can be contacted at:
011 704 2440
Email: tanya@samed.org.za