SASCI Submission

Notice No 5870: "Competition Act (89/1998) as amended (The Competition Act): Invitation for the public to comment on the draft interim block exemption for tariffs determination in the Healthcare Sector, 2025", Government Gazette No 5211 of 14 February 2025

(hereinafter Proposed Block Exemption "PBE")

16 May 2025

To the Minister of Trade, Industry and Competition, Minister Tau

For the attention of: Dr Ivan Galodikwe
By email IGalodikwe@thedtic.gov.za

1. About SASCI

South African Society of Cardiovascular Intervention (SASCI), an affiliated group of SA Heart, the professional body representing cardiologists in South Africa. Cardiovascular conditions are one of the most impactful diseases on the South African population, responsible for almost 1 in 6 deaths.[1]

SASCI's members, who are providing the patients with what is called "interventional cardiology" is an important stakeholder in the draft regulations as proposed. Patients have also been at the receiving end of inadequate funding, sometimes based on outdated coding systems, inconsistent or erroneous interpretation and application of codes. These codes are to give expression to known professional activities, some more risky and requiring skills (for which SASCI members have received additional training) than others.

SASCI has always supported the concept of collective negotiation on tariffs but has been unable to do so.

The PBE proposal on the table, however, is significantly different to what SASCI has provided comment on to the HMI. The nuances required to address our challenges are not accommodated.

[1] https://www.heartfoundation.co.za/wp-content/uploads/2017/10/CVD-Stats-Reference-Document-2016-FOR-MEDIA-1.pdf

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2. Exemptions versus price regulatory systems

Like many healthcare professional organisations, SASCI has always held the view that it is impractical for each individual practice (each "firm" in competition law language) to negotiate individually with all the schemes and/or administrators.

Many healthcare professional associations hold the view, as SASCI does, that medical schemes, often through their administrators, hold considerable market power. The Medical Scheme and/or Administrators exclude professionals from seeing their beneficiaries through several strategies, such as large co-payments, preferred provider or designated provider appointments, paying beneficiaries directly unless the provider charge exactly what the scheme is willing to fund, etc. They often exclude healthcare professionals by not including the hospitals or other facilities within which a professional practice, leaving professionals at the mercy of large, powerful entities such as hospitals and administrators.

Individual practices are unable to individually negotiate the terms of providing services to medical scheme beneficiaries, and the associated fees.

It is for this reason that other societies, such as the Orthopaedic Association, the Independent Practitioner Association Federation and the Physiotherapy Society have, in the recent past, sought exemption from the Competition Act. None of those exemptions were granted.

An overview of the Proposed Block Exemption ("PBE") however paints a picture not of individual or groups of practices getting together, and collectively negotiating tariffs with groups of funders, or with individual funders of healthcare (i.e. medical schemes), but rather of a statutory price-setting mechanism of which the mechanisms, processes and outcomes are very much controlled by the National Department of Health, with some input by the Council for Medical Schemes. The language used is very much that of price-setting, and mandatory compliance with tariff thus set, that will cover every single aspect of medical scheme benefits.

It is also apparent that this collective determination process, facilitated by government entities will affect all healthcare professionals, whether they are, in the immediate world of SASCI's members, clinical technologists, nursing professionals, occupational therapists, physiotherapists, biokineticists, or other specialists, such as pathologists, radiologists and anaesthesiologists. The interventional cardiology service that a patient receives from all of these professionals, who could be all involved in a single incident, will therefore be affected – all but the hospitals and facilities.

Also affected will be the suppliers of the equipment, implants, consumables and disposables used by SASCI's members. Medicines formularies will also be affected.

The treatment guidelines which SASCI, and other cardiology groupings follow, as set based on scientific studies and best clinical practice, will also be subject to the "collective determination" system.

It seems that no part of medical practice will be left untouched by the PBE, very similar to what is contained in section 39 of the National Health Insurance Act, 2023. The PBE indeed does allude to the NHI. The monitoring mechanism set out in par 16.3 of the PBE is indeed the NDoH's NHI unit. The long and short of the matter is that the NHI Act requires contracting to start in 2026 and further contracting by 2028. Whilst it is known that the NHI Fund will not have the means to afford services at current private sector tariffs, nor to afford the range and scope of services and products available in the private sector, intervention is needed to achieve such affordability levels by depressing tariffs and limiting the scope of available treatment tools.

The PBE is a subterfuge to control prices in order for the NHI Fund to afford the services rendered by private healthcare professionals.

3. Non-compliance with the Competition Act

Given the Competition Commission's refusal to approve applications for exemptions for both healthcare professional groups, and funder groups (the BHF), it seems odd that a block exemption would now suddenly meet the criteria for exemptions as set by the Competition Act.

Section 10 (10) reads as follows:

The Minister may, after consultation with the Competition Commission, and in order to give effect to the purposes of this Act as set out in section 2, issue regulations in terms of section 78 exempting a category of agreements or practices from the application of this Chapter.

Section 2[2] of the Competition Act contains a number of objectives, the only conceivable purpose aligned to the PBE being "conditions … within such market … that

[2] *2. The purpose of this Act is to promote and maintain competition in the Republic in order—*
(a) to promote the efficiency, adaptability and development of the economy;
(b) to provide consumers with competitive prices and product choices;
(c) to promote employment and advance the social and economic welfare of South Africans;
(d) to expand opportunities for South African participation in world markets and recognise the role of foreign competition in the Republic;
(e) to ensure that small and medium-sized enterprises have an equitable opportunity to participate in the economy;
(f) to promote a greater spread of ownership, in particular to increase the ownership stakes of historically disadvantaged persons; and

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tends to impede, restrict or distort competition in connection with the supply or acquisition of those goods or services".

The PBE must be rationally connected to the above purpose, which purpose must be specifically set out. It is unclear what specific conditions in the market the PBE aims to address. The PBE only mentions the "notable vacuum in tariff negotiations" (par 4) or "gaps in tariff determination" (par 5). It seems to equate "negotiation" with "determination".

The PBE laments the "negotiations conducted on a bilateral basis between some healthcare providers and funders" (par 4). However, block exemptions, as being voluntary, would lead to exactly this. This again highlights the actual objective behind the PBE namely, to set the tariffs at levels deemed by government to be acceptable.

The PBE also seems to be of the view that, in spite of competition law prohibiting such fee negotiations between, for example, SASCI on behalf of the various practitioners it represents, and funders, that this is a current practice. This is not the case, not for SASCI, nor for any other professional provider association that SASCI knows of.

The PBE is therefore *ultra vires* the Competition Act, in that it is used to create a "wide regulatory framework for … multilateral tariff determination." It does not provide a framework for "agreements", nor for "practices". Instead, it creates a government-controlled and government-set of structures and systems that, in effect, will *determine* prices.

The Competition Appeal Court has in the past emphasized the "importance of freedom of pricing" and warned against "converting courts into price regulations".[3]

Furthermore, the inclusion of medicines and medical devices would lead to market exclusions for such suppliers, which would contravene section 8 of the Competition Act.

4. Not what the HMI recommended

The HMI identified a plethora of issues relating to the health sector and proposed a number of solutions which it explicitly indicated should not be implemented

(g) to detect and address conditions in the market for any particular goods or services, or any behaviour within such a market, that tends to impede, restrict or distort competition in connection with the supply or acquisition of those goods or services within the Republic.

[3] *Sasol Chemical Industries Limited v Competition Commission* (131/CAC/Jun14) [2015] ZACAC 4; 2015 (5) SA 471 (CAC); [2015] 1 CPLR 58 (CAC) (17 June 2015).

"piecemeal" and the specific "sequence" for the implementation of reforms are important. [4]

For example, the exclusion of hospitals from the HMI's (quite different) recommendations relating to a Multi-Lateral Negotiation Forum (MLNF) was very much related to the necessity to address the hospital licensing system,[5] and the awarding of practice code numbers[6]. Here the PBE therefore departs from what the HMI actually recommended. Failing the implementation of the recommendations relating to hospitals, the exclusion of hospitals from the MNLF is no longer rational.

And as with other recommendations, an interim collective bargaining process was proposed by the HMI.[7] It recommended that, within a period of three years, all bilateral negotiations between hospital groups and funders must be on the basis of alternative reimbursement models (ARMs).

The HMI also made clear that one of the failures that have led to the state of affairs at that time, was that -

25. The regulatory bodies have failed to implement the existing provisions of the National Health Act in a coherent manner. Specifically, this failure refers to provisions relating to price determination, a centralised licensing system, the setting up of a unified national health information system and the measurement of quality of healthcare services. As is evident, these provisions are predominantly related to the supply side.

The above remains true till today, and the PBE is not a shortcut to remedy such failures.

Another key recommendation by the HMI relates to the risk adjustment mechanism (RAM),[8] without which scheme options will continue to face differing financial- and clinical risks, therefore being unable to provide any standardized benefits. The RAM in its previous version, the REF – the Risk Equalisation Fund, is one of the further unimplemented reforms, under the Medical Schemes Amendment Bill of 2007.

In relation to tariff negotiation, the HMI recommended –[9]

(a) A process of *negotiation*.

(b) The setting up of an independent entity (the Supply Side Regulator for Health – SSRH) to facilitate such negotiation, with an interim solution under the auspices of the CMS, but noted that the CMS (as the regulator of

[4] HMI Final Report, 2019, at page 210 – 211, par 9.
[5] HMI 2019, pages 215 - 219, par 48 – 74.
[6] HMI 2019, pages 219 – 202, par 75 – 92.
[7] HMI 2019, page 221, par 93 – 100.
[8] HMI 2019, page 119, par 99 – 104.
[9] HMI 2019, page 223 - 225, par 118 – 138.

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funders) would be perceived to be biased, the same perception of bias would of course hold true now that the NHI Act is in place, and the DG being the person responsible for health districts.

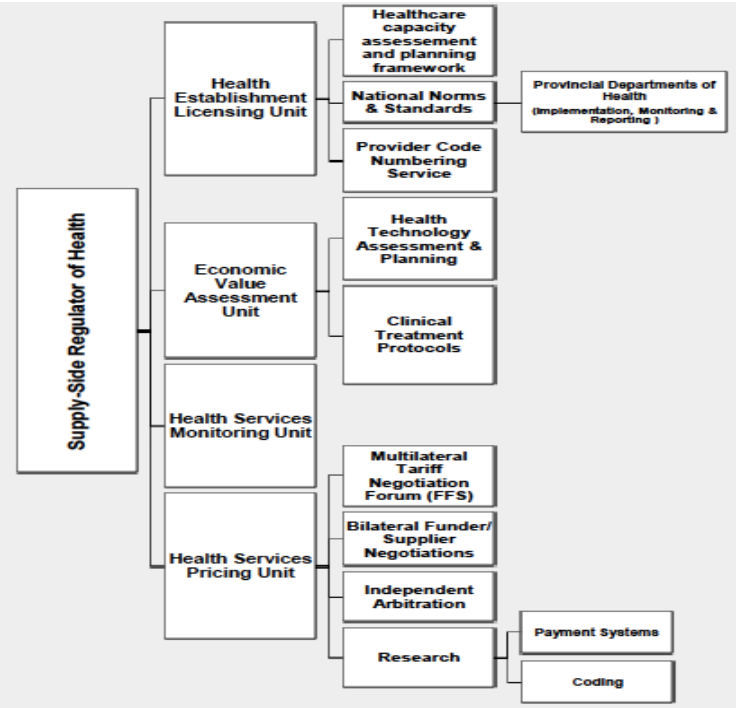
(c) Representatives of providers, funders, patients will comprise the MLNF, not representatives *appointed by the NDoH*.

(d) The negotiated tariffs would only apply to the PMBs, with non-PMB negotiations only being guidelines, the reason for this being that no scheme is obligated to cover non-PMBs and where it does so, it is in its absolute discretion.

(e) Separate functions, not to be negotiated, relating to economic evaluation (i.e, HTA) and treatment guidelines.

(f) Coding being a research-based function, not a topic for negotiation.

The 2018-interim HMI Report depicted the SSRH's structure as follows:



It is understood that the NDoH rejects the notation of an independent entity such as the SSRH, as related to the fact that the National treasury would not approve another schedule 3 PFMA entity. However, ironically so, the NHI Act proposes all public health facilities (hospitals) to become "components of (national) government"[10]. The Public Finance Management Act, 1999 (PFMA) defines a "national government component" as "a national government component listed in Part A of Schedule 3 to the Public Service Act, 1994", and the same with a provincial component. This means that all public hospitals will in effect be under the ultimate control of the National Department of Health, which will be the entity that will have a determining say in the PBE, but being "autonomous"[11] and "semi-autonomous"[12].

[10] Section 7(2)(f), section 32(2)(c) and the Schedule to the National Health Insurance Act, 2023, creating a new section 31A in the National Health Act, 2003.
[11] Section 32(2)(b), NHI Act, 2023.
[12] Section 7(2)(f)(iv), section 57(4)(a), NHI Act, 2023.

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5. Conflicting provisions with other legislation

The HMI pointed to regulatory failures, notably in the non-implementation of key sections in the National Health Act, 2003. The PBE cannot cure such defects, create a shortcut that avoids implementation of existing statutory provisions; nor can it set up parallel systems in law, with resultant conflicting and contradictory provisions.

The most glaring conflicting provisions are, amongst others:

- The Medical Schemes Act, 1998 (MSA) and Medical Schemes Regulations, 1999:

    - Medical schemes are empowered in terms of the managed care regulations to set treatment guidelines and medicines formularies on the basis of evidence-based medicine (as defined in the regulations), taking into account cost-effectiveness and affordability, based on each scheme options levels. The PBE contains no such qualifiers and simply authorise "the collective determination of … medicines formularies and treatment protocols/guidelines" (PBE par 2.3, par 7.3, par 8.3 and par 9.6.3). Furthermore, medical schemes are obligated to create exceptions to formularies and guidelines under circumstances outlined in the regulations.

    - Medical scheme options must be self-supporting, in terms of section 33 of the MSA. In the absence of a risk adjustment mechanism (RAM), as recommended by the HMI, requiring of all medical scheme options to fund the collectively determined tariffs, and use the collectively determined formularies and treatment guidelines would create unsustainable options, or options that are not linked to the contributions of beneficiaries. In practice, the collectively determined tariffs would have to be the lowest possible common denominator.

    - Two-yearly review of the PMBs, as set in the Explanatory Notes to the PMB list, as contained in Medical Schemes Regulations, 1999 (Annexure A), and as empowered by section 29(1)(o), the scope and level of which each scheme must set for itself, as "may be prescribed".

    - Section 59(3) of the Medical Schemes Act, 1998, provides clear authorization for schemes to "claw back" payments made in error, e.g. where benefits were not legally due, where there is misconduct (e.g. over-charging or billing incorrect codes), etc. There are therefore powers in the Medical Schemes Act afforded to medical schemes to address issues with coding, e.g. inconsistency. Collective determinations will rob schemes from this power.

- The Health Professions Act, 1974:
    - This Act determines that it is an offence to "practice" if not registered (section 34). "To practice" includes the giving of advice (section 17), within the determined scope of each specific profession (section 33). What it means to "practice", to "diagnose", to "treat" is not up for negotiation, but is determined by the profession in accordance with professional standards. The tools of the profession, such as medicines and medical devices, are subject to scientific criteria, and its use and sequencing and subject to the globally accepted definition of "evidence-based medicine".[13]
    - The HPCSA Ethical Guidelines (Booklet 19: Guidelines on matters relating to ethical billing practices[14]) require the publication of fees up front, and the agreement thereto by patients in writing, and prior to services being rendered.
    - The HPCSA Ethical Guidelines (Booklet 11: Guidelines on over-servicing, perverse incentives, and related matters[15]) defines and governs instances of over-servicing, perversity and the likes.
- The National Health Act, 2003, one of the laws which incomplete implementation over the past 20 years have been identified by the HMI has one of the key failures leading to the *status quo*, or where provisions have already been implemented:
    - Provision[16] for the creation of a reference price list by regulation. That remains unimplemented 15 years since the first RPL system was declared unlawful. This is in spite of good pointers provided by the High Court[17] as to where the NDoH went wrong.
    - Provision[18] for regulations on the Essential Drug List and an Essential Equipment List (i.e. formularies).
    - Chapter 10, creating the Office of Health Standards Compliance (OHSC), and the accompanying quality norms and standards, which has the authority

[13] Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS (January 1996). "Evidence based medicine: what it is and what it isn't". *BMJ*. 312 (7023): 71–72. doi:10.1136/bmj.312.7023.71. PMC 2349778. PMID 8555924.
[14] https://www.hpcsa.co.za/ethics
[15] https://www.hpcsa.co.za/ethics
[16] Section 90(1)(v), National Health Act, 2003.
[17] *Hospital Association of South Africa Ltd v Minister of Health and Another* (37377/09, 37505/09, 21352/09) [2010] ZAGPPHC 69; 2010 (10) BCLR 1047 (GNP) ; [2011] 1 All SA 47 (GNP) (28 July 2010).
[18] Section 90(1)(d), National Health Act, 2003.

to enforce those standards, with the largest challenges being experienced in the public sector[19], the powers of which cannot be subject to "collective determination" (PBE, par 2.3, par 6, par 7.3, par 8.3,) or "collective recommendation" (PBE, par 9.6.3). Empowering the OHSC with adequate resources to not only inspect and certify more facilities, but to also assist with remedial steps, should be the priority, not generating standards or metrics by collective action.

- Ministerial Advisory Committees, which can only be appointed in terms of section 91 of the National Health Act, and which would apply to the "Coding Committee" and the "HTA Committee", and which requires that such committees' composition, functions, remuneration and the likes be published in the Government Gazette. Most significantly, such Committees must relate to the achievement of the National Health Act's objective, not those in the Competition Act or its regulations.

- The process of informed consent to treatment makes a discussion on the treatment options and the *cost* thereof, mandatory in section 6 of the National Health Act, 2003. What is lacking is the implementation and *enforcement* of this section. What treatment, and at what cost, will not have been pre-determined by the MLNF (or the TGB).

6. Vagueness and internal contradictions in the PBE

It is a seminal criterion, entrenched in section 1(c) of the Constitution, 1996, that the law must be certain, clear (i.e. not vague), apply equally, be rational and not be subject to determinations by persons or entities not empowered by law to do so. The PBE however does not comply with the principle of the rule of law.

Below we provide a paragraph-by-paragraph analysis of instances where the above principles are not adhered to:

6.1 Definitions

Although defined, the phrase "competitively sensitive information" only appears in one context, namely paragraph 15, relating to an unknown, and undefined, "independent facilitator" for the sharing of data. No further details are provided, and other

[19] See the various inspection and certification reports available at https://ohsc.org.za/publications-report-2/, the latest being that dated September 2024: https://ohsc.org.za/wp-content/uploads/2025/02/Biannual-Report-April-September-2024-inspectionscertification.pdf.

paragraphs seem to indicate that certain information, irrespective of its senstitive nature, would have to be provided.

The word "firm" is defined as "an association". SASCI, and many other healthcare professional groupings are set up as associations not for gain, under a constitution. SASCI does not trade and is not in and for itself a "firm". Its members are firms, i.e. practice owners (firms), as well as employees of practices or professionals working in association with practices (such as the clinical technologists, or nursing professionals working in catheterisation laboratories ("cath labs")). The Competition Act itself attributes another meaning to "association", recognizing it is an association of firms,[20] and not a firm itself.

It must also be noted that healthcare professionals registered at the HPCSA cannot practice in a trust. There is a limited exemption[21] to practice in incorporated companies.

The following words and phrases are used in the PBE, but without definitions, rendering their meanings and applications unclear:

- "Codes", as opposed to the defined "standardized codes". In reality there are various sets of codes, e.g. ICD-10 (diagnostic codes, signifying the condition a patient has), CCSA (Complete CPT® for South Africa consists of the American Medical Association's Physicians' Current Procedural Terminology (CPT®), MDMC (SAMA Medical Doctors' Coding Manual), NAPPI® (National Pharmaceutical Product Index, a unique coding system used in South Africa for identifying pharmaceuticals, medical devices, and other healthcare products, owned by Medikredit), etc. In addition, the NDoH has signaled[22] its intention to introduce different sets of codes to those currently in use, presumably in view of the NHI Act.

- "Consistent pricing", which appears to signify something along the lines of the medicines single exit price, however that is not clear.

- "Determined", as opposed to another word used, namely "predetermined" (tariffs) as well as "collective determination", tariff "setting", the differences, and significance of such differences not being clear.

[20] Section 4(1), Competition Act, 1998 refers to "an association of firms".
[21] GNR.706 of 15 April 1994: Exemption of juristic persons from the operation of certain provisions of the Act (Government Gazette No. 15627), Health Professions Act, 1974.
[22] Notice No. 6395 *Coordination of National Health Information Systems* Government Gazette No. 51362 of 1 October 2024.

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- "Funders", which could, generally, include medical schemes, the RAF, the Compensation Fund, provincial departments of health, the Compensation Commissioner for Occupational Diseases in Mines and Works, employers in the case of bargaining council healthcare funding arrangements, the exempted insurance products, etc. However, a description in par 14 includes "managed care companies" and "administrators", neither of which are funders, as, both are, in competition law terms, suppliers of managed care- and administration services to medical schemes. The HMI made very specific recommendations that these groups are not to be included in their proposed negotiation structure.[23]

- "Government", which in the context of a negotiation structure, appointed by the DG, could include any entity.

- "Medicine tariffs" and "medicine codes", whereas medicines do not have any "tariffs" – only the Single Exit Price as determined by the Medicines Pricing Regulations of 2005. It could however also refer to tariffs charged by nurses and other healthcare professionals in administering medicines, such as vaccines – but that is by no means clear in the draft regulations.

- "Providers", which would generally include all healthcare professionals (whether allopathic or alternative), all facilities, networks of providers, etc.

- "Stakeholder(s)", a word that is used to give rights to an undetermined and indeterminable group, in relation to collectively determining tariffs (par 3); who have to submit data (par 9.12); and who should have access to determined tariffs (par 9.17). Then there are "all interested parties" mentioned in par 9.14. From this it is clear that the word may have different meanings in different paragraphs.

- "Standardized tariffs" (as opposed to "pre-determined tariffs", and "consistent" pricing.

- "Specific categories of agreements or practices", but none are specified or defined, other than the broad outlines in the PBE relating to codes, tariffs, formularies, protocols and quality matrices.

- "The sector" meaning the health sector, but not clear whether it includes both the public and private sectors, and within the private sector, which of the funders of healthcare are included.

6.2 Background

[23] HMI 2019, par 151 – 153, page 227.

The background lists the impetus for the PBE as the HMI recommendations. As SASCI pointed out above, the proposal is a far cry from what the HMI actually recommended.

The background also lists several issues, some indicating the purpose of the PBE. This purpose is an important consideration when evaluating the rationality of the PBE. These purposes or objectives include:

- Preventing anti-competitive practices (par 2), but the PBE does not identify what those practices are, and how the PBE would address such undisclosed practices.
- Supporting the sustainability of healthcare services (par 2), but sustainability differs from scheme option to scheme option. The same for practices, where viability differ, even within a discipline such as interventional cardiology.
- Increasing access to healthcare (par 2), which SASCI believes is doubtful, given that the cost-drivers of increasing premiums, i.e. anti-selection, the absence of mandating medical scheme cover and the failure to introduce risk adjustment mechanisms, are not being addressed.
- Reducing costs (par 3), whereas hospitals and other cost drivers, such as utilisation, age (included the fact that young, healthy and employed persons do not belong to schemes) remain unaddressed.
- Promoting universal access to health, although not really clear how, given the policy statements to reduced medical scheme coverage over time (par 3).
- Enhancing quality of healthcare (par 3), but which is already the statutory mandate of the OHSC under the National Health Act.
- Addressing inefficiencies and disparities, although not clear what inefficiencies or disparities are being referred to (par 4).

Par 5 states that there is an "immediate need" to address the current gap in tariff determination. The question is, why now, 6 years after the publication of the HMI report, 15 years after the RPL High Court ruling and some 23 years after the consent orders and fines imposed by the competition authorities?

Par 6 makes clear that the objective is actually to ensure a "smooth transition" into the lower-resourced environment of the NHI, where the NHI Fund would not be able to afford the current pricing levels of the private sector providers. Given the price-determination powers of the NHI Benefits Pricing Committee, which in terms of recently released draft Regulations will become effective once agreed to by the Minister of Health,[24] and the necessary contracting by 2026 and 2028 respectively, the objective can only be to depress prices in view of such powers being exercised by 2026 and 2028.

[24] Draft regulation 25(7), Proposed Governance Regulations, Notice No 5950, Government Gazette No 52224 of 6 March 2025.

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6.3 Purpose

Par 7 stipulates that the three exempted activities (tariffs; coding; quality, medicines formularies and treatment protocols/guidelines) serve the purpose of section 2 of the Competition Act, by exempting such activities from:

- Section 4(1)(a), i.e. collusion that substantially prevents or limits competition;
- Section 4(1)(b)(i), i.e. directly or indirectly fixing a purchase or selling price or trading conditions;
- Section 5(1), i.e. agreements between parties in a vertical relationship.

SASCI notes that sections 4 and 5 of the Competition Act, and hence the exemptions thereto, applies to *firms* directly, and not to a body set up by the NDoH (i.e the MLNF or TGB), or any other entity, to commit such acts of collusion.

It remains unclear how an entity not directly mandated and representing a firm, such as the MLNF and the TGB, can (a) negotiate on behalf of such a firm; and (b) enter into binding agreements on behalf of a firm (i.e. a practice in the case of SASCI's members).

Par 7.1. to 7.3. repeats throughout the PBE, sometimes in exactly the same wording (e.g. par 8.1 to 8.3) and sometimes with wording changes (par 9.6.1 to par 9.6.4). The reason for this variation is not clear. What the PBE mean with Healthcare service tariffs" vs "procedure" vs "treatment code" is unclear.

Par 7 also sets the purpose as contributing to "affordability" of "quality" healthcare services applicable to PMBs and no PMBs -

- By reducing "cost" (as opposed to prices)
- By contributing to the prevention of over-utilisation of healthcare services.

Given that there are no specific steps in relation to alleged over-utilisation, and no definition thereof, the inclusion of this objective is irrational. In addition, this is something within the scope of the HPCSA (Booklet 11), and a matter that medical schemes are empowered to deal with under section 59(3) of the Medical Schemes Act, 1998.

6.4 Categories of agreements or practices exempted

The collective determination of tariffs is understood to mean the tariffs that the MLNF will determine through its constituent members, as appointed by the DG of Health. How the third-party "determined" tariff becomes an agreement, is not clear, neither how it would become "binding" (par 10.4) and "enforceable" (par 10.1 and 10.2).

6.5 Framework for collective determination

6.5.1 Tariff Governing Board (TGB)

The TGB is, in effect, a statutory body, set up by legislation (the PBE). Its members are appointed by the DG of Health, and includes, as a chairperson, an official of the NDoH, as "Chief Tariffs Manager" (par 9.2). The DG and the CMS "establish" and "oversee" the TGB (par 9.1), but only the DG appoints the TGB (par 9.3).

The chairperson would, by definition, by working for and in the NDOH, be conflicted (par 9.3.2). The establishment and oversight roles of the NDoH and the CMS are exactly the (perceived) conflicts and bias the HMI foresaw.

As mentioned before, the NDoH, the MoH and the NHI Fund Advisory Committees will be involved in the setting of prices and the contracting of services by the private sector into the NHI, with the DG also overseeing the entities from the public sector side contracting into the NHI. Significantly, therefore, the NDoH, its staff and the DG will therefore have access to the information submitted by firms into the tariff determination process.

They are therefore not unbiased and will be conflicted as funders and purchasers of healthcare services from private providers.

It is unclear what the oversight roles of the NDoH and CMS entail, given that the TGB in itself would fulfil some type of arbitration and final determination role (par 9.10 and par 10.3). It does however mean that, in the final instance, tariffs will in effect be determined by the NDoH and the CMS.

It is unclear what type of qualification, skills and experience would include that of "tariff determination methods and practice" (par 9.3.3), given that healthcare services have never been price-regulated in the past.

Surprisingly, the TGB has open-ended powers ("inter alia" – par 9.4) that exceed those listed as the specific agreements and practices that form the subject-matter of the PBE, namely:

- In what amounts to an unauthorized delegation of legislative power, the power to issue terms of reference, guidelines and rules for tariff determination (par 9.4.1).

- Consultation with the Coding and HTA Committees, although the application of the outcome of such consultation is not clear, given the powers of the MLNF (par 9.4.2). The terms of reference of these Committees are not known, neither whether their mandates would be limited to the private sector, or include both health sectors,

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and the impact that would have on coding – it being known that coding in the sectors differ significantly, even for goods such as medicines. HTA also differ as the financial means and affordability thresholds are similarly different and even differ from scheme option to scheme option.

- The power to establish rules relating to the inability to reach agreement on tariffs and the inability to reach agreement on the process to determine tariffs (par 9.4.3.1 and 9.4.3.2), which powers are in conflict with the final determination power afforded to the TGB in par 9.10 and 10.3).

- The power to establish rules relating to the "deviation from the determined tariffs" (par 9.4.3.3). What this means is not clear at all: does this mean that the TGB will act as a type of "pricing police", or does it mean that deviation from agreed tariffs would be possible, but some type of application must be made to the TGB (i.e. a non-party to an agreement allows for a variation to the agreement?), or could there be "in principle deviations", or does this only refer to bilateral agreements, which would be a deviation from the determined tariffs? Could this "deviation" relate to global fees, per diems, value-based pricing? And if that is the case, it means that the collectively determined tariffs would be binding upon all, those who participated by nominating persons for appointment and who submitted data, and those who did not.

- The TGB is also given the power (in contravention of the mandate[25] in the Medical Schemes Act) for it to "collaborate" on the *review of the PMBs* (par 9.4.4). This review is not part of the PBE's and as SASCI has pointed out above, is a statutory duty. Here one cannot but mention the failure of the CMS to take action each time it has undertaken and reported that the PMB review was rejected by the MoH, and the MoH's steadfast view to not review the PMBs, at most agreeing to add primary healthcare to it – a project that also, nonetheless, has after some 6 years, come to naught.

- The TGB is authorised to undertake a "price-cost assessment" (par 9.4.5 and 9.16.2). The MLNF is however also tasked with this function (par 9.16). Price-cost assessment is a methodology that relates to the establishment of excessive pricing, and as section 8ff of the Competition Act is not part of the scope of the

[25] The mandate as found in the Medical Schemes Regulations reads as follows:
A review shall be conducted at least every two years by the Department that will involve the Council for Medical Schemes, stakeholders, Provincial health departments and consumer representatives. ... These reviews shall provide recommendations for the revision of the Regulations and Annexure A on the basis of—

(i) inconsistencies or flaws in the current regulations;
(ii) the cost-effectiveness of health technologies or interventions;
(iii) consistency with developments in health policy; and
(iv) the impact on medical scheme viability and its affordability to Members

PBE, is inappropriate. Most significantly, the cost-base of practices differ widely, even within a sub-speciality (e.g. cardiology) and within the special interest group that SASCI's members comprise, namely *interventional* cardiology. Getting to some average, a mean or a median would imply that those practices below such average, mean or median would have to attempt to "make do" with lower tariffs. The same for practices that focus on different aspects of cardiology, or have practices with specific age, disease or demographic profiles, or that services only certain, or mainly certain medical scheme beneficiaries.

Another aspect worth mentioning is the difference in actual practice costs. Setting up a Cardiology practice is a huge financial expenditure. Purchasing equipment such as ECG machines, treadmills, echo-cardiography machines, where no code exists for "equipment hire" in order to assist with the financial impact of such equipment, does have a negative effect of the income of a Cardiologist. There is a portion of the current RVU (Relative value unit) in the MDCM that is attributed to practice cost. However, the calculations of such "practice cost' portion is relevant to the USA market where the medical providers are employed by the hospitals and the hospital buy the equipment. In South Africa, the medical practitioners buy their own equipment. The cost of equipment must be factored into the tariff, as applicable to the South African Private Healthcare environment. To undertake a price-cost assessment of only SASCI's members, the financials of more than 100 firms would have to be assessed.

Adding other healthcare professionals, it may be tens of thousands – an impossible task within the stipulated 60 days deadline (par 9.16.2). SASCI also notes that the "competitively sensitive information" override does not apply here, and there appears no link to the facilitator envisaged in par 15.

- Par 9.4.6 is another example of unauthorized delegation of statutory powers – the DG is granted with the power to agree to any other functions reasonably necessary under the PBE.

6.5.2 MLNF

The DG also appoints the members of the MLNF (par 9.5). Such members are described as "representatives", but to what extent such a member would be actually representing, for example, SASCI's members, is not clear. To represent someone in negotiations, there should be a mandate provided to the representative. The representative should also know the sub-speciality to such an extent that such a person is able to make the case relating to the specific (procedure) codes and tariffs, and to respond to the representative(s) from funders, for example.

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In SASCI's view the construct of a third party, appointed to negotiate and ultimately determine the "maximum tariffs" (par 9.6.1) and "recommend … standardized" codes (par 9.6.2), is impractical and unworkable.

There seems to be two options at the MLNF in relation to coding (par 9.6.2):

(a) The Coding Committee would have "developed" codes applicable to the scope of practice of interventional cardiology; or
(b) If not, the MLNF would recommend "standardized codes" to that Committee.

This is vague in the extreme. It is also divorced from the current reality, where there are codes and descriptors currently being used by interventional cardiology practices (firms), which codes are reimbursed by medical schemes, in some cases to different levels. There are also global fees being paid for certain types of interventions (e.g. Trans-Aortic Valve Implantation - TAVI).

To illustrate the impracticality of the development of standardized codes, one could take the thousands of codes applicable to various healthcare disciplines, as for example published by the Compensation Fund annually, or the various Reference Price Lists of 2006. Or the brand-new application of the newly published[26] draft coding systems, which includes the WHO's ICHI, LOINC, etc. And if so, how will the sector move from the current systems into these brand-new systems, whilst those also being subject to collective determinations?

The PBE provides no details as to how the standardization would take place, nor how tariffs would be attached to the codes during the process of "determination".

The following functions of the MLNF (par 9.6.3), namely quality measurements, medicines formularies and treatment guidelines are aspects that should not be up for negotiation. These are scientific functions, and functions already carried out by other bodies, whether the OHSC or schemes themselves in terms of other legislation, i.e. the National Health Act and the Medical Schemes Act and the sets of regulations thereto. The HMI did not recommend these functions to fall under the negotiation structure.

There is a similar problem with par 9.6.4, where in the absence of the HTA system being established in terms of the National Health Act, the MLNF would be "sourcing" what is termed "relevant evidence". HTA is an extremely complex and highly technical area. It cannot simply be "sourced".

[26] Notice No. 6395 *Coordination of National Health Information Systems* Government Gazette No. 51362 of 1 October 2024.

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The HMI made various recommendations in relation to health technology assessments, none of which are being followed in the PBEs, most significantly that the HTA and guidelines functions are separate from the tariff negotiation function. The HMI noted, for example:

188. … Therefore, the absence of regulations on HTA is a significant regulatory failure.[27]

This regulatory failure cannot simply be "plugged" as part of a tariff negotiation process undertaken by third party appointees of the DG of Health.

It also made clear:[28]

It should be noted that guidance on how HTA is performed elsewhere should guide South African practice if only to avoid reinventing the wheel and to ensure the early establishment of an effective HTA unit. Consideration should be given to examples from the Philippines and Thailand who incrementally developed their own capacity for HTA by working in partnership with relevant bodies internationally. The practice of contracting specific HTA assessments to academic institutions should also be explored.

…

Specifically, standards of care, evidence-based treatment protocols and processes for conducting health technology assessments to assess the impact, efficacy and costs of medical technology, medicines and devices relative to clinical outcomes, must be developed. The process of developing HTAs, pharmaco-economic and standards of care evaluations should be based on standard accepted approaches. Where appropriate, collaboration with representatives of patients, academia, regulators such as SAHPRA and CMS, and national and international experts should be ensured.

All findings, positive or negative, of the economic value assessments should be published to stimulate competition, to mitigate information asymmetry, and to inform decisions about strategic purchasing by the public and private sectors.

The above extract also makes clear that HTA results are tools used in reimbursement decisions, and not topics for negotiations or determination.

Par 9.7 gives the MLNF the right to agree on its own process to determine the tariffs. This is not only vague, but again an unlawful delegation of legislative authority. There are no legislative guardrails, and all aspects of the process will be left to the DG-appointed members of the MLNF. It remains wholly unclear how a professional group such as SASCI would "enter" the process of tariff negotiation, how it would bind its members, what the timeframes would be, etc.

[27] HMI 2019, page 93.
[28] HMI 2019, page 222, par 102 - 104.

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It is also not clear how, as is the case with block exemptions usually, one would exit, if an agreement cannot be reached – it seems that once "in" one would be bound by the process and the ultimate tariff as determined by the TGB (par 9.4.3, par 9.10 and par 10.3). This means that SASCI's members would be forced into an agreement by having entered the negotiation system, which violates a key principle of the law of contract and undermines the very nature of block exemptions as voluntary, which, oddly so, is recognized in par 17.

Par 9.8 list the excluded practice code numbers (i.e. those entities are still bound by the Competition Act and are not exempted, and not subject to the tariff- and coding determination dispensation) and include facilities where cardiologist may continue to see patients, such as step downs. These exclusions have numerous unintended consequences:

- Where a global fee, per diem or other collective fee is paid to the facility (i.e. one of the entities with excluded practice code numbers), the interventional cardiologist (and their income) would not be affected by the block exemption-determined tariffs.
- Where healthcare professionals, e.g. clinical technologists, are employed by such a facility, their services will also be unaffected by the tariff determination.
- Where medical devices are billed through a facility, such devices (whether capital equipment, consumables, implants, etc.) will not be affected by the PBEs, if billed by a healthcare professional, it will be subject to the tariff determination.

The above indicates unequal application of the law to similar situations and similar services or products, which violates the legality principle, and section 9 of the Constitution.

SASCI notes that, although "medicines tariffs and codes" are excluded (par 11.4), the practice code number for pharmacies (code 60-) are not excluded. This leaves the services of pharmacists unclear as to whether within, or outside of the scope of the PBE.

Medical devices are included by implication as only medicines are excluded (par 11.4), but specifically mentioned in par 2.2, par 7.2 and par 8.2. But no other reference is made in the PBE relating to medical devices and diagnostics and their suppliers. No details are provided in relation to how negotiations on medical devices are to take place. There is also no differentiation between the types of medical devices (capital equipment, consumer-devices, diagnostics, implants, assistive devices, etc.), neither is any attention given to the fact that some medical device suppliers do have practice code numbers (see, for example codes 90-001 to 90-008, claiming directly from funders, whilst others sell to providers or facilities). Also, this creates inconsistency and inequality in the application of the law.

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Par 9.9 states that decisions will be taken by consensus. However, how that consensus is reached in a way that would, for example, indicate that SASCI and its members are in agreement with what was thus collectively determined, is not clear.

It is assumed that "sufficient consensus" means full agreement between all members of the MLNF. Where this does not occur, it means that tariff determination will take place by, in most instances, the TGB (par 9.10).

6.5.3 Process

It seems that the MLNF will receive proposals by entities such as SASCI (par 9.11). However, such proposals will be made "through the CMS" for purposes of "validation and archiving". There seems to be a conflict between the TGB which also has the function to validate (par 9.4.5 and par 9.16.2), with the CMS (par 9.11) and with the MLNF (par 19.16). How such validation exercises will be undertaken and if there are differences of opinion, how those will be resolved, are not clear.

Although it is said that the data must be submitted to the CMS, which data the specific "stakeholder" intends to rely (par 9.12). However, the stakeholder would have to rely on the DG-appointee to make the case and negotiate for their proposed codes and tariffs – how will a non-SASCI person know what the SASCI data means, and how it should be used during the "negotiations"? And, based on previous experience in the RPL, who will generate the data for all the professional groupings that participate, and within what timeframes?

The extent to which confidential and commercially sensitive data will be protected, is also not clear.

Par 9.12 also refers to a "fairer" and "more transparent" process, without indicating with what the process is compared to be more fare, or more transparent. In any event, for SASCI to be able to respond to, for example, the information that the DG-appointee or appointees for funders would rely on, such data would somehow have to be disclosed to SASCI *beforehand* so that it could gather data, formulate its responses and mandate the appointee who represents interventional cardiology, to participate in the collective determination process. In any event, in order to propose tariffs, providers would have to be in a position of information symmetry.

At present, healthcare professionals are not in possession of the complete claims picture, but schemes do have that. Medical schemes, and specifically administrators, have data across professional disciplines, all facilities, specific technologies, diagnostics, disease incidence, etc.

The sequencing of the process, including processes of mandates, return to professional societies and the amendment of mandates based on the determination- or negotiation process is not clear at all.

Both par 9.12 and 9.13 refer to "cost" and "pricing" data. This seems to indicate that practice cost studies would, again, as was the case with the RPL, be required. These studies are time-consuming and expensive and will be even more so when having to undertake such engagement through the DG appointee(s).

To further complicate matters, it is not only the directly affected groups, i.e. funders, providers and patients who will participate, but "all interested parties" (par 9.14). This would necessitate some publication of information somewhere along the determination / negotiation process.

Par 9.15 makes the CMS responsible as the data repository. This falls outside of the CMS's current statutory mandate (i.e. it is *ultra vires* the Act that governs the CMS). It is also difficult, even for medical schemes data, as is evident from the recent severe narrowing of what was the data always included in the "industry report". In order to warehouse such data, data parameters would have to be agreed on, software developed, and other costs incurred.

Par 9.15 also envisage the CMS providing "analytical support" to the MLNF. As such, the CMS and the NDoH would have to obtain specific funding from National Treasury to undertake this task and be subject to the Auditor-General's assessment of such tasks, including it in performance plans and annual reports.

6.5.4 Validation (par 9.16)

SASCI has pointed out above the conflicting mandates on validation and the assessment of tariffs as "cost-based", as well as the vagueness in terms of process, including sequencing.

Given that medical schemes must submit benefit options and rules to the CMS each year by September, the time it takes to undertake practice cost studies and obtain line-by-line data from medical schemes, plus the time for mandates, negotiations and return mandates, plus contracting on what was agreed, or then determined by the TGB as the final determination, it is highly unlikely that processes would be complete within a 12-month period.

6.5.5 Publishing

It is unclear why all of these entities would be obligated to publish tariffs. The arrangements are voluntary, recorded in contracts, and not binding on anyone outside

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of such agreements. The public or other interested parties would have no need to access such tariffs, as it would not apply to them.

The wording in par 9.17 also seem to indicate the tariffs are indeed *determine*d by the MLNF and not *agreed to* – colluded to – between competing firms horizontally, or vertically between (some) medical schemes and some providers.

6.5.6 Bi-lateral negotiations

Par 9.18 appears to only permit bi-lateral collective determination for entities that have participated in the MLNF process. This is unlike any other block exemption, where any two, or more parties can, voluntarily, avail themselves of the benefit of the block exemption.

Par 9.18 again makes apparent that the PBE is nothing but a smokescreen for the NDoH to embark of a price setting process.

It also seems strange that it would not be possible to increase tariffs, which should be possible if, for example, providers take on a greater risk, agree to undertake specific steps to lower utilization, or agree to specific reporting requirements, etc.

The PBE is also silent on what happens with networks and DSPs, both of which are permitted under the Medical Schemes Regulations, 1999. Or agreements between specific funders and provider groupings on the utilization of specific technologies, or agreements on specific reimbursement models, such as value-based care, or global fees.

Par 9.19 and par 9.20 create two further functions for the TGB and the CMS, that of receiving contracts (it remains unclear what the TGB would do with such agreements) and "monitoring" by the CMS.

SASCI stresses again that the PBE creates a whole new set of functions for the CMS that is not included in the Medical Schemes Act, 1998.

6.6 Requirements for agreements

Par 10.1 refers to the agreements being legally enforceable. It is assumed that it would only be legally enforceable upon those who enter into it. This means that, if SASCI does not sign an agreement, it would not be binding on SASCI or its members.

However, as the lack of agreement will be resolved by the TGB, it seems unclear how the then-TGB-determined tariff would become binding on SASCI.

Par 10.2 and par 10.3 attempt to force contractual provisions of a specific nature into the agreements, by requiring that all such contracts –

(a) Agree to TGB having the power to "make a final determination" – it being unclear how that can be done ex post facto, and creating the impression that contracts would be entered into *before* the tariff determination process starts; and

(b) Agree to provisions on deviations, which would only appear after the tariff determination process is compete.

Par 10.2 grants further powers to the TGB, not listed elsewhere, namely the "enforcement" of tariffs. What exactly that means, and why that power is not listed under par 9.4 is not clear.

Par 10.2 and par 10.3 is confusing in terms of its meaning, timing and sequencing and appears to vary the principles of the law of contract.

The effect of par 10.3 and 10.4 is that, up front, and even where the MLNF does not reach agreement, parties will agree to whatever the TGB determine of the tariffs. This cannot be correct, and flies in the face of the statutory obligation on medical schemes to ensure benefit option viability (section 33, Medical Schemes Act), and the obligation on firms to ensure that they are able to be viable too, pay their staff, etc.

6.7 Exclusions

The exclusions, as addressed above, make no sense. Both for what is explicitly excluded, but also for what is then *not* listed as excluded, and how such suppliers and providers are then to be catered for in the tariff- and other determination processes.

SASCI has also pointed to the anomalies and unequal application of the law created with the exclusion of hospitals and other facilities. Another example relates to ambulance services – the practice code number of such services are included in the PBE, but the moment the patient is transferred to a facility, that patient's care is no longer subject to the PBE. Where the ambulance service is owned by a facility, part of the service will be subject to the PBE, and part not.

6.8 HDPs and SMMEs

Although the general policy in competition law to ensure the inclusion of HDPs and SMMEs is understood, the role that these classifications insofar as providers are concerned, will play within the context of the PBE is not clear.

It should be noted that thousands of healthcare provider firms will be SMME's including members of SASCI. However, how the PBE will assist such firms is not clear,

6.9 Scope of the exemption

It must be noted that the HMI did not recommend that administrators of medical schemes can negotiate collectively in the MLNF on behalf of more than one open scheme.[29]

The HMI also did not propose that managed care organisations negotiate collectively. It must also be borne in mind that managed care organisations could be either on the provider or on the medical schemes (funder) side. In any event, managed care agreements are subject to the approval and regulatory authority of the CMS, which includes approval of the specific nature and extent of risk transfers. This simply cannot be done on a collective basis.

Par 15, somewhat out of the blue, after extensive mention of data earlier in the PBE, refers to "competitively sensitive information". It also creates another functionary, a "facilitator" not referred to anywhere else in the PBE.

The description of cost-price, and cost-based analyses (par 9.4.5, par 9.10, par 9.12, par 9.13, 9.16.2, etc.) by their very nature would fall within this category, but there are no details as to who this facilitator is, what its functions would be, when this would be triggered, etc.

6.10 Monitoring

Par 16 suddenly states that the CMS *"and/or"* the MLNF must supply the record of the tariff determination processes. However, the CMS fulfills a limited role, as would the HTA- and Coding Committees. These entities are not placed under the same obligation to supply such information, including "competitively sensitive information". In par 18, reference is only made to the CMS and the Commission as being able to request such information. Par 18 and par 16 are therefore contradictory.

The CMS (as regulators of medical schemes) and the NDoH (as regulator, manager and owner of health facilities and purchaser of healthcare) are hopelessly conflicted and cannot act as neutral parties in this process. The HMI did foresee this and therefore recommended the SSRH as an independent entity.

It also seems unclear why parties other than the Competition Commission would require such details.

6.11 Commencement and duration

[29] HMI 2019, par 151 – 153, page 227.

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The PBE has a limited life of three years. SASCI does not believe that the appointments, processes and criteria set in the PBE would be implementable in three years' time.

SASCI however notes that the NHI's contracting by 2028 would be exactly three years from 2025 and strengthens the perception that the PBE is not to assist medical schemes, but to enable contracting by the NHI Fund.

7. Conclusion

SASCI is of the firm view that the PBE is unlawful and unconstitutional. It is also unworkable and tainted by political objectives to price-regulated provider tariffs in view of the NHI (which, incidentally, is three years from 2025, is phase 2 ending in 2028). As drafted, the PBE is vague, contradictory and confusing.

Even if the PBE would be possible, any savings will be minimal and will not lead to a reduction in medical scheme premiums. It may lead to the opposite, i.e. increase costs for funders and providers, as well as the costs to the NDoH and CMS in setting up the various bodies and roles required to implement the PBE.

SASCI urges the Minister of Trade, Industry and Competition to withdraw the PBE.

A proper, carefully considered exemption, so as to allow for collective bargaining by professionals, who are at an information and negotiation disadvantage towards much larger and more powerful entities such as medical scheme administrators, is required. In conjunction with this, the unimplemented reforms in the medical schemes environment, as well as the provisions in the National Health Act, must be fulfilled, to effect meaningful change in the health sector.

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