30 June 2020

Attention: National Treasury

By email: CommentDraftLegislation@treasury.gov.za

RE: SOUTH AFRICAN MEDICAL TECHNOLOGY INDUSTRY ASSOCIATION COMMENT ON THE DRAFT PUBLIC PROCUREMENT BILL

1. Introduction – About SAMED

SAMED, the South African Medical Technology Industry Association is a not-for-gain association and strives to be the voice of the South African medical technology and in vitro diagnostics industry. SAMED is committed to ensuring a sustainable medical technology industry that enhances patient access to innovative solutions. We give our members a collective, objective and credible platform to engage with all stakeholders.

SAMED's members include multinationals, distributors, wholesalers and local manufacturers of medical devices, medical equipment and in vitro diagnostics (IVDs) (collectively referred to as 'medical technology') as well as the South African Laboratory and Diagnostic Association (SALDA) and the Medical Device Manufacturers Association of South Africa (MDMSA).

Medical devices and IVDs, play a vital role across the continuum of patient care (prevention, screening, diagnosis, treatment and rehabilitation). As such the medical technology sector plays a significant role in providing effective and efficient health care for all South Africans and particularly so in the fight against the COVID-19 pandemic.

Data from a member survey which assessed SAMED members' current experiences and perceptions of the public procurement processes in South Africa have been included in our submission to supplement our views and recommendations. A total of 35 member companies participated in this survey. Questions ranged from their current participation in tender processes to their recommendations on practical aspects of the draft Procurement Bill, based on their current experiences.

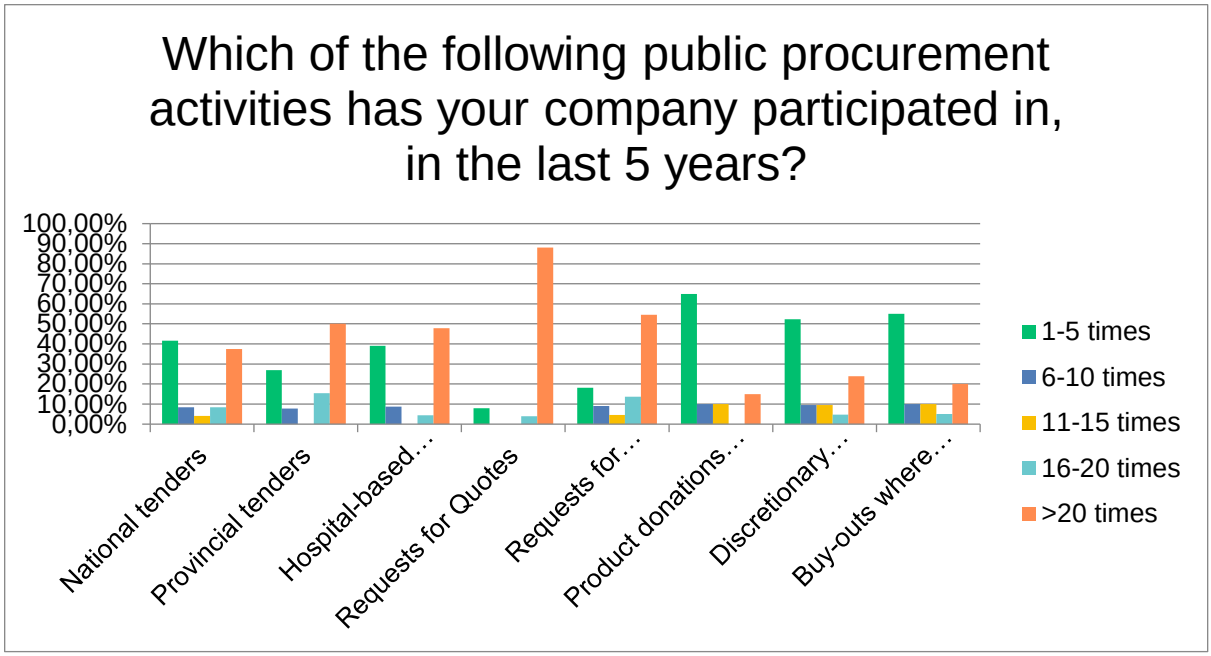

Figure 1: Level of participation of SAMED members in public procurement processes (n=27)

Approximately, 40% of respondents were awarded contracts for less than 10 line items while another 24% of respondents received contracts for more than 60 items.

2. INDUSTRY LEGAL AND REGULATORY FRAMEWORK

SAMED members are subject to various laws and regulations and guidelines. The manufacturing, sale and supply of medical technology are subject to, among others:

2.1. The Medical Device Code of ethical marketing and business practice

To ensure that its members conduct themselves ethically and in compliance with the laws of the country, particularly in their interactions with healthcare facilities, both public and private, healthcare professionals and especially patients or members of the public, SAMED has developed a code of conduct that all SAMED members must comply with.

2.2. The Medicines and Related Substances Act 101 of 1965 as amended ("Medicines Act")

This Act aims to regulate who may and may not manufacture and sell medical devices in South Africa. It also sets the requirements of how and who can manufacture and sell medical devices in South Africa. It also regulates the advertisement and marketing of devices. And provides for the setting of prices of medicines in South Africa. It is through this Act that SAHPRA (below) has been established.

Further, the regulations promulgated in accordance this Act, prohibit the donations and provision of medical devices for free, under section 18A and 18B of that Act.

Only 4 companies from respondents participated in donations processes and indicated that they had experienced issues with the following areas: Medicines Act exemption, donations processes and donations contracts.

2.3. The South African Health Products Regulatory Authority ("SAHPRA")

The South African Health Products Regulatory Authority is a body established under the Medicines Act to regulate and implement the provisions of the Medicines Act.

SAHPRA regulates the types of medical technology, that must be listed, and the companies that must be registered prior to manufacturing, wholesaling, distributing and supplying of medical technology. Oversight with regard to quality, safety and effectiveness of medical technology is governed by SAHPRA. Procurement policies and practices must therefore align with that of the legislative and regulatory requirements for medical technology. Procurement officers in the institutions must be aware of the requirements on bidders emanating from the Act and SAHPRA, particularly bids for medical devices and technology. Bidders in the health sector must be compliant with the Act and SAHPRA as part of the criteria for qualification to bid.

2.4. National Health Act 61 of 2003

Medical technology is used by healthcare professionals on patients. The National Health Act permits only people registered as healthcare providers, to provide healthcare. These healthcare providers may be registered under the Health Professions Act, the Nursing Act or the Allied Professions Act. Anyone not registered may not treat or touch a patient for purposes of providing healthcare. The medical technology industry has a responsibility to ensure that those who buy or use their technology have the legal right to do so.

2.5. Health Professions Act 56 of 1974

This Act regulates healthcare professionals registered in terms thereof, such as medical doctors, dentists, and other specialists. The Act requires the healthcare professional to act in the best interest of the patient. The Health Professions Council of South Africa ("HPCSA"), is the regulatory body established in terms of the Health Professions Act to implement and bring to life the provisions of the Act. The Health Professions Act prohibits healthcare professionals from owning shares in a medical device company unless such company is a publically listed company, see Rule 23. There are also strict

rules in the Health Professions Act that govern the relationship between healthcare professionals and the medical device industry. These must be taken into consideration when procuring from medical technology companies. And the healthcare institutions and healthcare professionals working therein must have the skills and knowledge to check that these requirements are adhered to and form part of the criteria for qualification to bid.

.

2.6. National Health Insurance Bill (NHI Bill)

This Procurement Bill must be drafted taking into consideration the NHI Bill which has already been introduced in parliament. The procurement of health products (medicines and medical devices and technology) under this Bill must take into consideration the provisions of the NHI Bill and the two must be aligned for such procurement and ensure that there are no conflicts. SAMED has in its submission on the NHI Bill dated 29 November 2019, indicated its full support of the NHI Bill, in recognition of the fact that the NHI Bill intends to fulfil the Constitutional obligation on government under section 27(3) to take measures within government's available resources to achieve the progressive realisation of the right to access to healthcare services under section 27(1)(a) and to ensure wider coverage of healthcare.

The NHI Bill establishes the NHI Fund from which *"…must actively purchase healthcare services, health goods and health related products…from suppliers that are certified and accredited in accordance with the provisions of the Act and any other applicable law",* clause 5(1)(b) of the NHI Bill.

SAMED expressed in its submission that the NHI Bill is not clear on how medical technology will be procured. SAMED wishes to re-emphasise the issue relating to the fact that patients with *"…different conditions will require…different technologies for the effective treatment and care…"* SAMED 2019 NHI submissions. Also that patients with the same disease may require different modes of treatment and therefore it is essential that the required technology is available at the relevant point of care, including primary, secondary, tertiary and quaternary levels.

2.6.1. SAMED has identified critical issues of concern that must be addressed:

2.6.1.1. There must be alignment further on the centralised vs de-centralised procurement systems as the NHI Bill envisages that procurement will be centralised while under this Procurement Bill the procurement is done by entities.

2.6.1.2. Whether provinces will have a budget for, procure and fund medical technology and the extent thereof and how the NHI Fund will feature in such procurement.

2.6.1.3. How the price-regulatory framework of the NHI Bill will affect the Draft Procurement Bill.

2.6.2. The NHI Bill envisages the establishment of lists and formularies for essential medical devices, which is supported by SAMED, however as proposed in our NHI Bill submission, the lists such list must be in place provided that:

"- A transparent, objective and reasonable process, including an appropriate HTA process, is followed in the determination of these lists.

- *Provision is made for procurement from small- and medium-sized medical technology suppliers, including from previously disadvantaged suppliers, whilst acknowledging that some of these suppliers might not have a national capability.*
- *The process of procurement must be clear and efficient. It must, for example, be clear how frequently a service provider or health establishment could procure from the formulary coupled with appropriate reimbursement arrangements.*
- *Suppliers must be timeously reimbursed."*

These principles are aligned with the proposals made by SAMED under this Draft Procurement Bill, in addition to the principle evidence-based medicine and appropriateness of care, and empowering procuring institutions to go outside such lists in order to secure the principle appropriateness and evidence-based medicine.

Any bidders who are subject to these applicable laws must be assessed for compliance therewith and if found to be falling foul of these applicable laws, must be excluded from bidding, where appropriate. Such decisions can only be made if the procurement policies and officers at the institutions address these applicable laws and bid committees are also au fait therewith. Duplicate requirements for compliance must be avoided where compliance with SAHPRA is established. This is cumbersome of suppliers and unnecessary.

3. GENERAL COMMENTS

3.1. The Bill aims to create a single regulatory framework and SAMED is in support of this initiative as it will create a much-required level of certainty, and limit the number of documents which members have to be familiar with and comply with. This will limit the risk of non-compliance and in some instances, be time and cost saving.

3.2. On the other hand, the concern is that some of the necessary requirements and provisions of the consolidated pieces of legislation or guidelines, may be omitted in the process of the consolidation and therefore, care must be taken in so doing.

3.3. Best Practice

It is also recommended that the basis of procurement, especially of medical technology in South Africa, move away from a price-based procurement model to that of a value/outcome-based one and be structured to take into consideration all factors that impact procurement of medical technologies, and consider for example outcomes and life-cycle cost of delivery and services.[1]

A survey conducted amongst the member of SAMED, the following product attributes were ranked in order of importance for bid specifications: (n=15), with the most important being patient outcomes, followed by value of innovation, value-added services, product quality with product pricing featuring as the least important aspect for consideration.
This is important to consider as acquisition costs are not necessarily related to overall costs which would also take into account downstream costs such as hospitalisation, cost of complications, cost of diminished outcomes due to inferior product usage, etc.

[1] https://www.medtecheurope.org/resource-library/most-economically-advantageous-tender-value-based-procurement-meat-vbp-initiative-overview-january-2018/

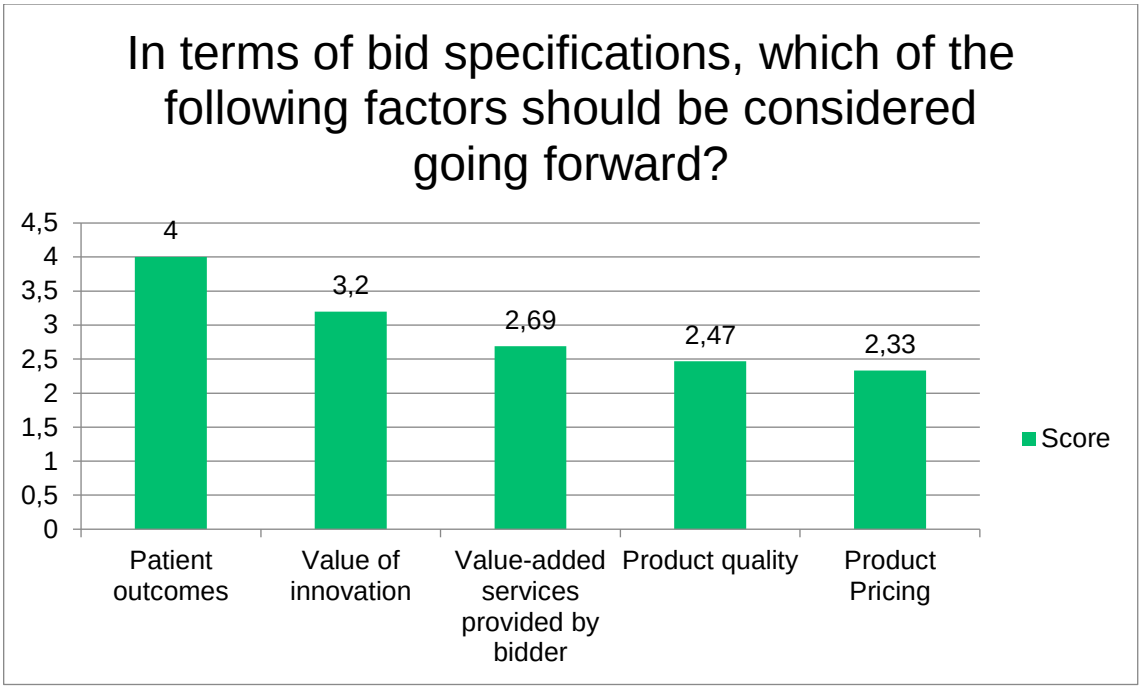

Figure 2: SAMED member scoring on the most important considerations for bid specifications

The procurement of medical technology based solely on price, is restrictive on healthcare providers on how they treat patients, and this is in contrast with the Health Professions Act and Regulations and Rules, that seek to provide autonomy of the healthcare professional when making decisions regarding treatment of patients. *"By choosing one solution over the other, procurement authorities impact the care being offered to patients and encourage the industry and other healthcare stakeholders to act in specific ways."*[2] *"Deciding which healthcare technologies to procure, and how to procure them, becomes a recurring policy dilemma in a climate of austerity. In an environment of budget constraints, innovative or high-value technologies can be marginalized. This can lead to an exaggerated focus on commodity purchasing, whereas outcome-based purchasing should be the aim."*[3]

In accordance with the HPCSA, a focus on price- based procurement may be seen as a threat to the autonomy of healthcare professionals:

"The HPCSA requires that healthcare practitioners should at all times act in the best interests of their patients and regard the clinical needs of their patients as paramount. To this end, a healthcare practitioner should always … maintain professional autonomy, independence …. Any conflicts of interest, incentives or forms of inducement that

[2] Above at 1

[3] https://www.advamed.org/sites/default/files/resource/809_good_practices_for_the_procurement_of_innovative_medical_technology_final_tagged.pdf

threaten such autonomy, independence … and ethical rules and policies that do not accord first priority to the clinical needs of patients, are unacceptable."[4]

In order to avoid this type of restriction, and to meet the needs of both the treating healthcare professional and varying patients, the tenders for medical devices should not be exclusive. The tender system should adopt various models that will ensure availability of multiple individual models of devices to suit every patient and also be flexible enough to allow for new technology to be introduced. This will also force companies to compete on value and innovation that will ultimately improve patient outcomes and save the state on the cost of healthcare, based on the value-based considerations.

The following are examples of initiatives undertaken in other jurisdictions between governments and industry, in an attempt to achieve value-based and patient-centric procurement of medical technologies:

3.3.1. The EU Directive 2014/24/ on public procurement ("the EU Directive"),[5] encourages the best-price quality ratio criterion in procurement. This is in accordance with article 67(2) of the EU Directive. This directive, under Article 67 requires contracting authorities to base award of public contract on the most economically advantageous tender or "MEAT". Article 67 of the EU Directive explains MEAT as:

"2. The most economically advantageous tender from the point of view of the contracting authority shall be identified on the basis of the price or cost, using a cost-effectiveness approach, such as life-cycle costing in accordance with Article 68, and may include the best price-quality ratio, which shall be assessed on the basis of criteria, including qualitative, environmental and/or social aspects, linked to the subject-matter of the public contract in question. Such criteria may comprise, for instance: ***[our emphasis underlined]***

(a) quality, including technical merit, aesthetic and functional characteristics, accessibility, design for all users, social, environmental and innovative characteristics and trading and its conditions;

[4] https://www.hpcsa.co.za/Uploads/Professional_Practice/Conduct%20%26%20Ethics/Booklet%2011%20Guidelines%20on%20over%20servicing%20perverse%20incentives%20and%20related%20matters.pdf

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02014L0024-20200101

(b) organisation, qualification and experience of staff assigned to performing the contract, where the quality of the staff assigned can have a significant impact on the level of performance of the contract; or

(c) after-sales service and technical assistance, delivery conditions such as delivery date, delivery process and delivery period or period of completion."

This approach by the EU Directive is widely supported by the medical technology industry in that region, who now work together with hospitals and healthcare institutions to adopt MEAT, by designing guidelines and among others a tool that took into account patient and societal outcomes in the tendering process. This approach was supported by other procurement organisations in other countries in the EU.[6]

3.3.2. Defining the "value" in the value-based procurement" is very critical in the development of value-based procurement policies. Value is holistic, it encapsulates all aspects of the device's expected impact on healthcare outcomes, among others, which are in almost all cases important features of a value assessment and as equally important as cost factors.[7] Value is defined as:

3.3.2.1. *"…patient health outcomes per unit of currency spent*[8].It is accepted that "*the list of features which could contribute to a [medical] device's value will vary from case to case."*[9]Some of the features that listed are: *"direct medical costs…, cost of maintaining, cleaning and storing the device; other ongoing operating costs, including efficiencies achieved in other areas due to introduction of the device.; upgrade costs.; staff training and other employment costs.; disposal costs."*[10]

3.3.2.2. Factors associated with patient outcomes are recognised as equally important and that these should also form part of the value assessment of a medical technology, i.e. "*delivery efficiencies, technical benefits/merits,; clinical effectiveness, including reductions in morbidity or mortality or as measured by patient-*

[6] Above at 1
[7] Above at 3
[8] Above at 3
[9] Above at 3
[10] Above at 3

reported outcomes and patient satisfaction and preference.; reliability and service level of the vendor/manufacturer, including warranty, maintenance, customer care and clinical training and support.; societal benefits, e.g. improved patient quality of life, reduction in spend outside the health budget (i.e. productivity and social care gains due to fewer missed days of work).; environmental effects, e.g. sustainability."[11]

3.3.3. An article by the Boston Consulting Group ("BCG")12 on Procurement, confirms that they have developed a value-based procurement frame-work with industry in Europe, and that the framework is aligned with the new EU directive. The framework places at its core the simple value-based health-care equation of patient outcomes divided by the costs of achieving these outcomes. The framework is presented as a solution to two problems experienced in the EU, that is variation in patient outcomes and spiralling costs. For example: *"In the Netherlands, whose health care consistently ranks among the best in Europe, there is a ninefold variation in the rate of post-surgical complications from radical prostate surgery.… In Sweden, the complication rate for some patients who under- go cataract surgery can be 36 times that of other patients."* The second problem stated in the article is spiralling costs. This was experienced in the Netherlands where healthcare spending rose seven times faster than GDP from 2004 through to 2014.[13] Value-based procurement can cure both problems, as it focusses on both patient outcomes and costs and industry can assist with value based healthcare but public procurement can be a major barrier as most institutions purchase goods based on up-front purchase costs.[14]

3.3.4. Encouraging Innovation

Procurement must include innovative products.

An article on EU Regional Policies, Good Practice: Stimulate innovation through procurement,[15] proposes innovation procurement where policy makers can use the procurement process to foster innovation for the benefit of public authorities.

---

[11] Above at 3

[12] https://www.bcg.com/publications/2015/medical-devices-technology-procurement-unexpected-driver-value-based-health-care.aspx

[13] Above at 12

[14] Above at 12

[15] https://ec.europa.eu/regional_policy/sources/good_practices/GP_fiche_30.pdf

The article proposes public sector involvement in innovative products in two ways, the PPI or Public Procurement of Innovative Solutions and PCP.

PCP Pre-Commercial Procurement or R&D is when *"public procurers organise different tendering stages where alternative solutions from different technology providers are compared. The solutions are evaluated at critical milestones, namely design, prototyping and testing, and only the best ones move on to the next stage."* In this case the state will acquire the license free rights to use the solution.

PPI on the other hand refers to a situation where the state would procure an innovative solution in the prototype stage in order to accelerate its market readiness at a desired price-quality ratio. Because the public is a buyer, the industry will have an incentive to bring innovative solutions to the market overcoming issues of market uncertainty.[16]

The South African private sector is more open to innovation than the public sector, which is one of the causes of disparities between private and public healthcare. This must be improved upon in SA.

All these above referenced policies advocate for considerations of patient-outcomes when procuring health goods and services and for value to not only be placed on immediate cost of the products but long-term costs based on such patient outcomes. Procurement in the public health sector in South Africa is based on the essential medicines list (EML), and for devices, the envisaged but not yet operational, Essential Equipment List. Procurement based solely on these lists will be to the detriment of patients as they (the lists) do not factor in appropriateness of care and evidence-based medicine. These lists must make provision for considerations of appropriateness and evidence-based medicine for each patient. Institutions and healthcare providers should be empowered to procure in a way that will ensure best outcomes.

3.3.5. Differentiation between medical technology and pharmaceutical products

How procuring authorities view and treat medical technology is very critical. It must be recognised that the terms of contracting medical technology will not be similar to those of procuring a pharmaceutical product. It is recommended that there be a

[16] Above at 15

separate contract and bid documents for medical devices that is customised for the specific purpose of procuring medical devices. See paragraph 4.5.2 below.

It is hereby recommended that the definitions of medical devices and technology in the tender process must be aligned with the definitions under the Medicines and Related Substances Act and SAHPRA. It has been experienced that items that form part of medicines/pharmaceutical products are defined as devices.

Further, and as per SAMED's NHI Bill submission, due to the complexity of medical technology, procurement of medical devices should be tailor made to accommodate such complexities such as sub-specialities of devices. Some devices may be grouped in broad categories but for some it may not be possible to achieve. SAMED provided examples such as external fixators which must be divided into upper and lower limbs and sterile versus non-sterile, single use versus multiple use.

Further recognition that reimbursement of suppliers under the NHI Bill and the Draft Procurement Bill must be aligned. SAMED has made proposals under the NHI Bill submission that includes the emphasis that reimbursement for medical technology is unique due to the uniqueness of the medical technology industry. There must be recognition that the *"processes, methodologies and expertise used in pharmaceutical evidence appraisals, are not always applicable to medical devices and no single approach should be applied to the diversity of medical technology in multiple service delivery settings"* SAMED NHI Bill submission.

4. COMMENTS PER CHAPTER

4.1. Chapter 1: Definitions, Objects, Application and Administration of the Act

4.1.1. Objects of the Act:

4.1.1.1. In respect of the primary objects of this Act under clause 2 which:

"…are, with due regard to section 217 of the Constitution, to—

(a) ensure that the State utilises and leverages procurement to—

(i) advance economic opportunities for previously disadvantaged people and women, the youth and people with disabilities small businesses; and

(ii) promote local production;

(b) develop economic capacity in the Republic, through the

provision of opportunities for local suppliers to participate in procurement; and…"

This clause refers only to local "suppliers" and does not refer to other players in the value chain of the medical technology industry e.g. multinationals, distributors and wholesalers. We recommend that consideration be provided as to how to support and promote production pertaining to all players in the medical technology industry.

4.1.2. "Value for money" is referred to under section 2, (b) (ii) is defined under definitions as follows:

"value for money"—

(a) means increasing output for the inputs used or minimising inputs used to attain the output or reducing the cost of inputs used to attain the output while maintaining quality and achieving the intended outcomes;

(b) in relation to a public-private partnership agreement, means the provision of the institutional function or the use of State property by a private party in terms of a public-private partnership agreement which results in a net benefit to the relevant institution with respect to cost, price, quality, quantity, risk transfer or a combination thereof; or

(c) in relation to infrastructure, means the optimal use of resources to achieve intended outcomes."

however, there must be an explanation as to how value will be calculated and defined and HTA and other health economic studies must be included in the process. Please refer to clause 3: General comments for proposals on value-based procurement, which we propose must be part of the definition.

4.2. CHAPTER 2: PUBLIC PROCUREMENT REGULATOR, PROVINCIAL TREASURIES AND PROCURING INSTITUTIONS

4.2.1. Clause 4: Establishment of Public Procurement Regulator

SAMED agrees with the establishment of a Public Procurement Regulator, ("PPR"), however there must not be duplication of roles between the Public Procurement Regulator and SSRH as proposed under the Health Market Inquiry. There should also be provision made under this draft Bill for how the Public Procurement Regulator will be regulated, a code of conduct must be in place for

the PPR. We propose that King IV Codes be used to determine the conduct of the office of the PPR.

4.2.2. Clause 5: General Functions of the Regulator

SAMED agrees with the functions of the Regulator, however we propose the following amendments:

4.2.2.1. 5(1)(e)**:** The clause provides that the PPR will intervene where there is *"serious persistent material breach"*. If left as is, the provision may give rise to the escape of "minor breaches". And where minor and major breaches are not defined, there is a risk that the determination will be left to subjectivity, which might create inconsistencies and unfairness.

We propose **t**he following should be implemented: Definition of what are considered "major" breaches and what are "minor" must be provided and all breaches must be identified and dealt with accordingly, major and minor. Guidelines or triggers should be provided to identify at which point officials should intervene.

4.2.2.2. Clause 5(1)(b)(ii) provides for the training and professional development of officials involved in procurement but it does not provide for standards and measurement against these standards. Standards must therefore be developed and all training must be developed and delivered against a set of standards which are measured and verified on a continuous basis.

4.2.2.3. Clause 5(1)(b)(iii) provides that the PPR guide officials to encourage institutions to engage procurement professionals in their procurement units. The words "encourage" and "engage" do not provide clarity for this function.

Procurement specialists are vital and should have a thorough understanding of the legal requirements which impact them. The clause should be clear as to what the officials must engage the procurement professionals on and what the requirements are of the procurement professionals. Institutions must engage institutions to engage procurement professionals in their procurement units.

4.2.2.4. Clause 5(1)(c) provides for the PPR to promote and ensure the integrity of the procurement system and monitor and integrate revisions and learning in procurement from institutions with

oversight of the procurement system, but does not provide for a measurement or a standard. We propose that King IV or similar guideline be used as a standard.

4.2.2.5. Clause 5(1)(d) provides for PPR to develop and implement measures to ensure transparency in the procurement process and promote public involvement in the procurement policies of institutions. The measures must define the type of public involvement and the strategy to ensure transparency. All government expenditure should be made transparent to the public. Reporting of expenditure to the public must be published by way of a gazette.

4.2.2.6. Clause 5(1)(f) allows the PPR to reconsider decisions of institutions where necessary as envisaged in this Act; but it does not define under which circumstances decisions can be reconsidered. The wording “where necessary” does not provide clarity and leaves this process open to subjectivity. The circumstances under which the PPR can reconsider decisions must be properly defined.

4.2.2.7. Clause 5(1)(h) provides for the PPR to continuously revise and provide guidance on procurement and the procurement system; No information is provided on how this will be done e.g. workshops or training and who will offer guidance as well as how often. More detail needs to be provided to ensure transparency and meeting of necessary requirements.

4.2.2.8. Clause 5(1)(k) provides for the PPR to promote the use of technology in procurement. It is not clear from this clause as to what technology and what it will be used for. For example, will it be an ERP system that every supplier will have access to, and if so, who will provide the financial outlay in order to be able to use technology. Will this be covered by the bidders or the institutions? More details are required as to what this technology will entail and how this will impact vendors as well as clear roles and responsibilities with respect to implementation, financial accountability etc. toward the system.

4.2.2.9. Clause 5(2)(b) provides the PPR to, in accordance with this Act establish data retention and reporting requirements applicable to institutions. Detail should be provided with regards to compliance

with POPI and other data compliance laws and who will have access to the data, why, and how it will be managed. This is critical, as the data should accordingly only be accessed and used for purposes of procuring goods in terms of the Act.

4.2.2.10. Clause 5(2)(c)(ii) The PPR may, in accordance with this Act allow the public to observe their adjudication processes for procurement above the prescribed threshold, unless for a national security reason, the institution is permitted by the Regulator not to allow the public to observe in a specific matter. While the Minister under clause 121(1)(l) may prescribe this procedure, there is no provision as to the circumstances under which procurement thresholds can be breached. The word "national security" must be defined for clarity and certainty, and we propose that this is aligned with the definition under the National Strategic Intelligence Act 39 of 1994.

4.2.2.11. clause 5(2)(d) refers to the determination of a model procurement policy. The Bill must define the criterion and process to be followed in the determination of a model procurement policy.

4.2.2.12. Clause 5(2)(f) provides that *"The Regulator may, in accordance with this Act issue a directive to declare certain procurement practices as undesirable";* The meaning of "undesirable procurement practices" is not provided. This must be defined and listed up front in order to avoid subjectivity and unfairness and in order to provide clarity.

4.2.3. Clause 10: General Procurement Requirements

4.2.3.1. Clause 10(1) provides that **"**Institutions must, in the execution of their duties, strive to achieve the highest standards of equity, taking into account the need to obtain the best value for money in terms of price, quality and delivery having regard to set specifications and criteria. How is "value for money" being assessed with respect to the procurement of medical technology and services? The standards / process by which value for money will be assessed must be defined for medical technology and services e.g. evaluation via HTA, FDA, CE, ISO, SAB etc. Please refer to clause 3 regarding value-based procurement and innovation.

4.2.3.2. Clause 10(2) provides that bidder may not be excluded from participating in procurement on the basis of nationality, race, religion, gender or any other criterion not related to his or her eligibility or qualification, except to the extent prescribed in terms of this Act. Is this the only requirement? How will BBBEE status influence the participation and outcome of the bidding process?

Solution: The role of BBBEE in the procurement process should be defined

4.2.3.3. Clause 10(3)(a) provides that bidders must only contract with tax compliant bidders. It must be taken into consideration that while the Bill is encouraging that local manufacturers and suppliers be supported, it is important to note that instances where the new SME may not yet be tax compliant or companies that ~~is~~ are not tax compliant or do not have SAHPRA license as required by section 22 of the Medicines Act. Consideration must provide for exceptions in certain circumstances.

4.2.4. Clause 12: Duties of Institution

12(e) provides that an institution must identify the appropriate standard bid documents ~~to~~ be used by the institution, suppliers and potential bidders. We propose that such documents provide for differentiation between pharmaceutical products and medical devices, alternatively that there be one set of documents for each.

.

4.3. CHAPTER 3: PROCUREMENT INTEGRITY

4.3.1. Clause 16 and 17: Codes of conduct and General conduct of officials in procurement.

SAMED fully agrees with the adoption of a Code of conduct in section 16. This will ensure the integrity of the procurement process and limitation of bias. However, clarity is needed on whether or not the code of conduct affects the 'bidder' or if a separate code of conduct will be adopted for bidders.

4.3.2. Clause 18: Disclosure of interest by official

We agree fully with the "Disclosure of interest by officials", this again will motivate the move of the general conduct away from potential corrupt bidders. We have proposed that officials not be allowed to tender.

4.3.3. Clause 21: Undue influence

"Undue influence" under clause 21 refers to "no person shall". This must also be made clear and must also include ~~even~~ other officials of the institution.

4.3.4. Clause 22: Debarment

Debarment under clause 22 is a fair sanction to deter any contravention of the Act. There must however also be sanctions against officials if found to contravene both the 'code of conduct' under clause 16 and the Act. This must be clarified, and we propose that debarment from procurement function will be an expectable action in addition to actions in terms of the labour laws.

4.3.4.1. Clause 22(3) is not clear as to how the debarment period will be determined. This must be identified upfront and we propose that it be based objectively on the offense.

4.3.4.2. It is also not clear from this clause how or where the debarment order will be published, whether in a gazette or by other means, clause 22(8).

4.3.5. Clause 24: Automatic exclusions from procurement processes

We are in full agreement of this sanction to deter corruption and non-compliance with both the code of conduct and the provision of the Act.

4.3.6. Clause 25: Publication of debarred bidders and suppliers

SAMED is in full agreement with under clause 25, for reasons as mentioned above. We suggest that the related details are erased from record once the period of the sanction expires.

4.4. CHAPTER 4: PREFERENTIAL PROCUREMENT

4.4.1. Clause provides: *"26 (1) The Minister must prescribe a framework for preferential treatment for categories of preferences, and the protection or advancement of persons, or categories of persons, previously disadvantaged by unfair discrimination, in procurement.* The term "previously disadvantaged" must be defined, and we propose that it must be in line with the BBBEE Act and include "unfair discrimination in procurement" as proposed under this clause, but must include conditions of quality, best practice and outcomes.

4.4.2. SAMED is in full support of the objectives of this and the BBBEE Act. A concern overall remains the delivery and standard of goods being supplied. There must be a clear criteria or process to follow to ensure that the SME if engaged are able to deliver the quantities and quality for the duration of the tender period. The risk to the end user or patient is high in the health sector if quality and access are compromised. Provisions must be made with regards to costs, manufacturing sites and safety of supply by SME's.

4.4.3. *Clause 26(2)(c)(i) ".Measures to promote categories or a category of people or business or sector…"* There is no clarity for the basis of the selection of any of the categories selected hereunder and why they would deserve preference. This must be clarified within the bill.

4.4.4. The Framework by the Minister must include "*measures for preference to set aside the allocation of contracts to promote goods that are manufactured in the Republic"* Clause 26(2) (c)(ii).

SAMED is in full support of this initiative as it will impact positively in the growth of the economy in the Republic. The concern is:

4.4.4.1. What impact this will have on the supply of tried and tested medical technology and innovative products already in use. This must also be implemented in a way that will not disrupt treatment of patients and place them at risk.

4.4.4.2. There must be a thorough plan prior to implementation on how local manufacturing product quality and clinical trials will be put in place and ensured, and standards must not be lowered.

4.4.5. The Framework to include *"measures for preference to set aside the allocation of contracts to promote—*

…

(iii) local technology and its commercialisation;

(iv) services that are provided by a citizen or citizens of the Republic;

(v) the creation of jobs or intensification of labour absorption;

(vi) enterprises based in townships, rural or underdeveloped areas;*" Clause 26(2).*

SAMED is in full support of prioritising local economy and job creation, provided that quality and standards are not compromised. Patient safety must be a priority,

Local ownership and manufacturing and local employment must be considered or recognised when weighting is applied for BBBEE.

4.5. CHAPTER 5: PROCUREMENT METHODS AND BIDDING PROCESS

4.5.1. Clause 27: Procurement methods and principles

The Minister is empowered under this clause to prescribe procurement methods, requirements and procedure to be followed. It is our proposal that these envisaged

methods include procurement outside of tender that still comply with the constitutional principles of fairness, equitability, transparency, competitiveness and cost-effectiveness, particularly for health products and services, that will allow flexibility and further ensure the uninterrupted supply of services. Further that the methods address.

We propose further that the clause deal with buy-outs, donations, discretionary spent, RFQ's and RFP's.

4.5.2. Clause 28: Invitation to bid

4.5.2.1. This clause is not explicit as to whether the invitation to bid is open to all or only to some. This must be made clear.

4.5.2.2. There must be sufficient timelines for submission of bids, these time-lines must take cognisance of the type of bid and the amount of detail and technical input required for such a bid.

4.5.3. Clause 29 : Bid documents

4.5.3.1. Bid documents must in all instances specify the documentary evidence or information required to demonstrate the bidder's qualifications, their ability to deliver the required stock and manage stock and sustain supply for the duration of the contract.

4.5.3.2. The bid documents must be different for devices. It is our experience that the attempt to fit devices in the same bid documents as pharmaceutical products has caused frustrations and a lot of times time wastage as the authorities more often than not have had to go back to bidders to clarify certain issues not catered for in the documents.

4.5.3.3. Often the bid documents are amended after the call to bid. This causes a lot of delays and wasted efforts as companies invest a lot of time, effort and resources responding to calls for tender. This must be avoided as much as possible. We strongly support the functions of the bid specification committee under clause 58 and 59 of the Bill. See our proposals on clause 58 and 59 below, in avoiding the revision of bid documents.

4.5.3.4.

4.5.4. Clause 30: **Qualification criteria for bidders**

4.5.4.1. We recommend that the following underlined words be added to clause 30(2)(f): *"(2)(f)…registration and licensing with the relevant professional or regulatory body and/or in terms of applicable legislation…"* This is because SAHPRA, as aforementioned is the body established for the registration and licensing of bidders in the health sector, however reference is made to a "professional body" and SAHPRA is a statutory regulatory body.

4.5.4.2. Clause 30(3): The requirement or criteria to prove qualification to supply, the documentary evidence to demonstrate qualification must be standard for all and must be contained in the Bid documents under clause 30.

4.5.4.3. There must be clarity as to the accreditation requirements, and the authorities must know what the certification requirements are for bidders and not require duplicate requirements where there is equivalence between one certificate and the other.

4.5.5. Clause 33: Deadline for submission of bids

There are currently a lot of requests to extend prices offered due to slow processing by the institutions. Prices are impacted by extensions and should be managed better in the bidding process, and this must be defined in this section, e.g. how the extensions of bids will be managed. We propose further that the words *"at least"* be removed in order to have a definitive term, and that the deadline be a definitive 4 weeks.

4.5.6. Clause 35: Bid validity period

Clause 35(1) provides that ***"****A bid remains valid for a period not exceeding 180 days which must be specified in the bid documents."* We propose that in instances of price adjustments, if the period exceeds 180 days, that the bid must be managed in a shorter period e.g. 90 days.

Further, we propose that circumstances under which a contract may be extended be set out in the Bill. We propose a separate clause. This must include the price negotiations involved for the period of the extension. It is a common occurrence that bids are extended without any price adjustments.

4.5.7. Clause 36: Opening of bids

4.5.7.1. Clause 36(2) provides that *"An institution may deviate from the opening of a bid as provided in the bid documents if the institution*

informs all bidders of such changes before the date set for the opening of bids." We propose that this notice must not be less than 3 days.

4.5.7.2. Clause 36(4) provides for the reading out of bidder names and bid amounts. We propose that this be done at a time when competition and that all privacy laws have been observed.

4.5.8. Clause 37: Examination and evaluation of bids

Clause 37(7) provides: *"…identifying the bid with the lowest evaluated price that meets the qualification."* We propose that the qualification criteria include elements of quality, durability and efficacy and include compliance with the definition of value as proposed under clause 3 above.

4.5.9. Clause 38: Rejection of bid or proposal

Rejection of bids under clause 38, must include *"a bid by a family member of an official may at any time before or after the award of the contract be rejected."*

4.5.10. Clause 39: Cancellation of procurement

4.5.10.1 It is proposed that an institution must also be able to cancel procurement in instances where there is poor quality warehousing etc. This must be added as clause 39(1)(j).

4.5.10.2 In order to avoid cancellations or withdrawals, calls for bids must not be sent out unless the conditions under clause 39 are ruled out first. It must be borne in mind that companies invest a lot of time and effort to respond to the calls to bid and while cancellations may in certain instances be justified and unavoidable, it is our proposal that everything must be done to avoid calling on bids where there is a possibility of a withdrawal or cancellation, that it the presence of one or some of the circumstances listed under clause 39, that may justify such cancellation or withdrawal.

4.5.10.3 There must also be sufficient time to provide testing volumes.

4.5.11. Clause 41: Verification of bidders or suppliers

Clause 39(2): SAMED supports the creation of a register of debarred bidders created by the Procurement Regulator. However, the Regulator must ensure that the time-frames for the sanctions are adhered to, together with applicable privacy laws, to avoid any prejudices.

4.5.12. Clause 42: Award of procurement contracts

4.5.12.1. This clause does not address matters of subcontracting by bidders. This must be included. Whether or not bidders can sub-contract and on what basis that can be done must be included.

Consideration in this case must also be had to the fact that in the health sector, the requirements by the Medicines Act may make it impossible to sub-contract, e.g. section 22H, where the supply-chain is stringent e.g. supplier to wholesaler and wholesaler to end-user). For sub-contracting to work these strict provisions must be revised.

4.5.12.2. Further, contract terms must be clear and upfront and re-negotiations with institutions after the tender must be prohibited, as it is unfair to bidders who did not win the tender. The process and criteria for in-contract price adjustments must be clearly articulated upfront, and must not be prejudicial the non-successful bidders.

4.5.12.3. This clause does not establish a time-frame for announcement of successful bidders. The system must be improved, as it often happens that the announcements are delayed. We propose that a time-frame be set within which the decision is made and announced. We propose 90 days after closure of the tender and reasons must be provided to the unsuccessful bidders at the same time why they were not successful.

4.5.12.4. Split or shared awards must be addressed properly in this clause in order to avoid conflict between parties.

4.5.12.5. This clause must also address in shared tenders the issue of autonomy of healthcare providers who act in the interest of the patient and appropriateness of care. Often the system in place at the institution dictates which products the health professional must use, regardless of compatibility, i.e. appropriateness and the concept of evidence based medicine, which is globally accepted to ensure appropriateness of care[17]. Autonomy and appropriateness of care are mostly affected by

[17] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3789163/.

tenders where there is only one winner, meaning in most cases, no diversity of products and therefore no diversity of treatment to suit diverse population of patients, who will not all benefit from the limited products supplied to institutions by the winning bidder.

4.5.12.6. Off-contract purchases must also be addressed, with regards to when and how this will be done to avoid delays or inability to supply or stock-outs. The current situation is that some of the awards are given to suppliers that do not have the financial means to supply.

4.5.12.7. Issues related to maintenance of equipment must be addressed in the bid documents and in the contract, relating specifically to liability, costs and frequency of the maintenance and repair.

Part 3: Transversal procurement

4.5.13. Clause 43: Transversal Term Contracts

No reference is included with regards to the requirement of the supplier's ability, or agreement to provide goods and services involved in transversal contracting. This is left to the determination of National treasury and Provincial treasury. Supplier's may not have available infrastructure to supply or support in order to provide adequate supply to the department requesting to procure these goods. We recommend that an additional clause be included as clause 43(9) requiring National Treasury and relevant Provincial Treasury to require written agreement with the supplier to ensure proper support is available for transversal contracting.

4.5.13.1. In accordance with Part 3 Demand Management sections 68 and 69 of the draft Bill, institutions are required to prepare an annual demand management system and procurement plan. These have specific criteria they need to adhere to, as well as comply with budget availability. Clause 68(2)(b) specifically refers to the avoidance of emergency procurement wherever possible. We recommend the inclusions of the application of transversal contracts under the Annual Procurement Plan, risk budget adherence under Part 3, section 69 (2) (a).

We recommend that the application period when an institution can apply for a transversal contract be specified. We recommend that this in any case be only on an annual period, in accordance with

the required procurement plan, as per clause 69.

4.5.13.2. Clause 43(8)(a) Service level agreements (should they be applicable) to the goods, services or infrastructure should be included in the bid structure of the original contract.
Recommendation: Service Level Agreements should form part of the original bid. Remove clause 8(a).

4.5.13.3. Clause 43(8) (a) Suppliers who may be obliged to service a transversal contract may not have infrastructure in other provinces, outside of that of the original award location. Suppliers should be contacted by National and/or the relevant provincial treasury to ensure their ability to support services in additional territories. We recommend that a clause be added to require Treasury to obtain proof of infrastructure from the relevant supplier which enable it provide support to additional areas with under the service level agreements.

4.5.14. Clause 44: Public-Private Partnerships and approvals and agreement

This clause is welcome by SAMED. It is progressive. It creates an opportunity for industry to have a clear guideline, or reference document regarding the processes to follow when regard is had to public-private partnerships, which will create certainty in such relationships. However, measures and processes must be put into place to ensure the feasibility and sustainability of such partnerships and that industry is in a position to play a role in such developments. PPP's must be sufficiently transparent and ensure those involved in procurement decision making have the requisite technical and regulatory affairs experience and know how, particularly with regard to medical technology.

4.5.14.1. The risks undertaken by the private provider must be clearly articulated under this clause and under the applicable agreements. Whether or not they include warranties and service agreements. e.g. Who will take the liability if the stock runs out and the private party cannot dispense and the institution is unable to replenish. There must also be more and clearer accountability on both parties in these arrangements.

4.5.14.2. The agreements must include peer-review processes and be sufficiently transparent so as to enable both contracting parties to be held accountable. In addition to the qualification criteria by suppliers as recommended under this submission, clause 30 of the Bill, there must be alignment with regulatory requirements and/or other applicable legislation and authorities, e.g. SAHPRA.

4.5.14.3. Definition: Public Private Partnership must be defined in accordance with the Public Private Partnership Manual as follows: *"**public private partnership**" or "**PPP**" means a commercial transaction between an institution and a private party in terms of which the private party –*

(a) performs an institutional function on behalf of the institution; and/or (b) acquires the use of state property for its own commercial purposes; and (c) assumes substantial financial, technical and operational risks in connection with the performance of the institutional function and/or use of state property; and (d) receives a benefit for performing the institutional function or from utilising the state property, either by way of: (i) consideration to be paid by the institution which derives from a revenue fund or, where the institution is a national government business enterprise or a provincial government business enterprise, from the revenues of such institution; or (ii) charges or fees to be collected by the private party from users or customers of a service provided to them; or (iii) a combination of such consideration and such charges or fees;"

4.6. CHAPTER 6: SUPPLY CHAIN MANAGEMENT

Part 2: Supply chain management systems

4.6.1. Clause 52: Supply chain management system

4.6.1.1. Clause 52(2)(h) provides that the supply chain management policy must be consistent with "any other applicable legislation" e.g. Medicines and Related substances Act 101 of 1965, Health Professions Act etc. There must therefore sufficient knowledge and skills at the institutions to comply with these laws, or a provision be made for the institution to outsource to ensure that

there is compliance. The policies and systems must take into account these applicable laws.

4.6.1.2. Clause 52(3) We propose the addition of sub clause (j) as follows: *"(j) Service Agreement"* on the equipment.

4.6.1.3. Delay in deliveries by couriers are often very costly to suppliers and this must be addressed under the supply chain management system.

4.6.1.4. Currently order do take long to generate, which means that payment will take longer to come through. This system must ensure efficient turn-around times that are adhered to and accountability where these are not complied with.

4.6.2. Clause 53: Establishment of procurement units

4.6.2.1. Clause 53(1); The definition of 'Institution' has been excluded. Definition of 'Institutions' in Applications and Administration of the Act refers to the definitions as applied in the Public Finance Management Act (PFMA) in section 1, Schedule 1, Schedule 2 or 3. These sections and schedules of the PFMA do not specify, nor include any Healthcare or Medical institution and "hospitals" are not defined in the Bill and it is not clear if they form part of "Institution". Must provide for clarity and inclusion into the current definition or definition.

The exclusion of Hospitals, and other healthcare or Medical places of care will allow for these units to be excluded for following a standardised procurement plan as proposed in the bill.

4.6.2.2. Clause 53(2)(c) refers to reporting on the performance of the supply chain, however there is no criteria provided for the measurement of the performance.

4.6.2.2.1. Without criteria being provided for the measurement of this performance, this could be left to the determination of each individual institution and would lack conformity to ensure efficiency.

4.6.2.2.2. We propose that criteria be provided for the measurement of the performance of the supply chain system.

4.6.3. Clauses 55: Appointment of bid committee members and 56: Technical advisers and subject experts

4.6.3.1. Care must be taken when the committees are disbanded and instated, in instances where committees are abruptly disbanded, it causes delays in the tender process, which not only results in prejudice to the bidders but also to the patients as it results in the delay of supply of critical health products. A provision/exceptions must be put in place by the Minister to address this issue and that will allow for continuity of the process while a new committee is being established in order to avoid a gap.

4.6.3.2. Clause 55(2)(c): We welcome the inclusion of technical advisors in terms of clause 56. However, we propose that clause 56(1) provide that technical advisers always be part of a bid committee, and may only be excluded in participation where the matter in accordance to the accounting officer does not require technical experts.

4.6.3.3. Their exclusion from the bid committee is a significant challenge, particularly when preparing and evaluating bid documents which will be well prepared and identified.

4.6.3.4. This is a specific issue which has been recognised within the Medical Device sector where incorrect goods have been procured due to lack of insight by experts within the field. There are a number of challenges facing public hospitals where clear errors have been made in the issuing of contracts, which have either allowed for the incorrect procurement of goods intended for a specific purpose, or alternatively neglected to include all items that are required for application within the sector. For example, the exclusion of Revision surgery items in the Gauteng GT/GDH/128/2016 placed the department in the position of having to pay for several items, instead of the single item being replaced.

4.6.3.5. Allowing for technical experts within the committees will reduce costly errors in the construction and evaluation of tenders.

4.6.4. Clause 57: Procedures of bid committees

Clause 57(1): We propose that procedures of bid committee meetings be standardised to avoid overlooking critical requirements and to avoid errors. And the following wording is proposed in substitution of the current:

"A bid committee must adhere to prescribed standards for meetings of the committee, subject to any directions as may be determined by the accounting officer or accounting authority."

4.6.5. Clause 58: composition of bid specification committee

4.6.5.1. Clause 58(a): There is no definition of 'requisite skills' provided in the Bill. We propose that minimum skills be set out. This will minimise challenges that the decisions of the committee may face. If the skills of the chairperson are not adequate this may cause the chairperson to fall short and him/herself not be able to identify the appropriate individuals best skilled to provide input on decisions This is critical when developing bid specifications. The exclusion of this in current circumstances within the Medical Technology environment has resulted in a number of critical exclusions, and incorrect purchase being made. An example of this is the procurement of Capital Equipment which was not compatible with the applicable hardware and software within the hospital environment, resulting in wasteful expenditure.

4.6.5.2. Clause 58(b): There is no inclusion of technical experts in the specification committee. Technical experts must be allowed to be part of the committee when procuring medical technology.

This exclusion is a specific issue which has been recognised within the Medical Device sector where incorrect goods have been procured due to lack of insight by experts within the field. There are a number of challenges facing public hospitals where clear errors have been made in the issuing of contracts, which have either allowed for the incorrect procurement of goods intended for a specific purpose, or alternatively neglected to include all items that are required for application within the sector. For example, the exclusion of revision surgery items in the Gauteng GT/GDH/128/2016 placed the department in the position of having to pay for several items, instead of the single item being replaced.

4.6.6. Clause 59: Functions and Proceedings of bid specification committees:

The impact and importance of the bid specification committee is critical, especially within the medical technology sector in order to eliminate the inefficiencies and wasteful expenditure which has become prolific within the healthcare framework.

The bid specifications issued are often inaccurate or not clear and this often results in time-wastage. The functions of the bid specification committee must include developing accurate and clear bid specification in accordance with the needs of the institution. This function must define the needs of the institution as those that are informed by the healthcare providers, and also protect the autonomy of the healthcare practitioners as required by the HPCSA and the Health Professions Act. Where a specification is excluded, such exclusion must be supported by the Act. New technology must be considered/ included in the bid specifications. Historical data often forces authorities not to consider locally manufactured/new technology. See comments on best practice in paragraph 3.3.4. where government can encourage innovation. Currently even in instances where local manufacturing is supported by other departments, e.g. DTI, there is no off-take due to dependency on historical data that excludes local manufacturing.

SAMED has undertaken several supply chain projects in conjunction with various provincial health entities over the past few years, a common challenge raised amongst all of these identified the Bid Specifications Committee as being a key area in overcoming these efficiencies and wastefulness. In January 2019, SAMED finalized a training project with the Eastern Cape Department of Health to consider the challenges within their supply chain structures. Expressing needs and demands and developing clear Tender Documents and Technical Specifications. Clinicians have the knowledge to express needs and demands for technology and supplies, but Supply Chain staff have to translate these into a tender. There is a need for close cooperation between clinicians and SCM staff to forecast and quantify needs, and to develop the technical specifications, but this is not always happening as it should be. Another issue is to develop technical specifications that are well-understood by suppliers, given also the enormous and growing amount of technology on the market. Cooperation and information-sharing practices between public providers and suppliers is essential. Hospitals within a provincial sector need closer cooperation amongst them to share information on successful tender documents and good technical specifications and share the burden of preparing those documents. Many items are needed by all hospitals, and not making use of each other's (knowledge) resources is ineffective and inefficient.

We propose that there must be inclusion of sharing of best-practice procurement principles, especially in consideration of the Bid Specification Committees.

4.6.7. Clause 60: Composition of bid evaluation committees

Clause 60(a)(ii): We propose that the bid evaluation committee must include a person who is an end user of the product in question, with the clinical skills and expertise on the use of the required product.

4.6.8. Clause 61: Functions and proceedings of bid evaluation committees

4.6.8.1. Clause 61(1): the evaluation process must include the evaluation of the actual products. In light of the prohibitions on sampling and bonusing of medicines and medical devices in terms of the Medicines and Related Substances Act 101 of 1965, section 18A and 18B. The prohibition will affect the evaluation of medical devices and technology, and therefore hinder the making of informed decisions by institutions. Medical devices were exempted from this prohibition until December 2021[18] and both medicines and devices we recently exempted from the prohibition by the Minister of Health, for 3 years from 2020, until May 2022[19], however, it still remains uncertain what will happen in the future should these exemptions not be made permanent or extended. In order for evaluations to be properly done, we propose that the Bill allow for the sampling for purposes of evaluation.

4.6.8.2. Clause 61(4): We propose that no government employee, family member or associate of an employee should be allowed to bid for government tenders.

4.6.8.2.1. Allowing government employees, or anyone related to, or associated to a government employee should be allowed to participate in any tender procedures. Should this be allowed, this will allow for corruption to take place.

4.6.8.2.2. We propose that clause 61(4) be reworded to exclude all government employees, family members and associates of government employees.

Proposed wording: *"No bid submitted by a government employee, a member of, or a technical advisor or subject expert assisting, and bid committee of the institution, or by a family member or an associate of the member,*

[18] R. 685 of 19 May 2019 "The Medicines and Related Substances Act (101/1965), as amended: Exemption of Medical Devices and In-Vitro Diagnostics (IVDS) from the provisions of sections 18A and 18B of the Act" *Government Gazette* No 42465.

[19] https://www.gov.za/sites/default/files/gcis_document/202005/43346rg11117gon585.pdf.

advisor or expert, may be considered by the bid evaluation committee."

4.6.9. Clause 62: Composition of bid adjudication committees

4.6.9.1. Clause 62(a)(i). Definition of 'requisite skills' is not provided in the draft Bill and we propose that this be defined. Refer to comments under Clause 58 above.

4.6.9.2. Should this definition not be provided; the chairperson may not be able to identify the appropriate individuals best skilled to provide input. This is critical when adjudicating bid submissions. The exclusion of this in current circumstances within the Medical Technology environment has resulted in a number of critical exclusions, and incorrect purchase being made. An example of this is the procurement of Capital Equipment which was not compatible with the applicable hardware and software within the hospital environment, resulting in wasteful expenditure.

4.6.10. Clause 63: Functions and proceedings of bid adjudication committees

63(1)(c) We propose that provision be made for cancellations, amendments, extensions or transfers throughout the bid process. For instance, where critical errors are identified with a contract which has been published, these options should be allowed from point of publication.

We also propose that clear time-frames be set in place for the bid adjudication committee in order to ensure compliance with the overall turn-around times.

4.6.11. Clause 64: Decisions of accounting officer or accounting authority on recommendations of bid adjudication committee.

64(a)(b) It is proposed that this decision, and the reasons, therefore, should be made public to allow for transparency within the process, limit any opportunity for corruption. Provided that this is done within the applicable data privacy laws.

4.6.12. Clause 65: Disagreements between bid evaluation committee and bid adjudication committee

This decision/recommendation, and the reasons, therefore, should be made public to allow for transparency within the process, limit any opportunity for corruption. Provided that this is done within the applicable data privacy laws.

4.6.13. Clause 67 Measures to prevent abuse of supply management system

Clause 67 (a)(b) refers to taking “reasonable steps”. There is no definition of reasonable provided and this may create ambiguity and inequitable application of rules. We propose that the definition be provided that sets out parameters and measures to prevent abuse, without a definition, what is considered reasonable may be subjective, and as such open to manipulation and the opportunity for corrupt practices.

4.6.14 Clause 68(2)(b) provides that the demand management system must be aimed at ensuring that the quality and the quantity of the goods satisfy the needs of the institution. There is often a discrepancy between estimated demand quantities and ordered quantities. See comments on clause 68 above. Planning (clause 52) and inventory management (clause 76), as addressed below is very critical as well for these purposes.

Part 3: Demand Management

4.6.15 Clause 68: Demand management system

Demand Management processes within Supply Chain are extremely lengthy. Poor planning, communication and time management are significant challenges. This has been recognised, especially within the medical technology environment. A lack of needs understanding, continuously changing budgets and adherence to proposed demand plans are preventing an efficient application of a demand management plan. Therefore:

4.6.15.1 Clear submission, evaluation and approval timelines are required in order for demand management to be successful.

4.6.15.2 There must be provision of an efficient, and automated system, as well as criteria to ensure demand management is applied successfully.

4.6.15.3 We propose the provision on the management and risk sharing of consignment stock.

4.6.16 **Clause 69: Approval of procurement plan**

4.6.16.1 Clause 69(2): We propose that the annual procurement plan be adhered to and must change within a budget period.

Within the current environment, the budget within an institution is constantly changing, which affects the ability of an institution to procure according to its annual procurement plan.

We also propose inclusion of criteria that ensures that institutions have to adhere to the agreed budget within a period in accordance with the approved procurement plan.

4.6.16.2 Clause 69(5): We propose that the review of procurement plan must include state of disaster conditions.

Part 4: Acquisition Management System

4.6.17 **Clause 70: Acquisition Management System**

4.6.17.1 Medical Technology has numerous compliance requirements which need to be adhered to. Consideration of both local quality regulations, and international quality standards need to be accounted for when applying any threshold values within the sector. This will allow for South Africa to ensure that they provide for the best quality products to both local patients/users as well as provide for opportunity for export.

4.6.18 Clause 71: Strategic Procurement

We propose that a definition be given to the term “strategic procurement”. The concept of Strategic Procurement is imperative for the success of a value-based system, which considers need and quality above that of cost. Strategic Procurement must ensure that products are quality assured, follow Good Manufacturing Practice (GMP) and suppliers are of undisputable ethical behavior. Tender documents and procurement processes are to respect anti-corruption, BBBEE, environmental and fair competition regulations and practices. Purchase of equipment and devices should be based more on “value for money” and “life-cycle costs” principles, which includes calculation of (patient) outcomes and benefits of a service and including cost of installation, training, maintenance, depreciation and decommissioning into the evaluation criteria instead of current practices of cheapest price or separation of purchase and maintenance tenders/contracts – e.g. by implementing the MEAT (most economically advantageous tender) criteria, see clause 3 above for MEAT.

Part 5 - Contracts and Contract Management

4.6.19 **Clause 73: Contract Management**

4.6.19.1 Clause 73(2)(b): Contract monitoring: there must be clear provision of clear parameters and timelines for monitoring and reporting and the criteria of contracts.

4.6.19.2 73(2)(e) That there is a Communication process notifying industry when price adjustments are allowed and the window period must be provided.

4.6.19.3 Contract performance and adherence to reporting mechanisms is critical for the success of any strategic procurement process. We propose that there be established a system of communication on supply chain planning and strengthening of performance by holding regular meetings with clear agenda's, reporting and action items, responsibilities and escalation models at unit/departmental level, institutional level and interinstitutional/provincial level.

Part 6: Logistics Management

4.6.20 Clause 74: Logistics management system

4.6.20.1 Clause 74(1) The Logistics Management system should be standardized (as far as reasonably possible) across all sectors for efficiencies, rather than allowing the accounting officer to determine a system of choice. Allowing for a standardized system will be a critical to harmonization for procurement structures.

4.6.20.2 We propose further measures to ensure contract performance and adherence to reporting mechanisms which is critical for the success of any strategic procurement process. We propose communication on supply chain planning, performance and regular meetings with clear agenda's, reporting and action items, responsibilities and escalation models at unit/departmental level, institutional level and interinstitutional/provincial level.

4.6.20.3 74(2)(c)(ii) We agree that stock levels must be maintained and recorded. And sustained supply must be a binding agreement.

4.6.20.4 The challenge currently faced on delivery to institutions is that often the proof of delivery is signed off by the unauthorised person. The institution must take liability and indemnify the suppliers where this is the case as the suppliers do not have control over the personnel in the institutions.

4.6.21 **Clause 75**: **Institutional instructions and standard operating procedures for logistics management.**

4.6.21.1 We propose that logistics management systems must be applied to consignment stock principles.

4.6.21.2 The current operating systems within the healthcare sector do not accommodate consignment stock, an element which continues to cause significant challenges and payment issues for all provincial health departments. The difficulty experienced in getting payment is also proving that the stock has been utilized.

4.6.21.3 Clause 75(a)(b) We propose that the consideration needs to be provided for the application of inventory management systems when dealing with Consignment Stock principles.

4.6.21.4 Within the healthcare sector, specific patient needs require product to procured without following standard procurement processes. The product required is not able to be identified until a surgical procedure is underway and is often patient specific. Current inventory processes do not account for this structure, and as such creates significant procurement challenges and supplier payment issues. Allowance within the healthcare institution for a systematic approach which allows for procurement structures accommodating the procurement of consignment stock principles is integral to the success of an inventory management system in healthcare institutions.

4.6.21.5 Late payments must be avoided and there must be process in to hold accountable institutions that negligently cause the late payment to suppliers. While other provinces are timeous, there are some that are lagging. Late payments can run into millions of Rands for a single supplier and affect the sustainability of businesses and un-employment levels in the country, but most critically they affect the supply of critical products to the patients.

4.6.21.6 We propose that a requirement for the inventory management system to include a contract relating to consignment stock, addressing issues of ownership and liability, structures and to allow for the supplier access to the stock and application of electronic of virtual stock-taking.

4.6.21.7 Delivery at depots: The challenges experienced at depots include the delays in processing of orders.

4.6.22 Clause 76: Inventory management

4.6.22.1 Clause 76(1): We agree that monitoring of and lawful disposal of damaged, spoiled, obsolete or slow moving items. We propose

that expired items be added and we propose further that this function be performed by a pharmacist.

4.6.22.2 Inventory management as provided for must be inclusive of consignment stock and supplier access be added.

4.6.22.3 Inventory management must be efficient, as there are instances where stock goes missing within the system after delivery and at times this results in the supplier not being paid until the stock is located/traced, which process often takes months. This is particularly often the case with walking implants.

4.6.22.4 We propose a contractual agreement, governance and transparency in health institutions particularly a clear establishment of requirements and process, documentary or otherwise relating to the ordering, invoicing and payment processes and a better reporting process.

Part 7: Movable Asset Management

4.6.23 Clause 77: Moveable asset management system

4.6.23.1 Movable Asset is not defined in the Bill and this is required to give clarity.

4.6.13.1. Cause 77(2)(b): Section 18A and 18B of the Medicines Act prohibits medical device and pharma companies from providing donations of medicines and medical devices. This must be addressed, institutions must be allowed to receive donations and the patients must benefit from such donations and institutions must have access to samples for demonstration and vetting. The

4.6.13.2. The Bill must allow free supply of loan sets and capital equipment where consumables can then be procured by the institution. These equipment/devices are in most instances out of financial reach of the public sector and the prohibition may limit treatment to patients. Allowing the free supply of varying devices/equipment will ensure that the institutions have choices at their disposal which will enable them to utilize a device that is suitable for the patient at any particular time.

4.6.13.3. Of great importance, there must be agreements in place for all placements, donations and free supply of moveable assets and

the agreement must address the support to be provided by bidders.

4.6.13.4. All applicable legislation, in this case the Medicines Act must be considered when drafting the Bill and the Department of Health must be engaged to ensure that the supply of medical devices and technology as aforesaid.

4.7 CHAPTER 7: INFRASTRUCTURE DELIVERY MANAGEMENT

4.7.15 Clause 81: Application of this Chapter

4.7.15.1 We propose that the entire Chapter 7 and Part 2, must apply to all government institutions.

4.7.15.2 Clause 81(3)(a): A definition of "public-private partnerships" must be provided and we propose that it be in accordance with the definition provided for under National Treasury Regulations **2005.**

Part 2: Infrastructure procurement and delivery management by departments, constitutional institutions and 3A and 3C public entities

4.7.16 Clause 86: Use of contract of another organ of state

The clause provides as follows: "*The accounting officer or accounting authority of an institution may make use of a contract arranged by another institution as prescribed and in accordance with any applicable standard for infrastructure procurement and delivery management*." We propose that in accordance with the proposal made under clause 43, provide proof of availability of infrastructure of each supplier that will enable use of that supplier as envisaged under clause 86.

4.8 CHAPTER 8: DISPOSAL OF ASSETS

4.8.15 **Clause 90: Application of this Chapter**

We agree partially to the method of disposing of assets, however the chapter doesn't address the difference between 'standard financial assets' i.e. buildings, vehicles and cash equivalents, and medical devices as assets. As a suggestion, a distinction must be made in the chapter on Medical devices that needs to be disposed in a manner that complies with the regulatory standards of the medical technology industry where traceability is of great importance.

4.9 CHAPTER 9: DISPUTE RESOLUTION

Part 1: Reconsideration and Review

4.9.15 Clause 94: Reconsideration or review of decision

Clause 94(2) It is not clear how the fee will be determined for the review. We propose that fees be prescribed by the Minster by notice in a Gazette.

4.9.2 Clause 95: Prohibition on contract award during reconsideration or review proceedings

Clause 95(4): The maximum allowed extension must be set to avoid evergreen agreements that may not be beneficial to the institution in the long run. The criteria for approving extension must be transparent and the reasons for the extension be reasonable e.g. not be due to lack of action from the institution.

Part 2: Reconsideration by institution

4.9.3 Clause 96: Reconsideration by institution

Clause 96(3) Must provide proper time frames for "reconsideration". The provision reads:

"An institution <u>may</u> dismiss an application for reconsideration if the application was not submitted within 10 days <u>of the date the bidder became aware</u> of the circumstances giving rise to the application for reconsideration or of the date when that bidder <u>should have become aware</u> of those circumstances, whichever is earlier."

4.9.3.1 The word "may" must be removed or a basis provided as to the circumstances under which the dismissal will not be made.

4.9.3.2 The decisions made by the institution must be transparent and publicly published and therefore a reconsideration application must be made 10 days from the date of the publication. The words *"from the date the bidder became aware of the circumstances"* or *"should have become aware"* are not very easy to determine and open to abuse. They create uncertainty and must be deleted.

Part 3: Provincial Reconsideration procedure

4.9.16 Clause 97: Reconsideration by provincial treasuries

Clause 97(5)(c) remove the words "at least" they create uncertainty. The provision must read: *"…the provincial treasury must communicate its decision in writing, within 30 days from the…"*

4.9.17 Clause 98: Reconsideration by Regulator

We propose that the words “at least” be removed from the provision. These words will create uncertainty. The provision must read: *“…The Regulator must issue a written decision, within 30 days…”*

4.9.18 **Clauses 101: Composition of Tribunal and 102: Qualification of members:**

We propose that the composition the tribunal and qualification of members of the tribunal must include a person with clinical expertise or at least allow for experts to be called specifically as it relates to the products in question.

4.9.19 Clause 104: Disclosure of interest by members

Clause 104(2) (a), (b) and (c): Provides a member must disclose interest in a matter, however if a conflicted member participates, it does not invalidate the decision, then the disclosure serves no purpose. We propose that the decision be reviewed where a member participated without disclosing, disciplinary steps be taken against such member. And where a member discloses, the member must be recused from the deliberations, similar to the process followed under section 75 of the Companies Act 2008.

4.9.20 **Clause 106: Finances of Tribunal**:

Financing of Tribunal cannot be from any other source, without transparency this to prevent corruption and bribery. It is proposed that the Tribunal disclose in its financial reporting on an annual basis all its sources of income.

4.9.21 Clause 111: Review Proceedings

4.9.21.1 Clause 111(1)(b) Review proceedings to be conducted with *“little formality and technicality.”* It must be clarified as to what technicality and formality refers to. Technicality may not be done away with as discussions may require a technical discussion or even expert depending on the subject matter. Formality may be dispensed of but matter of the law must be complied with including the fair administration of justice requirements in terms of Promotion of Administrative Justice Act, particularly when decisions are being made that affects bidders.

4.9.21.2 Clause 111(5)(b) One Must be a commissioner of or officer of the peace to be able to administer oaths.

4.9.21.3 Accessing this process must be made easy and the contact details and personnel must be available. Currently access for the appeal process proves to be a challenge.

4.9.21.4 The review process must allow parties to also challenge the bid specifications.

4.9.22 Clause 112: Tribunal Orders

4.9.22.1 Clause 112(1)(f) Any cost compensation must be reasonable and documentary proof thereof provided.

4.9.22.2 Clause 112(4) An application to review may be dismissed if "frivolous, vexatious or trivial" we provide a process be followed to determine that the application is "frivolous, vexatious or trivial" and the words be defined. The clause be amended to read as follows: "The Tribunal may, by order, summarily dismiss an application for review of a decision if the application is found to be frivolous, vexatious or trivial." It is important that a finding be made after a thorough determination. The words "frivolous, vexatious or trivial" must also be defined.

4.9.22.3 Time-frames must be provided for under this clause, i.e. the turnaround times for the tribunal. The decisions and the basis of the decisions must also be transparent and in line with PAJA. The current appeal process is not always timeous or transparent.

4.9.22.4 There are instances where certain tenders are not called for in specific provinces and only one province is called to bid, and supply in the country, thereby excluding suppliers in certain provinces who have the capacity to supply. This must be avoided and where it is the case, it must be justified in terms of the Act. i.e. no suppliers, limited stock requirement which will not justify contracting in all provinces etc. This process and circumstances of excluding other provinces must be set out under this clause.

4.10 CHAPTER 10 - GENERAL PROVISIONS

Clause 117: Requires the use of a quotations based procurement system; the clause is silent as to whether it will be a competitive quotation system. We propose a three quote system in order for companies to compete on price as well as other value-based procurement criteria as referred to under Clause 3.

4.11 RECOMMENDATIONS

The Procurement policies envisaged in the draft Bill must take value-based procurement and innovation into consideration, and the Bill must recognise and give life to the approach.

SAMED appreciates the vast economic gap between the EU and South Africa, and we are by no means suggesting that South Africa matches what the EU is doing. We are proposing that at the least, this proposal be considered taking into consideration the South African economy and limitation of resources. We do recognise that the Constitution of the Republic under section 27(2) does provide that the state must "take reasonable legislative and other measures, within its available resources, **[emphasis underlined],** to achieve the progressive realisation.." of the "…right to access to have access to healthcare services…"

SAMED is therefore prepared to be a resource to the government, to work with and support government in fulfilling its section 27(2) obligation, by among others, the implementation of value-based procurement, development of tools and guidelines in order to achieve the realisation of the right to access to healthcare service.

Yours sincerely

Tanya Vogt
SAMED Executive Officer
Email: tanya@samed.org.za
Tel 011 7042440/0836010343