SAMED
advancing patient care through MedTech

11 April 2022

Attention: National Treasury
By email: CommentDraftLegislation@treasury.gov.za

RE: SOUTH AFRICAN MEDICAL TECHNOLOGY INDUSTRY ASSOCIATION COMMENT ON THE DRAFT PREFERENTIAL PROCUREMENT REGULATIONS, 10 MARCH 2022 (GOVERNMENT GAZETTE NO 646206)

1. Introduction – About SAMED

SAMED, the South African Medical Technology Industry Association is a not-for-gain association established in 1985. SAMED is committed to enabling a sustainable, ethical and transformed South African medical technology industry that ensures patient access to medical technologies. Medical technology plays a vital role across the continuum of patient care and effective healthcare delivery (prevention, screening, diagnosis, treatment and rehabilitation).

SAMED's members include 200+ multinationals, distributors, wholesalers and local manufacturers of medical devices, medical equipment and in vitro diagnostics (IVDs) (collectively referred to as 'medical technology').

SAMED recognises that effective procurement of medical technology makes a significant contribution to the quality of care offered by the health system to the public. SAMED supports procurement regulations and systems that are ethical, efficient and effective, that aim to combat corruption, that comply fully with the laws of the country and that promote competition in the market. More specifically, SAMED promotes the goal of procurement systems that take into account the unique characteristics of medical technology.

2. Medical technology poses unique challenges to procurement systems and should be taken into account when arriving at specifications and goal setting requirements

Medical technology undergoes rapid cycles of improvement and requires variation to meet individual patient and healthcare professional needs. Medical technologies are not standard commodities. A medical technology procurement system needs to take account of the product improvement cycle as well as the need to accommodate clinical variation among patients. A system that considers only the lowest price will tend to favour older technology and may eliminate models which would meet different clinical and patient needs. Procurement planning should allow for:

- Improvements to be introduced within contract structures in order for patients to benefit from innovation.

- Non-exclusive contracts, allowing for multiple models and types, to meet the needs of different healthcare providers (HCPs) and patients.

Medical technologies often remain implanted in a patient or in use at a hospital for many years. Much of the cost and economic value of medical technologies lies not in the purchase price but in servicing, technical support, training and education provided by the supplier. For example, much of the service and support for implantable devices is done after implantation. Additional hospital procedures to remove, replace or adjust devices add greatly to overall costs. To be cost efficient, a procurement system must take into account the value of the medical technology over the duration of the patient's clinical condition. Maintenance and servicing of medical equipment is critical. Procurement managers should be wary of suppliers who offer a good price, but do not provide maintenance services or guarantee availability of spare parts. Some medical technology require additional equipment to function, and a supplier should be willing to provide and support such equipment. The goal for any medical equipment is to ensure full functionality across its life cycle.

In some surgery it is impossible to establish upfront the exact type and size of device or implant required, and a range of products must be available to the surgeon as options. A clear and efficient procurement-to-payment system needs to be established to address the unique process of consignment inventory. The main control in such a system is validation of the products actually used during the operation.

The table below lists specific considerations that apply to procurement of medical technology

Characteristics	Consideration for medical technology (relative to pharmaceuticals)
Lifecycle and product capability	Medical technologies have a shorter product lifecycle due to more rapid advancements in technology. Evolutionary changes and software updates are frequently made and extend product capability.
Value attribution	The nature of medical technologies means that the benefits they deliver are often indirect. For example, technology may improve diagnostic accuracy or facilitate mobility for a faster return to work. It can be more difficult to measure the value created because this is often realised in the future or in another area of the wider healthcare environment.
Categorisation	There is an extremely wide range of medical technologies (from clinically consumable devices, to specialised implants and complex diagnostic systems) and these vary in use and function.
Utility and transition	Use of medical technology involves a wide range of methods and techniques and often requires additional training, certification and specialist support. Most medical technologies are administered in a clinical setting.
Cost calculation	Medical devices often require a range of supporting consumables, maintenance, support services and contingency equipment. This complicates the calculation of base device costs.
Pricing stability	Prices of medical technologies for a clinical indication are often volatile as a result of new technologies becoming available and the upgrading of supporting software for the device. These developments may render older technologies obsolete.

Intellectual property	Medical technologies are often protected by multiple patents. However, "design-arounds" are common, with alternative device designs precluding a product's exclusive position in the market.
Clinical trial evidence	Detailed clinical trial evidence is less common for devices than pharmaceuticals, especially in the case of new and innovative products. Various regulatory bodies do not require the same standard of evidence for approval of devices.
Options	A range of different medical technologies is often needed to achieve flexibility in treatment to cater to different patient needs and varying experience levels of clinicians.

3. General comments on the regulations

At the outset SAMED confirms that it is fully supportive of the transformational imperatives in the Constitution of the Republic of South Africa, 1996 ("Constitution").

SAMED understands these regulations to be an interim measure until new procurement legislation in the form of what was proposed in the Draft Procurement Bill of June 2020 is passed. SAMED looks forward to updated legislation that logically and practically incorporates all aspects of state procurement in a single piece of legislation.

SAMED also understands that there are constraints inherent in the Preferential Procurement Policy Framework Act, 2000 ("PPPFA"), and that the regulations, as proposed, are as a result of that framework.

Our comments below are therefore framed by this, and the details set out below. The medical technology industry (and SAMED members in particular) are subject to various legislation, regulations and guidelines. These include, among others:

3.1 Curbing Corruption via the Medical Device Code of ethical marketing and business practice

To ensure that SAMED members conduct themselves ethically, particularly in their interactions with public and private healthcare facilities, healthcare professionals, patients and procurement officials, SAMED has developed a code of conduct that all SAMED members must comply with. Responsibility for curbing and combatting corruption vests both with procurement authorities and the medical technology industry. SAMED recommends that all medical technology companies selling to organs of state are required to be a signatory to the Medical Device Code of Ethical Marketing and Business Practice.

3.2 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 technology in South Africa. The South African Health Products Regulatory Authority (SAHPRA) is a body established under the Medicines Act to regulate and implement the provisions of the Medicines Act. Oversight with regard to licensing and product registration including quality, safety and performance 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 must be aware of the regulatory requirements on medical technology bidders. Bidders in the health sector must be compliant with the Medicines Act and related regulations as part of the criteria for qualification to bid.

3.3 National Health Act 61 of 2003

Medical technology is used by healthcare professionals on patients and in the course of healthcare delivery. 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.

3.4 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 that healthcare professionals act in the best interest of the patient. The Health Professions Act prohibits healthcare professionals from owning shares in a medical technology company unless such company is a publicly listed company (see Rule 23). The Health Professions Act contains rules and has associated ethical guidelines that govern the relationship between healthcare professionals and the medical technology industry. These must be considered when procuring from medical technology companies. Healthcare institutions and healthcare professionals must have the skills and knowledge to check that these requirements are adhered to and form part of the criteria for qualification to bid.

4 SPECIFIC COMMENTS:

4.1 The definition of "acceptable tender" (regulation 3(2))

The definition of "acceptable tender" is defined in the Preferential Procurement Policy Framework Act (PPPFA) as:

"any tender which, in all respects, complies with the specifications and conditions of tender as set out in the tender document".

SAMED is concerned that this definition leaves the discretion solely in the hands of the Bid Specification Committee, who may not necessarily be experts in the field to which the required goods or service to be procured, relate.

SAMED recommends that this definition requires further consideration and refinement, as bid specifications in relation to the procurement of medical technology must consider the legal frameworks medical technology companies are subject to, as afore mentioned, i.e.:

- Compliance with the Medicines and Related Substances Act and the prescripts by SAHPRA pursuant to that Act;
- Compliance with the Health Professions Act, 1974;
- Compliance with the National Health Act, 2003 on who can render healthcare services.

What constitutes *appropriate* "specifications and conditions" is not stipulated in law and this poses a concern as it may lead to procurement of medical technology that is not fit for purpose, of poor quality, potentially supplied by suppliers without SAHPRA licences and ignore requirements relating to who is qualified to administer, use, maintain or service the medical technology.

Herewith some examples where this has occurred:

- PPE procurement during COVID-19

Irregular procurement of PPE materials by various Government Departments of Health during COVID-19. PPE was procured from non-SAHPRA licensed companies, that did not have the required experience or knowledge in ensuring the PPE products complied with the appropriate local and international quality standards. This resulted in millions spent on incorrect and/or poor quality PPE products, at the expense of Healthcare Workers, Patients and the fiscus.

- National Treasury Note 5 during COVID-19

A number of standards listed for items under Note 5 appeared to not align with international minimum standards. There was also a lack of local testing capability.

- Advanced wound care medical technology products

Advanced Wound Dressings are not medicines with generic standards. There are no generic standards in this area and every manufacturer makes different products. For example, a primary application burn dressing that stays in place for a single day will certainly be cheaper than a primary application burn dressing that stays in place for up to 14 or 21 days. However, the overall treatment period is not considered in specifications and it is likely to be significantly shorter for the dressing that is not changed (the patient goes home earlier) not to mention the associated costs of the additional 13 dressing changes required for the daily change product versus the 14 day product. There was no inclusion of these consideration factors in that specific Tender, which now leaves the task of deciding all the more challenging for those assessing it.

In some bid documents efficacy parameters for all of the Items that do not have a SANS specification are missing and even those that have SANS specifications do not stipulate any efficacy parameters for evaluation. Errors, omissions and duplicates are noted. For example, the content of ibuprofen in the ibuprofen foam dressing should be **0.5mg**/cm2 and it's noted as **0.5g**/cm2, which is significantly out.

In comparison, the UK NHS typically uses Formularies in Advanced Wound Care, in preference to Tenders, with choices selected by a multidisciplinary group from a wide range of products.

- Incorrect size, box quantities and brand names

Different manufacturers package medical technology in different quantities. Specifications seem to favour a particular manufacturer by stipulating size, a box quantity and a brand name.

This prevents cost effective decision with only certain sizes (e.g. small) or packs with certain quantities being awarded. This could be problematic for example in burns where a burn is large and the anticipated volume usage for these dressings will be elevated because you are only awarding the small size and the majority of burns are larger in South Africa – 15x15cm + 20x30cm dressings & rolls are more typically used in burns. Thus by only awarding the small size, you are now forcing clinicians to patchwork & overlap several small dressings that will take more 10x10cm dressings overlapped than it would have taken 15x15cm + 20x30cm dressings to do the same job – ie by only awarding the small size, you impact the cost-effectiveness of the product negatively vs awarding a range of sizes for the job at hand.

Clinical efficacy is also often not assessed in terms of the outcomes of the submitted products on real wounds in the day-to-day clinical setting.

The typical limited awards in this Contract that have been repeated over the years also fail patient care, as well as our doctors and nurses in several respects, not least, again, clinical care, patient access, availability of choice and cost-effectiveness:

- Gloves tender

There was a tender for examination and surgical gloves issued by National Treasury which identified 'Nitrile' as a basic material requirement for the items on the contract. This was then applied to each and every item on the tender. Unfortunately, 'Nitrile' is not a material utilised in the manufacture of sterile surgical gloves. This issue was raised with both treasury and NDOH at the specification meeting, but no one was able to respond to the query.

They also applied SANS standards for incorrect products in the specifications. Sterile gloves were required to test against non-sterile testing specifications, and non-sterile items required compliance with sterile testing requirements.

Again, this is another example where 'knowledgeable' specialists were not included in specification parameters.

- Incorrect designation threshold

Incorrect designation threshold of 100% on a national wound care tender that nobody could meet as no similar products were being manufactured locally. This resulted in most supplier's applying for exemption from the dtic, and those suppliers that did not get their exemption letters in time were disqualified based on incorrect designation.

SAMED proposes a definition of "specifications and conditions" that includes, for example the following:

"with due consideration of compliance with legislation applicable to the goods or services, and, where applicable, with due consideration of input by professionals working in the specific fields in which the goods or services would be applied or utilised".

It is imperative that relevant users i.e. healthcare professionals, nurses, clinical engineers, possible patients or others be included in the bid specification process, as they are the persons who would oversee the use of the product, or themselves use it on patients. In some cases, the input by healthcare professionals such as podiatrists, certain medical specialists, generalists, etc. are imperative. The procurement process for medical technology should include individuals with relevant expertise and their advice should be incorporated into the design of tenders.

SAMED proposes:

Independent committees that include clinicians and medical device experts with no self-interest in relevant tenders can offer useful insight into quality-focused purchasing and help develop appropriate tender specifications.

For example, one of the provinces established a specialist committee made up of specialist surgeons to assist in preparing the tender item list.

This has ensured that all specific requirements have been fulfilled in order to ensure extensive patient care. It has also prevented wastage and ensured clinician choice and the best product for the patient.

4.2 "Specified goals" (regulations 4(2) and 5(2))

SAMED supports the rationale underpinning the proposed regulations that that each entity issuing tenders develop its own transformational goals.

The definition of these goals, as:

> "(*i) contracting with persons, or categories of persons, historically disadvantaged by unfair discrimination on the basis of race, gender or disability*"

SAMED supports public sector hospitals and health districts having the authority to make autonomous product purchasing decisions in response to local needs.

This does however introduce, for the medical technology industry potential legal and practical uncertainty. Historically tenders relating to medical technology could be issued as transversal tenders, as provincial (Department of Health) tenders, and as facility tenders for example via a specific public health facility, metropolitan and municipal clinics, statutory bodies, such as the NHLS – National Health Laboratory Services. Reference was also made to a supplier's Broad-based Black Economic Empowerment ("B-B BEE") status and for some tenders, local designation thresholds.

The PPPFA also states that the goals "*may*" include contracting with historically disadvantaged groups or compliance with the Reconstruction and Development Plan.

It is unclear as to why this reference to the Reconstruction and Development Plan, which is defunct and has been superseded by numerous other policies, for example the national development plan, in the health sector.

For any *other* goals set, the empowering Act (the PPPPFA)'s section 2(1)(e), requires those goals to be *measurable, quantifiable and monitored*. Even so, where such goals may require specific performances (e.g. levels of localisation or specific employment equity targets), it may be impossible to achieve in the period between the bid being advertised and awarded.

If various entities set different 'goals' for tenders for different products, suppliers may have to meet different, and potentially contradictory transformational goals. This would introduce significant legal- and practical uncertainty. Legal certainty is a key tenet of the Constitution in the rule of law, as entrenched in section 1(c).

SAMED is concerned that the vague nature of the goals could make bid specification committees and/or procurement officials susceptible to possible undue influence to adopt goals that may imply only certain, but not all, potential bidders. This might be challenged from a competition law perspective.

The goals need to be clearly defined so that suppliers of medical technology will be able to anticipate what compliance would be required.

SAMED proposes*:*

The regulations should include a framework or process to inform and support procurement entities in the setting of transparent, appropriate, realistic and practical goals with sufficient time frames for suppliers to meet such goals.

Goal setting and other procurement or tendering activities of various entities should be monitored and evaluated on an ongoing basis to ensure that the above principles are achieved.

An independent appeals mechanism – such as a dedicated tribunal – should be established By National Treasury for companies that have reasonable grounds for contesting a tender award to lodge an appeal.

Consideration should be given to making a goal, use and compliance with the open contracting data standard (see https://standard.open-contracting.org/latest/en/), which would minimise opportunities for corruption.

Tendering should also be conducted in accordance with applicable international trade agreements, including those of the World Trade Organization (WTO).

4.3 Deadlock-breaking: "objective criteria" (regulation 8)

SAMED is of the view that a deadlock-breaking mechanism by the drawing of lots is unfair, and not in alignment with procurement as envisaged in the Constitution of South Africa i.e.:

217. Procurement.—*(1) When an organ of state in the national, provincial or local sphere of government, or any other institution identified in national legislation, contracts for goods or services, it must do so in accordance with a system which is* ***fair****, equitable, transparent, competitive and cost-effective.*

(2) Subsection (1) does not prevent the organs of state or institutions referred to in that subsection from implementing a procurement policy providing for—

(a) categories of preference in the allocation of contracts; and

(b) the protection or advancement of persons, or categories of persons, disadvantaged by unfair discrimination.

(3) National legislation must prescribe a framework within which the policy referred to in subsection (2) must be implemented.*

The absence of reference to tenders that can be split, or awarded to more than one bidder, is concerning. It could also affect the appropriateness of product and/or supply of medical technology to patients (and therefore their section 27 constitutional rights), should a "winner takes all" bidder be unable to supply. For example, in the Orthopaedic sector there are numerous treatment options available, this would only be determined at point of procedure. Not all suppliers are able to provide every type of medical technology required as this is often patient specific and/or what product the surgeon has been trained on. As a result, multiple suppliers and products are required in order to provide appropriate quality care for patients.

Public tendering should be structured in a manner that encourages competition among potential suppliers and avoids the artificial restriction of the healthcare marketplace. Limits should be applied to the size and duration of tender contracts, so as not to create or perpetuate market monopolies. Multiple-source contracts are generally preferable in the medical technology sector, so that a diverse range of products and services is available for clinical use.

In instances where product pricing and quality are similar, multiple awards should be made to ensure supply chain continuity. Criteria that have the risk of impeding supplier competition and reducing the participation of small and medium-sized enterprises (SMEs) without a national footprint – clearly a disadvantage in a lower- and middle-income country (LMIC) setting such as exists in South Africa, should be avoided.

SAMED proposes the addition of the following statement:

"Regulation 8 should not be construed as implying that split tenders and joint awards are not possible"

4.4. Uncertainty as to meaning of tenders relating to "generating income" (regulations 6 and 7)

The differentiation between regulations 4 and 5, versus 6 and 7, is not clear as it pertains to the medical technology industry. When the industry, and here specifically the diagnostics industry, supplies products to the NHLS, for example, NHLS uses this to generate income by billing for the tests conducted with those products. SAMED does not believe that on-selling by the NHLS should be included within the scope of regulations 6 and 7, but requests clarity in order to ensure its appropriate application.

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