Comments by SAMED on the Competition Inquiry

Statement of Issues and Guidelines

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Who SAMED is

SAMED, the South African Medical Device Industry Association, is a trade association representing more than 160 medical device and IVD (In Vitro Diagnostics) companies operating in South Africa. One of our stated objectives, as the representative association for medical device and IVD companies in South Africa, is the promotion of and emphasis on ethical principles and practices voluntarily agreed upon amongst our members, published in Codes of Marketing and Business Practice which is binding on all members, and as such we believe that we are aligned with the objectives of the commission as per Section 2 of the Competition Act which defines the purpose of the Commission as, inter alia, "to promote the efficiency, adaptability and development of the economy"; and "to provide consumers with competitive prices and product choices". These objectives speak to the creation of an ethical environment where fair competition and Free Market Principles prevail.

SAMED is of the opinion that competition in the medical devices sector in the Private Healthcare market is robust and that this investigation will demonstrate this fact.

We are, however, concerned that the Public Sector has been excluded from this inquiry as it is here that we believe that the competitive environment has broken down. Several SAMED Members have withdrawn supply of medical devices to the Public Sector due to ongoing issues related to non-payment, opaque and inconsistent tender and procurement processes and corruption, the greatest negative impact of which will be on patients accessing the public healthcare system. This is clearly visible in the many documented cases of tender irregularity and related overcharging, and we urge the Commission to widen its scope to include Public Healthcare facilities as well.

The types of products that SAMED's members market and sell

Medical Devices can be considered as any technology used to save lives in individuals suffering from a wide range of conditions. In its many forms, medical technology is already diagnosing, monitoring and treating virtually every disease or condition that affects us. Medical technology can be familiar, everyday objects such as sticking plasters, syringes or latex gloves. Alternatively, it could also be spectacles, wheelchairs and hearing aids.

Meanwhile, at the high technology end of the scale, medical technology includes total body scanners, implantable devices such as heart valves and pacemakers, and replacement joints for knees and hips. In fact, there are more than 500,000 medical technologies currently available and they all share a common purpose: improving and extending peoples' lives.

The delivery of healthcare services is a complex area consisting of multiple interventions, products and services that need to be clear in definition and purpose. As stated in its comments in the draft Terms of Reference of the Inquiry, SAMED proposes that the phrases "medical device" and "IVD" be used (and defined as in legislation – Act 72 of 2008) when referring to the types of technology and equipment, such as those listed below as per the Global Medical Devices Nomenclature (GMDN) Agency:

Code	Classification	Example
01	Active implantable technology	*Cardiac pacemakers, neurostimulators*
02	Anaesthetic and respiratory technology	*Oxygen mask, gas delivery unit, anaesthesia breathing circuit*
03	Dental technology	*Dentistry tools, alloys, resins, floss, brushes*
04	Electromechanical medical technology	*X-ray machine, laser, scanner*
05	Hospital hardware	*Hospital bed*
06	In vitro diagnostic technolog	*Pregnancy test, genetic test, glucose strip*
07	Non-active implantable technology	*Hip or knee joint replacement, cardiac stent, trauma nails, plates and screws*
08	Ophthalmic and optical technology	*Spectacles, contact lenses, intraocular lenses, ophthalmoscope*
09	Reusable instruments	*Surgical instruments, rigid endoscopes, blood pressure cuffs, stethoscopes, skin electrodes*
10	Single use technology	*Syringes, needles, latex gloves, balloon catheters*
11	Technical aids for disabled	*Wheelchairs, walking frames, hearing aids*
12	Diagnostic and therapeutic radiation technology	*Radiotherapy units*
13	Complementary therapy devices	
14	Biological-derived devices	
15	Healthcare facility products and adaptations	
16	Laboratory equipment	

Pharmaceuticals, on the other hand, are effective when absorbed and metabolised by the body, operator skills are rarely relevant, they have long product **life cycles** (10 to 20 years compared to the **2 to 4 years of medical devices**), high barriers to entry and patent exclusivity. There are fewer products and there are limited variations of dosage or form.

Medical devices are typically based on mechanical, electrical, information technology and systems engineering, and stem from ideas typically generated in a clinicians practice. Outcomes often depend on surgical skill, medical devices have a short life cycle (2-4yrs) and there are lower barriers for competitive product entry – "fast followers". Proliferation of versions, features and accessory combinations abound. Medical devices also require maintenance and specific training and upgrading – attributes not found in medicines.

The various references to consumables in the Statement of Issues, in particular as to pertains to relationships, should consider the variations in who uses and owns the devices, and how that use comes about (e.g. doctor-used, doctor-owned, hospital-used, hospital-owned, patient-used, patient-owned), including differences between large capital equipment ("capex"), general equipment (beds, etc.), consumables (swabs, devices used in conjunction with or as part of other (durable) devices, etc.) and implants and certain single use items.

Market challenges faced by SAMED members are multi-factorial

At the outset it must be noted that the medical devices market is extremely vulnerable to exchange rate volatility (more than 90% of medical devices are imported into SA) as well as transportation costs such as fuel prices (many devices requiring technical support by the companies providing such devices), which has an impact on the environment within which devices are sold. And as devices are in most instances not sold directly to consumers, the industry is vulnerable to the way in which funders (medical schemes) and hospitals budget for, procure and reimburse devices.

There are various challenges and features of the medical device market which affects the way in which one views the statement of issues:

- The level and/or absence of skills in the health sector and the types of products necessitate hands-on involvement of companies in the use of the device; e.g. company representatives are often required to provide support in the clinical environment.

- 'Unknown or unacknowledged costs" i.e. the necessity of ensuring training, retraining and skills development of healthcare professionals and other users of devices to ensure correct use of devices (at least R31.7m for 47 companies participating in a survey for last audited year)[1]; cost of delivery of products used in emergency cases e.g. trauma surgery due to accident, cost of keeping stock, cost of maintenance and support;
- The supply chain for medical devices can be complex, and is significant e.g. the necessity of the industry to provide, due to surgeon and other shortages, as well as critically urgent time constraints, consignment sets and reverse logistics, in order to ensure access to devices needed by patients;
- The impact of managed care as cost-reduction objectives, sometimes without consideration for patient outcomes and with no or little emphasis on evidence-based medicine and cost-effectiveness (as opposed to cost-reduction), sometimes defaulting to the availability or not of devices and services in the state sector as the standard of care to be applied to medical scheme beneficiaries.[2]

Comment on Statement of issues

Reference is made in the statement of issues to healthcare professionals as limited to persons registered at the HPCSA. There is a multiplicity of professionals involved in care and devices e.g. Doctors, surgeons, physiotherapists, radiologists, radiographers, pathologists, nurses etc. Nursing practitioners, for example, play an important role in ensuring that patients have information and are in involved in the use of devices in fields such as wound care, stoma therapy, oxygen provision and the like. Other professionals that use medical devices who are not covered by the HPCSA include biomedical engineers, technicians, clinical engineers, laboratory technologists etc.

Two elements need to be looked at: the **inter-relationships** between the markets, and the **position of consumers** in each of the markets [par 5].

Par 34 states that it is noteworthy that the consumables market includes the market for medical technology and devices and "the Panel wishes to understand the impact of consumables on costs and competition in private healthcare". SAMED has previously proposed, and does so again, that the **terminology "consumable" be changed**, as it is bound to create confusion in the Inquiry as, in the health sector, consumables refer only to certain types of products that are used and excludes capital equipment, implants and the like.

[1] KPMG 2014 *Industry overview and economic impact assessment for the South African medical technology industry*, prepared for the South African Medical Device Industry Association (SAMED).

[2] SAMED has prepared a significant submission on these topics, and can make this available to the Panel on request.

Par 43 refers to price regulation. SAMED wishes to highlight that, due to the unfortunate categorisation of some devices (called "combination devices") as medicines (which has been the topic of a recent court case[3]), some devices have been subjected to medicines price regulation. Whereas in a highly competitive device market, it is possible to remain responsive to affordability constraints, for medical devices subject to medicines **pricing** regulations, this is not possible.

Insofar as price regulation is mooted as a mechanism to avoid **harm** to consumers, SAMED wishes to refer to two articles, which also pertains to the tension that might exist between appropriateness of care (inappropriateness being harmful to patients) and cost:

- Pope "Legislating low prices: cutting cost or care?", *Backgrounder*, No 2834, August 2013;
- Noval et al *The impact and cost of health sector regulation* Australian Centre for Health Research, 2010.

Par 55 refers to cost, prices, access and innovation. SAMED welcomes the fact that **innovation** would form part of the analysis, as well as the business impact on employment, and smaller- and medium-sized business, which make up the bulk of SAMED's members. It is important to note that innovation is not to be discouraged and that due recognition be given to the nature of device innovation. The cost of innovation necessitates a return on investment – if not reached, South Africa will not be able to access innovative medical devices.
The lack of incentives and a growth plan for the devices industry is also only now being addressed by the Department of Trade and Industry, a factor which should be considered by the Panel in the Inquiry.

Any medical device supplier should be able to be **viable**, which means in order to continue to compete, and provide access to healthcare, its business should be sustainable. This means that it is not only an analysis of price that is relevant, but also the impact on the industry, the specific supplier and the right of access to healthcare (which includes access to medical devices) which should be considered. **Without viability, availability, as a component of access to healthcare, is not achievable.**

It must be understood that, as **medical device regulations** (which govern the quality, safety and performance of devices), will most likely only be operative at the soonest in 2016, a key element that influences the market, i.e. product registration and the licensing of firms (save for electro medical equipment), is not yet operative.

[3] Gelderma v the MCC and others, North Gauteng High Court, decision of 12 June 2014.

Such a framework could in future have both positive, and negative impacts on patient access and competition, in that regulatory delays (as is the case with medicine) will impact on availability and competition, and is likely to increase the cost of doing business, but also in that quality of products and suppliers would be ensured, i.e. benefit patient access and care. As this is an envisaged, future system, this issue should be considered, but cannot be definitely addressed, and the market post such regulatory intervention would be different than currently.

The ownership of medical device companies has, globally (e.g. the USA prohibits doctor-trading), been a bone of contention. This is as, when owned by providers, vertical integration occurs. From a professional ethics perspective, the HPCSA believes that this should not be permitted, as patients are then not provided with options.

Understanding medical devices and the dynamics that influence, and should influence device choices, is important, as are **provisions in health legislation**, such as the HPCSA Ethical Rules, the National Health Act and the Medical Schemes Act, as well as the Consumer Protection Act. Reference to these legal frameworks should be included in the Statement of Issues.

Reference is made to the "**relationships**" between medical device suppliers and funders (providers of healthcare finance), providers and facilities respectively. It is not clear what is meant by "relationships" and SAMED proposes that the term be unpacked. For example, does it include an investigation into contractual relationships between the parties mentioned (which is mentioned in the Statement of Issues), an investigation into marketing and sales practices, an investigation into pre-contractual engagements, an investigation into price setting, etc.?

The impact of **implicit price setting**, such as the price increases recommended by the CMS annually, which impacts on medical device pricing, should also be considered.

Healthcare works in **complex algorithms**, where much more than the price of a device is to be considered. Moving from one intervention to another on an algorithm when treating a patient, carries risks for both the patient and the provider (which includes the risk of being sued or charged by a professional body). These complexities also manifest in relationships between stakeholders, which are vitally important to ensure **appropriateness**. For example in theatre, the surgeon, the device supplier, the hospital's nursing staff and the anaesthetist all engage with each other and the equipment they use and are vital to ensure appropriate care. Therefore the existence of these relationships should be encouraged and is in the best interest of the patient.

A further term used in the statement of issues is that of "**affordability**". This should, as the Constitutional Court decided in the well-known health sector dispensing fee (medicines pricing) case, include consideration of not only affordability, but also **availability**, both of which impact on the right of access to healthcare. Therefore affordability cannot be seen in isolation. Ensuring viable businesses in healthcare, be it medical practices, hospitals or device suppliers, is as important to ensure access to healthcare as "affordability".

A related concept that is as important in healthcare, is **appropriateness**. Due to the nature of human bodies, not all devices would be appropriate for, or even work, for all patients. This is a specific challenge faced by device suppliers in their interactions with medical schemes, who tend to look at devices as just price-related. What is cheapest, is not necessarily right for a patient. The use of so-called designated service providers in the supplier environment is an example of this approach.

One cannot reduce devices (or other goods or services in healthcare) to their prices and/or the existence of relationships. One should also consider the **nature of medical device product development**, which is incremental, costly and based on previous experiences and research and development. For example, the first HIV tests brought into South Africa were extremely expensive. However, had they not been imported, albeit at huge cost, there would not have been subsequent developments, increased volumes and, in the end, price and competition benefits. In this the role of medical devices in the cost and provision of healthcare is not linear - healthcare professionals and their patients have and should have a number of choices when it comes to using medical devices, so as to ensure **appropriateness** of care. In addition the skill and experience of the professional regarding the use of a particular device will impact the quality of care provided. So too, the choice of device made could have **long-term implications**, and implications for other parts of the market (e.g. quality of life and days in hospital, the need for life-long assistance and rehabilitation, etc.).

On the **exclusion of the public sector** from the Inquiry, SAMED (its members participating in the KPMG Survey indicated some 30% of the value of the businesses is derived from the public sector) is adamant that the private healthcare sector cannot be viewed in isolation from the public sector –

- The weak public sector has, in SAMED's view, a significant impact on competition in the private sector.
- The failings in training and skills of healthcare professionals and allied workers have to be addressed post-qualification through training and exposure to devices and device innovations. These are additional costs of doing business that are borne by the medical device suppliers.

- The public health sector is an extremely late payer, sometimes only paying many months or even years after the product is used. SAMED members therefore have real costs they have to bear as businesses trading in both the public and private sectors. Certain SAMED members have also decided not to sell products to the public sector due to payment inefficiencies. This in turn limits competition in certain markets.
- It must also be noted that medical schemes erroneously use the public sector level of care as the reimbursement level for private schemes. This is a fallacy, as the accounts rendered (if at all) in the public sector do not correspond with the actual cost of the service and products used.

It is understood that, although the outcome of the Inquiry is not pre-set, it is understood that some stakeholders would want the outcome to serve as a justification for price regulation. SAMED urges that, prior to recommendations of this nature being made, a regulatory impact assessment be undertaken. Experience in the NHRPL, medicines price increases, etc. have shown the unintended consequences of price regulations.

Conclusion

The Commission is asked to appreciate the lack of a medical device regulatory (licensing and registration) framework, and the negative implications of this in terms of quality, safety and performance and also the impact on patients who rely on healthcare professionals to make choices on their behalf in terms of the choice of medical devices used.

The importance of health outcomes, and not mere cost or price, in healthcare should be considered and worked into the manner in which the Commission analyses matters. Health outcomes should be foremost in evaluating levels of appropriate care. This is of particular importance insofar as the Enquiry's focus on managed care is concerned.

SAMED welcomes the opportunity to comment on the statement of issues, and looks forward to further guidance of the information and submissions that would be required from SAMED.

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