PRINCIPLES OF PROCUREMENT FOR MEDICAL DEVICES

GUIDANCE DOCUMENT DEVELOPED BY
THE SOUTH AFRICAN MEDICAL TECHNOLOGY INDUSTRY ASSOCIATION

Recommended Minimum Requirements Checklist	
Registrations, Licences, Certifications and Regulatory Compliance	
SAHPRA – South African Health Products Regulatory Authority medical device establishment licence in order to manufacture, distribute, import, export and wholesale medical devices (whichever is relevant to the activities of the supplier). See: https://www.sahpra.org.za/medical-devices/ and for a list of licenced medical device companies see: SAHPRA Medical Device Establishment Licences 02 June 2020 Department of Health (Radiation Control) licence for electromedical equipment, where applicable	
CE Mark, FDA approval or evidence of certification/registration in another regulated country recognised as a stringent regulatory authority, e.g. IMDRF (International Medical Device Regulatory Forum) member countries, See: www. http://www.imdrf.org, i.e. For a medium to high risk (Class C) and high risk (Class D) medical device or IVD proof of pre-market approval or registration for the medical device or IVD from at least one of the following regulatory authorities; □ Australia's Therapeutic Goods Administration (TGA) i.e. inclusion in the Australian Register of Therapeutic Goods □ Brazil's ANVISA (National Health Surveillance Agency) approval and registration; □ Canada's Medical Device Licence to market; □ The European Union's CE certificate, to show conformity to all obligations for medical devices as required by the Medical Devices Directives; □ Japan's Marketing Authorization Holder (MAH) licence; □ USA's FDA's Center for Devices and Radiological Health (CDRH) Premarket Approval (PMA) or Premarket Notification 510(k) clearance. □ Evidence of IVDs approved under the *World Health Organisation* (*WHO) Prequalification of In Vitro Diagnostics Programme* will also be accepted.	
Evidence that the device complies to an applicable regulatory and/or product standard, for example, SANS, DIN, EN, ASTM, AAMI, BS, AU, pharmacopoeia [not an exhaustive list], or	
Evidence that the device complies with EU Directives and relevant SA legislation for performance and safety, where applicable, see: Medical Device IVD Essential Principles	
Department of Health (Radiation Control) licence for electromedical equipment, where applicable	
ICASA registration for medical devices that emit radio frequencies, where applicable	
Is the medical device manufactured from biocompatible materials, where applicable, per ISO10993-1?	
Compatibility, where applicable	
Is the medical device compatible with the institution's Information Management System?	
Is the medical device compatible with other equipment relevant to its use?	
Is the medical device compatible with the water quality available?	
Is the medical device compatible with the electrical power available? (For example, is a UPS required?)	
Is the size and weight of the medical device compatible with the space allocated to it for installation/storage?	
Is the institution accepting the medical device able to protect the medical device from electromagnetic fields, vibrations /radiation aeration	
Skills, Support and Training, where applicable	
Has a user specification/requirements document been developed to support the purchase of the medical device?	

Are there appropriately skilled/trained users for the level of care provided in the institution that can use the medical device?	
Do the users meet regulatory/licensing requirements?	
Is the supplier able to provide training for the medical device?	
Is the supplier able to provide appropriate after sales service and support?	
Is the model nearing end of life cycle – obsolete technology	
Is there a local service provider for repairs/ servicing	
Risk Considerations	
Has risk management been conducted to support the purchase of the medical device?	
Is inherent risk associated with the medical device minimised by the supplier and institution via appropriate warning labels, instructions for use, training offered, etc.	
Is the receiving institution able to manage residual risk associated with this medical device?	
Additional Documentation	
Material Safety Data Sheets, where applicable	
Clear directions for use	
Other possible costs to factor in	
Direct medical costs., e.g. laboratory or diagnostic tests, provider services (including physicians and allied caregivers), as well as hospitalization and sub-acute care	
Costs 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	
Ethics	
Does the supplier abide by a code of ethical marketing and business practices? (which one) are they registered with any association?	
Value adds	
Delivery efficiencies	
Technical benefits/merits	
Safety, i.e., ability to lower or minimize adverse events or complications	
Clinical effectiveness, including reductions in morbidity or mortality or as measured by patient-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 or green technology	
Other	
Local manufacturer	
B-BBEE level	

PURCHASING FRAMEWORK

A list of items that must be considered before concluding a purchasing decision:

Budget	
Is there budget for this product?	
Out of which budget will this product be paid?	
Product	
For what purpose will the medical device be used?	
With what tissues does the medical device need to be compatible?	
With what other devices / equipment does the medical device need to be compatible?	
Has a medical device specification been developed? [List of minimum requirements.]	
Does the medical device perform at the level required in regulation/standards?	

Is the medical device: Single/Multiple use?	
Is the medical device easy to clean?	
Is the medical device purchased intended to be used sterile/not sterile?	
Can medical device be resterilised with a validated sterilisation method?	
Location	
Where will the medical device be used?	
With what utilities does the medical device need to be compatible? (Power, water)	
With what IT systems does the medical device need to be compatible?	
On what level of the building should the medical device be installed?	
What requirements will be required of the location for the effective management of the medical device? (Sterility, protection from radio frequencies, electromagnetic /ionising radiation, vibration, dust, extreme temperatures, refrigeration)	
Will the location management be prepared to build/renovate in order to accommodate this medical device?	
Can the medical device be disposed of appropriately?	
User	
Who will use the medical device?	
What type of patients will the device be used on?	
What type of skills/training/licencing is required of the user (including patients) of this medical device?	
What other attributes would be required of the user?	
In the absence of the user, is there another qualified person who could use this medical device?	
Supplier	
What attributes/level of competence is required of the supplier of this medical device?	
Is the supplier capable of installation and validation of the medical device?	
Is the supplier capable of providing training/technical support to the user?	
Is the supplier capable of providing servicing and preventive maintenance for the medical device?	
Does the supplier have a recognised Quality Management System?	
If no, can the supplier demonstrate that they can comply with each aspect of a quality management system?	
Can the supplier track and trace where their medical devices have been sold/installed in the case of product issues or product recall?	
Does the supplier have post-market surveillance reporting capabilities?	
Does the supplier have complaint handling capabilities?	
Is the supplier a registered, credible legal entity that has a verifiable relationship with its manufacturers?	
Purchaser (Healthcare Institution)	
Is the SCM department / purchaser aware of the Medical Device Regulations? See: 20161209_Medical Device Regulations_Gov Gazette 40480	
Is there a process to verify goods received against specifications? First time delivery and on an ongoing basis?	
Is there a procedure for monitoring supplier performance?	
Is there a procedure for reporting medical devices defects and adverse events? See SAHPRA guidelines in this regard: Recalls Vigilance Medical Devices IVDs	
Is there a process at institution level for developing purchasing criteria?	
Does this process review items that are mandatory, essential, preferred, not required?	
Is there a process(es) that is suitable for different types of medical devices e.g. equipment, implantables, surgicals, consumables, etc.?	
Does the process allow for new innovative technologies to be evaluated / demonstrated?	

What is innovation?

Innovation is about finding new approaches – including new technology as well as new applications of existing technology, and new models for services and solutions - in order to improve patient outcomes, enhance efficiency, or extend the reach of care.

Innovation is about value creation. An idea that is not transformed into some form of social or economic value is not considered innovation. Within the healthcare system, innovation can improve the quality and efficiency of health services, thus contributing to improved population health (social value). For example, innovation can decrease waiting times, length of hospital stays, morbidity and mortality. In addition to obvious social and patient care benefits, innovation also contributes to the affordability of healthcare service

What is value?
Value can be defined as patient health outcomes per unit of currency spent. Value, therefore, encompasses both cost and non-cost factors. The list of features which could contribute to a device's value will vary from case to case, but we list here some of the most typical features of value.

Value encapsulates **cost-related factors which go beyond the initial purchase price**. These cost factors are life-cycle costs and costs relating to ownership and include:

- direct medical costs., e.g. laboratory or diagnostic tests, provider services (incuding physicians and allied caregivers), as well as hospitalization and sub-acute care.
- costs 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.

Equally important are **factors associated with patient outcomes or those involving total budget savings**. All of the following should form part of the value assessment of a medical device:

- delivery efficiencies.
- technical benefits/merits.
- safety, i.e., ability to lower or minimize adverse events or complications.
- clinical effectiveness, including reductions in morbidity or mortality or as measured by patient-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.

Value-based purchasing means procuring medical devices with reference to healthcare outcomes and not merely to satisfy technical requirements. Value is not just about cost, but also and principally about the broader patient health and societal benefits conferred by a medical device. To achieve value, procuring authorities should focus on spending well, rather than spending less.

Value is a holistic concept which covers all aspects of a device's expected impact on healthcare outcomes, recognising that financial, clinical and societal factors are, in almost all cases, important features of a value assessment and on an equal footing with cost factors. The cost analysis itself should go beyond price and take into account life-cycle costs and the broader efficiencies which may be generated by sourcing high-value products – even a device with a high initial price could well end up saving money when its overall economic and clinical context is considered.

The terminology for the procurement process that attempts to account for some of the factors beyond initial purchase price, or non-price factors, varies from jurisdiction to jurisdiction. The standard term, as promoted by the United Nations and by a number of national jurisdictions, is the principle of "best value for money." In the European Union, the term is "most economically advantageous tender" (i.e. MEAT). Both these terms mean a broad and all-encompassing focus on value in opposition to a narrow focus on cost. For instance, the United Nations' procurement division defines "best value for money" as "the optimisation of whole life costs and quality needed to meet user requirements, while taking into consideration potential risk factors and resources available", which means that price alone is not necessarily determinative of best value[1]. In fact, these terms and practices have come into existence and greater prevalence as jurisdictions have had to come to terms with the negative results of procuring solely on lowest price.

Assessment of the value of a medical device needs to account for the following crucial information inputs:

- From whose perspective is the technology being evaluated? Jurisdictions vary in their preferred perspective, e.g. social payer, provider, health authority or fund.
- What is the pace of innovation for the device category? Many device categories go through rapid and frequent incremental improvement, involving lower risk and faster development cycles than drugs, with relatively few break-through leaps in innovation. Pharmaceuticals may be the model for some procurement teams and may, in most cases, be a mistaken benchmark.
- Does the device allow reduced expenditure on other healthcare products and/or services? Some innovative devices may offer a system solution which may simplify or eliminate related procedures and their associated expense.
- Do the assessment of innovation and the medical context include the opinion of clinicians who use the devices? [1]

PURCHASING BEST PRACTICE:[1]
Five principles designed to help lower procurement costs and system risk, while enhancing overall performance:

1. **Evaluate the total cost of care:**
   Less expensive products purchased to achieve immediate savings may generate greater costs in the long term. High-quality and innovative products that carry a higher initial procurement price can often generate improvements in patient care and reduced cost over alternative practices
2. **Ensure clinical input:**
   Cross-functional involvement of physicians, medical staff, administrators, data analysts, and other stakeholders in product selection ensure sufficient range of treatment options and guarantee that clinical needs are met
3. **Use flexible contracts:**
   Provisions for new product adoption help assure that contracts are flexible enough to provide rapid access to newly released advanced technologies
4. **Encourage supplier diversity:**
   Multiple-supplier contracts allow a larger number of suppliers into the market, which strengthens competition and ensures stability of supply. Less competition also reduces the procurer's negotiation leverage in future rounds of purchasing, ultimately resulting in higher long-term procurement costs
5. **Fair and transparent procurement processes:**
   Minimise excessive bureaucracy and opportunity for corruption

[1]*Ref: Ken Graves and Helen Chen, L.E.K. Consulting, "Global best practices in medical device procurement – A road map to system success" January* 2011

[1] Advamed. Good Practices for the Procurement of Innovative Medical Technology