SAMED Member Guidance on Market Access for Medical Technologies in South Africa – Dec 2017 version

Contents

Executive Summary

SAMED - The South African Medical Technology Industry Association - represents the interests of 178+ South African Medical Device, Medical Equipment and In-Vitro diagnostics ("IVD") companies. SAMED's vision is to ensure a sustainable medical technology industry that enhances patient access to innovative solutions.
SAMED is committed to providing the Industry with a collective, objective and credible platform for engagement with all stakeholders.

The SAMED Health Economics and Reimbursement (HE&R) committee has prepared and combined a series of documents relating to introducing new technologies to South Africa and to assist SAMED members navigate what is a relatively complex reimbursement system environment.

The emphasis in health care in South Africa, is focused on delivering value, derived from improving outcomes and reducing costs; this is to be seen in the full context of the continuum of patient care and respective condition, and not limited to a specific event. All new technologies introduced into the health care system, where a health technology is defined as procedures, drugs, devices, equipment and processes (support systems) by which health care is delivered, need to be assessed in this context.

The contents of this document are a result of many years of experience of industry members who have given selflessly of themselves in producing this guide and sharing their experience, in the interests of aligning activities and improving patient access to medical technology.

This executive summary is intended to be a quick reference guide, with the key points and activities summarised in the tables below.

The general steps for introducing a new technology is explained first. Suppliers need to be familiar with the regulatory environment before launching a new business and/or technology. Products that enter the market at a competitive price to existing products are generally fast tracked to market on an auto approval basis; those falling into an existing category of product at a premium price will require good evidence, be it clinical and/or other value-added features and benefits, to support the premium. A technology that is unique and does not fall into an existing category, is likely to be escalated to the next level of review, referred to as Health Technology Assessment (HTA) in South Africa. This is usually an abbreviated process when compared to processes such as NICE and CADTH, but is still supported by international literature. After achieving reimbursement approvals, technologies may still need to pass through the respective private hospital approvals process to complete market access.

Steps	**Activity**	**Expected Timelines**
1	Market preparation for introduction of new technology (timelines are supplier dependent)	Company determined
2	Obtain Establishment Licence (timelines undetermined)	Regulator determined
3	Private hospital groups vendor registration (timelines variable subject to information submitted and individual group requirements)	Hospital determined
4	Product (NAPPI) Code Application	48 hours
5	Payer / Funder approvals (Approval; price negotiations; HTA)	3-12 months 0 (where mandate exists from funder to MCO*) to 3 months

6	Hospital group approval	Hospital determined

*MCO = Managed Care Organisation

The World Health Organisation defines Health Technology Assessment (HTA) as the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organizational and ethical issues of a health intervention or health technology.

New products that are introduced at a price premium with a claim of incremental benefit to an existing comparator, or a technology that truly represents a new category of technology but is considered expensive compared to current standard of care, will be escalated to HTA. Medical schemes are empowered, by the Medical Schemes Act, through their administrator/managed care organisations, to develop reimbursement policies for new technologies and the benefits that they provide for.

The administrators/managed care organisations have processes in place to do this, with varying degrees of rigor, thoroughness, formality and transparency. A few companies, namely Discovery, Medscheme, MMIHealth (the amalgamation of Metropolitan, Momentum, Providence healthcare administrators, CareCross and Hello Doctor) and Medical Service Organisation (MSO), contract HTA service to medical schemes (covering at least 80% of the insured population). They have processed that use a systematic approach to assessing technologies. This can take a minimum of 3 months to a maximum of 2 years, should there be extensive economic modelling required.

These organisations may each have their own templates to complete (available on request from each organisation) which should be completed, but are often limited with regards to information requested and/or fields provided for such information. SAMED has therefore created a HTA template and guideline for industry to use in the application for reimbursement that meets the needs of most medical schemes. This document was created in the interests of achieving harmonization in these applications and is based on various application forms used by medical schemes. The final product is a dossier that may be submitted with the initial application. Below are the main headings of each section of the final dossier.

Steps	**Main Sections**
1	Executive Summary
2	Applicant Details
3	Clinical Review
4	Technology Review
5	Economic Review
6	Organisational/Operational, Legal, Social and Ethical Review
7	Conclusion
8	References
9	Appendices

The final section of this guideline captures key principles that differentiate the medical device industry from other technology sectors in health care.

The principles below are intended to reflect ‘model principles” to ensure that the policy goals underlying the development, adoption and implementation of reimbursement systems in South Africa result in the best value for patients and fosters innovation in the medical technology industry. They are discussed in some detail in the body of the document and suppliers are strongly encouraged to become familiar with them as these principles aim to empower all in the industry in an effort to differentiate the industry from other sectors and demand that patient access to cost effective innovative technologies that improve outcomes should be everyone’s primary objective.

	Principles
1	**Device industry is unique:** 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 devices in multiple service delivery settings.
2	**Transparency:** Reimbursement policies should be vetted and implemented in an open process, in which the decision-making criteria and process for implementation are fully disclosed in advance to stakeholders.
3	**Timing, notice and comment:** Payers / Funders / Policy makers should provide ample time and opportunity for stakeholders - including members of public - for notice and comment on proposed policies.
4	**Stakeholder role and input:** Payers / Funders / Policy makers should be required to disclose and discuss the input provided and consider this input in finalizing benefit and reimbursement decisions.
5	**Consistency:** Payers / Funders / Policy makers should attempt to adhere to a predictable schedule for proposed updates and/or system reforms.
6	**Best value:** A payment system should recognize the resources needed to deliver a group of services, or entire episode of care. The resources should be from well-established clinical guidelines, reflect the long-term value of medical technology and not focus on short-term costs.
7	**Use market competition to evaluate the domestic price of the product:** There should be an acknowledgement that market forces are allowed to operate to maximize efficiency and improve patient care.
8	**Reward innovation**: There should be an acknowledgement that resources are needed to encourage innovation, which provides continuous progress in patient outcomes.

Conclusion:

This document aims to assist SAMED members in terms of the content of their applications for reimbursement of new health technologies.

Users are advised to ensure that persons who submit this content to providers (e.g. hospitals) and funders (e.g. medical schemes) are empowered with background knowledge and skills that are needed to interpret aspects that are covered in the document. SAMED suggests that members subscribe to the council for medical schemes distribution list, consider joining ISPOR (https://www.ispor.org/RegionalChapters/Chapter/SouthAfrica) and PCMA (http://pcma.org.za) and that they consider doing a course(s) in HTA. These are on offer at, amongst others, the University of Stellenbosch and the University of Pretoria.

Quality of submissions are closely related to success of the application and duration taken by the managed care administrator / organisation regarding funding of acceptable technologies.

1. South African Private Market Access Process Map

This section provides a roadmap of the market access and reimbursement processes required to launch a technology, whether new or as a line extension, into the South African Private Market. **Table 1** summarises each of the key steps in the process.

Table 1

Steps	Activity	Expected Timelines
1	Market preparation for introduction of new technology (timelines are supplier dependent)	Company determined

2	Establishment Licence (timelines undetermined)	Regulator determined
3	Private hospital groups vendor registration (timelines variable subject to information submitted and individual group requirements)	Hospital determined
4	Product (NAPPI) Code Application	48 hours
5	Payer / Funder approvals (Approval; price negotiations; HTA)	3-12 months 0 (where mandate exists from funder to MCO*) to 3 months
6	Hospital group approval	Hospital determined

*MCO = Managed Care Organisation.

The South African Healthcare sector is an industry in flux with many regulatory and other changes. Furthermore, the healthcare sector is moving from a distinct private and public-sector market, to a National Health Insurance (NHI) system that is expected to see a convergence of public and private sector activities.

It is anticipated that Health Technology Assessment (HTA) will play a pivotal role in how technologies gain access to the market going forward, and therefore a basic understanding of the principle requirements for local HTA's is a primary and strategic imperative. HTA will normally be applied to a new class or category of medical technology or a technology without a direct comparator currently in use. Emphasis is on maximising value through maintaining or increasing quality and maintaining or reducing costs.
The private healthcare sector is highly fragmented and many role players need to be consulted and managed throughout the application process. No single HTA agency exists in SA and individual organisations (funders; hospitals) using HTA may have their own rules and criteria that one needs to become familiar with wherever possible. There is no central body that performs HTA in a South African context, so each private company sets its own specifications and rules.

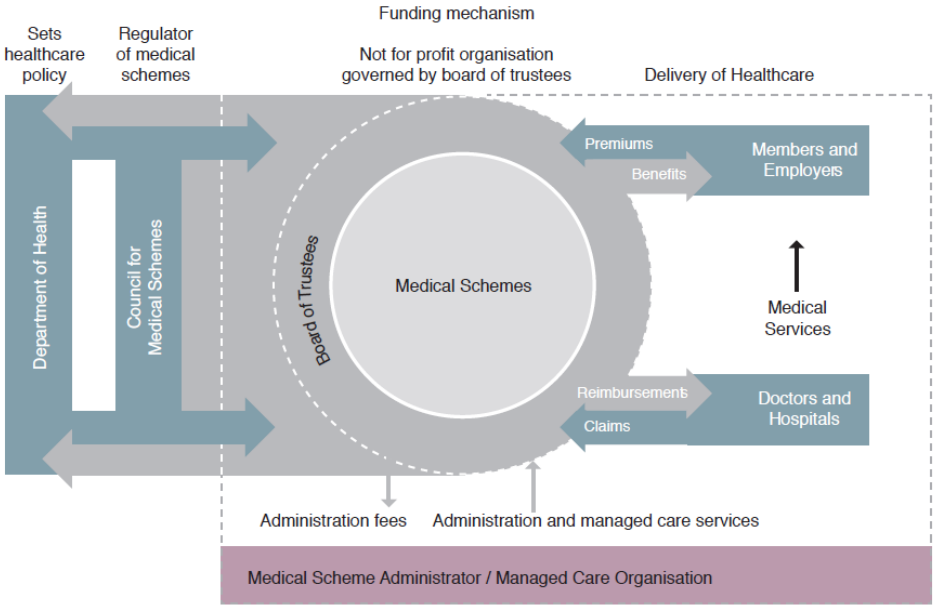
HTA is a range of processes and mechanisms that use scientific evidence to assess the quality, safety, efficacy, effectiveness and cost effectiveness of health services. HTA is commonly applied to pharmaceuticals, (including vaccines), diagnostic tests, medical devices, surgically implanted prostheses, medical procedures and other health interventions and programs. Questions to consider when preparing for market access is the following: Is it safe? Does it improve health outcomes? Is it cost effective? Is it affordable? Do benefit changes need to be affected in order to accommodate the technology?

Not all products will go through the HTA process and this document will provide a road map for various types of applications. It is highly advantageous to lobby for support from the prevailing society of doctors that will be using the technology, if an HTA is required.

To engage efficiently and effectively it is strongly recommended that suppliers familiarise themselves with the structure of the SA private payer industry and the relationship between stakeholders, namely, the medical scheme itself (core to the industry), the administrators and the managed health care/health risk managers (MHC/HRM) companies, as well as their respective roles and responsibilities, as this will define your market access strategy.

See Figure 1.
For example, an individual medical aid may contract to HRM to assess new technologies, who will make recommendations to their client schemes. Each HRM may, however, have its own application process and documentation that one has to be cognisant of and that has to be followed or completed.

Figure 1



Source: Mark Brand

The core of the private funding industry is the medical scheme, a non-profit organisation that provides benefits to members according to scheme rules and level of contribution. The scheme is managed by a board of trustees responsible for governance and ensuring that member interests are best served.

The board of trustees is responsible for the sustainability of the scheme, based on the financial position of the scheme and benefits in the options of the scheme.

The Council for Medical Schemes (CMS) is the regulatory authority responsible for overseeing the medical schemes industry and to protect the interests of medical schemes and their members.
The Board of Healthcare Funders (BHF) of South Africa is the representative organisation for medical schemes with a mandate to lobby other stakeholders effectively and influence policy where necessary on behalf of the industry.

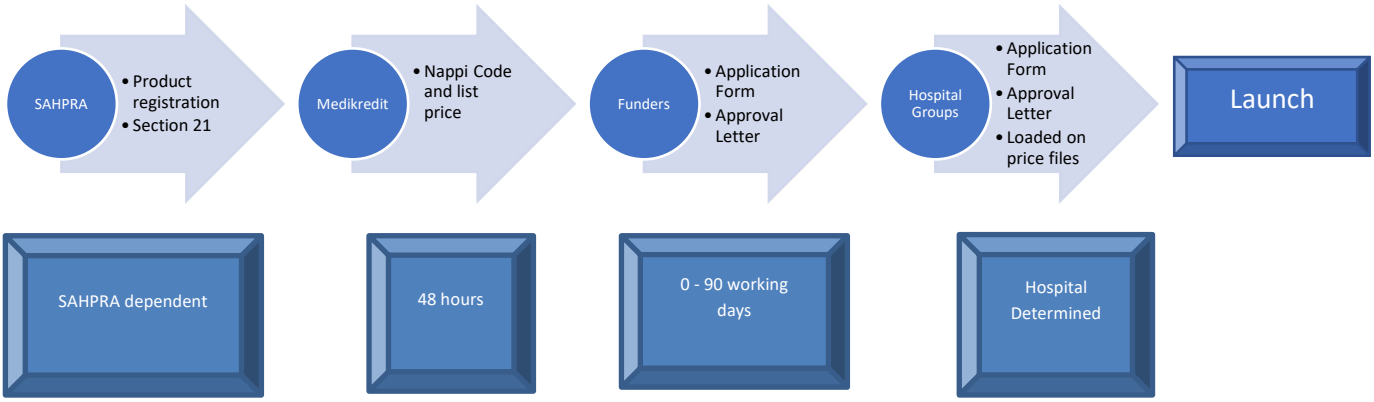
Medical schemes either own (in house) or sub contract (outsource) administration and/or managed health care services. The administrator registers members and beneficiaries of the scheme, manages collection of contributions, capture of authorisations, captures claims for claims processing, financial management tasks such as bookkeeping and reporting, and manages brokers where the scheme uses brokers. The managed healthcare organization (MCO) performs clinical and financial risk analysis, prospective and/or retrospective management of utilization of services (including hospital admissions, burden of disease, drugs, provider networks, preventative programmes, provider negotiations and technology/devices) and develops clinical management programs based on evidence based healthcare principles.

It is strongly advised to determine your reimbursement strategy upfront and manage expectations along the “short and scenic route” or “long and windy route”. These scenarios are illustrated by the flow diagrams below:

“Short and Scenic route”:

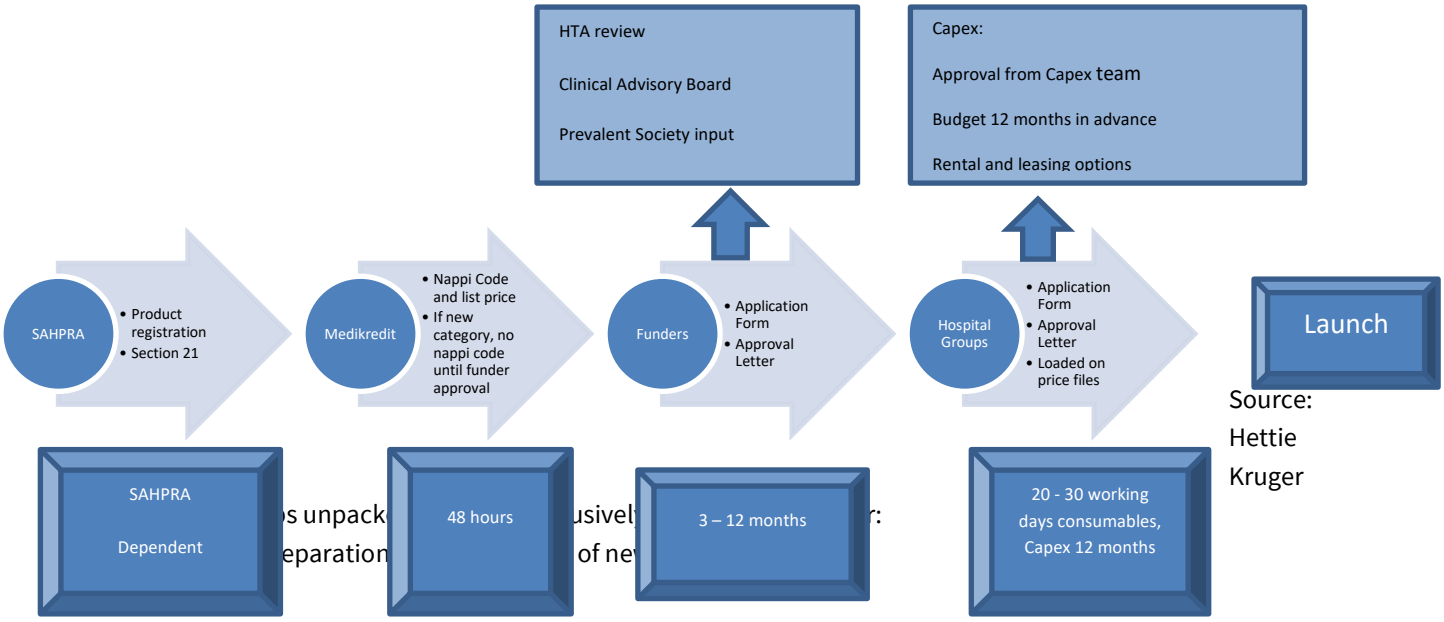
High Level Schematic Reimbursement Pathway

New technology/me too products that fall within or below the "current average pricing" bracket in



"Long and windy route":

New technology that is more expensive than the "current average pricing" in the private market – HTA involvement (see section 2. HTA Guidance for Achieving Reimbursement)



Source: Hettie Kruger

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- Suppliers are advised to become familiar with the Acts, Regulations and Guidelines that influence the business landscape namely the Medicines Act, the Medical Schemes Act, the Medical Device Regulations and associated guidelines.
- Confirm product regulatory requirements, whether your product is a medicine, medical device/equipment, or border line medical device.
- Request proof of relevant registration / quality certification from the manufacturer (e.g. FDA; ISO; CE etc)
- Consider internal product management requirements i.e. storage; product positioning; inventory etc
- Investigate competitive landscape, comparator technologies and pricing. This is used / may be requested for comparator analysis by funders and hospitals.

Useful links:

- Medicines & Related Substances Control Act 101 of 1965 http://www.mccza.com/Publications
- Medical Schemes Act 131 of 1998 https://www.medicalschemes.com/Content.aspx?130
- Medica lDevice Regulations http://www.mccza.com/documents/4a9ef319GG40480_09-12-2016_Medical_Device_Regulations.pdf

1.2 Step 2: Licensing of establishment (if not already done)

- New companies entering the market are required to obtain an establishment license from the South African Health Products Regulatory Authority (SAHPRA) as either:
  - a manufacturer licence to manufacture, import or export medical devices or IVDs; or
  - a distributor licence to import, export and distribute medical devices or IVDs; or
- Trading without appropriate licensing is considered illegal

Useful links:

- http://www.mccza.com/publications/index/1?grid-page=1

1.3 Step 3: Private hospital groups vendor registration

- Supplier must be registered as a vendor before being allowed access to hospitals
- Supplier should approach each hospital (buying) group to request details of registration process and relevant application forms, which may have different requirements.

- Products will not be allowed to be introduced until such time that the supplier has access.

Useful links:

- http://www.suppliers.netcare.co.za/live/content.php?Session_ID=c3d9bcc90d5e44fe469db03766e69fe8&Item_ID=4661
- https://forms.mediclinic.co.za/productrequests/

1.4 Product (NAPPI) Code Application

- All (consumable/disposable) products, the cost thereof being claimed by providers (hospitals and/or health care practitioners) are required by law to have a unique NAPPI code.
- Equipment codes are not issued by Medikredit.
- Register with Medikredit as a supplier using the *Manufacturer Supplier Registration V13* form
- Be familiar with the *NAPPI Code Allocation Policy Version 2.7* and *Procedures for request for New NAPPI codes*
- Complete form *Surgical NAPPI Request Template v13* providing relevant information for surgical devices; refer to the non-surgical template for anything other than surgical devices.

Useful Links:

- https://www.medikredit.co.za/index.php?option=com_content&view=article&id=13&Itemid=169

1.5 Payer / Funder approvals

1.5.1 Consumables/disposables

- This step will determine the complexity of the application, information requirements and duration of the process.
- New products will usually be classified and assessed as to whether it should be:
    - Auto approved:
        - Me-too technology (clinical outcomes same and price same or lower than comparator)
        - Me-too technology (somewhat higher price than comparator, benefit caps may exist, not classified as PMB)
    - Escalated to HTA:
        - New Innovative Technology (higher or same price as comparator)
        - Capital equipment and consumables
        - Me-too but with new technology inside, at a price premium
- Various strategies can then be followed that could lead to a successful reimbursement and market adoption outcome
- Following NAPPI code approval Discovery Health Administrators will proactively contact supplier via their Pharmaceutical Benefits Management department (PBM) PRICE_AND_PRODUCT_FILE@discovery.co.za who will provide a template requesting further product information
- The technology will be classified according to the Discovery classification system (classification algorithm available on request), which is generally based on product functionality; this information will include pricing
- Purpose of classification is for reference pricing

1.5.2 Billing code for new equipment

- Equipment used in hospitals and/or in the health care practitioners (HCP) practice may need a billing code
- Investigate if a billing code exists that applies to the new technology
    - If owned and used by HCP contact SAMA or ask a HCP
    - If owned and used by a hospital contact, relevant private hospital or refer to the private tariff list available from Mediclinic (link below)
- If a new code is required, this should be initiated by the respective user group e.g. HCP or Hospital; suppliers cannot apply for a code, it needs to be done via one of the above
- A new technology that is equipment will likely undergo the relevant HTA

Useful links:

- http://www.mediclinic.co.za/Portals/0/Documents/Patients/_root/Private%20Tariff%20Schedule%202017.pdf
- https://www.samedical.org/

1.5.3 Product classification

- Review processes applicable to various product types

1.5.3.1 Auto approval

- Applies to:
  - Me-too technology (clinical outcomes same and price same or lower than comparator) or
  - Where a mandate for the organisation exists to authorise payment up to a cost
- Should the product be found to fall within an existing category of device and within the reference price band of said device (calculated based on the average claims price of all devices within the category) it will be automatically (auto) approved

1.5.3.2 Price negotiation

- *Me-too technology (higher price than comparator) – Product review, cost effectiveness review and* price negotiation (Pin Process – Discovery)
- Should the product be found to fall within an existing category of device but at a premium to the reference price band of said device (calculated based on the average claims price of all devices within the category) it will be "pended" and a request will be made to the supplier
- Discovery iSEM team to complete a product information notification (PIN) form calling for further information on the product that might justify the premium price
- Should a dispute still remain regarding pricing then negotiations on price will follow, with reference to the average claims price in the relevant category of product

1.5.3.3 Health Technology Assessment

- New technologies are escalated to HTA when the following applies:
  - New Innovative technology – Product review, Cost effectiveness review and price negotiation – HTA
  - Capex and consumables – Product review, cost effectiveness review and price negotiation – HTA
- Price negotiations may still be entered into after HTA and economic evaluation
- Formal HTA processes exist with the following:
  - Discovery
  - Medscheme
  - MMI (Metropolitan/Momentum)
  - MSO
- The supplier should request respective templates where they exist and complete them
- As payer / funder templates and type of information required might differ it is recommended these are completed and followed as soon as possible by a full HTA submission dossier
- The HTA submission dossier is discussed in the next section

1.5.4 Approved product lists (APL)

- Letters confirming outcomes of HTAs will be sent to suppliers from respective funder
- An APL will be sent to suppliers confirming/declining reimbursement and listing all relevant product and nappi codes
- APL's are also shared with the hospital groups

1.6 Hospital group approval

- Majority of hospital groups require a letter from a funder to confirm reimbursement of the product
- Each hospital group has their own application document that has to be completed
- As with the funders, it is recommended the respective new technology application forms are completed but also include the HTA submission dossier

- Capital equipment has a specific additional process to be followed by each hospital group that could entail face to face meetings and presentations, as well as specific documentation that has to be submitted

2. Health Technology Assessment Guidance for Achieving Reimbursement

This guideline is intended to assist SAMED members with completing applications for reimbursement by medical schemes / administrators. It is based on the various funder and / or private hospital processes / application documents and gives some explanatory notes under various sections. We recommend that to become familiar with terminology used in HTA the following links are used to find various glossaries of terms.

- https://www.nlm.nih.gov/nichsr/hta101/ta101013.html
- www.who.int/health-technology-assessment/about/Glossaries/en/
- www.htaglossary.net/HomePage

The major sections in a typical dossier should comprise the following as per **Table 2**.

Table 2

Steps	Main Sections
1	Executive Summary
2	Applicant Details
3	Clinical Review
4	Technology Review
5	Economic Review
6	Organisational/Operational, Legal, Social and Ethical Review
7	Conclusion
8	Appendices

Preparation recommendations:

- Start the process of engaging funders at least 6 months pre-launch to ensure your products are reimbursed prior to entry onto the market.
- This should include preliminary discussions with funders to anticipate length of time to decision making and understand unmet need/s.
    - This application dossier is applicable to new products as defined below i.e.
    - any product with a new active ingredient/molecule/function of an existing product with a new indication/new use/function of a product with no existing comparator on the market
    - a product that makes a claim to cause improved clinical outcomes and/or superior efficacy (it should be the supplier's prerogative to submit any product for evaluation that may draw the attention of the funder to a technology with equivalent or improved effectiveness at the same or reduced price)
    - an innovative product that did not exist before

- The purpose of this application document should be to:
    - Generate a dossier of information that may be used as a tool for informing "all" stakeholders:
        - Funders
        - Hospitals
        - Internally
        - State
    - Consolidate all relevant information into a single source that will help expedite a decision
    - Avoid information dumping

These guidelines should be read in conjunction with the proposed dossier template. See Appendix: HTA Submission Template.

Executive Summary:

This could be the make or break of the submission and should capture all pertinent information contained in the submission as reflected by the headings below – do not repeat the headings but follow the same flow of the document.

The reviewer should be able to get a good feel of the content after reading this summary and should be able to point to sections of the dossier that are of most relevance and/or of interest.

When writing the executive summary, one should:

- Assume the reviewer is short of time
- Should be no more than 3 pages
- Tell the value story, based on the evidence and stakeholder unmet needs
- Let the reviewer know what information is in the document

The summary should embody the value proposition made to funders and other stakeholders, i.e. demonstrate what potential savings might be achieved with improved outcomes. All claims should be supported by the relevant (best available) evidence (based medicine) and price (i.e. you are obliged to provide cost detail).

The summary should follow:

- Description of the clinical problem, who it is intended to treat, the extent of the problem (epidemiology), what it is intended to replace (why is it better) or complement and what are the relevant outcomes.
- Description of clinical indications and the benefits of adopting the new technology – where it is used, what is the need and why?
- Brief reference to best available clinical evidence – what proof is there?
- Description of technology – what it does and how it does it?
- Pricing information – what is paid for it?
- Summary of economic value as demonstrated by economic analysis (i.e. cost effectiveness analysis and/or budget impact).

The executive summary should include a request to meet should it be necessary to have the opportunity to explain the technology in support of this submission.

2.1 Applicant Details:

Complete as per template – contact information is very important for future contact between the submitter and reviewing organisation.

2.2 Clinical Review

The PICOS analysis is a framework very well understood by epidemiologists and HTA assessors and provides a structured approach for submissions. It provides a good summary of the information of interest to assessors.

P	Patient, population and/or problem	Who does the technology apply to?
I	Intervention	Which main intervention, prognostic factor, or exposure is being considered?
C	Comparison or existing intervention (if appropriate)	What is the main alternative that is being compared to?
O	Outcome measured or achieved	What is intended to accomplish, measure, improve or effect? Clinical outcomes, costs, process efficiencies, combinations of these etc

S	Setting	Hospital, GP practice, Specialist discipline (mention discipline(s0), outpatients, Psych ward, Renal unit, associated providers (mention e.g. physiotherapy, psychotherapy, etc), dental…etc

It is useful to describe the health condition in a population the new technology is intended to treat as it solicits a response by payers to the problem condition and by describing shortcomings in current treatments it reinforces the opportunities for the new technology.

Acquiring epidemiology information assists with understanding the potential for this new technology and describes the business opportunity, useful for business planning and objective setting. It could be used as a measure for utilisation uptake, particularly for equipment and calculation of tariffs. This should include incidence (number of new case reported every year) and prevalence (the number of people living with the condition).

It describes what the potential impact may be on the funder, and may differ by funder depending on the disease profile this technology is meant to treat across the funder population i.e. an older population may be higher risk and younger, vice versa. It is recognised that this information is very difficult to get in the local context but if there are international burden of disease studies, in the absence of local, this could be used as a basis for extrapolation to the local situation. It is strongly recommended that methodology used to determine epidemiology data is properly referenced.

A lot of time is spent by reviewers trying to understand why the necessity to change from current standard of care and could be what most of their time is spent on. Assume that they will consult local peers (ideally) to investigate local clinical necessity of a new technology.

A comparator could be an existing procedure, (e.g. aortic valve replacement) other technology (e.g. standard aortic valve), drugs, watchful waiting (i.e. doing nothing).

If the applicant does not include this, it is left to the reviewer to make this determination, and it could be wrong. The comparator is typically the “control” versus which the new technology, the “test” is being evaluated.

A comparator could be your own product, or the standard of care. It is important to note that standard of care internationally may not be the same in South Africa so caution should be exercised with regards selection.

It is useful to include a literature review that illustrates the evolution of the new technology from early safety and efficacy studies, through comparative effectiveness studies to registry studies, where available, and the key outcomes. This could include reference to early animal studies and case studies/series, abstracts, press releases, although these are unlikely to be considered in the final appraisal process of the evidence. These studies should be published in peer reviewed journals (e.g. NEJM/Lancet/BMJ/JAMA etc)

Note that technologies that have received FDA clearance (i.e. pre-market approval - PMA) should mean that at least phase 3 trial data exists where comparisons have been made with regard to efficacy and/or effectiveness.

Applicants should however identify only what is considered the “best” available evidence and summarise accordingly in this tabulated format as per the template;

Author/s & Publication	Study Title, Type and Grading	Study design	Results/Conclusions
Last name, initials et al; Journal name;	Full study name As per hierarchy of evidence (e.g. Meta-	Where (single/multicentre), who (what type of	Key outcomes measured;

Date, page number etc	analysis; systematic review; RCT, Observational, etc) Level/grade of evidence	patients), how many (sample size n=?), what was studied (outcomes of interest), follow up	statistics of test vs control, P value and CI;

Electronic versions of original articles must be provided. Animal studies, case studies, case series and news articles will not be considered.

It is also of interest to list any trials under way concerning the new technology. These may generally be found on https://clinicaltrials.gov/ under the US National Library of Medicine.

Applicants should include any reference to recommendations/guidance based on assessments already completed by international HTA agencies such as NICE. This should be used with caution as economic information, while interesting, may not be generalised to the South African context.

It is highly recommended that the relevant speciality group is consulted prior to submission for guidance on their position of the new technology in the local context.

This should ideally lead to their producing a formal consensus position statement on the technology, with a view to supplementing this with the creation of a new clinical guideline or incorporation into an existing guideline. This is to support the decision-making process by funders, particularly with respect to patient selection and training.

There is a role for funders' medical departments to co-develop South African relevant guidelines and algorithms for devices and interventions and tests that are newly introduced by a health service discipline. Poor quality evidence may be supplemented by expert and consensus opinion's from local specialities and it is advised that this approach is used to offer the funder an alternative reference point.

2.3 Technology Review

This section should tell the reader everything about the technology, drawn largely from product fact sheets, instructions for use i.e. what it does and how it does it (i.e. mode of action and/or sequence of operation). It is important to indicate if the technology includes equipment and associated consumables, or either or.

Indications, contra-indications and relevant warnings and user related guidance should be listed. User types (health care professionals) and where the technology will be used must be explained. Explanations of any training strategy is of utmost importance, as this is also a determining feature for where and how it may be funded. Warnings are important as it describes level of clinical risk that is involved and this is often expected by reviewers and also talks to the expected skills requirements by users and consequent training programs.

Where possible, relevant coding information relating to the diagnosis (ICD10 – what condition is being treated) and the procedure (RPL/CPT – consultation, test or intervention code as to how the condition is being treated) must be supplied. This information provides relevant information for reviewers/funders to determine the relative prevalence of the condition within their population and how often and how it is being treated respectively. Include the base tariff on 2006 RPL if at all possible. If a service code (e.g. RPL or CPT or CCSA) does not exist, it will be valuable if this is indicated.

A key component to this is to include any information on international and local (if applicable) registration status details (as per the table provided) – please mark what is not relevant, but note that without registration from any of these international jurisdictions the submission will not be accepted. If a device has been registered in any of the other major markets other than stated then please include under other. It adds value.

It is also important to note the licensing and registration status of the importing establishment and product respectfully, as per the new South African medical device regulations.
Copies of all certificates should be provided where applicable.

2.4 Economic Review

This section should include all relevant product costs, as per NAPPI code, for all consumables/disposables. A price list could be provided in the body of the submission or as an appendix.
Here one needs to simply list all items and respective costs. If the consumables have multiple applications you could go a step further and list the typical consumables used per application. It gives the reviewer an insight into how the suppliers position the technology.

If this technology includes an equipment component then it is useful to calculate an appropriate tariff that should be charged to recover the cost of the investment, and is especially relevant to a hospital group as they typically negotiate an equipment fee with funders. Also reference utilisation rates (use sources described in your epidemiology analyses) according to anticipated number of cases per month using the equipment (utilisation should not exceed equipment capacity).

Operator costs and floor space occupied are typically excluded as inclusion will require more sophisticated modelling, not to mention doubtful access to this sort of hospital information. The simple model shown below is driven by utilisation and is most sensitive to increase/decreases.

EQUIPMENT (insert equipment name			
Capital Purchase Price (in Rands)		R580 000.00	Total price paid for the equipment including VAT
Annual Maintenance Contract	5%	R 29 000.00	Total price paid for the Annual Maintenance Contract
Useful Life of Equipment (in months)	60	R116 000.00	Lifetime of the equipment in months e.g. 36-60 months
Expected Return on Capital Amount (per annum)	15%	R 87 000.00	Average ROI on the capital amount i.e. what (before tax) interest can be earned from alternative investments?
Utilisation (cases per month)	140		Number of times the equipment will be used
Fee per use:		R 138.10	Proposed tariff for the equipment (or the income per case the institution will have to generate to cover the capital cost

Calculate an appropriate tariff for the use of the equipment; utilisation rates to be referenced according to anticipated number of cases per month of the equipment (utilisation should not exceed equipment capacity). Operator costs and floor space occupied are excluded.

Equipment ownership may be indicated as a determining factor for who is to be reimbursed.
Direct treatment costs are costs that are considered from the perspective of the organisation reviewing the technology i.e. applicants to confirm which costs to be used.

These may include:

- all medical costs falling directly on the health service (e.g. extra consultations generated, extra procedure costs, hospital costs, drugs, devices, staff, providers, lab etc) – include upstream and downstream costs relating to patient workup (pre-surgery e.g. diagnostics tests) and downstream costs (post-surgery e.g. physiotherapy/rehab).
- All non-medical costs that fall on patients and families (e.g. out of pocket expenses, travel, informal nursing) or on

employers (e.g. productivity or days absent from work). It may be good to reference but are not usually considered in an evaluation of this type. Note that indirect and intangible costs are not normally included, but is of value in closed schemes where there is close integration between the employer's HR policy and the scheme benefits.

All sources to costs above to be referenced appropriately.

It is advisable to include any relevant economic studies that have been conducted locally and internationally, failing which you may be asked to submit some basic information. This usually provides information on the cost effectiveness of a new technology over an old one but since local cost effectiveness data is difficult to access, assumptions need to be suitably referenced. It is deemed appropriate to use effectiveness data from international trials but cost data will have to be researched and determined locally. Direct cost data will usually be limited to hospital data (made up of ward days stay, theatre time and use of resources i.e. drugs and devices etc). Indirect cost data is for the most part not relevant to funders as it is typically not funded by them i.e. many costs outside of the hospital event and productivity costs.

It is useful to present an outcomes summary of each trial, or the best RCT (i.e. you may have more than one trial in this table as below) as this is what reviewers (especially clinical researchers) like to see at a glance (this the type of information that could also go into the Executive Summary AND/OR Value Proposition).

The ratios on the right i.e. absolute risk ratio (ARR), relative risk ratio (RRR), odds ratio (OR) and numbers needed to treat (NNT) respectively describe the clinical value between different interventions. This data is typically available from trials that have compared the new versus old and should reflect how effective the new technology is versus current treatment as per the chosen or desired outcome. This provides inputs into any economic modelling that you may choose to do and present.

Group	Description of HT	# Patients Rx	Outcomes	Measure	ARR	RRR	OR	NNT
New HT (Test)								
Comparator 1 (Control)								
Comparator 2 (Control)								

It is accepted that the required information may not be easily accessible. Please supply as much information as you can and expect that funders may require more information or specific interaction on this section.

It may not be necessary to perform an economic evaluation unless specifically required by the funder, but notwithstanding a variety of analysis that do exist (see below). It is recommended that at least a CMA or CEA is performed, supported by a budget impact and sensitivity analysis. There are 3 types of economic analysis one can do that will interest the funder:

- One or more of:
    - Cost-benefit analysis |CBA)
    - Cost effectiveness/utility analysis CEA/CUA
    - Cost minimisation analysis CMA
    - Budget impact analysis BIA
    - Sensitivity analysis

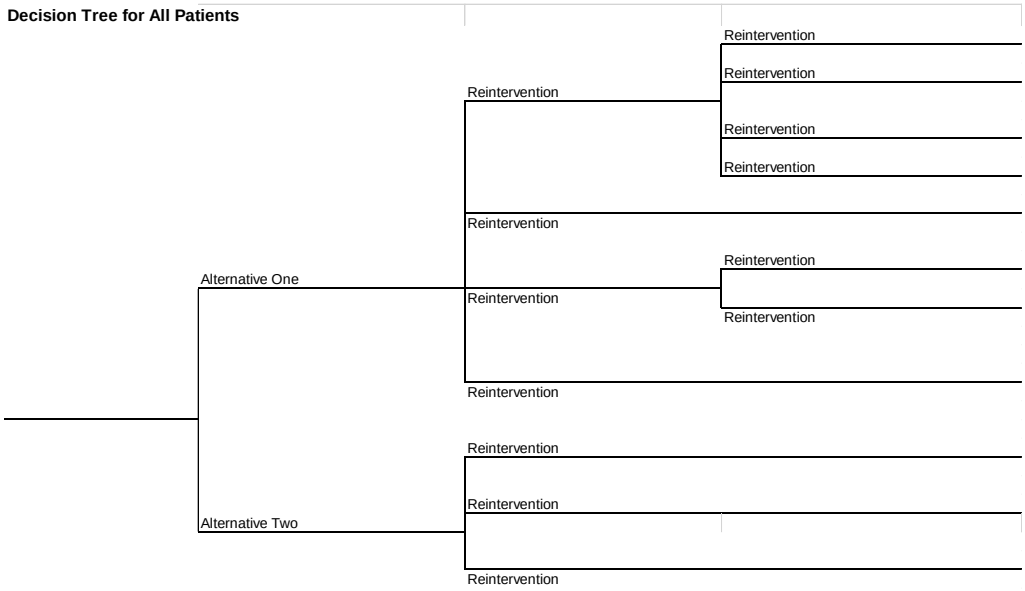
One can only conduct a CBA and/or CEA and/or CUA if a comparative study has been conducted i.e. a randomised or non-randomised controlled study that will provide outcomes of the new technology versus the comparator (as per the table discussed previously) expressed in relative gains or improvements in the condition being treated etc.

A BIA should represent the respective cost impact on the population being treated, subject to level population demographics, relevant epidemiology and level of adoption, between the new technology and the comparator. This is frequently not possible, but very valuable for decision making, where it is possible.

It is accepted that the required information may not be easily accessible. Please supply as much information as you can, and expect that funders may require more information or specific interaction on this section.

A sensitivity analysis provides information on how sensitive the model is to relative changes to any of the input variables e.g. price of the technology being reviewed.

Decision modelling may be conducted to predict costs over time as per the example below:



2.5 Organisational/Operational, Social and Legal Review (optional):

This section represents the softer but important values of the application and talks to the other key benefits to patients and society at large, founded upon the legal framework where relevant. It allows for a bit of "journalistic license", where the writers can express the true value of the new technology. It must be factually correct.

2.5.1 Legal Considerations

In respect of the technology under review, please comment on:

- Issues related directly to the technology in question such as patent licence issues, regulation, price controls, product safety, guarantee and liability issues, restrictions on marketing the technology directly to patients, etc:
- Issues related directly to the patient and his/her basic rights and freedoms, such as autonomy, informed consent, privacy and confidentiality, etc:
- Issues related to health care policy at the funder, local or national Government levels, etc:

2.5.2 Societal Considerations

In respect of the medical or surgical intervention under review, please comment on:

- What resources (staffing, funding etc.) must be allocated to ensure satisfactory outcomes when the technology is used in the appropriate healthcare setting?
- What resources (people, support, funding etc.) must be allocated when the technology is used post-hospitalisation, either at home or in the work place, to ensure satisfactory outcomes?

Appendix: HTA Submission Template

This template has been prepared for SAMED members to use when making applications to Funders for reimbursement of new medical technologies.

1. EXECUTIVE SUMMARY

2. APPLICANT DETAILS:

Name of manufacturing company or local distributor:

Sole Supplier of Brand: | YES | NO | (X applicable box)

Postal Address (Manufacturer):		**Postal Address (Distributor)**:	

	Primary Contact	**Secondary Contact**
Name		
Title		
Telephone		
Cell Phone		
E:mail		
Fax		

Please select one or more boxes that best describe your product: (x Boxes)

- [ ] Medical / surgical device
- [ ] Capital equipment
- [ ] In Vitro diagnostic test
- [ ] Screening test
- [ ] Pathology test
- [ ] Procedure
- [ ] Device-drug combination
- [ ] Single-use item
- [ ] Resposable item (indicate number of limited re-uses)
- [ ] Re-usable item

Type of submission (x Box)

- [ ] ***Original application (****a new application never previously submitted)*
- [ ] ***Re-submission (****submission of new information for a technology already evaluated)*

This application is comprised of: (x Box)

- [ ] Paper
- [ ] Electronic
- [ ] Paper and electronic (preferred, e.g. dossier + CD ROM)

Date of submission:

_____

Launch date in South Africa:

_____

3. CLINICAL REVIEW:

3.1. Population profile (epidemiology: incidence/prevalence)
3.2. Interventions and unmet clinical need/s
3.3. Comparator analysis
3.4. Outcomes Summary
3.5. Clinical flowchart or algorithm (where available)
3.6. Setting
e.g.

Group	**Description of Technology**	**# Patients Rx**	**Outcomes**	**Measure**	**ARR**	**RRR**	**OR**	**NNT**
New HT (Test)								
Comparator 1 (Control)								
Comparator 2 (Control)								

3.7. Literature review
3.8. References to local and international guidelines
3.9. References to international HTA agencies
3.10. Clinical evidence summary:

Author/s & Publication	Study Title, Type and Grading	Study design	Results/Conclusions
Last name, initials et al; Journal name; Date, page number etc	*Full study name* *As per hierarchy of evidence (e.g. Meta-analysis; systematic review; RCT, Observational, etc)* *Level/grade of evidence*	*Where (single/multicentre), who (what type of patients), how many (sample size n=?), what was studied (outcomes of interest), follow up*	*Key outcomes measured; statistics of test vs control, P value and CI;*

3.11 Clinical Trial Register:

Register Number	Type of study	Study design	Estimated completion data
	Meta-analysis; RCT; observational; registry etc	*Where (country/countries; single/multicentre), who (what type of patients), how many (sample size n=?), what is being studied (outcomes of interest), follow up etc*	

4. TECHNOLOGY REVIEW:

4.1. Technology Description
4.1.1. Product components
4.1.2. Mechanism of action/operating sequence

4.2. Indications for use:

4.3. Contra-Indications for use:

4.4. Warnings and user-related guidance:

4.5. Health care professionals who will use and/or administer the technology:

4.6. Training requirements for relevant health care professionals:

4.7. Health care setting where the intervention will be delivered: (x box)

Primary care (e.g. general practice)	
Specialist care	
Hospital theatre or ward	
Procedure room or outpatient facility	
Home care	
Other	

Relevant diagnosis	**Code(s)**	**Description(s)**
ICD 10 code(s)		
DSM VI code(s)		
NAPPI code(s)		
NHRPL code(s)		
CPT/ CCSA code(s)		

4.8. International registration(s):

Country	**Registration date and number**	**Registered indications for use**
USA (FDA)		
Conformité European (CE)		
Canada		
Australia (Therapeutic Goods Administration (TGA)		
Germany (HVN)		
Brazil ANVISA (National Health Surveillance Agency)		
Japan's Marketing Authorization Holder (MAH)		
World Health Organisation (WHO) for IVD's (Prequalification of In Vitro Diagnostics Programme		
Other		

4.9. South African registration (where applicable):

License type	**Yes/No**	**License number and Date of issue**
Establishment license		
Product registration		

5. ECONOMIC REVIEW

5.1. Consumable/disposable costs

NAPPI Code	**Product Code**	**Product Description**	**Recommended Selling Price (incl)**

5.2. Equipment:

5.2.1. Capital investment Annual maintenance

5.2.2. Depreciation factor i.e. expected life of equipment

5.2.3. Expected utilisation of equipment based on capacity

5.2.4. Expected return on capital

5.2.5. Proposed tariff/fee per use

5.3. Intended equipment ownership

Loan	
Rental	
User owned	

5.4. Direct Treatment costs:

5.5. Economic evaluation:

5.5.1. Cost effectiveness or cost minimisation analysis (CEA/CMA)
5.5.2. Budget impact analysis (BIM)
5.5.3. Sensitivity analysis
5.5.4. Decision modelling

6. ORGANISATIONAL/OPERATIONAL, LEGAL, SOCIAL AND ETHICAL REVIEW (Optional):

6.1. Organisational/Operational
6.2. Legal
6.3. Social/Societal
6.4. Ethics

7. Conclusion

3. SAMED Position on Reimbursement of Medical Technologies in South Africa

3.1 Globalisation of Reimbursement Systems

Most countries are struggling to find ways to address rising health care costs. Although governments recognize that there is no simple solution, many focus on the cost of medical technology as one of the contributing factors – despite its small share of each country's aggregate health care spending (generally about 6-7% of overall spending. Source: Global Medical Technology Alliance 2011). As they do so, governments consider a variety of policies regarding medical technology.

The last five years have seen a marked increase in countries looking outside of their own borders for classification, categorization and reimbursement policies to incorporate into their own health care reimbursement systems. Some of the efforts have involved wholesale importation of health care data or reimbursement systems, or aspects of those systems, from one country to another.

The principles below are intended to reflect 'model principles" to ensure that the policy goals underlying the development, adoption and implementation of reimbursement systems in South Africa result in the best value for patients and fosters innovation in the medical technology industry.

Table 1

	Principles
1	**Device industry is unique:** 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 devices in multiple service delivery settings.
2	**Transparency:** Reimbursement policies should be vetted and implemented in an open process, in which the decision-making criteria and process for implementation are fully disclosed in advance to stakeholders.
3	**Timing, notice and comment:** Payers / Funders / Policy makers should provide ample time and opportunity for stakeholders - including members of public - for notice and comment on proposed policies.
4	**Stakeholder role and input:** Payers / Funders / Policy makers should be required to disclose and discuss the input provided and consider this input in finalizing benefit and reimbursement decisions.
5	**Consistency:** Payers / Funders / Policy makers should attempt to adhere to a predictable schedule for proposed updates and/or system reforms.

6	**Best value:** A payment system should recognize the resources needed to deliver a group of services, or entire episode of care. The resources should be from well-established clinical guidelines, reflect the long-term value of medical technology and not focus on short-term costs.
7	**Use market competition to evaluate the domestic price of the product:** There should be an acknowledgement that market forces are allowed to operate to maximize efficiency and improve patient care.
8	**Reward innovation**: There should be an acknowledgement that resources are needed to encourage innovation, which provides continuous progress in patient outcomes.

3.2 Discussion of Principles

3.2.1 Device industry is unique:

Selection Methodology and Clinical Evidence:

Evidence appraisals for medical devices should include, but not be limited to, the best available evidence relevant to the technology under consideration. Appraisals should be pragmatic and consider non-randomized controlled trial and "real-world" data sources such as cohort studies with, for example, historic controls, case-control studies or observational data from registries, when assessing clinical effectiveness.

All relevant outcomes such as positive impact on cost-offsets (theatre time, duration of treatment, length of stay, blood loss etc), life years, quality of life, delivery/treatment setting, return to work data etc should be taken into consideration.

Reference to appraisals performed by international agencies should be treated with caution, as they are often performed with a specific perspective in mind, and may not be current. This is especially important when using economic data which are generally not transferable across markets.

Absence of highest level of evidence data should not be confused with absence of potentially significant value for patients, providers and payers.

Randomised controlled trials are regarded as the gold standard but may be inappropriate or inadequate, e.g.

- **Orthopaedic Implants** – Long-term follow up is needed and probably best accommodated by independent registries
- **Burn Therapy** – is it ethical to use an older, even if not obsolete technology as a comparator, when the psychosocial and employment impact of a serious burn injury can be lifelong?

Many other such examples exist. Depending on the nature of the device, and particularly where health economic arguments are being constructed, the following should be considered acceptable evidence:

- Cohort studies with historic controls in a population large enough to generate statistically significant results (Level III) and demonstrate an attempt to eliminate selection bias
- Systematic reviews and meta-analyses of published clinical results
- Reports provided by peer-regarded independent registries
- Publications in peer reviewed journals, with outcomes that are statistically significant

Local clinical trials should not be necessary if significant documented and validated international experience is available and if health economics components can be validated locally.

Local funder budget impact analysis may be hampered by an absence of reliable statistical information (e.g. epidemiology; clinical effectiveness and/or cost data); international and/or population based information may be referenced providing criteria are agreed to, or information from funder claims data should be provided on a confidential basis.

Knowledge databases. A variety of these are used, such as Hayes, Cochrane Collaboration, Medline, NICE, Asernip etc., but are not used consistently across all funders.

Each organization has a responsibility to provide all appropriate evidence (clinical and cost effectiveness and efficiency data) to funders of care. This evidence to be applicable to their requirements and discussed with relevant funder for appropriate approvals. Companies need to agree with funders which ones will be considered authoritative and the criteria that will be applied to supplementary clinical and health economics information provided between reviews. It remains the responsibility of individual companies to manage this engagement.

3.2.2 Transparency

A key element in any reimbursement system is transparency. Transparency calls for full public disclosure of the methods, criteria and rationales used to determine and adjust reimbursement rates, benefit levels, and market access. Transparency also demands timely disclosure in advance of changes to the particular reimbursement status, as well as the criteria and methods that will be used to make any changes.

3.2.3 Timing, Notice and Comment

The process should be clear, transparent and time-defined. Initial applications for reimbursement should be formally acknowledged by funders / payers, and should receive written notice of the outcome within a reasonable period (e.g. 60 to 90 days), together with an evaluation summary and relevant clinical and funding protocol.

Allowing for notice of proposed changes and opportunity for stakeholder comments are essential components of a successful reimbursement system. The concept of notice embodies formal channels for stakeholders to convey substantive, information regarding a proposed new or modified reimbursement policy. Publication of a draft policy should occur well in advance of policy implementation. The comment component, in reality public comment, refers to a meaningful opportunity to refine the policy before final decisions are made.

Essential elements are that notice is provided in advance of policy implementation, that proposed changes are described in sufficient detail to permit review by stakeholders, and that the comment period allows sufficient time for comprehensive comments to be developed and submitted. Notice and comment enables full disclosure and a balanced discussion of any changes that will potentially impact patients, physicians and industry.
An appeals process should exist to challenge negative decisions and the outcomes made known in less than the time for original appraisal (e.g. 30 days). All stakeholders should have the opportunity to participate throughout the process.

3.2.4 Stakeholder Role and Input

Payers / Funders and policy makers should allow all stakeholders, including industry, physicians and patient groups, an opportunity to provide a formal response and suggested refinements to proposed reimbursement policies.

Often, industry has the necessary expertise and experience to offer valuable insight into proposed policy initiatives and can offer suggestions or refinements that improve them. Industry may offer a perspective that may not be readily apparent to payers / funders / policymakers. When given an appropriate, proactive role, industry and other stakeholders can act as a valuable partner, providing crucial and beneficial policy refinements.

Giving industry an opportunity to participate in the policy process also encourages industry buy-in for the change. Industry's role should be ongoing, providing assistance with policy proposals in their early stage of development, comments and refinements in the later stages but prior to implementation, and input on periodic updates or refinements as they are formulated or considered.

Both health care professionals, experts from industry and payer organizations should be involved in designing the way in which a particular technology is assessed and appraised. Specialist user groups as well as industry representatives should be involved in the presentation of new health technologies for reimbursement, to inform and educate reviewers and to respond without bias to any clinical questions posed. Representation of local professional

societies would be beneficial if available and should accompany the submission of the HTA dossier. Industry experts and manufacturers should participate as equal partners.

3.2.5 Consistency

Consistency refers to a predictable model or cycle of updating policies or making refinements to payment methodologies that affect health care providers. The cycle or schedule of updates or refinements becomes more consistent when it occurs at specific, predictable intervals that are defined in advance. Inconsistency introduces uncertainty, which will tend to generate inefficiencies and hinder the optimal functioning of both the medical device market and the health care system overall.

3.2.6 Best value

The concept of *best value* embodies systemic incentives to encourage health care providers to deliver high quality care at a reasonable cost. Value is a function of both quality and costs. Patients cannot determine the value of care based solely on its cost, but must also consider the quality of the care provided. Cost should be based on the resources needed to deliver a group of services, or entire episode of care. The resources should be identified from well-established clinical guidelines. Episodes of care should be constructed based on clinical information specific to the condition or disease, not on artificially fixed time periods. Episodes of care to evaluate quality and costs should span a period long enough to capture all relevant information on both outcomes and associated costs.

A low initial price is not necessarily indicative of high or best value. Value needs to be assessed over time, with considerations for successful outcomes, rather than focused on costs of a single procedure or patient encounter. For example, a medical product that lasts longer may have an initially higher price, but may actually prove less expensive than another product when additional clinical benefits or product life are considered. To determine best value, a health care system should rely on timely and accurate data and comprehensive definitions, including consideration of recovery times, length of stay, lost productivity from days absent from work, and other factors contributing to the overall value of the health care provided.

Measures of value that are poorly designed or improperly configured over too short of a time period not only do not represent best value, but also may put patient health and technological innovation at risk. A reimbursement system that fails to incorporate appropriate systemic incentives for best value is likely to incur not only higher long-term costs, but poorer patient outcomes. Such an improperly designed system could inhibit the adoption of new and improved technologies, as value is underestimated. The use of best value principles that recognize benefits that accrue over an episode of care or the useful life of a product can better capture patient benefit and more accurately reflect real long-term costs.

3.2.7 Use market competition to evaluate the domestic price of the product

SAMED supports reimbursement systems that serve the needs of patients through open and fair competition between suppliers, and which reflect local market conditions. Reimbursement systems should not be barriers to patient access and to development and introduction of technologies by innovator companies.

All types of products exhibit a range of price variation, both within and between countries. Medical devices are no different in this regard, and may be even more distinct due to their range of complexity and the need for service and patient and physician training after the sale. Price variations occur both locally and internationally because of:

- Historic price levels;
- Currency exchange rates;
- Differences in retail margins;
- Differences in regulatory and product liability systems;
- Differences in costs of distribution, sales, service and overhead;
- Differences in health care structures and purchasing methods;
- Differences in product lines and types; and
- Differences in the available mix of competing products and treatment options.

SAMED proposes that managed care entities adopt market-based approaches reflecting the existing conditions in South Africa, to appropriately reimburse medical technologies, and to support innovation and ensure patient access to the most innovative therapies.

Where national epidemiology statistics and treatment outcomes data are not easily available in the public domain, payers and providers should be prepared to share local claims data for the population of relevant economic models that may be used to inform local pricing decisions.

This will improve the precision and relevance of any cost-comparative or budget impact analyses prepared and submitted to support a reimbursement decision.

3.2.8 Appropriately reward innovation

Reimbursement systems should encourage innovation to produce the best patient care. Such systems should include mechanisms for prompt recognition of new technologies as they come onto the market, without undue waiting times. These mechanisms should also have the capacity to recognize the additional clinical benefit that the new technology may provide. Technologies that are able to provide evidence of better outcomes or clinical benefit than existing products should be eligible to receive additional reimbursement. The standards and criteria that are required for eligibility for new categorization and additional reimbursement should be clearly enumerated, with criteria adopted based upon input from patients, the medical profession and industry.

Evaluations should not restrict access to new technologies that are proven to be safe but have limited effectiveness data, which often becomes available after being in use for a period of time. Absence of high level of evidence data should not be confused with absence of potentially significant value for patients, providers and payers.

This is especially important when considering devices intended for surgical use which are often associated with a learning curve effect whereby their effectiveness can only be properly evaluated once healthcare professionals have adjusted their practice to incorporate the new technology. The learning curve phenomenon and the continuous – often incremental – improvement process associated with medical device technology must be taken into account.

To support timely access to promising technologies that have limited but promising evidence of significant potential impact alternative funding mechanisms may be explored, such as “conditional reimbursement” or “coverage with evidence development” (e.g. registries). This would allow a technology to be funded for a period of time, during which effectiveness evidence is generated. This could initially be limited to restricted patient populations (indications), selected centers, with appropriately trained healthcare professionals, which offers a means to manage effectiveness uncertainties.

This will satisfy the legitimate needs of patients and healthcare professionals to have access to the most promising innovative technology and to simultaneously provide a stronger evidence base.

References:

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3. Medtech Europe: Six Key Principles for the Efficient and Sustainable Funding & Reimbursement of Medical Technologies, http://www.medtecheurope.org/sites/default/files/resource_items/files/6%20Key%20Principles%20for%20the%20Efficient%20and%20Sustainable%20Funding%20%26%20Reimbursement%20of%20Medical%20Technologies%20170509_0.pdf
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5. Global Medical Technology Alliance: HTA Position Paper, http://www.globalmedicaltechnologyalliance.org/papers/GMTA_HTA_PaperFinal-10-2012.pdf
6. Key principles for the improved conduct of health technology assessments for resource allocation decisions. Int. Journal of Technology Assessment in Health Care. 24:3 9(2008)