SAMED Position Paper and Guidance for Members
Market Access, Reimbursement and HTA pertaining to Medical Technologies in South Africa
August 2024 Version

Contents

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List of Abbreviations

ASERNIP	Australian Safety & Efficacy Register of. New Interventional Procedures
BIA	Budget Impact Analysis
CADTH	Canadian Agency for Drugs and Technologies in Health
CBA	Cost-Benefit Analysis
CE	"Conformité Européenne" (French for "European Conformity")
CEA	Cost-Effectiveness Analysis
CMA	Cost Minimisation Analysis
CMS	Council of Medical Schemes
CUA	Cost Utilisation Analysis
FDA	Federal Drug Administrator
GMDN	Global Medical Device Nomenclature
GMTA	Global Medical Technology Alliance
GTIN	Global Trade Item Number
HCP	Healthcare Professional
HE&R	Health Economics and Reimbursement
HRM	Health Risk Managers
HTA	Health Technology Assessment
ISO	International Standards Organization
IVD	In Vitro Diagnostic
MCO	Managed Care Organisation
MHC	Managed Health Care
NAPPI	National Pharmaceutical Product Index
NHI	National Health Insurance
NICE	National Institute of Clinical Excellence
PBM	Pharmaceutical Benefit Association
PMB	Prescribed Minimum Benefit
SAHPRA	South African Health Products Regulatory Authority
SAMA	South Africa Medical Association
SAMED	The South African Medical Technology Industry Association
WHO	World Health Organisation

Executive Summary

SAMED - The South African Medical Technology Industry Association - represents the interests of its members - South African Medical Device, Medical Equipment, and In-Vitro diagnostics ("IVD"), collectively termed medical technology, companies. SAMED's vision is to ensure a sustainable, diverse, transformed and ethical medical technology industry that enhances patient access to quality, safe and effective medical technologies.

SAMED is committed to providing the industry with a collective, objective, and credible platform for engagement with all stakeholders.

Medical Technology suppliers need to be familiar with the regulatory environment before launching a new business or medical technology. In order to access the South African market, companies selling medical technologies in South Africa have to obtain a SAHPRA licence to do so and must be ISO 13485 certified. The only current exemption from this requirement are companies selling only Class A non-measurable, non-sterile medical technologies.

SAMED has prepared this guidance document including an HTA template to assist SAMED members obtaining market access into the private health sector. It covers medical scheme reimbursement and HTA requirements as well as private hospital procurement processes for existing, 'me too' (medical technologies that have comparator already in the market) and innovative (novel) medical technologies.

The various medical schemes have various reimbursement and HTA processes and application forms for completion, with varying degrees of rigour, thoroughness, formality, and transparency.

This guidance document includes a dossier that aims to assist SAMED members in terms of the content of their applications for reimbursement or HTAs to medical schemes. We have attempted to take into account all the various medical schemes' application forms and requirements and 'harmonise' them into one dossier.

The private hospitals also have their own application forms, procurement processes and requirements and we have attempted to outline what these are.

Members are advised to ensure that persons who submit these application forms to providers (e.g. hospitals) and funders (e.g. medical schemes) are empowered with background knowledge and skills needed to interpret aspects covered in this document. SAMED suggests that members subscribe to the council for medical schemes distribution list, consider joining ISPOR and PTCMA 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.

SAMED urges members to use the GMTA's global medical technology reimbursement principles to underpin their engagements with medical schemes and private procurers. These principles are summarised in the next section.

1. Global medical technology reimbursement principles

Globalisation of Reimbursement Systems

Most countries are struggling to find ways to address rising health care costs. Although governments concede to no simple solution, much focus has been on the cost of medical technology as one of the contributing factors – despite its small share of each country's aggregate health care spend (generally about 6-7% of overall expenditure). As they do so, governments, private funders and procurers consider a variety of policies regarding reimbursement and procurement of medical technology.

Over the years there has been a marked increase in countries looking outside of their borders for classification, categorisation, and reimbursement policies to incorporate into their 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.

Medical Technology Reimbursement Principles

I.	**The medical technology industry is unique:** Processes, methodologies and expertise used in pharmaceutical evidence appraisals are not always applicable to medical technology, and no single approach should be applied to the diversity of medical technology in multiple service delivery settings.
II.	**Transparency:** Reimbursement policies should be vetted and implemented in a transparent process, in which the decision-making criteria and process for implementation are fully disclosed in advance to all stakeholders.
III.	**Timing, notice and comment:** Payers / Funders / Policymakers should provide ample time and opportunity for stakeholders - including members of the public - for notice and comment on proposed policies.
IV.	**Stakeholder role and input:** Payers / Funders / Policymakers should be required to disclose and discuss the input provided and consider this input in finalising benefit and reimbursement decisions.
V.	**Consistency:** Payers / Funders / Policymakers should attempt to adhere to a predictable schedule for proposed updates and system reforms.
VI.	**Best Value:** A payment system should recognise the resources needed to deliver a group of services for the 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.
VII.	**Use market competition to evaluate the product's domestic price:** There should be an acknowledgement that market forces are allowed to operate to maximise efficiency and improve patient care.
VIII.	**Reward innovation:** There should be an acknowledgement that resources are needed to encourage innovation, which provides continuous progress in patient outcomes.

Discussion of Principles: The device industry is unique

Selection Methodology and Clinical Evidence

Evidence appraisals for medical technology should include, but not be limited to, the best available evidence relevant to the technology under consideration. Assessments should be pragmatic and consider non-randomised controlled trial and "real-world" data sources such as cohort studies with, for example, historical 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, may not be current and transferable across markets.

The absence of the highest level of evidence data should not be confused with the 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.

a) Orthopaedic Implants – Long-term follow up is needed and probably best accommodated by independent registries.
b) 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 severe burn injury can be lifelong?

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

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

This is depicted in the following figure.

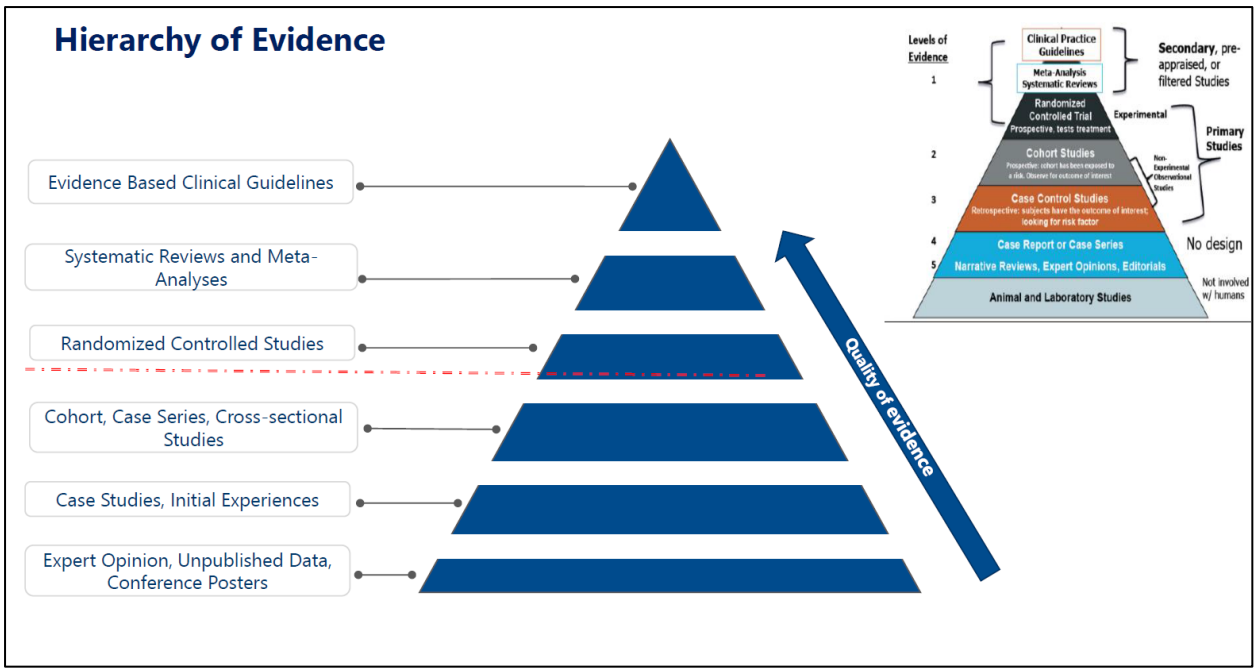


Figure 1: Hierarchy of Clinical Evidence
(Source: Hierarchy of Clinical Evidence, extracted from Discovery Health Centre for Clinical Excellence SAMED Update on 17 November 2020, slide. 11. See: Discovery health – Centre for clinical excellence)

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. The use of local patient registries to collect patients' pre-, peri- and post-procedural parameters can also be explored, e.g. SA orthopaedic registry, TAVI.

An absence of reliable statistical information may hamper local funder budget impact analysis (e.g. epidemiology, clinical effectiveness, and cost data). International and population-based information may be referenced providing criteria are agreed to, or the inclusion of funder claims data.

Knowledge databases and assessments by other HTA agencies: A variety of these are used, such as Hayes, Cochrane Collaboration, Medline, NICE, ASERNIP, INAHTA etc., but are not used consistently across all funders.

Each SAMED member is responsible for providing all appropriate evidence (clinical, cost-effectiveness and efficiency data). This evidence will apply to their requirements and be discussed with the relevant funder for approvals. Companies need to agree with funders which evidence will be considered authoritative, and the criteria used to supplement clinical and health economics information provided between reviews. It remains the responsibility of individual companies to manage this engagement.

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 and the criteria and methods used to make any changes.

Timing, Notice and Comment

Reimbursement and HTA processes should be clear, transparent and time defined. Initial applications for reimbursement should be formally acknowledged by funders and 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 approach 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 adequate time for comprehensive comments to be developed and submitted. Notice and comment enable full disclosure and a balanced discussion of any changes that will potentially impact patients, physicians, and the industry.

An appeals process should challenge adverse decisions and the outcomes made known in less than the time for the original appraisal (e.g. 30 days). All stakeholders should have the opportunity to participate throughout the process.

Stakeholder Role and Input

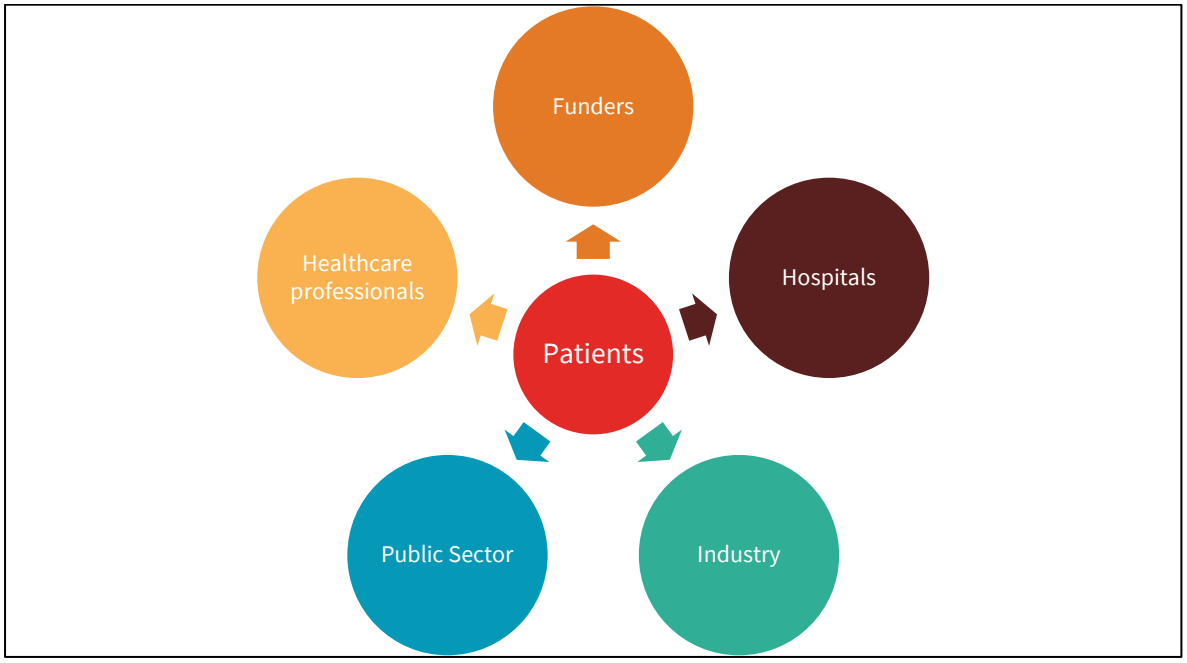


Figure 2: Stakeholder Mapping

Payers / Funders and policymakers should allow all stakeholders, including the industry, physicians and patient groups, an opportunity to provide a formal response and suggested refinements to proposed reimbursement policies, refer to Figure 2 for stakeholders to consider.

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

Allowing the industry to participate in the policy process also encourages industry buy-in for the change. Industry's role should be ongoing, assisting with policy proposals in their early stage of development, comments, and refinements in the latter stages but before implementation, and input on periodic updates or improvements as they are formulated or considered.

Both private and public health care professionals, experts from industry and payer organisations, i.e. a multidisciplinary team, should design how a particular technology is assessed and appraised. Specialist user groups and industry representatives should be involved in presenting new health technologies for reimbursement, informing, and educating reviewers, and responding without bias to any clinical questions posed. Representation of local professional societies would be beneficial if available and should accompany the HTA dossier submission. Industry experts and manufacturers should participate as equal partners.

Consistency

Consistency refers to a predictable model or cycle of updating policies or making refinements to payment methodologies that affect health care providers.

The process or schedule of updates or improvements becomes more consistent when it occurs at specific, predictable intervals defined in advance. Inconsistency introduces uncertainty, which will generate inefficiencies and hinder the optimal functioning of both the medical technology market and the healthcare system.

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 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 the 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 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 focusing 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 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. The total cost of treatment vs price should be included in the competitor price evaluation.

Measures of value that are poorly designed or improperly configured over too short of a period do not represent the best value and 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 recognise benefits that accrue over an episode of care or the useful life of a product can better capture patient benefit and reflect real-world, long-term costs. Value perceived from the patient (quicker recovery time, early return to work, reduction of pain) and value for healthcare facilities and surgeons should be considered. For example, the medical technology might enable the surgeon to include fewer steps in theatre technique which ultimately can reduce theatre time.

Cost offset modules should be included – whereby the cost of the device might be more, but due to the saving in theatre time, there is a cost offset between the premium of the product and additional theatre time.

Use market competition to evaluate the domestic price of the product

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

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

I. Historic price levels
II. Currency exchange rates
III. Differences in retail margins
IV. Differences in regulatory and product liability systems
V. Differences in costs of distribution, sales, service and overhead
VI. Differences in health care structures and purchasing methods
VII. Differences in product lines and types and
VIII. 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, appropriately reimburse medical technologies, and support innovation and ensure patient access to the most innovative therapies.

Where national epidemiology statistics and treatment outcomes data are not readily 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

data sharing will improve the precision and relevance of any cost-comparative or budget impact analyses prepared and submitted to support a reimbursement decision. Medtech suppliers are urged to reiterate this in their engagement with funders. A mechanism to address this needs to be developed and agreed upon by all parties involved.

Appropriately Reward Innovation

Reimbursement systems should encourage innovation to produce the best patient care outcomes. Such systems should include prompt recognition of new technologies as they come onto the market, without undue waiting times. These mechanisms should also have the capacity to recognise the additional clinical benefit that the new technology may provide. Technologies that can provide evidence of better outcomes or clinical benefit than existing products should be eligible to receive additional reimbursement. The standards and criteria required for new categorisation eligibility and additional reimbursement should be enumerated, with measures adopted based on patients' input, 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 some time. The absence of a high level of evidence data should not be confused with the absence of a potentially significant value for patients, providers, and payers.

These considerations are essential for devices intended for surgical use, often associated with a learning curve effect whereby their effectiveness can only be rigorously 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 technology must be considered.

Timely access to promising technologies that have limited but favourable evidence of significant potential impact can be supported by exploring alternative funding mechanisms, such as "conditional reimbursement" or "coverage with evidence development" (e.g. registries).
These alternative reimbursement models would allow a technology to be funded for some time, during which effectiveness evidence is generated. These models could initially be limited to select patient populations (indications), selected centres, with appropriately trained healthcare professionals, which offers a means to manage effectiveness uncertainties.

These alternative reimbursement models will satisfy patients and healthcare professionals' legitimate needs to access the most promising innovative technology and simultaneously provide a more substantial evidence base.

The quality of medical technology supplier submissions is closely related to the duration taken and successful decision by the managed care administrator/organisation regarding the funding of technologies.

2. South African Private Market Access Process

The South African Healthcare sector is dynamic experiencing regulatory and other changes; furthermore, as the healthcare sector transitions from a distinct 2- tier private and public-sector market to a National Health Insurance (NHI) system, a convergence of public and private sector activities is expected.

Health Technology Assessment (HTA) will play a pivotal role in how technologies gain access to the market in the future. Therefore, a basic understanding of the principal requirements for local HTAs is a primary and strategic imperative. HTA will typically be applied to a new class or category of medical technology or technology without a direct comparator currently in use. Emphasis is on maximising value through maintaining or increasing quality and maintaining or reducing costs.

The 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. As there is no central entity that performs HTA in a South African context, each organisation using HTA and developing policies sets its own specifications and rules.

HTA is a range of processes and mechanisms that use scientific evidence to assess health services' quality, safety, efficacy, effectiveness, and cost-effectiveness.

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

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 a new technology for market access include the following:

1. Is it safe?
2. Does it improve health outcomes?
3. Is it cost-effective?
4. Is it affordable?
5. Do medical scheme/funder benefit changes need to be affected to accommodate the technology?

Not all products will go through the HTA process, and this document provides a road map for different access pathways. It is highly recommended to lobby for support from the relevant professional society of doctors that will be using the technology if an HTA is required.

The local HTA process is usually an abbreviated one in comparison to NICE and CADTH but often requires that it be supported by international literature. After achieving medical administrator / scheme reimbursement approvals, technologies still need to pass through the respective private hospital approval process to complete market access.

Discovery Health, Medscheme, Momentum Health Solutions and Medihelp contract HTA services to medical schemes and have processes that use a systematic approach to assessing technologies.

This review may take a minimum of 3 months to a maximum of 2 years, should there be extensive economic modelling required. This lead time may be extended in the case of a decline i.e decision to exclude from benefits and reimbursement and subsequent appeal. Appeals may be entertained if they relate to interpretation issues of the original assessment, however, new clinical evidence may only be submitted 12 months from date of notification.

Products that enter the market at a competitive price to existing products are generally fast-tracked to market on an auto-approval basis. Alternatively, those falling into an existing reimbursement category at a premium price will require good evidence, be it clinical or other value-added features and benefits, to support the premium. Unique technology that does not fall into an existing category or products with a higher price than the benchmarking price is likely to be escalated to the next level of review, referred to as Health Technology Assessment (HTA) in South Africa. HTA supports funder protocol development. According to the Medical Schemes regulations, protocols must be developed based on evidence-based medicine (EBM), considering cost-effectiveness and affordability. EBM is the conscientious, explicit, and judicious use of current best evidence in making decisions about beneficiaries' care. Individual clinical experience is integrated with the best available external clinical evidence from systematic research.

New products 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 the 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 for which they provide.

For efficient and effective engagement, it is strongly recommended that suppliers familiarise themselves with the structure of the SA private payer industry and the relationship between stakeholders and their respective roles and responsibilities, as this will define your market access strategy. **See Figure 3**. The South African Healthcare Private Funder Landscape

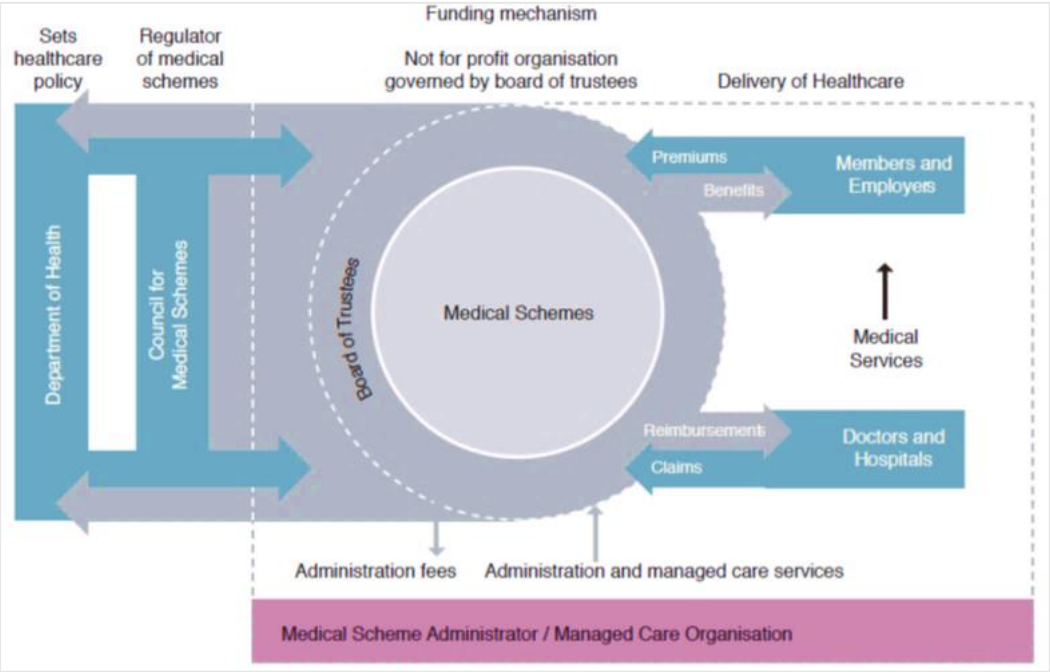


Figure 3: The South African Healthcare Private Funder Landscape (courtesy of Mark Brand)

For example, medical schemes may contract to a health risk managers(HRM), aka managed care company, to assess new technologies, who will make recommendations to their client schemes.

However, each HRM has its particular application process and documentation that one has to be aware of and which has to be followed or completed.

The core of the private funding industry in South Africa 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, elected by members, who are responsible for governance and ensuring members' interests are best served, including how member contributions are spent on benefits offered. The board of trustees is responsible for the scheme's sustainability, based on the scheme's financial position and benefits in the scheme's respective options.

The Council for Medical Schemes (CMS) is the regulatory authority responsible for governing the medical scheme industry and protecting medical schemes and their members' interests.

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. Established in 2015, the Health Funders Association (HFA) is a non-profit organisation representing stakeholders involved in the funding of private healthcare in South Africa. Full membership of the Health Funders Association is open to all medical schemes and administrators, while associate membership is open to managed care organisations. Medical schemes either own (in-house) or subcontract (outsource) administration or managed health care services. The administrator registers the scheme's members and beneficiaries, manages the collection of contributions, captures 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 organisation (MCO) performs clinical and financial risk analysis, prospective and retrospective management of the utilisation of services (including hospital admissions, the burden of disease, drugs, provider networks, preventative programmes, provider negotiations and technology/devices). It develops clinical management programs based on evidence-based healthcare principles.

It is strongly advised to determine your reimbursement strategy in advance and manage expectations along the "short and scenic route" or, the "long and windy route", scenarios of each as illustrated by the flow diagrams overleaf:

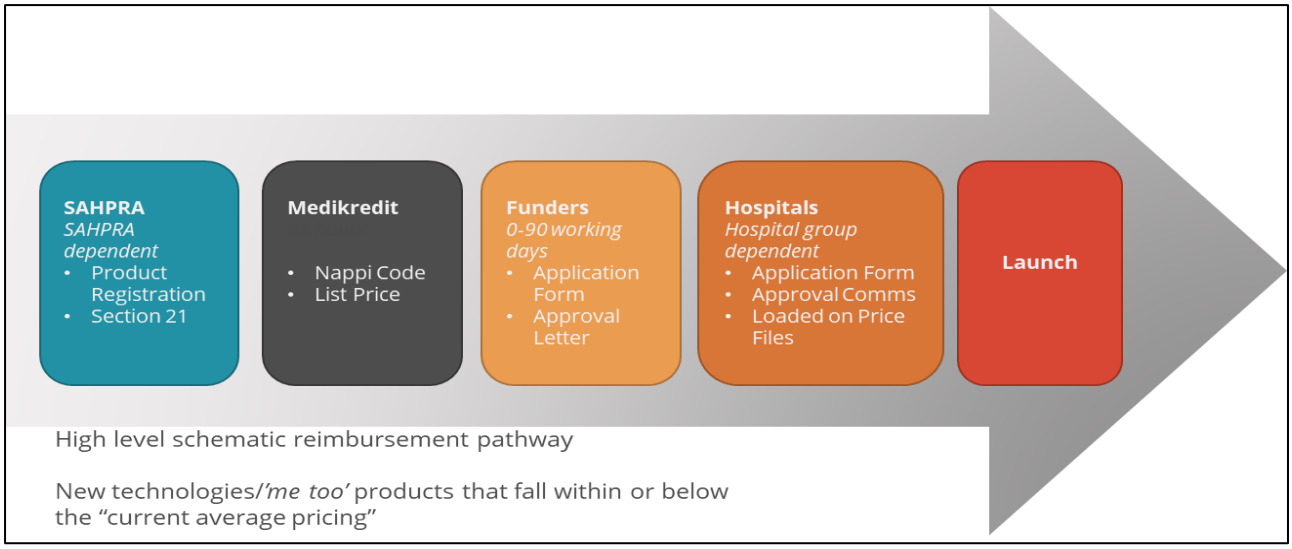


Figure 4: Short and Scenic Route to Market Access

Note, new technology takes a minimum of 12 months for approval at the Funder level.

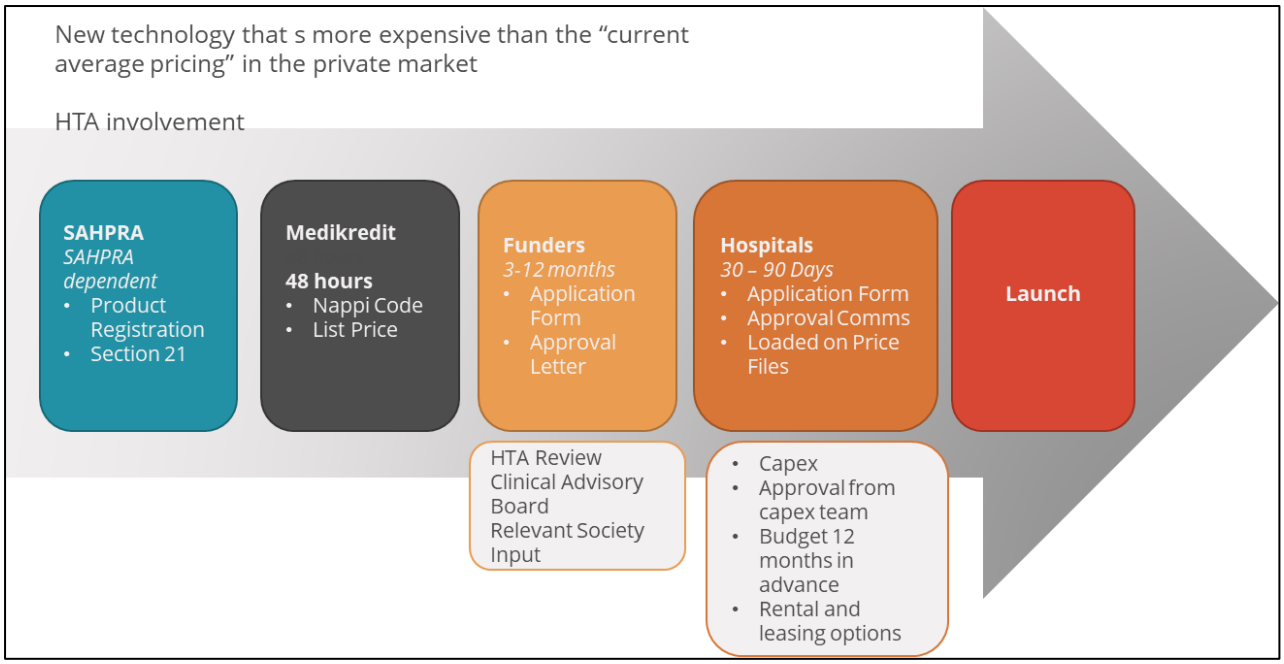
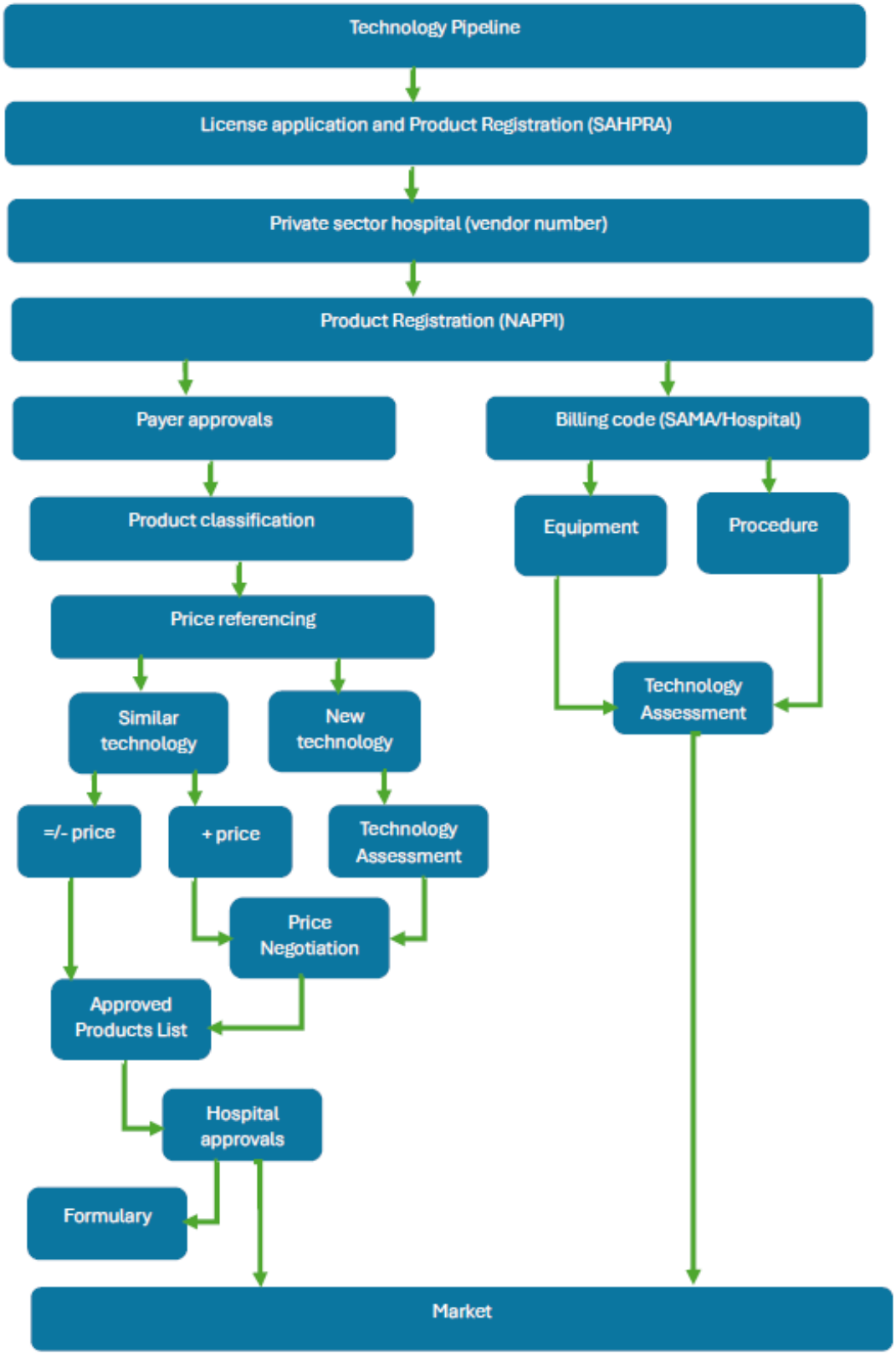


Figure 5: Long and Windy Route to Market Access

The following process diagram represents the market access process and reimbursement pathways a medical technology is required to navigate, whether new or as a line extension, for access to the South African Private Market.

The below pathway represents each step in the process for private sector market access.



2.1 New Technology Pipeline: Market preparation for the introduction

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

Useful links:

I. Medicines & Related Substances Control Act 101 of 1965
II. Medical Schemes Act 131 of 1998
III. Medical Device Regulations

2.2 Licensing of medical device or IVD establishment

New companies entering the market are required to obtain an establishment license from the South African Health Products Regulatory Authority (SAHPRA) as either a:

a) Manufacturer licence to manufacture, import or export medical devices or IVDs; or
b) Distributor licence to import, export, and distribute medical devices or IVDs; and/or
c) Wholesaler licence to wholesale medical devices or IVDs

Trading without appropriate licences is considered illegal.

Useful link:

I. https://www.sahpra.org.za/licences-and-permits/

2.3 Private hospital groups vendor registration

a) The supplier must be registered as a vendor before access will be allowed to hospitals.
b) The supplier should approach each hospital (buying) group to request details of the registration process and relevant application forms, requiring different requirements.
c) Products will not be allowed to be introduced until such time that the supplier has access.

Useful links:

I. https://www.netcare.co.za/Netcare-Suppliers/Suppliers-Application-Form
II. https://forms.mediclinic.co.za/productrequests/
III. https://www.lifehealthcare.co.za/about-us/clinical-and-support-functions/procurement/
IV. https://www.lenmed.co.za/hospital/lenmed-head-office/

2.4 Product (NAPPI) Code Application

All (consumable/disposable) products, the cost thereof being claimed by providers (hospitals or health care practitioners), are required by law to have a unique NAPPI code. Medikredit does not issue equipment codes.

a) Register with Medikredit as a supplier using the Manufacturer Supplier Registration V16 form
b) Be familiar with the NAPPI Code Allocation Policy Version 2.7 and Procedures for the request for New NAPPI codes.
c) Complete form Surgical NAPPI Request Template providing relevant information for surgical devices and the non-surgical template for anything other than surgical devices.
d) All application requires inclusion of the product GTIN, GMDN and Medikredit classification.

Useful links:

I. https://www.medikredit.co.za/index.php?option=com_content&view=article&id=13&Itemid=169
II. https://www.medikredit.co.za/index.php?option=com_content&view=article&id=92&Itemid=212

2.5 Payer / Funder approvals

The process of new product introduction varies across different medical scheme administrators and funders. SAMED advocates for establishing an independent HTA body that standardises processes and eliminates bias due to affordability.

2.5.1 Product classification (function) and referencing (price)

Following NAPPI code approval Discovery Health Administrators will proactively contact the 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 purpose of classification is to conduct a reference/benchmarking price analysis.

Similarly, Medscheme Clinical Coding and Tariff Department (CCTD) also review and add New product NAPPI codes to their systems as received by Medikredit and enquiries about the funding status of NAPPI codes can be sent to CCDT@medscheme.co.za

Funders using such tools will ask typically for relevant product information (codes – NAPPI; product, GMDN and descriptors; product descriptions; classification; comparator NAPPI codes; regulatory approvals and List and (average) Nett pricing.

New products will usually be classified (Discovery classification system algorithm available on request), based on function, utility and performance) and assessed as to whether they should be directed along the following reimbursment application pathways, each with their own relative complexities, information requirements and duration:

2.5.1.1 A similar product (me-too) technology (similar function and price) – AUTO APPROVED

i) Defined as a product having similar function and clinical outcome at a price equal or lower than comparator pricing in the category.
ii) Confirmation of comparator and product falls within an existing category of device,
iii) Confirmation the product falls within the reference price band of the above device category (based on the average claims price in the category).
iv) Fulfilling both the above conditions advances to Auto Approval status.
v) Product approval may still be subject to an agreed price level at which the device is authorised for reimbursement.
vi) Approval letter sent to supplier and Approved product list (APL) circulated for use with hospital buyer approval process.

2.5.1.2 A similar product (me-too) technology (similar function, higher price – NEGOTIATION

i) Defined as a product having similar function and clinical outcome, but price is higher (price premium) than comparator pricing in the category.
ii) Confirmation of comparator and product falls within an existing category of device.
iii) Confirmation the product falls within the reference price band of the above device category (based on the average claims price in the category).
iv) If product has a higher than acceptable price, using the Discovery example, the ISEM (Surgical Risk) team requests supplier to complete a product information notification (PIN) form calling for further information on the product to review the product and any other value adding argument that might justify the premium price.
v) During this phase the device is not reimbursed, approval is PENDED, and supplier notified.
vi) Upon confirmation of comparator and agreement on a negotiated price, the product advances to APPROVAL status.
vii) Product approval may still be subject to an agreed price level at which the device is authorised for reimbursement.
viii) Approval letter sent to supplier and Approved product list (APL) circulated for use with hospital buyer approval process.

2.5.1.3 A new category of innovative product technology – Health Technology Assessment (HTA)

i) Defined as:
   (1) a product that is innovative, with or without new indication and application falling outside of current categories with or without a direct comparator.
   (2) Capital equipment without an equipment code ie new, and related consumables.
ii) Suppliers will be required to submit a new product introduction application form for HTA using templates available from
   (1) Discovery (Figure 6: Discovery CCE HTA process for new technology)
   (2) Medscheme (Figure 7: The Medscheme HTA Process. New HTA submissions should also be sent to CCDT@medscheme.co.za
   (3) Momentum Health Solutions
   (4) Medihelp
iii) Suppliers should request relevant templates (devices and/or IVD) where they exist and complete them; note that these templates ask for different information.
iv) Price negotiations may still be entered into after HTA and economic evaluation.

v) As funder templates and type of information required might differ, it is recommended these are completed but supplemented as soon as possible with by a comprehensive HTA submission dossier (see sample SAMED HTA template).
vii) During this phase the device is not reimbursed, approval is PENDED, and supplier notified.
viii) Upon completion of HTA process (minimum 6 months), the supplier is notified of approval or decline.
ix) Appeals may only be allowed after 12 months of receipt of such decline letter, ONLY if new evidence is available, not previously submitted.
x) Immediate appeals, may, however, be entertained if the application considers there have been possible misinterpretations of the evidence in the original HTA submission.
ix) Product approval may still be subject to an agreed price level at which the device is authorised for reimbursement.
x) Approval letter sent to supplier and Approved product list (APL) circulated for use with hospital buyer approval process.

Examples of HTA processes are given below.

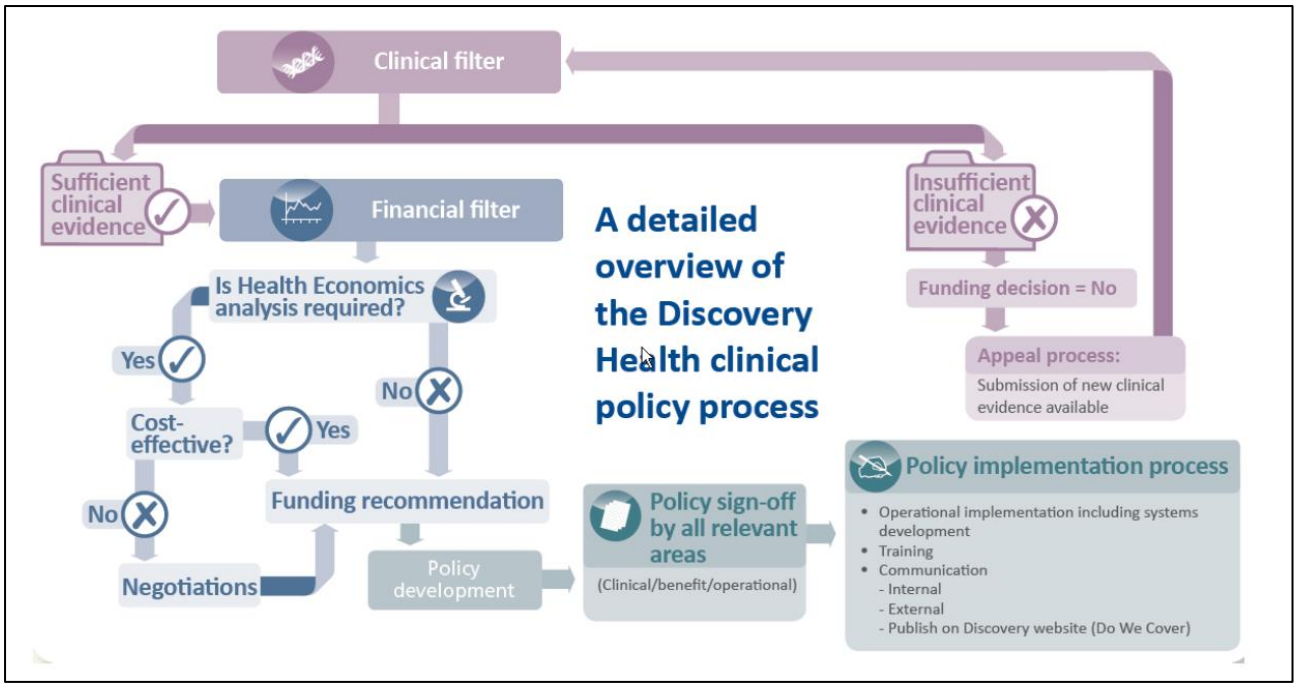


Figure 6: Discovery Centre of Clinical Excellence (CCE) HTA process for new technology (Source: Discovery presentation November 2020)

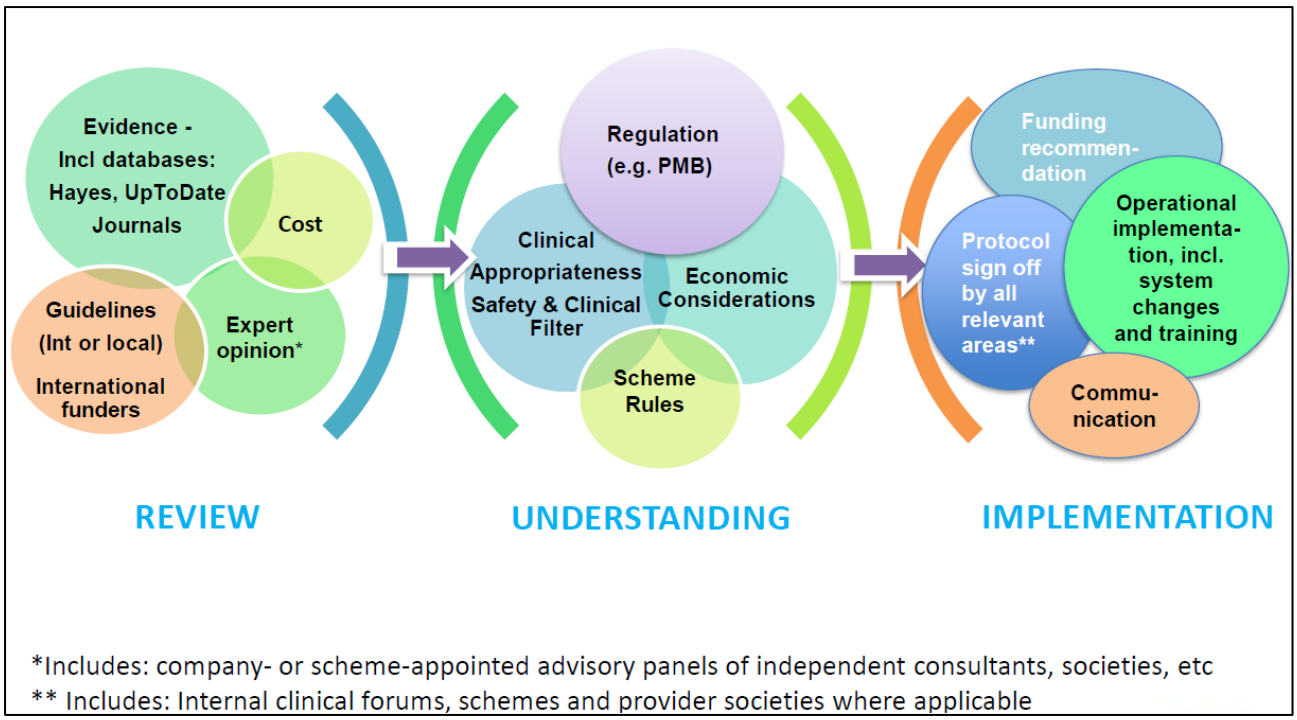


Figure 7: The Medscheme HTA Process (Source: Medscheme presentation July 2024)

2.5.1.4 New innovative medical equipment, with or without disposables

1) New equipment (with or without a disposable component) that is escalated to HTA will likely require a new tariff (billing) code that allows the service provider (health care practitioner (HCP) and/or hospital) that purchases the equipment to bill a patient for its' use to recover the capital invested.
2) Alternatively, the service provider may consider the equipment as a "sunk" cost, and recover this investment via other sources of income e.g. ward and/or theatre tariff.
3) A supplier can investigate if a tariff code exists that may apply to the new technology by contacting the following, where:
   a) If purchased by a healthcare practitioner (HCP), contact a HCP, HEALTHMAN (link below) or the South African Medical Association (SAMA) via email coding@samedical.org or via their contact details on the website below.
   b) If purchased by a hospital, contact the relevant private hospital.
4) There is no application process for suppliers to use to attain a new equipment code as this falls within the domain and responsibility of the respective purchaser/owner of the equipment.
5) There are two pathways for the respective service provider to apply for a new code, as illustrated in **Figures 8 and 9**.
6) In either case, it is recommended that the supplier still prepares the relevant HTA dossier that can be used by the relevant service provider for their deliberations and negotiations; this is highly recommended prior to the service provider beginning their engagement with funders.
7) The supplier may, via the economic evaluation and modelling, make recommendations for an equipment appropriate tariff, but this remains the domain of the respective service provider and funder negotiations.
8) Funders and providers will usually request completion of the HTA before entering into discussion with each other on the tariff value.

9) Upon approval for funding and confirmation of a code and tariff, as negotiated above, the funder may still negotiate with the supplier for better pricing on related consumables, if applicable.

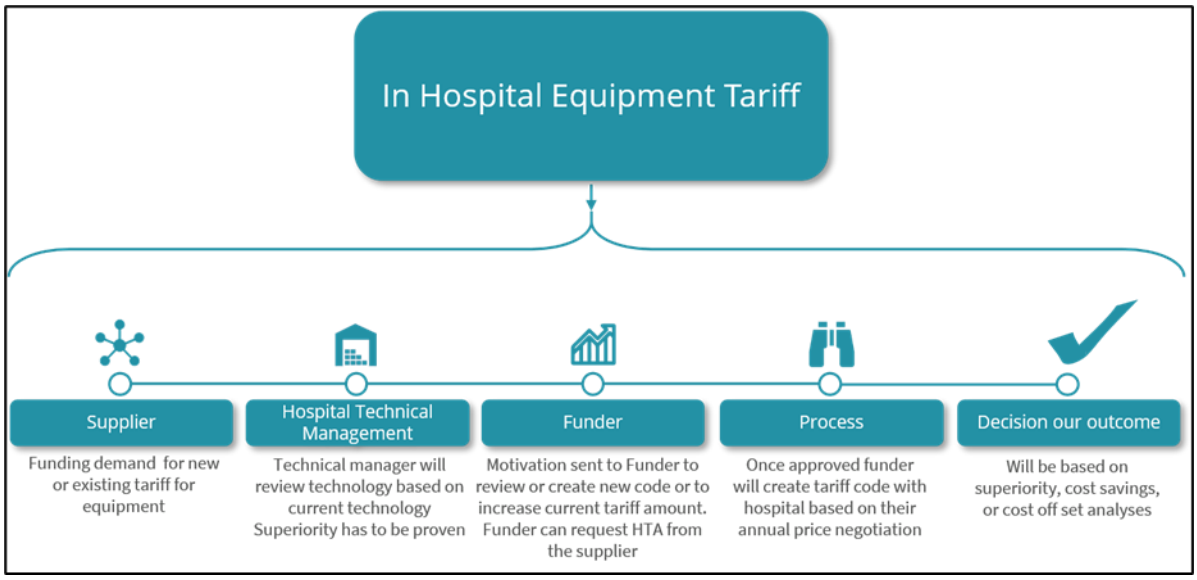


Figure 8: In Hospital Equipment Tariff

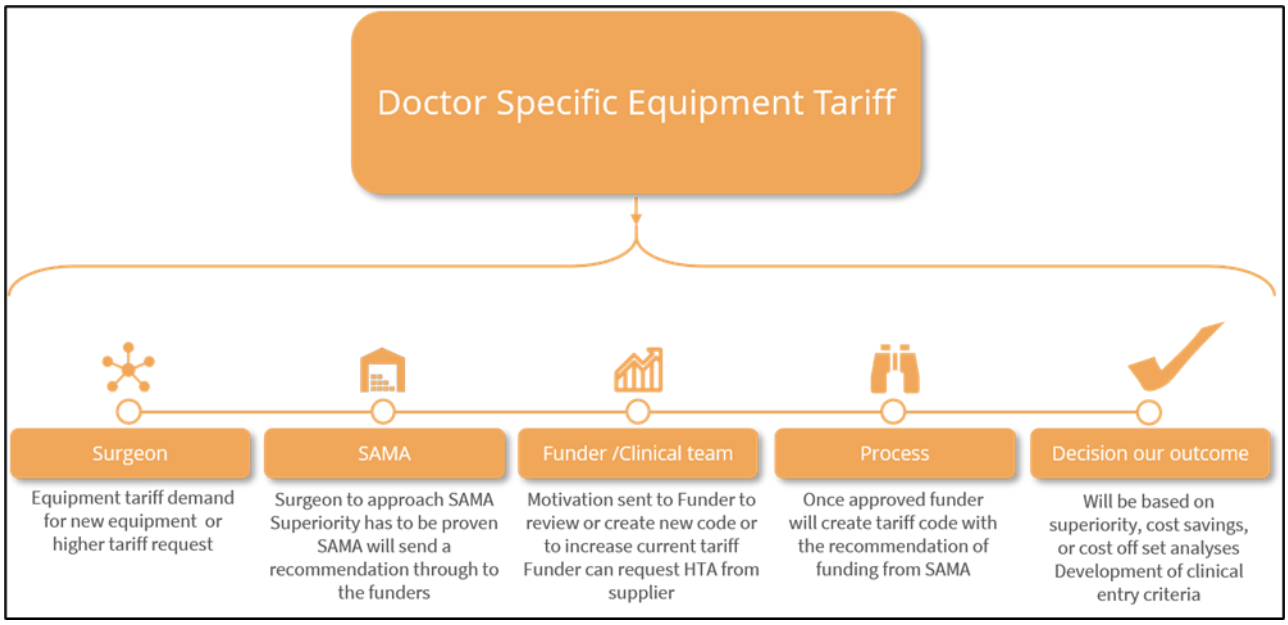


Figure 9: Doctor Specific Equipment Tariff

Useful links:

I. https://www.healthman.co.za/Tariffs
II. https://www.samedical.org/

2.6 Approved Product Lists (APL)

1. Letters confirming outcomes of HTAs will be sent to suppliers from the respective funder.

2. An APL will be sent to suppliers confirming/declining reimbursement and listing all relevant product and Nappi codes.
3. APL's are also shared with the hospital groups.
4. Approved products may be funded according to the categories below

4.1 Fee for Service- Product is reimbursed at the approved price when claim on individual Nappi codes
4.2 Alternate Reimbursement models
4.2.1 Fixed Fee- Product is included in a negotiated fee payable to the facility for a particular procedure which includes the use of disposable and implantable medical devices. Healthcare professional services may not be included in this fee.
4.2.2 Global fee- The product will be reimbursed as part of a Global fee arrangement in which one set amount is claims from the Scheme and will include medical devices, drugs, hospital and healthcare professional costs.
4.2.3 Other models include preferred or designated service provider or network arrangements.

2.7 Hospital Group Approval

1. The majority of hospital groups require a letter from a funder to confirm reimbursement of the product.
1. Each hospital group has its application document that has to be completed to conduct a hospital based HTA.
2. Alignment of the pricing submission to the hospital group with the MediKredit and Orderwise systems is crucial to a successful application.
3. As with the funders, it is recommended the respective new technology application forms are completed but also include the HTA submission dossier.
4. The HTA request is not as comprehensive as with funders. ISO Certification, Country of manufacturing, and product safety is crucial.
5. 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 particular documentation that has to be submitted.

3. Health Technology Assessment Guideline for Achieving Reimbursement

This guideline should be read in conjunction with the HTA Dossier Template in Appendix A of this document.

This guideline is intended to assist SAMED members with completing applications for reimbursement by medical scheme administrators, funders and hospitals. It is based on the various funder and private hospital processes, including application documents and gives some explanatory notes under each section. We recommend becoming familiar with HTA terminology available in a number of different glossaries (see links below).

Useful links:

I. https://www.nlm.nih.gov/nichsr/hta101/ta101013.html
II. https://www.who.int/publications/i/item/WHO-EMP-PAU-2015.5
III. www.htaglossary.net/HomePage

The major sections in a typical dossier should comprise the following:

a) Executive Summary
b) Applicant Details
c) Clinical Review
d) Technology Review
e) Economic Review
f) Organisational/Operational, Legal, Social and Ethical Review
g) Conclusion
h) Appendices

Preparation recommendations

1. Start the process of engaging medical scheme administrators and funders at least six months pre-launch to ensure your products are reimbursed before entry into the market.
2. This preparation should include preliminary discussions with funders to anticipate the length of time of review outcomes and understand funders unmet need/s.

This application dossier applies to new medical technologies as defined below i.e.

1. an innovative medical technology that did not exist before.
2. a current medical technology with a new active ingredient/indication/function with a unique indication/new use/additional benefits.
3. a medical technology that makes a claim of improved clinical outcomes 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 technology with equivalent or improved cost offset analysis at a cost-effective price).

The purpose of this application dossier should be to:

Generate a dossier of information that may be used as a tool for informing "all" stakeholders while consolidating all relevant information into a single source that will help expedite a decision. Avoid information dumping.

The dossier is a critical component of the submission. It should capture all pertinent information 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 interest.

a) Executive Summary

When writing the executive summary, one should:

- Assume the reviewer is short of time
- It should be no more than three 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 potential savings with improved outcomes. All claims should be supported by the relevant (best available) evidence and price (i.e. you are obliged to provide pricing information).

The summary should include:

1. 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 the relevant outcomes.
2. Description of clinical indications and the benefits of adopting the new technology – where it is used, what is the need, why is it necessary, i.e. the clinical entry criteria.
3. A brief reference to best available clinical evidence – what proof is there?
4. Description of technology – what it does and how it does it?
5. Pricing information – what is paid for it?
6. Summary of economic value as demonstrated by economic analysis (i.e. cost-effectiveness analysis, budget impact analysis or cost-benefit analysis).

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.

b) Applicant Details

Complete as per template – contact information is essential for future contact between the and applicant and assessing organisation.

3.1 Clinical Review

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

P	**Patient, population, or problem**	To whom does the technology apply?

I	**Intervention**	Which primary intervention, prognostic factor, or exposure is being considered?
C	**Comparison or existing intervention (if appropriate)**	To which intervention is the main alternative being compared?
O	**The 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 / funders to the problem condition. By describing shortcomings in current treatments, it reinforces the opportunities for the new technology.

Acquiring epidemiology information helps understand the new technology's potential and describes the business opportunity. This is useful for business planning and objective setting.

It could be used as a measure for utilisation uptake, particularly for equipment and calculation of tariffs. The PICOS tables should include incidence (number of new cases 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 funder by funder depending on the disease profile the 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 complicated to get in the local context. Still, if there is a global burden of disease study, this could be used as a basis for extrapolation to the local situation in the absence of local. It is strongly recommended that the methodology used to determine epidemiology data is referenced correctly.

Reviewers spend a lot of time trying to understand why it is necessary to change from the current standard of care. One must assume that they will consult local peers (ideally) to investigate the local clinical need for 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 determine, and it could be wrong. The comparator is typically the "control" versus which the new technology, the "test", is evaluated.

A comparator could be your product or the standard of care. It is important to note that the standard of care internationally may not be the same in South Africa, so caution should be exercised regarding 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 essential outcomes. The literature review could include a reference to early animal studies and case studies/series, abstracts, and press releases. However, these are unlikely to be considered in the evidence's final appraisal process. 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 exist where comparisons have been made about the efficacy and effectiveness. Notably, Real-World Data has increased in value as it includes evidence extracted from Real-world settings, versus strict clinical trial settings (refer Figure 1).

Applicants should identify what is considered the "best" available evidence, refer to Figure 1, 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; 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

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 underway 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 institutes such as Cochrane or BlueShield and international HTA agencies such as NICE and AETNA. These global recommendations and guidance should be used with caution as economic information, while interesting, may not always be generalised to the South African context.

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

This consultation should ideally lead to producing a formal consensus position paper on the technology, specifically focused on the ideal patient for the therapeutic intervention, to supplement this with creating a new clinical guideline or incorporation into an existing guideline. This position paper is to support the decision-making process by funders, particularly for 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 newly introduced by a health service discipline. Low-quality evidence may be supplemented by expert and consensus opinions from local specialities. It is advised that this approach is used to offer the funder an alternative reference point.

3.2 Technology Review

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

Indications, contra-indications and relevant warnings and user-related guidance should be listed. User types (e.g. nurses, health care professionals, patient etc) and where the technology will be used must be explained. Explanations of any training strategy are of utmost importance, as this is also a determining feature for where and how it may be funded.
Warnings are important as they describe the level of clinical risk involved, and reviewers often expect this to meet users' expected skills requirements 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 disease 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 other major markets other than stated, please include it under other. It adds value.

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

3.3 Economic Review

This section should include all relevant product costs 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 list all items and respective costs only. 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 you, the supplier positions the technology.

If this technology includes an equipment component, it is useful to calculate an appropriate tariff that should be charged to recover the investment cost 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 the 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. Other financing options can be explored, such as placing or rental of equipment. Note all figures are fictional examples.

Equipment (Insert Equipment Name			
Capital Purchase Price (in Rands)		R580 000.00	The total price paid for the equipment, including vat
Annual Maintenance Contract	5%	R 29 000.00	The total price paid for the annual maintenance contract
Useful Life of Equipment (In Months)	60	R116 000.00	The 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 a Use:		R138.10	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 equipment's use; utilisation rates to be referenced according to the anticipated number of cases per month (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 considered from the reviewer's perspective 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, additional procedure costs, hospital costs, drugs, devices, staff, providers, lab etc.) – include upstream and downstream expenses relating to patient workup (pre-surgery, e.g. diagnostics tests) and downstream costs (post-surgery, e.g. physiotherapy/rehab).
- All non-medical costs covered by 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 useful to reference but are not usually considered in an evaluation

of this type. Note that indirect and intangible costs are generally not included but are of Value in closed schemes where close integration between the employer's HR policy and the scheme benefits.

All sources relating to costs mentioned above should 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 this information. These studies usually provide information on the cost-effectiveness of new technology over an old one. Still, 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 like to see at a glance. This type of information could also go into the Executive Summary 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 comparison 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 possible 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 does 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 three types of economic analysis one can do that will interest the funder:

One or more of:

1. Cost-benefit analysis |CBA)
2. Cost-effectiveness
3. Cost utility analysis CEA/CUA
4. Cost minimisation analysis CMA

You are likely to conduct only a CMA or CEA analysis, depending on the availability of appropriates evidence. Any of these should be accompanied by a Budget impact analysis BIA.

Numerous health economic studies can be conducted, i.e. a CBA or CEA or CUA, if a comparative study has been undertaken, i.e. a study that will provide outcomes of the new technology comparator. These Health economic studies can then express relative clinical gains or improvements in the condition being treated etc.

Within **HTA** there are several types of economic analysis which are commonly used: cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA), and cost-minimisation analysis (CMA). These are briefly described below[1]:

CBA: An economic analysis that considers both the costs and benefits of investing in a particular health technology compared with an alternative strategy. Costs and benefits are typically measured in present value monetary terms.

CEA: A form of analysis that considers both the costs and effectiveness of investing in a particular health technology. Effectiveness can be measured in a variety of ways such as number of falls, number of hospital visits, length of recovery time or an improvement of quality of life for instance. CEA returns a result in the form of cost per outcome.

CUA: A sub-form of CEA that takes into account the incremental costs versus incremental utility provided of a new health technology. Utility gain is a measure of qualityof life improvement that uses quality adjusted life years (QALYs) as units.

CMA: The health technology under consideration has been deemed equivalent in efficacy to that of current practice and as such only the cost is of concern. The new technology will be adopted if the true cost of funding is equal or lower than the cost of current treatment.

A **BIA** should represent the respective cost impact on the population being treated, subject to population demographics, relevant epidemiology, and adoption level, between the new technology

[1] Reference: https://haiweb.org/wp-content/uploads/2015/08/HTA-final-Aug2013a1.pdf

and the comparator. A Budget Impact analysis is frequently not possible but valuable for decision making, if available.

It is accepted that the required information may not be easily accessible. Please supply as much information as possible 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:

3.4 Ethical, Legal, Social and Organisational (ELSO) Review (optional):

See: https://www.eunethta.eu/wp-content/uploads/2018/01/HTACoreModel3.0.pdf

This section represents four domains providing an opportunity to discuss the respective consequences (intended and unintended) of implementing or not implementing a healthcare technology. Each are made up of an hierarchy of topics and issues intended for discussion in the relevant context relating to the technology. It should be sufficiently researched and factually correct.

3.4.1 Ethical Analysis

Technologies can influence norms and values. Moral values and norms form the basis of social life and play a key role in shaping the context in which health technologies are used. Ethical analysis aims to provide a thorough understanding of prevalent social and moral norms and values that need to be considered during the HTA and in the decision-making process. Moral value that societies attribute to the consequences of implementing a technology is affected by socio-political, cultural, legal, religious, and economic differences.

In addition to the ethical aspects of using technology, the domain also covers moral and ethical issues related to the consequences of performing the health technology assessment (HTA). These are, for example, questions about the ethical consequences of choosing specific endpoints ethical problems related to the types of clinical research and economic evaluation.

The issues stem from the general values of the population, aims of the healthcare system and values arising from the use of a technology. The ethical domain includes six different topics, covering nineteen issues (Table 1 Pg255).

Ethical analysis also reflects the fact that HTA is a value-laden process. Performing an HTA should not be considered as a purely technical tool for maximising the health benefits of technology, since benefit maximising is of itself a normative aim that carries a priori assumptions about the goals of healthcare and healthcare expenditure.

3.4.2 Legal Analysis

The objective of this domain is to assist with detecting rules and regulations which need to be taken into consideration when evaluating the implications and consequences of implementing a health technology. Rules and regulations have been established to protect the patient's rights and

societal interests. The rules and regulations may be a part of patient rights legislation, data protection legislation, or health care personnel's provisions, rights and duties in general.

Proper knowledge of relevant legal questions has significant consequences for decision-making. Legal issues in HTA will be increasingly important as norms of professional ethics are continuously codified into statutes, as government produce ever more health-technology-related legislation. The rapid innovation processes of new technologies put the policy and decision-makers in situations where they need to know the legal implications of implementing and not implementing a technology, and the roles and responsibilities of different actors, e.g. patients, providers (hospitals and health care practitioners) and payers.

This domain has eight topics covering eighteen issues.
With respect to the technology under review, please comment on:

1. 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.
2. Issues related directly to the patient and their fundamental rights and freedoms, such as autonomy, informed consent, privacy, and confidentiality, etc.
3. Issues related to health care policy at the funder, local or national Government levels, etc.

3.4.3 Social Aspects

This domain takes patients or individuals in whose care a health technology is used as a point of reference in an HTA and relates to issues relevant to *patients, individuals, and caregivers*, but excludes healthcare professionals. Social Aspects are related to *social groups,* that is specific groupings of patients or individuals that may be of specific interest in an HTA, such as older people, people living in remote communities, people with learning disabilities, ethnic minorities, immigrants etc.

Patients, caregivers or individuals can provide unique perspectives about experiences, attitudes, preferences, values and expectations concerning health, illness, service delivery and treatments that can inform HTA. Patients, caregivers and individuals will have a range of perspectives and an HTA should seek to gather as much evidence as possible to understand these wide-ranging views.

There may be some social groups that are particularly important to consider for a specific health technology or for which there is a policy imperative for special consideration (such as those with disabilities) or in which the value of the technology may be different (such as ethnic minorities) and these may need to be specified

A technology may be implemented in a hospital, primary care or at home. However, implications for patients may extend far beyond the original setting of the technology. Patients and caregivers attribute specific meaning and significance to health technologies, to which they may attach feelings of hope, fear, perhaps uncertainty, as well as societal values.

This domain contains three topics and eight issues (Table 1; Pg 348) that seek to identify evidence from the patients, individuals, caregivers, and social groups about:

- The burden of living with the condition being studied
- Experiences of current health technologies.

- Experiences with and expectations of the health technology being studied (in particular what would be valued most from the technology and issues regarding managing technology administration and side-effects).

3.4.4 Organisational Aspects

This domain considers different resources (e.g. material artefacts, human skills and knowledge, funding, attitudes, training, work culture) need to be mobilised and organised when introducing a technology, and their respective consequences, in the most appropriate settings. Issues could include e.g. work processes and patient/participant flow, quality and sustainability assurance, centralisation, communication and co-operation, managerial structure, and acceptance of a technology.

There are various stakeholders besides staff and patients, at various levels, e.g. payers, providers and suppliers, who usually have different aims for and expectations of the technology.

The organisational domain includes five topics covering 15 issues (Table 1; Pg 303), representing the most important organisational issues, but their relevance depends on the specific technology and needs.

The growing focus on organisational issues in HTA indicates an acknowledgement that many resource allocation decisions in the provision of technologies are of crucial importance, and organisational aspects in an HTA influence the behaviour of managers and health professionals. Organisational aspects in HTA may clarify most of the challenges and barriers in implementing health technologies and, hence, they could influence the impact of health technology assessment.

Appendix A: HTA Dossier Template

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

1. EXECUTIVE SUMMARY
2. APPLICANT DETAILS

Sole Supplier of Brand: | Yes | No | (X applicable box)

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

	Primary Contact	Secondary Contact
Name		
Title		
Telephone		
Cell Phone		
Email		
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	
Disposable Item (# Of Times)	
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	

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
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 and 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 the 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 Date**
	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
4.2. GMDN Code & Description
4.3. Product components
4.4. Mechanism of action/operating sequence
4.5. Package Insert:
- Indications for use
- Contra-Indications for use:
- Warnings and user-related guidance

4.6. Health care professionals who will use or administer the technology:

4.7. Training requirements for relevant health care professionals:
4.8. Health care setting

Primary Care (E.G. General Practice)	
Specialist Care	
Hospital Theatre or Ward	
Procedure Room or Outpatient Facility	
Home Care	

Relevant Diagnosis and Procedure Codes: Type Of Code	**Code(S)**	**Description(S)**
ICD 10 CODE(S)		
DSM VI CODE(S)		
NAPPI CODE(S)		
NHRPL CODE(S)		
CPT/ CCSA CODE(S)		

4.9. 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 AUTHORISATION HOLDER (MAH)		
WORLD HEALTH ORGANISATION (WHO) FOR IVD'S (PREQUALIFICATION OF IN-VITRO DIAGNOSTICS PROGRAMME		

OTHER		

4.10. 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 the 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 (BIA)
5.5.3. Sensitivity analysis
5.5.4. Decision modelling

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

a) Organisational/Operational
b) Legal
c) Social/Societal
d) Ethics

7. CONCLUSION

Appendix B: Important Contacts

Discovery Health

- Classification and listing on the DH price file: PRICE_AND_PRODUCT_FILE@discovery.co.za
  - Surgical NAPPI queries and approvals and price increases/price file updates: ISEM@discovery.co.za
  - New Health Technology Submission: CPUWatchList@discovery.co.za
  - Health Provider Queries: HEALTHPARTNERS@discovery.co.za

Figure 10: Centre for clinical excellence: Process Flow
(Source: Discovery presentation November 2020)

Medscheme:

- Device pricing and funding queries and HTA applications submissions: Clinical Coding and Tariff Department: MCOSNAPPICODING@medscheme.co.za
- Follow-up on HTAs in progress: Health Policy Unit (HPU) technology: hputechqueries@medscheme.co.za

Momentum Health Solutions

- HTA Submissions: ClinicalPolicyUnit@mhg.co.za

Medihelp

- Health Technology Assessment hta@medihelp.co.za

Netcare Head Office

- https://www.netcare.co.za/Netcare-Suppliers

Life Health Care Head Office
https://lifehealthcare.mobiworkx.com/pages/contact

Mediclinic Head Office

- Online application https://forms.mediclinic.co.za/productrequests/
- Follow up emails: admin.procurement@mediclinic.co.za

Hospital Group Procurement Contacts

Mediclinic	There are 4 regional procurement capital managers each of which have 4/5 individual hospital procurement managers	• medimail@mediclinic.co.za • +27 21 809 6500
Life Healthcare	Each has a product specific responsibility	• Contact page
Netcare	Each has a product specific responsibility	• Contact page • +27 11 301 0000
Lenmed		• info@lenmed.co.za • +27 (0)87 087 0600
Busamed	Not centrally procured; each hospital does their own procurement	
Advanced Day Clinics:		• info@advancedhealth.co.za • 012 346 5020

References:

1. Essential Principles of Safety and Performance of Medical Devices, Global Harmonisation Task Force Study Group 1, May 2005
2. Medtech Europe: Medical Device Industry Position on HTA
3. Medtech Europe: Six Key Principles for the Efficient and Sustainable Funding & Reimbursement of Medical Technologies
4. Global Medical Technology Alliance: Global Reimbursement Principles
5. Global Medical Technology Alliance: HTA Position Paper
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)