SUBMISSION BY SA Heart®, SASCI and HeFSSA

HEALTH TECHNOLOGY ASSESSMENT BY THE NATIONAL DEPARTMENT OF HEALTH

1. Introduction

This submission is in response to a series of documents published by the National Department of Health in July 2021.[1] Comment was invited "on the proposed methods over an extended consultation period acknowledging the complexity of HTA methods and variety of stakeholder groups that may have an interest in this field".

There can be no doubt that healthcare professional organisations, such as SA HEART, whose members work in the public and private sectors with the goods (health products namely medicines and medical devices) on a daily basis.

SA HEART® Association (SA HEART®) is an organisation of doctors, allied professionals and scientists involved with cardiovascular patient care, teaching and research in South Africa. It's vision is to advance cardiovascular healthcare for all living in South Africa with the mission to champion equitable, sustainable healthcare, to lead and innovate in cardiovascular sciences, to educate professionals, members and community nd to influence cardiovascular healthcare policy. Through its members, branches and Special Interest Groups it aims to achieve this through the 4 strategic pillars of Science, Education, Member and Policy.

SA HEART® and two affiliated Special Interest Groups SASCI and HeFSSA developed this submission.

South African Society of Cardiovascular Intervention (SASCI) is an organisation of physicians, scientists, and allied professionals with the purpose to advance the development of cardiology and coronary revascularisation and to provide minimally invasive, image-guided diagnosis and treatment of cardiac medical conditions. It also acts in an advisory capacity to funders; industry; members and the government on matters relating to interventional cardiology. The latter is a branch of cardiology that deals specifically with catheter-based treatment of heart diseases and includes procedures such as

[1] https://www.knowledgehub.org.za/elibrary/notice-request-comment-updating-health-technology-assessment-methods-guide-inform.

angioplasty and Trans Aortic Valve Implantation (TAVI). The society is also a key enabler of CPD accredited education in interventional cardiology.

HeFSSA is the special interest group affiliated to the South African Heart Association with the official mandate to look after heart failure. The society was established as a non-profit Section 21 company in 2005 with the mission to promote education and research as well as collaboration on issues relating to heart failure in South Africa. HeFSSA activities include to issue Africanise guidelines based on predominantly the most recent ESC Guidelines and to express official opinion on clinical noteworthy developments. HeFSSA is highly active in education and training the focus is on the referral network including cardiologists, physicians, general practitioners, and allied professionals.

SA HEART®, SASCI and HeFSSA supports the intention of the framework currently largely proposed for medicines, to create a "more explicit and consistent terminology for the way that evidence is generated", which is then used to include products on the essential medicines list (EML).

This important project has two important elements: its linkage into legislation and other policy objectives, as we outline below, and the technical aspects of "assessing value for money". Our contention is that the first aspect is not in place – where HTA fits into the current, and envisaged legal and policy frameworks. Without such consideration, the HTA project will remain a policy piece outside of the objective of larger, consistent health sector transformation.

The required template response form on the technical aspects of the proposed HTA methods Guide, is attached to this submission.

2. The legal- and policy framework

It is unclear within which legal framework the HTA policy will operate, and apply to the EML. There are, at present, however no regulations to frame the HTA and EML-development processes. We believe that this regulatory framework is critical to ensure that the process of inclusion- and then also the process of exclusion of products and technologies, are consistent, transparent, and most importantly, lawful. The reason is that these activities constitute limitations of rights, of patients, of healthcare professionals, and of suppliers of products into the larger health sector. Such limitations must pass not only muster under section 27 of the Constitution, but also section 36.

The only law that mandates the establishment of the EML is the **National Health Act, 2003**. It states as follows in section 90(1)(d):

> *(1) The Minister, after consultation with the National Health Council or the Office, as the case may be, may make regulations regarding—*
>
> *(d) the development of an essential drugs list and medical and other assistive devices list;*

These regulations were never made, and its absence renders the whole Essential Medicines List open to legal challenge.

There are various other legal- and policy frameworks at play at present:

There is a **Pharmaco-Economic Evaluation Guideline** ("PEE Guideline"),[2] published by the Director-General of Health in terms of the 2005 Pricing Regulations.[3] This would be used for private sector sales only, and the objective is that it would influence the Single Exit Price of the product. This Guideline has never been implemented or applied, for neither existing nor new medications where it would be an important consideration as part of the new product price information to be submitted in terms of Pricing Regulation 19.

It remains unclear whether the National Department of Health (NDoH) will run the two systems of economic evaluation in parallel – one based on the PEE Guideline, and another in place for the Essential Drugs Programme (EDP)?

However, a single medicine or medical device could face yet another set of assessments: the **Medical Schemes Regulations, 1999**, empowers medical schemes, individually, to set its protocols and formularies on the basis of evidence-based medicine, taking into account cost-effectiveness and affordability pertaining to that scheme. Each medical scheme, by law, is entitled to undertake its own cost-effectiveness and affordability studies, and decide on the inclusion or exclusion of a product from a formulary for its patient base, and its budget. The non-implementation of a risk-adjustment mechanism, also strongly recommended by the Health Market Inquiry (HMI), imposes significant

[2] R. 68 Medicines and Related Substances Act (101/1965): Regulations relating to a transparent pricing system for medicines and schedules substances: Publication of the guidelines for pharmacoeconomic submissions Government Gazette No 36118 of 1 February 2013.
[3] GNR.1102 of 11 November 2005: Regulations relating to a transparent pricing system for medicines and scheduled substances, as amended.

burdens on both the medicines- and medical device technology sectors – it has to respond to different criteria set by different medical schemes at different times.

Given the current Minister of Health's clear indication[4] that **the HMI recommendations** will be implemented, consideration must be had for the above factors, to create a coherent, consistent legal framework for assessing the value of a product in the health sector. This means that the current process must consider the recommendations of the HMI in relation to HTA, and the independent structure proposed as a vehicle to undertake this.

Regarding the envisaged **role of HTA in the NHI**, no principles are set, and it is not made a criterion for the work of either the Office of Health Products Procurement (OHPP), nor of the Benefits Advisory, or Benefits Pricing Committees. The Bill simply states:

> *7 (4) Treatment must not be funded if a health care service provider demonstrates that—*
> *…(d) no cost-effective intervention exists for the health care service as determine by a health technology assessment*

And then, in terms of the transitional measures, section 57(3), the following is envisaged:

> *(d) The Ministerial Advisory Committee on Health Technology Assessment for National Health Insurance, which must be established to advise the Minister on Health Technology Assessment and which must serve as a precursor to the Health Technology Assessment agency that must regularly review the range of health interventions and technology by using the best available evidence on cost-effectiveness, allocative, productive and technical efficiency and Health Technology Assessment.*

Ministerial Advisory Committees (MAC) are established in terms of section … of the National Health Act.

> ***91. Minister may appoint committees.**—(1) The Minister may, after consultation with the National Health Council, establish such number of advisory and technical committees as may be necessary to achieve the objects of this Act.*

[4] https://www.dailymaverick.co.za/article/2021-08-30-we-are-in-uncharted-waters-but-we-will-get-out-of-it-working-together-says-health-minister-joe-phaahla/: "His intention to start a process to implement the recommendations of the Competition Commission's Health Market Inquiry into the private healthcare sector"

(2) When establishing an advisory or technical committee, the Minister may determine by notice in the Gazette—

(a) its composition, functions and working procedure;

(b) in consultation with the Minister of Finance, the terms, conditions, remuneration and allowances applicable to its members; and

(c) any incidental matters relating to that advisory or technical committee.

We are unaware of the appointment of such a MAC and its terms of reference. It is also not clear, given that the HTA MAC is referred to the in the NHI Bill (i.e. another law), how that would relate to the National Health Act's mandates, i.e. will it relate to the potential of regulations relating to the Essential Medicines List and the Essential Equipment List, and/or to the provision for regulations relating to "health technology" in section 90(1)(r) which states that regulations can be made on "health technology"?

The above issue raises important questions during this transitional period:

With medical schemes, being proposed to add primary healthcare based on the Essential Medicines List and the Standard Treatment Guidelines for primary care, it would mean that this way of conducting HTA, rather than the PEE Guidelines, would apply.

The HMI recommends an **independent body** responsible for health technology assessments and treatment guidelines, no such proposals are found in the documents up for comment, nor in the NHI Bill and the work of the MAC envisaged in the NHI Bill, is unknown.

We support the establishment of such an independent HTA body, so as to ensure that assessment of value are unfettered by the interests of any specific stakeholder.

3. Purpose, scope and application

Although the comments form states that this would apply to "HTA in the public sector" and the EML applies only to the public sector at this stage, medical schemes are referred in the document. Affordability levels and budget impact between the public- and medical schemes sectors, and even within the medical scheme sector differ significantly. The scope and application of the proposed methods must be clear.

The National Drug Policy, 1995[5] (which had been envisaged in the time of Minister Motsoaledi's 10-point plan[6] to the revised and updated, states that the EML, or Essential Drug List, as it was called then has the following purpose:

> *Essential drugs are drugs that are required to treat the majority of conditions that are prevalent in a country in a cost-effective and efficient manner. The concept does not imply that no other drugs are useful, but that these drugs are the most needed for the health care of the majority of the population. They should therefore be available at all times, in adequate amounts and in the proper dosage forms.*

It therefore would, by definition, not cover many of the technologies and products used by the members of SA HEART®, SASCI and HeFSSA whether in the public or private sectors, and definitely not cover treatments for rarer conditions. As the HTA methods are proposed, it does appear that its application would be beyond what would be deemed "essential".

The main document in numerous places refer to medical schemes . It is unclear whether mean that this proposed HTA system will also apply to medical schemes, in spite of the specific legal framework created for medical schemes in the Regulations to the Medical Schemes Act?

Another important consideration is that the Essential Medicines List contain the "Standard Treatment Guidelines", and is not a stand-alone list. However, these Guidelines are limited to the products that then appear on the EML, cover just the general, and most basic, of treatments.

The EML also contains, and is expanded, mostly with reference to products long-genericised. Health technology assessments are, for the most part, associated with the introduction of new technologies. The linkages and usefulness of the HTA methods might therefore be limited only to innovators.

4. Comments of a more technical nature

From a healthcare professional point of view, the proposed HTA methodologies still appear costly and complex. Can South Africa, and those who would have to submit information in terms of this system, be able to afford this? Of concern is whether the implementation of this system would hamper access to innovation in the South African market, or not. A further concern is the absence of data. It is

[5] https://www.sapc.za.org/Media/Default/Documents/Reference%20-%20National%20Drug%20Policy%20for%20South%20Africa.pdf.
[6] https://www.mm3admin.co.za/documents/docmanager/2D5ED792-878C-4371-9575-8281A96BBB26/00023294.pdf.

impossible, with current datasets, even in the medical schemes sector, to track the effects of care. Even basic data on prevalence and incidence is lacking. Legislation pertaining to the collection of such data (the National Public Health Institute of South Africa (NAPISA) Act, 2020) is in place, but not being proclaimed and therefore incapable of being implemented. Neither is there any legislation mandating recordkeeping in line with stipulated coding systems (ICD-10 or similar) to enable the collection of data, as well as prescribed formats for health records (also still lacking but possible under the National Health Act[7]). The important building blocks of a coherent, consistent, practical and lawful HTA system are therefore still absent.

The cover letter to the documents under comment states that the "HTA Methods Guide" aims to "gather and produce" evidence on "clinical efficacy, safety, effectiveness and affordability". Clinical efficacy, safety and effectiveness form part of product registration criteria set by the Medicines and Related Substances Act, 1965, for both medicines and medical devices (see sections 14 and 15, as well as the regulations to the Medicines Act on product registration). This raises an important policy- and legal consideration: If a product is found to be clinically efficacious by SAHPRA, but not by the NDoH as part of its HTA assessment – what is the implication of this for products? Would it simply mean not being included on the EML, or could it have other implications?

We also note that health outcomes are mentioned throughout the various methods and stages of evaluation. This is an important consideration for healthcare professionals who care for patients, and who also take legal liability for the outcomes of care.

Our Members have been on the receiving end of systems that reduce healthcare interventions to product costs, in spite of better health outcomes, appropriateness and overall savings. A good example is its ongoing battle in relation to TAVI (Trans Aortic Valve Implantation) procedures. Despite robust data that the cost of the TAVI procedure is, as minimally invasive, far less than open heart procedures, there are still limits to the prosthesis funding, which is a sub-limit on the overall funding, and which, if exceeded, leads to the procedure not being funded at all. This is despite funders approving the procedure.

Of serious concern is the absence of the globally accepted principle of evidence-based medicine[8] in the Methods Guide. That should be the heart of decision-making in healthcare. This is also the

[7] Section 13.
[8] Masic et al Evidence "Based Medicine – New Approaches and Challenges" *Acta Inform Med.* 2008; 16(4): 219–225.

principle that ensures that all, and not only some, or the majority, of patients received appropriate care.

5. Conclusion

SA HEART®, SASCI and HeFSSA consider it mandatory that NDoH engage with the medical profession who are appropriately trained and suitably qualified to make decision (advice) on technologies related to interventional cardiology including issues with the current EML and STGs, the implications of HTA and its experiences as healthcare professionals working in a field that is technology-rich, and dependent on innovation.

The involvement of healthcare professionals registered in a specific field is imperative. They are the only persons registered, authorised and accountable for the treatment (or not) of patients within specific fields. All too often persons who are not duly qualified and experienced make decisions on procurement (which would be the end-result of an HTA system) that unreasonably and unjustifiably limits appropriate, evidence-based access to care for patients. The formalised inclusion of healthcare professionals in a particular field of specialisation, including experts in, for example rehabilitation (physical and occupational) is imperative.

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Published online 2008 Dec. doi: 10.5455/aim.2008.16.219-225.

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

Annexure 1: Consultation Response Form

REQUEST FOR COMMENT: Updating of Health Technology Assessment Methods Guide to Inform the Selection of Medicines to the National Essential Medicines List

Consultation: 9 July 2021 – 4 October 2021

Thank you for participating in the consultation on the Health Technology Assessment (HTA) Methods Guide to Inform the Selection of Medicines to the National Essential Medicines List (EML).

We are interested in hearing your thoughts about the following:

- Are the methods specifications *appropriate* in the South African context?
- Are the methods specifications *feasible* in the South African context?
- Is the *structure* of the HTA Methods Guide appropriate?
- Is the language and approach in the HTA Methods Guide *clear and understandable*?
- Are there any *major gaps* in the methods that may be useful for the assessment of medicines in South Africa?
- Are there any *factual inaccuracies* that should be corrected?
- Specific feedback on the sections in the HTA Methods Guide.

The information collected will be used to inform and update the HTA Methods Guide that will be used for the assessment and appraisal of medicines when considering selection to the National Standard Treatment Guidelines and Essential Medicines List.

We invite comments from any interested individuals and institutions. We regret that we will not provide individual response to comments or suggestions.

When responding, we ask consultees to keep in mind that the aim of the HTA Methods Guide is to clarify, formalize and standardize existing HTA methodological practice for generating evidence to inform decision-making in this technical area. The HTA Methods Guide does not provide guidance on procedural aspects of the technology assessment process, e.g. governance structures, decision-making frameworks, or stakeholder engagement. We cannot incorporate any comments that falls outside of the scope of the Methods Guide.

Submitting your responses

Please use this consultation form to provide your comments. You do not have to provide comments for all sections.

Consultation responses and requests for further information should be emailed to Janine Jugathpal on Janine.Jugathpal@health.gov.za by 4 October 2021.

Your co-operation in this regard is appreciated.

ABOUT YOU

To help us understand your comments, please indicate the name of the organisation and department you work for next to the relevant category. Alternatively, if you are responding as an individual, please provide your job title or description of your role.

Responding on behalf of an organisation

Category	Name of organisation and department
Department of Health	
Academic body	
Research unit	
Professional organisations	SA Heart Association (SA Heart) South African Society of Cardiovascular Intervention (SASCI) Heart Failure Society of South Africa (HeFSSA)
Public / patient advocacy group	
Industry body	
Life sciences consultancy	
Medical aid	
Regulatory body	
Other	

Responding as an individual

Job title/ description of your role:

This is joint submission prepared by SA Heart, SASCI and HeFSSA

RESPONSE TO CONSULTATION

GENERAL FEEDBACK

1. Are the methods specifications *appropriate* in the South African context?
We are concerned that this project does not consider the applicable legislative frameworks, and the two important developments, namely the HMI recommendations and the NHI Bill. *The non-implementation of the NAHPISA Act, and the lack of availability of applicable data on disease incidence and prevalence, as well as mortality and morbidity data pose significant hurdles to the appropriateness of the methods.* *Lastly, but important, is that there is no cost data available for the public sector to the level of granularity to, for example, state what the effect of a medicinal intervention is on the patient later-on, and the cost of such interventions and its effect.* *In the private sector there is some data on what a hospital day, or an hour in the cathlab may cost, but no such data exists for the public sector.* *It is not even possible to obtain public information on pharmaceutical spend on, for example, statins, or stents, in the public sector.* *Defining 1 QALY = 1 DALY = R38599.00 poses a challenge to new innovations, in our context, new devices, because of the high cost of devices and protheses. This is also due to exchange rates prevailing at any time and must be considered when assessing cost-effectiveness of existing and new technology as the disproportionate cost of potentially game changing technology may prohibit or delay their introduction into the market to the long-term detriment of the community. It is also unclear as to if this amount is derived in such a way that it could be a sound benchmark and referring to it could lead to it been entrench as "the number" without been validated.* *The infrastructure (systems) must be created that will allow collection to accurate data that is used for the HTA evaluations.*
2. Are the methods specifications *feasible* in the South African context?
We remain concerned that the HTA system should not increase the cost of products, and lead to a stifling of access to innovation or create systems where the HTA process becomes detrimental to access to care for patients.
3. Is the *structure* of the HTA Methods Guide appropriate?
Our members are not experts in HTA but cardiovascular medical devices are being developed continuously and CEA and assessments may be uniquely biased (see above) so we suggest that a separate process be set up for the device industry.
4. Is the language and approach in the HTA Methods Guide *clear and understandable*?
Terminology used must align with definitions set in legislation and other policies, so that the Guide is not divorced from such other regulatory frameworks.
5. Are there any *major gaps* in the methods that may be useful for the assessment of medicines in South Africa?
SA Heart, SASCI and HeFSSA supports the recommendations of the HMI in relation to an independent HTA body.
6. Are there any *factual inaccuracies* that should be corrected in the HTA Methods Guide?
Medical Society members are not experts in HTA and cannot comment.

Specific feedback on the sections in the HTA Methods Guide

Please consider the appropriateness and feasibility of methods specifications, describe major gaps and factual inaccuracies identified, and provide suggestions for improvement.

1. INTRODUCTION

1.1	HTA in South Africa's public health system	The outcomes of evaluations under this system is understood to only feed into the EML and in future the EEL. It is unclear whether, given the extreme constraints in resources in the public sector, the magnitude of this system would be, in itself, cost-effective.
1.1.1	Guiding principles for HTA in South Africa	If HTA is, as the Guiding Principles suggest, anchored in UHC, it should consider the NHI Bill, and the reference to the Ministerial Advisory Committee on HTA. We do not agree that HTA is a "political" process. It should be a process driven by an independent body, based on science and stakeholder (societal) inputs. We agree that the emphasis should be on health outcomes, which necessitates the implementation of the HMI-recommended OMRO – Health Measurements Research Organisation. Without this, the HTA process would be unmeasurable as having recommended technologies that lead to better health outcomes.
1.2	Stakeholder engagement	Patient special interest groups must be formally included in HTA assessment processes, and not just be the recipients of HTA decisions or as only "stakeholders" to be consulted on the HTA methods. They, as should healthcare professional association, form part and parcel of the assessment process.
1.3	Topic prioritisation process	"Medicines, Medical devices, Diagnostic / diagnostic techniques, Screening tool / screening techniques, Medical procedures, Vaccines and Public health programmes" are identified as HTA "topics". It remains unclear what this means – these appear to the product types to which HTA could be applied, but it only applies, at this stage, to medicines?
1.4	Tiers of assessment	Reference is made to a technical review, but not to the technical reviewers, the structure within which they will function, their appointment and nomination, their qualifications and the likes. These structures should be clearly defined from the outset. The type of analysis. (e.g. bespoke or a comprehensive cost-effectiveness analysis, or a clinical review) will require different skills sets.
	Other comments	Analysis of any type will be driven by data derived from coding and or financial claim systems. Without quality data any cost analysis will be fatally flawed. Therefor coding will be a corner stone of any HTA system.

2. TECHNOLOGY ASSESSMENT SCOPE DEVELOPMENT

It is stated that this will be provided by the Essential Drugs Program to the entity that will be making a submission. It infers that the persons doing this, will report to the National EML Committee. This work will be done under the auspices of a "Lead reviewer". It is unclear to SASCI, on a practical level, how many. lead reviewers would be required, and what the budget for this endeavour would be.

3. ASSESSMENT

3.1 STAGE 1: TECHNICAL REPORT

3.1.1	Clinical evidence	*The evaluation of clinical evidence can only be done by persons duly registered, i.e. educated, trained and experienced in a particular field.*
3.1.2	Economic evidence	*As stated above, cost information in the public sector is not available. It is not known what an hour in theatre costs, or a day in hospital in ICU versus a general ward, or any specific component thereof (e.g. diagnostic tests, screening, medicines, staff costs, etc.). We note that in this section ONLY pharmaceutical costs are required. A health outcome, and evidence-based assessment would have to include the IMPACT of a technology, and the REQUIOREMENTS thereof. For example, where administration of the medicine or device requires specific training, supportive tests and/or screening, those are to be incorporated into the cost assessment. The same for treatments that require hospital admission, or the intervention (or lack thereof) causing hospital admission because of the effect of that decision. Some of these element s are included under "feasibility" but must be COSTED. See sections 1 and 3 above*
3.1.3	Equity considerations	*No comment*
3.1.4	Social value considerations	*No comment*
3.1.5	Feasibility considerations	*Mention is made of "legal" considerations. The main problem however is that the proposed HTA system itself is currently without a legal "home", as is the EML. Please see the main submission.*
3.1.6	Recommendations	*No comment*
	Other comments	*No comment*

3.2 STAGE 2: ADDITIONAL ANALYSIS

3.2.1	Systematic review	*A clinical review can only be undertaken by persons duly registered in a specific field.*

3.2.2	Cost-comparison analysis	*Significant data gaps exist. It is unclear where an HTA "applicant" will obtain for example the costs listed in table 14, e.g. Drug acquisition cost (which would include more than the tender / bid price, or the SEP); Drug administration and monitoring costs; Costs of additional associated interventions (such as companion diagnostics); Cost of healthcare appointment; Costs of management of adverse events. The data sources listed in table 15 does not include cost data, and to a lesser extend only includes price data (noting that the NDoH's SEP database has been offline for more than 18 months now)*
3.2.3	Budget impact analysis	*This analysis also assumes the provision of data actually not readily available or available at all, such as "prevalence and incidence data as well as mortality data".*
3.2.4	Rapid review of economic evaluations	*The Medical Society fraternity supports a system that would recognize analyses done elsewhere, as a more cost-effective and efficient way of HTA*
3.2.5	Cost-effectiveness analysis	*Concerns here relates to the availability of the information required, in particular insofar as those of competitors or of entities not in the same field, is concerned.*
3.2.6	Pricing analysis	*The requirement of global price comparisons is noted. One should bear in mind that prices in other countries may be subject to unique legislative, funding or reimbursement and/or economic circumstances. A pure price to price comparison would not be fair. In medical devices, the costs of operators, capital equipment, etc. would have to be accounted for. Global price comparisons are also significantly impacted on by exchange rates (which do fluctuate significantly).*
	Other comments	*None*

4. EVIDENCE APPRAISAL

The proposed structures to implement the HTA process is the Expert Review Committee under the relevant EML. No qualifications or experience is listed, neither is a process of comment or engagement with stakeholders included, patient groups, and professional associations.

SA Heart, SASCI and HeFSSA supports the recommendations of the HMI in relation to an independent HTA body.

Lastly, the implementation of the HTA model in terms of human resources, internal and external must be costed, as well as the costs of research, evaluations, and logistics (given the use of external persons on the ERC and HTA external experts).

OTHER COMMENTS

Please see our main submission.