SAMED commentary on CMS Circular25 of 2022:
Performance of HTAs by Managed Care Organisations and/or medical schemes – Statutory provisions and proposed way forward
20 May 2022

1. Introduction

The South African Medical Technology Industry Association (SAMED) is a not-for-gain industry association established in 1985. SAMED is committed to enabling a sustainable, ethical and transformed medical technology industry that ensures patient access to medical technologies.

SAMED represents the interests of 200+ multinationals, distributors, wholesalers and local manufacturers of medical devices, medical equipment and in vitro diagnostics (IVDs) (collectively referred to as 'medical technology' or 'MedTech') as well as the South African Laboratory and Diagnostic Association (SALDA) and the Medical Device Manufacturers Association of South Africa (MDMSA).

Medical technology plays a vital role across the continuum of patient care and effective healthcare delivery (prevention, screening, diagnosis, treatment and rehabilitation).

SAMED has been a long-time active participant and contributor to the regulatory requirements of medical technology and the discourse surrounding health technology assessment (HTA) in South Africa and particularly in relation to HTA of medical technology. SAMED has made submissions pertaining to National Health Insurance (NHI), the health market inquiry, the Counsel of Medical Schemes (CMS) and the National Department of Health which include our position on HTA. We have also developed a guidance document for our members to assist them with navigating the HTA requirements of the medical scheme funding environment. We are currently in the process of drafting a position paper for engagement with stakeholders which proposes the formation of an independent HTA agency for South Africa, including suggested archetypes, based on international research and we would welcome an opportunity to share this with the counsel.

SAMED welcomes the opportunity to provide comments on the CMS position and proposed way forward as referred to in Circular 25 of 2022 related to the performance of HTAs by Managed Care Organization and/or medical schemes and the initiative by the CMS to address this issue considering the importance of the use of HTA in the South African context to improve access to health for medical scheme members and the wider of objectives of Universal Health Coverage (UHC).

SAMED notes with concern the following statements in the circular, where:

1. The CMS will engage with the National Department of Health (NDoH) and the South African Health Products Regulatory Authority (SAPHRA) to discuss the potential of establishing an independent body charged with performing HTAs for all new medicines, technology, etc., which will then be available to all relevant stakeholders in both the public and private health sectors.

2. In the meantime, whilst the establishment of an independent national body to perform HTAs is under discussion/development, the private industry is called upon under the guidance of the CMS and, in terms of providing oversight over the process, to centralise the current HTA capacity that exists in the industry and form a voluntary, independent HTA task team/working group to conduct HTAs for the private medical scheme industry.

2. Separating a national, single HTA system from duties imposed on individual medical schemes by legislation

It is important to separate the objective of a single, national, independent HTA body, from the current duties places on medical schemes and managed care organisations in Chapter 5 of the General Regulations to the Medical Schemes Act. These duties, including the duties that are vague and those that are not properly implemented, are often the subject of the complaints that the CMS experience.

The development of an HTA structure, the outcome of which would inform funders, whether they are medical schemes, the public sector, or insurers, in their decision-making. It is key that the HTA function is not merged into, or engrained into the funding or reimbursement decision-making, and stands separate from it. It is for this reason why the CMS interim solution of schemes and other stakeholders co-operating in HTAs, is not acceptable.

Apart from the provisions in the Medical Schemes Act and regulations that remain applicable to individual schemes and managed care organisations, competition law prohibits this function from being centralised – such an approach would be anti-competitive, in that the conditions of trade would be determined through collusion by stakeholders. The envisaged "interim" phase, mentioned in point 2 of the Circular, is therefore a legal impossibility.

SAMED's comments are therefore separated into two areas:

- HTA as a centralised, independent process, and
- Cost-effectiveness and affordability considerations by schemes under Chapter 5 of the Medical Schemes Regulations, 1999.

3. An independent HTA body ("institutionalised HTA")

Health Technology Regulation: The role of a medicines and medical device regulator responsible for licensing and registration of entities supplying, in SAMED's case, medical technology, and confirms through registration such technology as safe, of good quality and performing as intended, (i.e. SAHPRA) is fundamentally different from:

Health Technology Assessment: which in SAMEDs view would be an entity assessing, as an independent third party, the value-for-money and related aspects of a specific technology, including related procedures, or approaches to healthcare service delivery. The outcomes of this process is applied, as is, or with variation, by entities making health funding / reimbursement decisions; and

Health funders / reimbursement entities / coverage bodies: These entities make decisions on the funding and/or reimbursement of healthcare. It would include medical schemes, managed care organisations, provincial departments of health and specifically central- and other public sector hospitals and in the future, the National Health Insurance (NHI) Fund.

A well-functioning, but separate Health Technology regulatory system (through SAHPRA) is necessary and a pre-condition for successful HTA.

Global experience, and local legal principles of administrative justice, and as contained in medical scheme legislation, constitutional law and competition law, **necessitate that the HTA function should be exercised as independent and free from any bias from stakeholder influence and conflicts of interest**.

Institutionalising HTA means establishing accepted processes, norms, and standards, developing critical skills, experience, knowledge, and building effective working relationships between stakeholders to support the use of HTA. This then is applied by funders and ensures that HTA becomes part of the decision-making process in the health system, even if it is initially limited in its use to specific technologies. For funders and reimbursement decisions, there needs to be a move away from the use of HTA for supporting formulary decision-making and health policy decisions, to rather improving access to innovation and patient access.

HTA has been an evolving discussion for over two decades, featuring in several policy documents, the NHI Bill,[1] Health Market Inquiry ("HMI")[2] and Presidential Health Compact[3]. In recognition of the need for developing skills and capacity, reference is made to the

[1] Section 7(40(b) refers to "a health technology assessment" and the formation of an HTA Ministerial Advisory Committee in section 57(3)(d) (available at: https://www.gov.za/sites/default/files/gcis_document/201908/national-health-insurance-bill-b-11-2019.pdf.)

[2] In paragraph 240, with details elsewhere in the Report, the HMI recommends HTA to be part of an independent Supply-Side Regulator for Health (available at: https://www.compcom.co.za/wp-content/uploads/2020/01/Final-Findings-and-recommendations-report-Health-Market-Inquiry.pdf.)

[3] See Commission / Pillar 2: HTA requires a costed implementation plan and an independent HTA Committee, amongst others (available at: https://www.thepresidency.gov.za/download/file/fid/1650).

establishment of scientific organisations who are positioned to guide and facilitate such training of skills required for conducting the technical elements of HTA as well as providing objective discussion forums for all stakeholders across the health sector. There has also been work done at the National Department of Health as part of the development of Standard Treatment Guidelines, but SAMED cautions against the use of medicines-models in undertaking HTA on medical technology.

A common thread throughout these documents is for the need for the establishment of institutionalised HTA, founded on the principles of independence, transparency, and participation (stakeholder engagement and consultation). There is, however, an absence of any empowering legislation for the formal establishment of an HTA agency, without which any recommendations will lack legitimacy and therefore enforceability.

SAMED urges consideration of these three developments, i.e. the NHI Bill, HMI and the Presidential Health Compact and the structures tasked with implementing them, as part of this CMS-initiative. Duplicative, and possible conflicting and resource consuming processes must be avoided.

In establishing an independent HTA entity for South Africa, SAMED believes that there are four aspects that must be addressed, namely:

• Governance: Three core values of governance i.e. independence, transparency and accountability are found to have major influence over the most successful HTA organisations.

• Structure: The functions and roles of the Health Technology regulator i.e. SAHPRA, HTA entity and coverage bodies (funders) must be exercised independent of one another, with the HTA function being free from any bias, influence and collusion from stakeholders and free from conflicts of interest.

• Process: This must be efficient (prioritisation; topic selection; avoid duplication), transparent, ensure procedural and administrative justice, comprehensive (assess all domains i.e. clinical, economic, ethical, social, legal and organisational) and communicated appropriately.

• Methods: Innovative approaches for the assessment of different technologies must be developed (considering the diversity of medical technologies), and be capable of accommodating learning curves, the use of observational data in assessing the comparative effectiveness, and control the diffusion and coverage with evidence development. EUNetHTA Core Model: Rapid reviews, mini HTA and full HTA.

4. Concerns relating to the manner in which funders implement criteria of cost-effectiveness and affordability under the Medical Schemes Regulations

SAMED concurs with the CMS conclusion that the current provisions under Chapter 5, and regulations 15, and 15A to 15J of the General Regulations to the Medical Schemes Act empower medical schemes and managed care organisations to undertake some form of HTA as part of managed care decision-making and the development on protocols and formularies.

These regulations do not empower collusion / co-operation between schemes, nor do they empower the setting up of a single, HTA agency / entity, which if done, would violate, and be in conflict with, the principled and successful approach to HTA, where the funder decision is then merged with the HTA process and outcome from an HTA agency.

The following regulations are examples of schemes or managed care organisations not implementing, or properly implementing the law. All of these elements are within the power of the CMS to clarify, to issue Circulars on, as well as policy documents. Its clarification and proper implementation therefore does not need to wait for either industry agreement, a collective body or an HTA agency being set up.

Regulation 15D (a) (iii): ***process for conducting appeals***

There is no explicit process for this, in particular where suppliers of medical technology are concerned.

Regulation 15D (b): ***clinical review criteria that are based upon evidence-based medicine, taking into account considerations of cost-effectiveness and affordability***

This is very narrow in scope from a process and methodological perspective. SAMED does concur that decisions should be evidence based. However, in practice decision-making on cost-effectiveness and affordability is often not clear, and the process requires greater transparency.

Regulation 15D (d): ***qualified health care professionals administer the managed health care programmes and oversee funding decisions, and that the appropriateness of such decisions are evaluated periodically by clinical peers;***

While the persons performing these on behalf of Managed Care Organisations are employees, full time or subcontracted, they are not necessarily qualified across all topics, and SAMED questions how often these decisions are evaluated by clinical peers.

Regulation 15D (e)*: health care providers, any beneficiary of the relevant medical scheme or any member of the public are provided on demand with a document setting out……*

Although this appears to apply *ex post facto*, this does not occur and one rarely has success in accessing these and this therefore limits the rights of service providers, suppliers and patients.

The above processes are being paid for as statutory duties on schemes and Managed Care Organisations, through premiums levied, as it should. Charging suppliers for conducting HTAs, which are neither complete nor transparent, is moot, as to our knowledge, this was not implemented nor is currently occurring.

Making comments or proposals on costs for recovery relating to a single HTA agency or entity, as above, is a different matter, but would be premature until such time that there is consensus on the governance and structure models of such an entity, and the required process and methodologies understood, all of which will dictate which resources are required and subsequent costs allocated.

5. Conclusion

SAMED stands ready, as a significant stakeholder, to contribute to the development of an independent HTA agency for both the private and public health sectors of South Africa aligned to that as proposed in the Presidential Health Summit, the HMI and the NHI Bill.

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