The South African Medical Technology Industry Association (SAMED)

Submission

in response to

the call for input

by

circular 6 of 2018: review of the prescribed minimum benefits – update and call for inputs

Submitted to:
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1. INTRODUCTION

The South African Medical Technology Industry Association (SAMED) would like to thank the Council for Medical Schemes (CMS) for the opportunity, provided through Circular 6 of 2018, to participate in the Review of the Prescribed Minimum Benefits (PMBs).

SAMED represents, promotes and safeguards the interests of the South African medical technology industry, which includes companies that import, distribute and manufacture medical devices, *in vitro* diagnostics (IVDs) and medical equipment. This industry is critical in ensuring healthcare delivery through the provision of medical devices, IVDs and medical equipment, for not only the treatment and prevention of all medical conditions, but also for the diagnosis of such conditions. SAMED is a non-profit voluntary association, established in 1985. It has 164 member companies of diverse profiles and size.

SAMED welcomed the publication of the White Paper on National Health Insurance (NHI) in 2017, recognising the opportunity to rectify the injustices of the past, honour the Bill of Rights, with specific reference to section 27 of the Constitution, which promotes access to healthcare services, as well as the need to align all legislation with this policy. SAMED supports access to universal healthcare and looks forward to engaging with the CMS throughout this process.

2. PRINCIPLES UNDERPINNING THE DESIGN OF THE NEW PMB PACKAGE

SAMED welcomes and supports the approach to change the exclusive nature of the current hospi-centric PMB package to a services-based package. It wishes to emphasise that the new package should continue to be reimbursed in full from risk benefits (and not from medical savings accounts and without co-payments or the use of deductibles) as currently provided for by the Regulations in terms of the Medical Schemes Act 131 of 1998.

In addition, SAMED supports the following principles underpinning the proposed service-based package:

- Simplicity and clarity;
- Clinical guidelines. SAMED would, however, like to call for a transparent process of guideline development, which should include all stakeholders, and which process must provide for regular review to provide for new developments;
- Consistency;
- Quality of care;
- Positive outcomes; and
- Cost-effectiveness of treatment options.

SAMED is also in support of the Criteria for Inclusion supported by the World Health Organisation (WHO) as presented by the CMS at the Advisory Committee meeting on 17 November 2017, namely:

- Consideration of the current health situation and burden of disease;
- Needs of the country, priority areas as stipulated in the National Development Plan (NDP) and the National Department of Health's strategic plan, and policy guidance by the NHI White Paper;
- Clinical effectiveness;
- Cost-effectiveness; and
- Affordability.

Although it is supported that the new package should consider the health status of the country, it is recommended that since this package will be applicable to the medical scheme population, at least in the initial stages and if major differences exist between the health status of the country and that of the medical scheme population, that the health status of the medical scheme population should be considered instead.

The design of a service-based package is challenging due to the experience and expertise gained in the private health sector with the current condition-based PMB package since its inception in 2000. SAMED would therefore welcome a pragmatic approach to the design of such a package.

It is essential that the PMB level of care for the proposed services should be objectively determinable in the interest of clarity and transparency. In addition, SAMED would like to propose two separate mechanisms, i.e. health technology assessment (HTA) processes, to accommodate for the review of both existing and new/innovative medical devices and IVDs for inclusion in the PMB level of care such as treatment algorithms at various service levels.

Furthermore, it would be imperative to ensure a continuous and regular review of this package to ensure that it remains appropriate, efficient and cost-effective. SAMED supports, as a minimum, a review of the package every two years with allowance for the introduction of innovative medical devices and IVDs at any point utilising a clearly defined process specific to this purpose.

3. DEFINITION, ROLE AND VALUE OF MEDICAL DEVICES AND IVDS

Medical technology[1] as intended in HTA refers to any medical device and IVD, which is used to save lives or transform the health of individuals who suffer from a wide range of conditions. In its many forms, medical devices and IVDs is already used to diagnose, monitor and treat virtually every disease or condition that affects people. Medical devices and IVDs assists with appropriate surgical and/or medical intervention for the specific condition, prevention or cure. There are more than 350 000 medical devices and IVDs currently available in South Africa and they all share a common purpose, namely to improve, extend and transform people's lives. Medical devices and IVDs can be familiar, everyday products such as blood glucose meters, sticking plasters, syringes or latex gloves. However, it also includes pregnancy tests, spectacles, wheelchairs and hearing aids. At the high-tech end of the scale, medical devices and IVDs includes molecular diagnostics, total body scanners, ultrasounds, life-supporting machines, implantable devices such as heart valves and pacemakers, neurostimulators and replacement joints for knees and hips[2].

A **"medical device"** is defined in the Medicines and Related Substances Act 101 of 1965 (Medicines Act) as:

"any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973) —

(a) Intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following:

(i) Diagnosis, prevention, monitoring, treatment or alleviation of disease;

[1] Medtech Europe The European Medical Technology Industry – in figures / 2018

(ii) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
(iii) Investigation, replacement, modification or support of the anatomy or of a physiological process;
(iv) Supporting or sustaining life;
(v) Control of conception;
(vi) Disinfection of medical devices; or
(vii) Providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

(b) Which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means."

IVDs are products, which provide medically useful diagnostic information by examination of a specimen derived from the human body. An "IVD" is defined in the Medicines Act as:

"a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes."

The value of the information provided by IVDs includes:

- Prognosis;
- Diagnosis;
- Therapeutic monitoring;
- Medication effectiveness or toxicity;
- Preventative screening;
- Community health and epidemiology; and
- Transfusion and transplant compatibility monitoring.

The common thread through all applications of medical devices is the beneficial impact on health, quality of life and in society as a whole. Medical technologies contribute to longer and better living and as such empower citizens to contribute to society for longer. In so doing, they improve the quality of care and the efficacy, efficiency and sustainability of healthcare systems. For the purpose of this submission the term 'medical device' refers to all medical technologies, including consumables, IVDs and medical equipment.

4. COST IMPACT OF MEDICAL DEVICES

The recent report published by the panel of the inquiry into the private health sector (i.e. the Health Market Inquiry [HMI]), entitled *Report on Analysis of Medical Schemes Claims Data - A Focus on Facilities*, of 15 December 2017, demonstrates that the cost of NAPPI-coded items (most medical devices are NAPPI coded) has increased at a slower rate than the other expense categories in hospital.

This confirms that medical devices are not the main cost drivers in the private hospital sector. In fact, increases have been below inflation, averaging 2.5% over four years from 2010 until 2014, as demonstrated by the following table from this report:

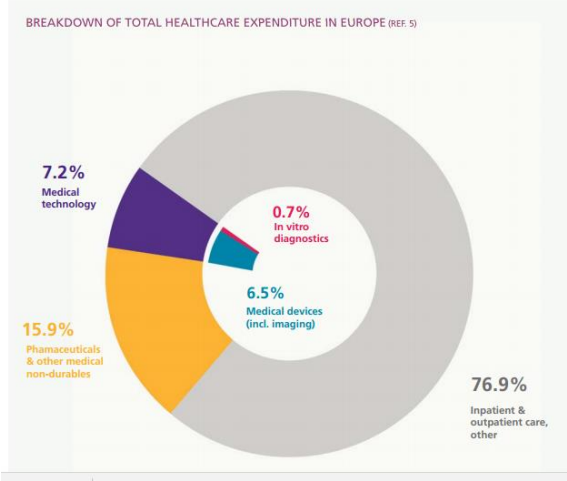
TABLE 40: HOSPITAL COST PER ADMISSION TRENDS BY TARIFF TYPE, 2010-14

Year	Ward	Theatre	NAPPI	ARM	Other	All
2010						
2011	10.19%	6.53%	2.20%	1.49%	11.20%	8.03%
2012	5.63%	6.54%	3.76%	14.64%	17.96%	8.10%
2013	8.74%	8.90%	2.06%	7.78%	12.00%	8.27%
2014	9.00%	7.53%	2.16%	27.03%	10.52%	8.41%
Average	**8.37%**	**7.37%**	**2.54%**	**12.34%**	**12.88%**	**8.20%**

[5] In this case 'Theatre' costs refer both to actual theatre fees as well as equipment charges for theatre equipment. It is therefore possible that 'medical' admissions could have theatre costs if the equipment fees are billed without a theatre facility fee code.

The expenditure by medical schemes on medical devices and IVDs as a percentage of total healthcare expenditure is not currently reported in the Annual Report of the CMS despite numerous requests to this end by SAMED to the CMS.

The following graph indicates that 6.5% of total health care spend is attributed to medical devices and 0.7% to IVDs in Europe:



Source: Medtech Europe The European Medical Technology Industry – in figures / 2018

1. European Patent Office, MedTech Europe calculations. Medical technology as defined by World Intellectual Property Organization (based on the WIPO IPC-Technology concordance as revised in August 2014). European countries refer to EU + Norway, Switzerland. Patents are attributed by the country of residence of the applicant.
2 EFPIA – The Pharmaceutical Industry in Figures. Key Data 2017. Europe refers to EU + Norway, Switzerland.
3 MedTech Europe calculation based on the data obtained from National Associations of 12 countries for the latest year available. Europe refers to EU + Norway, Switzerland.
4 WHO Global Health expenditure Database, Eurostat, BMI Research, MedTech Europe calculations based on the data obtained from National Associations of 15 countries for the latest year available.

5 BMI Research, WHO, Eurostat, EFPIA, EDMA, MedTech Europe calculations. Europe refers to EU + Norway, Switzerland.
6 BMI Research, MedTech Europe calculations. Manufacturer prices. Medical technology excluding in vitro diagnostics.
7 MedTech Europe - European IVD Market Statistics Report 2016.
8 Worldwide Medtech Sales by EvaluateMedTech® Device Area: Top 15 Categories & Total Market (2016 & 2022)- http://info.evaluategroup.com/MTWP2017-EMF.html

5. DIFFERENT APPROACH TO MEDICAL DEVICES AND IVDs IS REQUIRED

The medical device and IVD industry is unique and processes, methodologies and expertise used in pharmaceutical evidence appraisals are not always applicable to medical devices and IVDs. In addition, a single approach should not be applied to the diversity of medical devices and IVDs in multiple service delivery settings.

Medical devices and IVDs is characterised by constant innovation, which is the result of a high level of research and development within the industry, and of close co-operation with the users (e.g. health care practitioners, health facilities and patients). Products typically have a lifecycle of only 18-24 months before an improved or new/innovative product becomes available.

5.1. ACCESS TO INNOVATIVE MEDICAL DEVICES: PROPOSED PROCESS

SAMED proposes a process in terms of which specific resources should be made available for purposes of evaluating the impact of new and innovative medical devices and IVDs on South African patients from a cost benefit perspective. The ultimate objective is to ensure access by patients to appropriate, innovative and cost-effective technology.

This process should allow a select group of patients at an appropriate level of care to access and use the new innovation within a conditional reimbursement framework, whilst measuring predetermined outcomes. An HTA evaluation should occur to finally determine whether to incorporate such technology in the benefits.

5.2. ACCESS TO IVDS: PROPOSED PROCESS

The crucial role of IVDs is widely acknowledged. SAMED recommends that the CMS ensure that IVDs are considered as part of the PMB treatment algorithms and treatment guidelines and that a process be created for the consideration of new or innovative IVDs prior to the regular review timelines. Screening and diagnostics play a pivotal role in preventative care and ensuring the correct diagnosis and treatment is provided to the patient.

6. PROPOSED SERVICE BENEFIT CATEGORIES

It is not possible to comment on an informed basis on the comprehensiveness of the proposed service categories without a proper understanding of the exact services that would be included in each category. Hence the request that the consultation process in the design of the new package should be transparent and inclusive of all relevant stakeholders.

SAMED would, however, like to express concern about the omission of secondary care services from the package and request that this aspect should be further considered.

It should be borne in mind when designing the new PMB package that most medical services require some form of medical devices, IVDs or other medical technology. The final determination of medical devices and IVDs will depend on the final list of services to be included per category.

The identification of relevant and appropriate medical devices and IVDs for each service category and each service requires a multi-stakeholder approach and input as a result of multiple options available and the inherent complexity. SAMED's comments below should therefore only be regarded as preliminary and interim comments on the proposed categories.

SAMED would like to specifically support the inclusion of preventative care in the revised PMB package as it is submitted that this would contribute to the long-term benefit and sustainability of the healthcare sector and the overall improvement of the health of the population at large. For example, appropriate early screening and management of chronic conditions related to lifestyle diseases and / or genetically predisposed chronic conditions.
See http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2817%2933102-1.pdf#.WpZsiPBcdrY.email for another example for effectiveness of preventative care treatment.

SAMED would like to propose the additions/amendments below [underlined] to the service benefit categories as set out in Circular 6 of 2018.

A: **Maternal and Neonatal Services**

A.1 **Antenatal services**

- Laboratory antenatal tests including screening for fetal abnormalities and counselling
- Radiology services including 3D pregnancy ultrasounds. 3D Scans are the recommended standard

A.3 **Post-natal services**

- Counselling and treatment of postpartum depression and social workers

A.4 **Other services**

- Medical and surgical management of high risk pregnancies such as Diabetes Mellitus, Hypertension, Heart Failure Pre-eclampsia, etc.
- Counselling and treatment of post-abortion depression and complications
- Sterilisation and contraception

B: **Child Health Services**

- Immunisation against vaccine preventable diseases according to NDoH guidelines – and WHO acceptable standards
- Screening for developmental milestones and related remedial services
- Nutritional advice and eating plans to prevent non-communicable disease (diabetes) in later life and weight management of children. Stroke and heart foundation as reference and lifestyle interventions
- Medical and surgical management of these conditions

C: **Preventative Services**

- Screening for non-communicable diseases e.g. hypertension, hyperlipidaemia, diabetes - diabetic foot (wound care) and neuropathies, breast cancer, pap smear and cervical cancer – HPV DNA testing

- Medical and surgical management of these conditions
- Dental services
- Optometry

D: **Communicable and Non-Communicable Diseases Services**

- Specialised geriatric care, including foot care for diabetes
- Homeopathic and allied medicines
- Counselling for chronic conditions
- Medical and surgical management of these conditions
- Referrals for counselling for emotional support, spiritual or bereavement care
- Pain management should be added to the list of proposed conditions
- Dental services
- Optometry

E: **Mental Health Services**

- Medical and surgical management of these conditions
- IVD screening, diagnostic and management of patients – EEG and systemic screening

F: **Rehabilitation Services**

- Provision of basic assistive devices, including wheelchairs, walking aids, hearing aids, orthotics and occupational health prostheses
- Nutritional support
- Utilisation of step down facilities
- Medical and surgical management of these conditions

G: **Palliative Services**

- Medical and surgical management of these conditions

H: Emergency Services

- Burns and rehabilitation
- Traumatology
- Nationally co-ordinated STEMI program for AMI
- Nationally co-ordinated stroke management program
- Medical and surgical management of emergencies

It is submitted that the PMB level of care per service should be identified in accordance with recognised coding standards. Most categories of medical devices have NAPPI codes and could therefore be easily distinguished from pharmaceuticals. Capital equipment has a hospital tariff code for billing purposes, but is specific to each hospital or hospital group. IVDs have a national procedure code listing (which is outdated) for identification purposes. There are, however, NAPPI codes for specific reimbursed IVD tests.

7. SAMED'S POSITION ON HTA FOR EXISTING AND NEW/INNOVATIVE MEDICAL DEVICES

As stated before SAMED proposes a separate mechanism/methodology to that of pharmaceuticals regarding HTA processes for the review of existing and new/innovative medical devices and IVDs for inclusion in the PMB level of care, be it in treatment algorithms and guidelines at various service package levels.

SAMED supports and advocates sound and transparent HTA of medical devices with proper involvement of patients, healthcare professionals, and industry. This ensures:

a) Efficient decision-making;
b) Efficient allocation of resources; and
c) Informed uptake and diffusion of health technology.

If correctly carried out, HTA is also a useful tool to encourage and reward innovation. [3]

In the establishment of a separate mechanism / methodology of HTA for medical devices the following should be noted:

- **The device industry is unique:** the processes, methodologies and expertise used in pharmaceutical evidence appraisals are not always applicable to medical devices. A single approach should not be applied to the diversity of medical devices in multiple service delivery settings.
- **Transparency: HTA Policies** should be vetted and implemented in an open process, in which the decision-making criteria and process for implementation are fully disclosed in advance to stakeholders.
- **Timing, notice and comment:** Policy-makers should provide ample time and opportunity for stakeholders - including members of the public - for notice and comment on proposed policies.
- **Stakeholder input:** Policy-makers should be required to disclose and discuss the input provided and consider this input in finalising benefit and reimbursement decisions.
- **Reward innovation:** Policy-makers should reward innovation when making benefit and reimbursement decisions.
- **Consistency:** Policy-makers should adhere to a predictable schedule for proposed updates and/or system reforms.
- **Best value:** A payment system should recognise the resources needed to deliver a group of services, or entire episode of care. The resources should be identified from well-established clinical guidelines, reflect the long-term value of medical devices and IVDs and not just focus on short-term costs.
- **Market competition:** There should be an acknowledgement that market forces are allowed to operate to maximum efficiency and improve patient care.

[3] Joint Healthcare Industry Paper – MedTech Europe 2011

8. CONCLUSION

SAMED wishes to emphasise the need for an inclusive consultation process in the development of the new PMB package as it will have a far-reaching impact, initially on the private health sector, but with time as NHI matures, on the entire country.

All stakeholders, including patients, will be affected. As a result, continuous and regular consultation is essential. Sufficient lead time before the implementation of the package should be provided to all affected stakeholders to adequately prepare for such an event with specific consideration of the education of medical scheme beneficiaries who are used to the current package and whose disease benefits and medical scheme cover are likely to be affected by the new package.

SAMED would be willing to engage further with the CMS on this submission, should that be required, and in respect of the development of the new PMB package.