SUBMISSION

ON THE DRAFT MEDICAL SCHEMES AMENDMENT BILL

Published on 21 June 2018 for comment

Submitted by:

The Pharmaceutical Task Group (PTG)

Representing:

Generic and Biosimilar Medicines of Southern Africa (GBMSA)

Innovative Pharmaceutical Association South Africa (IPASA)

Pharmaceuticals Made in South Africa (PHARMISA)

Self-Medication Manufacturers Association of South Africa (SMASA)

Contents

1. Introduction

The members of the Pharmaceutical Task Group (PTG), hereby submit comments on the Medical Schemes Amendment Bill ("MSAB"), as published in the Government Gazette No 41726 of 21 June 2018.

The PTG represents four pharmaceutical industry associations: The members of the PTG are:

- Generic and Biosimilar Medicines of Southern Africa (GBMSA)
- The Innovative Pharmaceutical Association South Africa (IPASA)
- Pharmaceuticals Made in South Africa (PHARMISA)
- Self-Medication Manufacturers Association of South Africa (SMASA)

The members of the PTG supply more than 90% of the medicines in South Africa.

The PTG welcomes this opportunity to comment on the MSAB. This Bill proposes a fundamental change in the role and functions of medical schemes, and the relevant regulatory body, the Council for Medical Schemes (CMS).

The PTG believes that the proposed changes will have a profound effect on beneficiaries of medical schemes for the following reasons:-

- members of medical schemes are motivated to belong to medical schemes primarily to provide for catastrophic events[1] and in so doing, contribute to the scheme to ensure its financial sustainability;
- members who have been on treatment for conditions that fall under the Prescribed Minimum Benefits (PMBs) may be exposed, as the PMBs (as conditions) will no longer be part of the benefit offerings required by the Act; and
- members, as funders of the CMS through their medical schemes, will now have some of their CMS contributions, diverted to fulfilling functions of the NHI Fund (NHIF), with a possible reduction in the capacity of the CMS to address its core functions of protecting members through its complaints and accreditation activities.

The Health Market Inquiry's (HMI) recommendations are particularly relevant for these amendments, and it is recommended that the final report of the HMI inform the MSAB prior to its submission to Parliament.

Contact details:

Dr Tim Kedijang
PTG Chairperson
Cell: 083 4405740
ntnd@novonordisk.com

[1] See PMB list for the nature of the conditions contained therein, also see the Health Market Inquiry Draft Report 2 July 2018, page 91, par 97.

2. Introductory comments and key principles

- The PTG welcomes the focus on improved governance in the MSAB. This is in line with the recently published Health Market Enquiry HMI), which also recommended many areas deserving of attention to improve governance in healthcare.

- The requirement for more data reporting is welcomed. Increased information availability should lead to more better decision-making. The need for improved data was further supported by the HMI. The PTG however raises a concern in this submission about the intention to discontinue the Council for Medical Schemes (CMS) Annual Report, which is an important source of information for all stakeholders.

- The MSAB further establishes the link to the National Health Insurance Fund (NHIF) which is necessary. There remain queries on the transition to the NHI and the changing role of medical schemes, some of which we have raised on this submission.

- The pharmaceutical industry is committed to the following key principle: The Progressive realisation of Universal Healthcare Coverage (UHC) through implementation of National Health Insurance (NHI).

- The issue of benefits is addressed at length in the document. The switch from PMBs to service benefits, capping of benefits and the limitation of benefits, all raise uncertainty.

- Co-payments play a role in patient choice and access to appropriate care. There needs to be a balance and control of medical schemes' power to limit benefits to what is prescribed, for example, on formularies. Patients should be allowed choice and access to appropriate care, where the defined benefits limit what is available. There is agreement that punitive co-payments are undesirable.

- Despite rhetoric to the contrary the PTG is confident that medicines are not a cost-driver. The PTG requests the opportunity to present supporting empirical data to substantiate this statement. Marketers of medicines are required to present comparative or benchmark prices from nominated countries, when coming to market, in order to gain marketing approval.

- In response to incorrect and commonly held opinions on this point, the utilisation of generic medicines has reached proportions on a par with international markets, with generic medicines making up 67% by volume in the private sector and 91% by volume in the public sector. Supporting data is available and can be presented at the appropriate time.

- Pharmaceuticals are already providing Universal Access to medicines in South Africa, with the current tiered or multi-level pricing models, making affordable medicines available through State and Private sectors, while facilitating socio-economic

sustainability of the pharmaceutical industry. The Pharmaceutical Industry is the only regulated healthcare sector presently supplying goods and services to both the public and private sectors of our country, and accordingly its products are accessible and available to both private and public sectors.

- In order to ensure access to an ongoing supply of medicines, differential pricing allows responsiveness to the needs of particular geographies and differing circumstances. Without this balance, the security of supply of medicines is threatened.[2] Total product supply cannot exist on pricing levels achieved in the state sector and requires the present multi-layered system in order to ensure security of supply of medicines in our country.

- The need for a sustainable business environment, which in turn can contribute to the delivery of a UHC system, is underscored by the forthcoming Presidential Job Summit; Health Summit and Investment Summits which indicates the macro-economic policy directions of the country. Policy changes in health should fit into these strategic interventions.

[2] Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents. [cited 2018 September 19] Available from: https://faculty.wharton.upenn.edu/wp-content/uploads/2014/10/differential-pricing_3.pdf

3. Principles underpinning Social Solidarity, Equity and Access

Medical schemes are a manifestation of both the rights of access to healthcare, and the right to social security.

The rationale for the introduction of the Prescribed Minimum Benefits (PMBs), was to ensure that beneficiaries of medical schemes would not run out of benefits for certain conditions and find themselves forced to go to State hospitals for treatment.

The explanatory notes to the PMBs make the following clear:

The objective of specifying a set of Prescribed Minimum Benefits within these regulations is two-fold:

(i) To avoid incidents where individuals lose their medical scheme cover in the event of serious illness and the consequent risk of unfunded utilisation of public hospitals.

(ii) To encourage improved efficiency in the allocation of Private and Public health care resources.

The constitutional provision giving rights of access to healthcare and social security reads as follows (emphases provided):

27. Healthcare, food, water and social security.—*(1) Everyone has the right to have access to—*

(a) health care services, including reproductive health care;

(b) sufficient food and water; and

(c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.

(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

The wording in relation to social security is illustrative – it embodies the principle that where people can afford to contribute to their own social security (in this case social insurance through a common risk pool in a scheme), they should do so.

The MSAB also appears to draw on the rights of children in the Constitution. The Constitution however only provides children with the right to basic healthcare services (section 28(1)(c)). The Children's Act, however, provides children with stronger rights, and in particular protects children living with disabilities[3] and chronic conditions[4] with rights to support, to enable them to participate in their communities fully.

[3] Section 11(1).
[4] Section 11(2).

It would therefore be recommended that the amendments consider the provisions of the Children's Act, in particular where benefits that impact on disability and chronic conditions, are concerned.

The Constitution is also relevant to the proposed amendments as it affects the way in which powers are exercised, and whether documents are published as law, or only in a Gazette, or as circulars or as policy documents. Legislation should contain sufficient detail to allow decision-makers to act in accordance with the rule of law. Some of the amendments of constitutional relevance in this regard, include:

- Not publishing the benefits as law, as is the case currently, as part of the Medical Schemes Regulations. Failure to publish benefits as law means that the limitation of access to health and access to social security rights are limited on an ad hoc basis, and not as is required by section 36 of the Constitution "by law of general application".

- The delegation of certain powers to the CMS and/or Registrar could constitute an unauthorised delegation of legislative authority, as the Constitution requires of the legislature to make laws, and does not provide for delegation of authority to the executive to exercise these powers when and as they may deem fit. This introduces legal uncertainty and does not align with the rule of law. Examples in the MSAB include: –

    - The Council, in consultation with the Minister, determines "comprehensive service benefits" (section 32I).
    - The Registrar may, after consultation with the Minister, restrict benefits that schemes may provide, to prevent "duplicative cost" for the same benefit (section 34(4)).
    - The right to obtain information "from time to time" from schemes without the purpose thereof being clear (section 8A and 32J(2)). Further, such information could be made available publicly in terms of 32J(4) and provided to the NHI Fund.
    - Placing restrictions on a medical scheme "from time to time" on overall administration costs or on specific components thereof (section 44(8)).
    - Remuneration parameters for members of Boards of Trustees are to be published "from time to time" (section 56E).

The PTG recommends that the powers to be exercised by the Registrar, the CMS and the Minister, be delineated clearly in the Act and where relevant, published as regulations.

4. The exclusion of the Consumer Protection Act

Section 2A attempts to exclude the application of the Consumer Protection Act (CPA) to medical schemes. The legal process is outlined in section 5(3) of the CPA, which states as follows:

A regulatory authority may apply to the Minister for an industry-wide exemption from one or more provisions of this Act on the grounds that those provisions overlap or duplicate a regulatory scheme administered by that regulatory authority in terms of—
(a) any other national legislation; or
(b) any treaty, international law, convention or protocol.

(4) The Minister, by notice in the Gazette after receiving the advice of the Commission, may grant an exemption contemplated in subsection (3)—
(a) only to the extent that the relevant regulatory scheme ensures the achievement of the purposes of this Act at least as well as the provisions of this Act; and
(b) subject to any limits or conditions necessary to ensure the achievement of the purposes of this Act.

Section 5(5) of the CPA states that even if exempted, the provisions of sections 60 (safety) and 61 (strict liability for harm caused) can never be excluded from application goods.

The Consumer Protection Act outlines the following consumer rights which will be negatively affected should the CPA be excluded by the MSAB:

- Right to equality in the consumer market and protection against discriminatory marketing practices;
- Right to Privacy;
- Right to Choose;
- Right to Disclosure of Information;
- Right to Fair and Responsible Marketing;
- Right to Fair and Honest Dealings;
- Right to Fair, Just and Reasonable Terms and Conditions;
- Right to Fair Value, Good Quality and Safety; and
- Right to Accountability from Suppliers.

By excluding the CPA, the MSAB is creating legal uncertainty and violates the principle of equal benefit and protection of the law.

A reference to fair treatment of members in regulations, yet to be determined, is not the same as protection afforded in the Act, strengthened by other interacting laws, and not limited to the views of an entity.

It is strongly recommended that the CPA not be excluded in this manner, and for certain stakeholders in the health sector only, as it would further entrench information asymmetry and power imbalances in the health sector. The CPA currently provides significant protection to patients / beneficiaries, in relation to information, choice and consent.

5. Comprehensive service benefits (section 32I)

5.1 Service benefits and unintended consequences

The PMBs appear to be replaced with "comprehensive service benefits" in the proposed section 32I, however, section 29(1)(o) is not being amended. Section 29(1)(o) reads as follows:

"The scope and level of minimum benefits that are to be available to beneficiaries as may be prescribed".

This creates the situation that the "comprehensive service benefits" will be published in the Government Gazette by the Council, in consultation with the Minister, and would co-exist with the current PMB list as published in the General Medical Schemes Regulations, 1999.

"Comprehensive service benefits" are not defined in the MSAB, and it is unclear what exactly this term means. "Services" in all likelihood refer to professional services, used to bill services by healthcare professionals and health facilities (hospitals), as denoted by so-called procedure codes.

The CMS has the power to, just by notice in the Gazette, set limitations and conditions on the benefits.

Although it makes sense to say the service is funded, irrespective of the patient's diagnosis, no medical scheme would be able to fund all consultations or procedures potentially needed by all patients. This would then mean that some volume limit would have to be placed on these services. The effect of such a volume limitation would introduce exactly what the PMBs were intended to circumvent, that is the requirement for self-funding or use of State facilities by patients who run out of benefits, usually close to the end of the year.

These service benefits will leave the most vulnerable patients without adequate cover i.e. patients who require services beyond what is placed as the volume / utilisation limit.

In the "service benefits", it is not clear how medicines will be reimbursed.

The PTG is of the view that the comprehensive service benefits construct will lead to unintended consequences, including that patients may not receive appropriate care, or may receive no care at all, if service benefits are exhausted.

Such a fundamental change in the basic core of medical schemes is likely to cause severe hardship for many patients, and may cause actuarial and financial difficulties for schemes, as planning and systems would have to change fundamentally under such a regime.

5.2 Retention of the PMBs and a standardised benefit package as proposed by the HMI

The PTG proposes that the PMBs be retained, recognising the HMI finding that the PMBs are not a cost driver in healthcare.[5] There is therefore no cost-driving basis on which to amend the PMBs, or to abolish them.

The PTG proposes that the recommendations of the HMI with respect to medical schemes benefit packages, be implemented, as copied *verbatim* below:[6]

33.1 The mandated cover for Prescribed Minimum Benefits must be revised to make provision for out-of-hospital and cost-effective care for PMBs. This will remove the current incentive to admit patients to hospital, often at higher cost, for PMB care.
33.2. The PMB package be expanded to include primary and preventative care.
33.3. This revised PMB package should make hospital plans obsolete and will be replaced by the obligatory standard package.
33.4. The services provided for in basic obligatory package can be extended over time as cost savings allow for greater depth or breadth of care.
33.5. That PMBs be reviewed regularly, as provided for in legislation.
…

36. The mandatory minimum benefits, referred to as prescribed minimum benefits (PMBs) are currently only available in the form of diagnosis treatment pairs, rather than simple standard benefit designs, making it impossible to compare between schemes and options. To address the lack of comparability across scheme options and inability of consumers to compare the value of these options, the HMI proposes that a standardised benefit package be developed that must be offered by all schemes (the obligatory 'base benefit option').

37. Every person joining a medical scheme must buy the base option. The base option would cover catastrophic expenditure as well as some level of out-of-hospital and primary care. However, simply standardising the standard benefit package would not address the issue of affordability.

38. Because schemes would still be subject to the principles of open enrolment and community rating, the standard benefit option may be easy to interpret but would still be expensive in the absence of a legislated risk adjustment mechanism. Without risk adjustment, schemes would still have an incentive

[5] "73. The HMI was unable to find support for the assertion that PMBs are a primary driver of cost escalation in private healthcare" Health Market Inquiry, Draft Final Report, 5 July 2018, page 81.
[6] Health Market Inquiry, Draft Final Report, 5 July 2018, paragraphs 36 – 39, page 159.

to compete on risk factors such as age rather than factors such as value for money and innovative (alternative) models of care.

39. Therefore, alongside the standardization of benefits, a risk adjustment mechanism must be implemented. The risk adjustment mechanism will "equalise" risk associated with the standard benefit option across all schemes, with lower risk schemes being net payers and higher risk schemes being net receivers of disbursements from the risk adjustment fund. This will remove the current incentive for schemes to compete on low level competitive factors such as attracting a younger population.

5.3 Use of evidence-based medicines (EBM) to determine explicit disease and medicine inclusion in scheme benefit packages

The PMB or standardised benefit package should in its design give effect to the principle of evidence-based medicine, as found in the regulations to the Medical Schemes Act:

"evidence-based medicine" is defined as a systematic approach to clinical problem solving which allows the **integration** of the **best available research evidence** with **clinical expertise** and **patient values**.[7]

Adherence to this principle would ensure that all patients are able to obtain care that is appropriate for their health needs and that they do not face discrimination in cases of treatment failure, or when utilisation different from that of an uncomplicated or, "standard" patient, is required. Furthermore, such an approach would align with the constitutional principles discussed above.

5.4 Cost-caps, choices and co-payments

Section 32I proposes that the cost of each service be capped. No further details are provided as to how this is to be undertaken, and what the legal basis of such an analysis and subsequent capping would be. In particular, it would mean that the CMS would, in effect, be undertaking price-setting. This also runs counter to the HMI proposal for tariffs to be determined either through a multi-lateral process or through bilateral negotiations.

The PTG believes that any medicine should, in the current dispensation, be funded at its Single Exit Price (SEP), and that no cost-cap can be set by the new benefits that would exclude medicine that is appropriate for a patient.

It seems that the thinking behind the cost-capped benefits is to ensure scheme viability and the prohibition on co-payments. However, if the cap is set too low, patients may not be able to access care, as providers may not be able to render services at such capped rates. This would mean that, instead of part-funded care (or fully funded care if the PMB construct is

[7] Sackett DL, Strauss SE, Richardson WS,et al. Evidence-based medicine: how to practice and teach EBM. London: Churchill-Livingstone,2000

retained), the patient would have to pay for care out of pocket, i.e. not claim from their schemes at all.

The PTG believes that capped rates could have the unintended consequence of resulting in no payment by the medical scheme for a specific treatment. It leaves provider and patient with only two options – the patient has to pay in full for the care, or forfeit care altogether. It is clear that neither of these unintended consequences align with the right of access to healthcare, or social security.

Co-payments are not necessarily "bad" in all circumstances. The current Medical Schemes Regulations provide for two instances where co-payments are "good", i.e. not punitive, by giving effect to patient choice and/or clinical need:

- Patient voluntarily chooses a non-formulary medicine, and the scheme reimburses up to the level of the formulary' (regulation 8(5)); and
- Patient experiences treatment failure, (potential harm), or such as adverse events – all of which relate to clinical reasons that can be established and for which the patient should not be penalised (regulations 15H and 15I).

The implication of section 32I would be that the above scenarios are not catered for, which would result in the exclusion of patient choice, or the lack of provision for care under exceptional circumstances, where patients require care different from the described cost-capped service benefits. The PTG therefore strongly proposes that the PMBs, as well as positive co-payments, be retained, in the interests of patient access to appropriate care.

5.5 Rare diseases in the context of the benefit packages

One of the key vulnerable groups that is likely to suffer as a result of "service benefits", unlinked to conditions, is patients with rare diseases, or patients with diseases of which the prevalence is quite low.

The World Health Organization (WHO) defines a rare or orphan disease as a disease that affects less than 5 out of 10 000 individuals. Rare diseases can be grouped by affected organ systems or other pathological characteristics, and not by "service". Rare diseases are, in most cases, are serious, chronic and debilitating, often requiring prolonged and specialised treatments. In addition, they often result in some form of disability sometimes severe.

Section 31l(1(a)) states that comprehensive services benefits need to be determined. No definition is provided for service benefits. There is no indication if benefits are service-linked, how health goods, including but not limited to medicines, medical devices and IVDS, are to be covered. This is of concern to the PTG especially in light of designing benefits for rare or orphan diseases. Rare diseases present fundamentally different challenges from those of more common diseases, such as asthma. Patients suffering from rare conditions should be

entitled to the same quality of treatment as other patients with more frequently occurring disorders.

The PTG therefore proposes the implementation of a rare/orphan disease plan within the comprehensive service benefits conditions proposed in the MSAB, designed to more adequately address the needs of patients with rare/ orphan diseases. This includes diagnosis, treatment, care and support of patients with rare diseases.

6. The absence of a risk adjustment mechanism in the MSAB

The HMI found that one of the key interventions required to address market failure in the medical schemes sector, is the necessity to introduce a risk adjustment mechanism. Extensive research into a Risk Equalisation Fund (REF) was done in 2004 by the REF Task Group, an initiative led by the DoH and the CMS.[8] Given the three major proposals that will increase the financial burden on medical schemes, namely no waiting periods in relation to children; expansion of benefits into retirement, even where the scheme membership was linked to employment; as well as the changes in the contribution bands; consideration must be given to mechanisms to ensure better sustainability for all schemes. It should be ensured that all schemes face a similar risk-pool, and would therefore all be able to afford to provide quality levels of care as part of their benefits.

7. Linkages between the NHI and the MSAB

One of the significant reforms brought about by the MSAB, is in the duties of the CMS towards the NHIF. The CMS will also have to undertake significant, costly tasks in the development of the Beneficiary register and the Provider Register, for the NHIF.

The CMS's income depends close to fully on levies paid by schemes from member contributions. The question is whether the diversion of resources from the core mandate of the CMS, to a mandate whereby it would no longer only focus on being the regulator for medical schemes, is acceptable. The CMS would be a resource and an implementing agency for some activities of the NHIF. This would not be to the benefit of medical scheme beneficiaries, who rely on the CMS for the accreditation and monitoring of their schemes and administrators, the development of a reviewed set of PMBs, as well as adjudication of their complaints, expeditiously and thoroughly.

The PTG questions whether the diversion of the CMS to an additional mandate, without any additional resources (e.g. staff, income streams, infrastructure), to a function that is not its

[8] [Cited 2018 September 19]. Report available at http://www.medicalschemes.com/files/Risk%20Equalisation%20Fund/REF_Task_Group_Jan_2004.pdf

core focus as a regulator and protector of medical scheme beneficiary rights, will not be to the detriment of patients and schemes.

Medical scheme beneficiaries are now, by definition, required also to qualify as users under the NHI. This makes little sense, as medical schemes should be free to take any person on, within its own membership criteria. If the intention is to prevent any person from opting out of the NHI, that criterion must be set in the NHI Bill.

8. Information-gathering powers

The CMS has increased powers to collect and disseminate information, without the purposes, and use of such information being clear.

These include the power to ask "any" information from "any" private healthcare stakeholder, including pricing, cost and utilisation information, in terms of the amendment proposed as the new section 7(e). This would mean that the CMS would be able to access information not only insofar as it pertains to the claims and reimbursement by medical schemes, but "any" information, including information on cost. As the CMS has no price-regulatory, or other regulatory powers over any stakeholder (apart from over medical schemes, administrators and managed care organizations), this provision is too wide to pass constitutional muster.

The CMS also has powers in relation to the creation of two registers, one for patients, and one for providers.

The patient register, however, purports to assist in risk-assessment, but will not include any "health status". If anonymised, it would also not be a patient register, and merely a database similar to what the CMS in any event obtains when it does the CMS annual reports, and when they receive quarterly reports from schemes. If it aims truly to set a Beneficiary Register, it would have to contain identities, and if so, compliance with the Protection of Personal Information (POPI) Act would be important.

The Provider Register appears to re-create the Practice Code Numbering System (PCNS). However, it leaves wide powers for the CMS to request "such additional information or particulars" by notice in the Gazette. Any limitation to the privacy and information rights of any person or entity must be compliant with the POPI Act, and the Promotion of Access to Information Act (PAIA).

Of serious concern is that, although the information collected may be published ("disseminated"), the statutory duty on the CMS to publish its annual report in its customary manner, is being removed. This report has been, for many stakeholders, the only source of comprehensive, industry-wide information on medical schemes, including information such as reimbursement levels. Its removal will exacerbate current information asymmetry in the market and increase opaqueness and unaccountability.

The PTG strongly recommends that section 14 of the Medical Schemes Act not be repealed and that the well-established practice of publishing the CMS Annual Report, which includes amalgamated industry-wide data, be retained.

9. Conclusion

- Medical schemes serve an important purpose in protecting members from catastrophic events. The viability of medical schemes should be carefully considered against the proposed changes, that position them as serving purely a 'top-up' function.

- The recently published Health Market Enquiry Report (HMI) found that Prescribed Minimum Benefits (PMBs) were not a cost driver in the healthcare system. The envisaged replacement of PMBs with "service benefits", which are not defined, appears to be problematic in transition and possibly the service benefits will fall short of providing adequate care, which is currently based on therapeutic areas.

- The PTG strongly recommends that positive co-payments be retained, in the interests of patient choice and access to appropriate care.

- There are certain legal issues that are of concern in what is proposed, such as the exclusion of the Consumer Protection Act, the possible infringement of the POPI Act and the envisaged role of the Council for Medical Schemes, which seem to raise certain conflicts.