

RESPONSE TO THE
PROVISIONAL FINDINGS AND RECOMMENDATIONS
REPORT HEALTH MARKET INQUIRY (HMI)

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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)

1. Introduction

The members of the Pharmaceutical Task Group (PTG), hereby respond to the invitation to make comments on the Provisional Report of the Health Market Inquiry, published 05 July 2018.

1.1 Who we are:

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)

1.2 Follow up to the previous submission by the PTG

The PTG submitted a response to the Health Market Inquiry (HMI) 05 March 2015. We wish to highlight matters that were presented in that report as well as respond to pertinent issues for the pharmaceutical industry that were raised in the Provisional Findings and Recommendations Report.

1.3 Request to stakeholders

We note the request to stakeholders and approach our comments accordingly:

“Stakeholders are requested to provide submissions in respect of the proposed recommendations. Submissions should focus on the stakeholder's view of the recommendations, the proposed manner of implementation, the proposed entity responsible for implementing the recommendation, and the proposed timelines.”

In addition, the chairperson of the Panel urged (in paragraph 99 of his published presentation of the HMI Provisional Report) stakeholders “to engage constructively with the provisional report and provide detailed submissions in respect of our *provisional findings* and our *proposed recommendations*. Submissions should be *substantiated*, as far as possible, with evidence.”

We have seen however that several issues pertaining to our industry and the welfare of the patients that we serve, are not included in the recommendations. We have thus included several comments that have relevance that may not be included in the recommendations.

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2. Executive Summary

2.1 Introduction

The PTG congratulates the HMI on a process that was well-run, open and participatory, and which has generated a well-researched document containing implementable proposals, which will move the private healthcare sector forward.

As an introduction, it can be stated that the pharmaceutical Industry is the only supplier that caters for both public and private sectors and is one of only three that are price-regulated (brokers and pharmacists are also price-regulated). According to the Council for Medical Schemes Annual Reports, 'Medicines' is the only category that has consistently and significantly reduced as a percentage of the healthcare Rand over recent years.

2.2 Key principles informing our submission

The pharmaceutical industry is committed to the following key principles:

- The Progressive realisation of Universal Healthcare Coverage (UHC) through implementation of National Health Insurance (NHI);
- Enabling timeous access to innovative and generic medicines and technologies, through the South African Health Products Regulatory Authority (SAHPRA), that promote health outcomes and / or the increased affordability and availability of treatment;
- The adoption of sustainable pricing models for medicines;
- Creating a dispensation that is fair and sustainable with regards to distribution, logistics and dispensing fees, thus avoiding the need for alternative sources of income (e.g. bonusing, rebates, marketing & data fees);
- Promoting innovative patient access partnerships with private and public sector medicine purchasers and developing alternative reimbursement models (ARMs) aligned with international best practice, to enable patients to access the appropriate level of care, inclusive of innovative medicines / technologies, based on their respective individual clinical needs.
- The incorporation of patient value-driven initiatives that provide patients and consumers of medicines, clear and explicit means to access our medicines.
- The belief that a reduction in medical scheme administration fees could lead to an increase in resources for the funding of treatment.

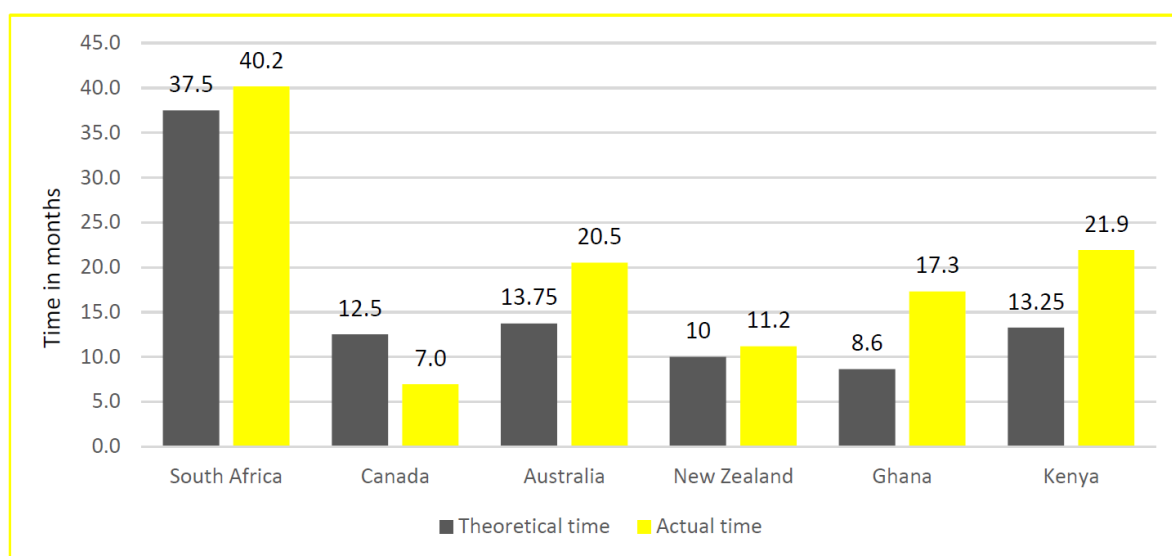
2.3 Key challenges facing the pharmaceutical industry

Currently, the pharmaceutical industry faces the following challenges in ensuring patient access and value-driven decision making by consumers and patients:

- South African consumers and patients need to wait considerably longer than other countries to access medicines due to long regulatory timelines experienced in South Africa which are in excess of international standards¹.

¹ <http://www.amcham.co.za/wp-content/uploads/2017/09/FINAL-December-EY-Report-Registration-for-Medicine.pdf>

Figure 6 – Comparison of the average theoretical and observed durations per country



- The pharmaceutical industry is one of only three healthcare stakeholders in the private sector that is subject to price regulation, the others being brokers and pharmacists.
- Patient access to Prescribed Minimum Benefit (PMB) medicines is limited by subjective interpretation of the Prescribed Minimum Benefit regulations particularly as it relates to the Diagnosis and Treatment Pair component of the PMB package.
- Patient access to medicines determined by managed care companies is based on price alone and not on objective value assessments.
- Access to chronic, lifesaving and life-enhancing medicines (PMB and non-PMB medicines) is controlled by Managed Care Organisations and funder protocols. Clinical entry criteria are applied which are not always transparent or evidenced-based, nor readily available to the consumer, patient, doctor or the pharmaceutical industry, as is required by regulation 15D of the Medical Schemes Act.
- In order to conduct value-based assessments for medicines in the South African context, large amounts of input data are required to objectively determine the value a medicine brings to consumers/patients. This data is partly held by Medical Schemes and their Administrators/Managed Care companies. There is therefore information asymmetry between the funding and supplier industries, as suppliers do not have access to data pertaining to downstream costs (e.g. hospitalisation). Limited clinical data exists in the private sector due to the factor that medical schemes collect data for payment transactions and not to monitor clinical outcomes over time. Therefore, the use of HTA has limited value in the current system.

3. Comment on key issues for the pharmaceutical industry

3.1 Medicines are not a cost driver in the private healthcare sector

The PTG welcomes the finding in Chapter 3, paragraph 132, that the cost of medicines has decreased. This is, according to the HMI, partly attributable to the Single Exit Price (SEP), as well as the introduction of the CDL treatment algorithms. We are, however, unable to find any substantiation that the CDL algorithms, which only cover some of the PMB conditions, often with low-cost medicines,

contributed to this decrease. What might have contributed is the increased implementation of various managed care initiatives, i.e. a combination of formularies, medicines exclusion lists, chronic disease limits or disease caps, mandatory motivation processes before patients can progress from one treatment to another, etc. Various healthcare professional groups, in their written submissions and during the public hearings, attested to the difficulty of ensuring appropriate treatment for their patients.

Although the SEP may be set by the regulations, the use of formularies largely determines the selection and reimbursement of medicines. Formulary listing negotiations further reduce the price of medicines. Due to the dominance and concentration levels of the two largest administrators and their respective managed care companies, the managed care interventions developed by these two entities effectively determines access and price levels for the entire private market.

However, despite the fact that medicines are not a cost-driver, medicines remain an item which is easily controlled by medical schemes, compared to consultations and hospital admissions or in-hospital care. A patient will not be denied access to a hospital, or a consultation with a provider, however a patient will be refused medicines on the basis that such medicine 'is not on the formulary'.

We also note medicines were not found to be an in-hospital cost driver (par 139 in Chapter 3), as theatre fees are now higher than medicines and consumables. Figure 3.11: The submissions made by some hospital groups that medicines form a very large part of in-hospital costs, appear to be untrue based on the data reviewed by the HMI.

Thus, pharmaceuticals are already providing Universal Access to Medicines in South Africa, with the current 2-tier pricing making affordable medicines available through State and Private SEP prices, facilitating socio-economic sustainability of the pharmaceutical industry.

3.1.2 Medicines are heavily regulated

It is against the backdrop of price regulation and managed care interventions, that other recommendations made in the Provisional Report should be viewed. Such recommendations are Health Technology Assessments, treatment guidelines and alternative reimbursement mechanisms. Unlike other suppliers and providers, the pharmaceutical industry is already heavily regulated and therefore any proposed regulatory interventions must be taken through a regulatory impact assessment.

3.2 Regulatory barriers

In terms of the mandate of the HMI to investigate the impact of regulatory processes and systems on the market, the PTG wishes to highlight two regulatory bodies which have a great effect on the supply of medicines:

- South African Health Products Regulatory Authority (SAHPRA) and
- National Department of Health (NDoH) with the Pricing Committee and Minister of Health.

Regulatory delays i.e. registration delays through SAHPRA, pose immense challenges to the effective and expeditious entry of products to the market and therefore affect patient access. To illustrate the current scenario, a recent communication from SAHPRA, sent to industry personnel, states:

“The comprehensive view of the baselinerevealed that SAHPRA inherited a backlog of 16,000 applications dating back to 1992. At current capacity and with current processes – assuming no new applications are received – it would take SAHPRA 8 years to clear the backlog.” Remedies are proposed in the same communication.

Proposals on ways in which the lengthy delays for registration can be truncated, have been made by the pharmaceutical industry to the former regulator, the Medicines Control Council (MCC) and more recently to SAHPRA. A key proposal is the recognition of the product assessments/registrations made in other jurisdictions, with standards acceptable to SAHPRA. This has, however, not yet been implemented.

The SEP pricing system is inflexible in effecting product price reductions and increases (that may be necessary in response to market changes) and is accompanied by delays and standardized responses to information submitted. There is also limited clarity regarding the role of the Director General, who acts on behalf of the NDoH, versus the role of the Pricing Committee, and versus that of the Minister of Health.

3.2.1 Limitations on participation in Alternative Reimbursement Models (ARMs)

ARMs models are often inclusive of medicines. With these models there is a risk of trade-offs between suppliers to increase their share of the fee, or to keep the overall fee low, and/or the expenses or input costs as low as possible. This risk increases where there are no outcomes measurements (short, medium or longer term).

The pharmaceutical industry is, as a result of the Single Exit Price, currently unable to participate in such risk-sharing models, as negotiation on price is not permissible. Further, the SEP pricing system does not allow innovators to enter into risk-sharing, patient support programmes, ‘pay for performance’ or other models important for the HMI-recommended (par 145 in Chapter 10) ARMs, such as global fees, or value-based reimbursement.

HMI recommends (par 155.6 in Chapter 10) that ARMs and Designated Service Providers (DSPs) should be measured by schemes not only on price, but also on value and outcomes. If not, any DSP that matches the DSP price should be allowed to render services. The PTG supports this approach.

3.3 Relationships in healthcare: Market power / supplier-induced demand

The HMI theory of harm wanted to probe market power of facilities “over the relationship of funders and the providers of medicines and medical devices”. Due to the dominance and concentration levels of the two largest administrators and their respective managed care companies, the interventions developed by these two entities effectively determines access and price levels for the entire private market. If a product is not reimbursed, it is difficult to exert any countervailing power to ensure supply to patients.

In terms of the business models alluded to (e.g. rebates), regulations are envisaged under the Medicines and Related Substances Act, 1965, to supplement the prohibitions on bonuses, rebates and incentives schemes (s18A), free supply (s18B) and marketing and promotional practices (s18C). The intention is that no bonusing or other form of incentive is allowed, nor is sampling allowed, which is intended to reduce the possibility of undue influence on the selection of medicines to the detriment of the patient. If properly implemented these regulations would serve to achieve the objective of

eradicating these practices that may skew the market. The industry has consistently, over a number of years, requested the urgent implementation of these sections and their accompanying regulations.

Section 18C is intended to promote the ethical marketing of medicines, beyond that which is provided in the marketing licence, as determined by SAHPRA. Self-regulation is, for much of the sector, the *modus operandi*, moderated through voluntary associations such as the Marketing Code Authority. This has been necessary due the lack of regulations for s18C. Legislating such Codes, as is envisaged by s18C, would be welcomed by all.

3.4. Health Technology Assessment (HTA)

The principle that Health Technology Assessment (HTA) should be available to assess whether a treatment constitutes “value for money”, is laudable. Although the PTG, in principle, supports the intention to promote the greater use of HTA in various aspects of healthcare, with the objective of improved decision-making by healthcare professionals, there are various practical concerns relating to its effective implementation in the current environment.

HTA is a "*multidisciplinary field of policy analysis, studying the medical, economic, social and ethical implications of development, diffusion, and use of health technology*" (“INAHTA”, 2018) and therefore should not be viewed narrowly to cover the therapeutic assessment and economic evaluation of new technologies only, thereby overlooking the social and ethical dimensions of HTA.

Medicine prices are in effect regulated, and prices of new medicines are subject to the various controls set out in Regulation 19 of the Pricing Regulations, 2005. The appropriateness of HTA under these circumstances and its applicability, and in what form, are important considerations.

The pharmaceutical industry is already utilising HTA in the form of Pharmacoeconomic studies or information required by medical scheme administrators. The role of a single HTA body would assist in ensuring better decision-making, while removing the problem of duplicative costs for suppliers to provide such information to various scheme administrators, as well as having to make submissions under the Pricing Regulations.

As a key stakeholder, the PTG would like to be engaged in the process toward the development of the Supply Side Regulator. We look forward to understanding how the proposed supply side regulatory framework will align with the existing regulatory framework and how it will impact the manner in which pharmaceutical products, specifically, are regulated.

The following considerations must inform the proposals relating to a new HTA agency situated within the Supply Side Regulator (SSRH) (par 63, 94 – 96 and figure 10.1 in Chapter 10):

- HTA is appropriate in assessing the value of innovative pharmaceuticals and perhaps biosimilars.
- HTA does not have a role in assessing the value of generic medicines, which are largely chosen on price.
- The information in HTA is usually understood by healthcare professionals but would be of no value to the patient, due to the complexity thereof. The patient largely depends on the healthcare professional for guidance in the selection of treatment.

- The application of HTA studies is useful for medicines used by large populations but does not have the same value for medicines which are used in small populations, or for rare diseases, which are generally known as ‘orphan drugs’. The sample sizes for these diseases are too small.
- HTA requires specialized skill sets which have limited availability in South Africa.
- Local data sets and epidemiology studies form the basis for HTA assessments in pharmaceuticals, which also have limited availability in South Africa. Moves are only now afoot to obtain this data through the National Public Health Institute Bill (Bill 16B of 2017), currently before the National Council of Provinces. The absence of a standardized National Health Information System also hampers such assessments.
- Claims data (e.g. on hospitalisation or downstream costs) should be transparent for objective analysis by all stakeholders.
- HTA studies carry a significant cost and this cost burden needs to be considered in determining the necessity for HTA. Failure to do so could lead to increases in the prices of medicines.
- There are legal provisions for the assessment of the cost-effectiveness of medicines (for existing- and new medicines) under the 2005 Medicines Pricing Regulations. This empowering legal framework has been in place since 2005, but has never been implemented, despite a set of Guidelines being published in terms of the Regulations on 1 February 2013 (Government Gazette No 36118), and republished for comment on 1 December 2017 (Government Gazette No 41278).
- All new products are subject to the submission of certain information to the NDoH, and are subject to interrogation by NDoH staff before price can be implemented;
- The requirement for HTA studies may further delay the introduction of new medicines to the market and impact patient access.
- Even if HTA studies are available, the ‘lowest cost’ imperative usually prevails. Choices may be made on price rather than value, as there is nothing to mandate funders to take cognisance of such studies. Reimbursement should be enforceable if HTA results are positive.
- If implemented, the system must avoid time delays created by the requirement for HTA assessments.

Provided the above issues can be addressed, and that HTA is found to be a necessary mechanism to address the costs of private healthcare, the PTG would support rational and reasonable mechanisms of economic value assessments, that are not duplicative nor cost-driving in nature.

Whichever HTA archetype is most suitable for South Africa, the PTG is of the view that independence and meaningful stakeholder involvement (inclusive of pharmaceutical suppliers) will be critical in successful design and implementation of HTA to capture the societal value of new technologies.

3.4.1. Price Regulation in the SSRH (par 107 – 136.3 in chapter 10).

In terms of the Health Services Pricing Unit of the SSRH, the PTG notes the similarities to the structure, which includes a system of independent arbitration, proposed by the CMS and the Department of Health in 2010.² The idea at that time was to include the Medicines Pricing Committee into that

² <http://www.medicalschemes.com/files/Health%20Price%20Determination/DiscussionDocOnPriceDetermination.pdf>.

structure. The SSRH figure refers to “bilateral supplier” negotiations. It is not clear if and how medicine pricing will fit into this process.

It should also be borne in mind that many professional services include medicines and medical devices (e.g. infusion fees, device hire-purchase fees, etc.) and therefore the negotiations or fee-setting systems will affect suppliers of health goods as well.

Par 131, as it pertains to providers, refers to the limitations of price-only negotiations and alludes to efficiency and quality as part of alternative reimbursement systems. A private sector move in that direction would also necessitate flexibility in medicines pricing, and possible mechanisms such as pay for performance, risk-sharing, etc. Care should be taken in considering such options, to avoid product selection in favour of more profitable risk-share models. Patient punitive measures, to deter usage, should also be avoided.

The PTG would support a review of the existing Pricing Regulations to enable patient access to medicines, on an innovative mechanism basis, as proposed by the review.

3.5 OMRO – the Outcomes Measurement and Reporting Organisation (chapter 9)

The PTG supports the establishment of an independent OMRO, implemented in a staged manner, based on existing registries, as a starting point.

Some registries, despite being mandated by law, such as the cancer registry, have not been successfully implemented, and it is a recommendation that a complete analysis of such registries be undertaken prior to the formalisation under OMRO.

The measurement of outcomes should inform reimbursement and benefit design decisions. Medical schemes commonly adopt a short-term view in their decision-making. The publication of such results will not alone drive behaviour change.

The PTG notes that there is no solution for this challenge in the proposals in chapter 9 and paragraphs 157 to 171 of chapter 10, and proposes that, apart from the information from an OMRO being made public, there should be some mandate on schemes to consider and apply such results.

3.6 Standardised benefits (par 36 – 39, chapter 10)

The proposal that benefits should be standardized to facilitate increased competition between medical schemes, appears positive. However, the meaning of standardization remains unclear. The current PMBs are in effect standardized benefits, the problem rather being around the lack of implementation of the definitions of evidence-based medicine, and the withholding of the exceptional measures for vulnerable patients, who may suffer harm, or whose treatment is not effective.

The problem therefore relates to the incorrect implementation of the PMBs and the wide-held belief, dispelled by the HMI in par 73 in chapter 5, that the PMBs are an in-principle cost driver. The PTG agrees with this finding that the PMBs are not a cost driver.

The PTG also agrees with the HMI that the PMBs, or any basic package, should form the heart of the social security rights that accrue to a person who buys medical scheme cover, all pursuant to section 27 of the Constitution.

On the inclusion of primary and preventative healthcare, it is acknowledged that firstly there are limited resources for the provision of healthcare. The intention to include primary and preventative healthcare, although laudable, will put further strain on the already limited resources. What is going to be sacrificed and or rationed to balance the expenditure without further resources being available? The inclusion of additional benefits within an existing funding envelope will necessitate trade-offs in terms of other benefits. Rationing however needs to be explicit and clear. Most important, there needs to be provision for cover during catastrophic events. The risk of catastrophic events motivates membership of medical schemes (page 91, par. 76).

A concern in relation to standardization is that it would lead to the exclusion or limitation of rights of vulnerable patients, who require treatment and care that is different from what would be the standard treatment. This includes patients such as those who face treatment failure, harm or adverse events. A key problem in the market is that this principle, although entrenched in the regulations, is not applied by schemes when protocols and formularies are set. The required care for these vulnerable patients is most often gained through costly legal and/or complaint processes.

The delivery of the PMBs should also be done in line with evidence-based medicine. This in turn relates to the Treatment Guidelines proposals of the HMI under the Supply Side Regulator of Health (SSRH) (par 94, chapter 10). The HMI reports that there is a lack of publicly available standards of healthcare and treatment protocols in the private sector. (Executive summary, par. 10 and 14). The legal authority to set evidence-based medicine guidelines lies within each profession, as the persons registered to make pronouncements on treatment sequencing and options. The definition of evidence-based medicine in the Regulations to the Medical Schemes Act should be affirmed as the basis for treatment guidelines. There are guidelines which are developed by the healthcare professionals across therapeutic areas, but unfortunately there is no regulatory framework in which to present and publicise these as an available resource. There is further no enforcement of their application. What is needed is the recognition of existing guidelines, which currently have no status in the regulatory framework. The enforcement should take place by the reimbursement principle through medical schemes. Where there may be no guidelines, international guidelines may become the reference.

The PTG recommends that local treatment guidelines, as developed by locally recognized clinician societies, be adopted as the prevailing standard of care and basis of funding. In the absence of local clinical guidelines, international guidelines should be reviewed and refined as the basis for funding.

3.6.1 The need for a Risk Equalisation mechanism

In terms of the general regulatory framework, we support the contention that the incomplete regulatory framework for medical schemes, namely the absence of a risk adjustment mechanism (the old "REF"), and the absence of mandating scheme membership, have, and will continue to have a negative impact on the pharmaceutical industry. The PTG supports the recommendation that a risk adjustment mechanism is needed (paragraph 39, Chapter 10). Risk equalization between the medical schemes would offer the opportunity for equitable care, irrespective of individual scheme risk.

4. Conclusion

The members of the PTG thank the HMI for the opportunity to offer the above comments.

The PTG supports the objective to demonstrate improved value in healthcare for the patient. The PTG supports the finding of the HMI that medicines are not a cost driver in the private healthcare sector in South Africa.

Medicines are universally available, with the pharmaceutical industry being the only private sector supplier to both the private and public sectors. Medicines play an important role in the prevention and treatment of disease. The appropriate use of medicines can lead to the more efficient use of resources, such as reduced hospital stays and improved quality of life, while consuming a relatively small portion of the healthcare Rand.

The local pharmaceutical industry is positioned to provide the medicines needed for the total population. There needs to be provision for the ongoing sustainability of the pharmaceutical industry, which is an important local resource as a supplier of medicines in addition to being an economic contributor to the country.

The PTG supports the objective of greater cost efficiency in the private sector and the striving for better measurement to ensure optimal outcomes and use of resources. We also note that many of the proposals could be achieved if the existing legal framework is properly implemented, or pending regulations or other provisions, are brought to their conclusion and implemented.

Various proposals, which are intended to lead to a better functioning market and offer innovative models, such as alternative reimbursement models (ARMS), are attractive to the suppliers of medicines. As detailed in our response, any possible participation by the pharmaceutical industry is however limited by the regulatory management of pricing, which lacks the flexibility required for participation in such models. There is a further concern that in such models, medicines may receive the least share and that best value medicines may be sacrificed.

- Ends -