

**Innovative Medicines SA position statement and submission  
on the review of the Prescribed Minimum Benefits in response to  
the PMB Review process as initiated by the Council for Medical  
Schemes**

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## 1. IMSA's view on the principles relating to the PMB Review

IMSA understands that the law requires *the review* of the PMBs to lead to recommendations to *revise* the regulations to the Medical Schemes Act and Annexure A on the basis outlined below in bullets. This takes place against the recognition of the law that there is a "constant change in medical practice and available medical technology".

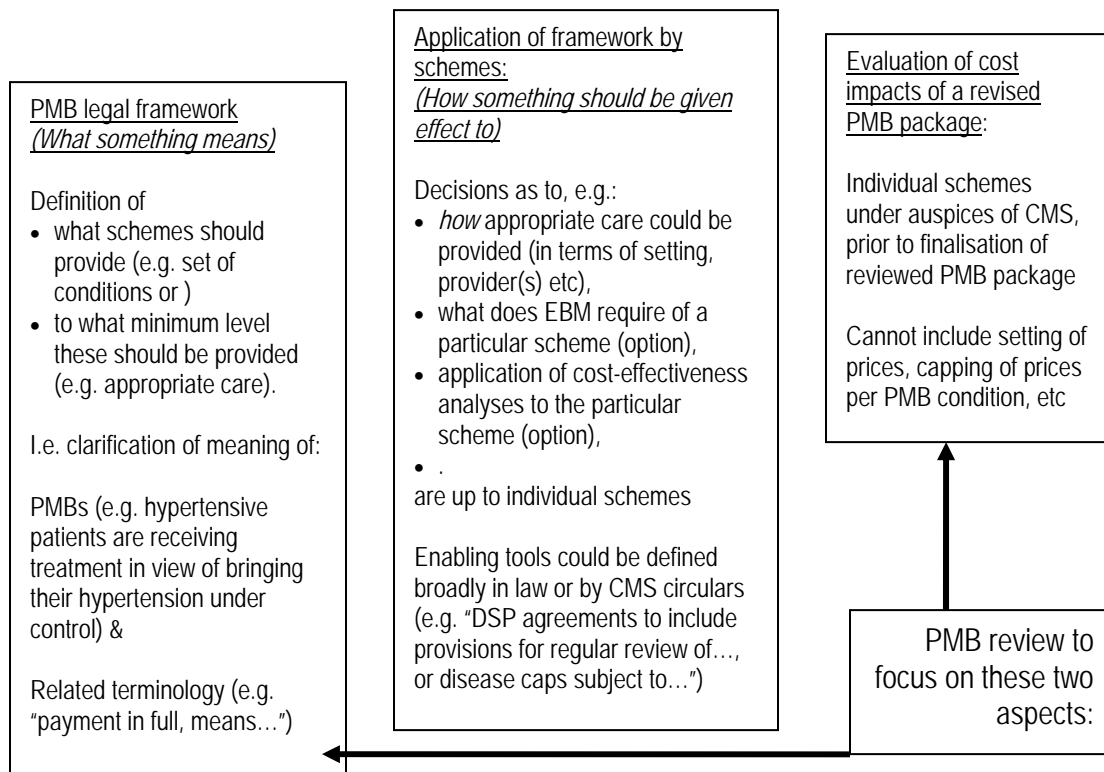
- Inconsistencies / flaws in current regulations
- Cost-effectiveness of health technologies or interventions
- Consistency in health policy development
- Impact on medical scheme viability and
- Affordability to members

IMSA agrees that there are certain challenges in the implementation of the PMBs. However, it interprets these implementation issues as a result of the lack of clarity on the regulatory and in particular the definition-side of the law, rather than entailing a need to agree specific implementation strategies.

The preamble to Annexure A requires that the following *monitoring* of the PMBs shall be undertaken by the Department of Health:

- The impact of the PMB provisions
- The effectiveness of the PMB provisions and
- The appropriateness of the PMB provisions

The impact, effectiveness and appropriateness are individual scheme issues, in which the CMS could facilitate, and is already facilitating in the CMS Annual Report and scheme returns.



Basically, IMSA recommends that the solution to the PMB challenges lies in obtaining clarity on “what something means in order to give effect to it”, rather than “prescribing how it should be given effect to” (i.e. the first block above, rather than the second). The lack of proper interpretation leads to a lack of proper implementation, something which results in the gaps created within the current PMBs.

Although IMSA supports the move towards a more comprehensive health insurance system, so-called standardisation would in the current environment amount to collusion, as agreement would be reached on the extent of pay-outs, but not on scheme income, scheme benefit design or scheme rules or beneficiary profiles.

## 2. The PMB Review within a constitutional framework

The Medical Schemes Act is a law which gives effect to the right of access to healthcare and access to social security, as envisaged in section 27(2) of the Constitution. Through the Act, a basic set of entitlements are created for each medical scheme beneficiary.

This fact has three important implications for the current review and these should be taken into account:

- Patients have a **right to appropriate care**, failing which the basic entitlement would be meaningless. We see the concept of **evidence-based** medicine as the legislative measure which enables the realisation of this right.
- Limitations to the right have to happen in a second phase, i.e. within the framework of access to appropriate care. Any **limitations** taking place through, for example, positive or negative lists **have to be applied within the framework set by definitions as to what would constitute reasonable interventions**, within the broader framework of evidence-based medicine. Similarly, agreeing on capping to disease up front, and in the context of this review, could amount to an unreasonable limitation to patients' rights of access to healthcare.
- **Patients have existing rights**, created by the current PMBs. This should be considered in the review process in particular if it leads to a reduction of such existing rights, either directly or through agreements on the acceptability of the particular mechanisms of limitation.

In the end, the results of the review should be to ensure greater access to healthcare and healthcare insurance.

## 3. A principled approach to the PMB Review

### 3.1 Competition law

The current review has to enhance a pro-competitive environment. Any aspect of the review which could lead to agreements on the level or extent of care provided, the settings, or tariffs, would be regarded as anti-competitive. In contrast, clarity of definitions and legal frameworks could increase competition and level playing fields.

### 3.2 Evidence-based medicine

The PMB review has to, as stated in the law, recognise developments in healthcare and technology. Short of agreeing on specific technologies, the only way in which this aspect can be incorporated into the current review, is by ensuring that PMB care is provided on the basis of evidence-based medicine. This would mean the institution of **mechanisms** to ensure regular reviews of what constitutes evidence-based medicine (in terms of how it is established, rather than what it should provide as an outcome), and of ensuring **transparency** in that regard and involving

experts and professional groups to determine this.

IMSA supports the principle established in regulation 15H and 15I, i.e. that evidence-based medicine should be first principle, and that all subsequent decisions on cost-effectiveness and affordability have to take place within that framework. IMSA also supports the definition of evidence-based medicine as provided in regulation 15. Reviews to the PMBs have to be done through this lens – and IMSA provides some examples of this below. A key issue in question identified by our members is the rigidity of protocols, and that this rigidity does not necessarily correspond with evidence-based medicine, i.e. provision should be made for a particular clinical outcome, whether very likely or less likely, so that a particular patient in that predicament does not face co-payments, or complex appeals processes.

It also believes that, instead of rigidly describing and standardising every step of PMB treatment (which would, apart from contravening competition law, also inadvertently lead to the lowest common denominator), evidence-based medicine, and good health outcomes should be the criteria against which the effectiveness of the PMBs are to be measured.

Healthcare professionals are best situated to evaluate what the standard of care should be generally, and how individual cases are to be dealt with within such framework. The principles of community rating and solidarity should facilitate what would constitute appropriate care, and which, in particular cases (the extent of which may differ from one disease entity to another), have to go beyond “standardised” care.

### **3.3 Continuity of care and existing rights**

Whatever the outcome of the PMB review, the principles of continuity of care and existing rights/entitlements have to be considered. The PMB review process should not lead to patients being moved from one type of treatment to another, with limited or no regard for continuity of care.

The principles applicable to instances where existing rights are limited or denied, i.e. consultation with affected persons and taking such concerns into account, have to be adhered to.

Extra effort may need to be taken to ensure that patient groups participate more actively in the current review process.

### **3.4 Standardisation of definitions**

Apart from the competition law concerns relating to standardisation of managed care tools, IMSA also submits that standardisation in the form of standardised lists, formularies, protocols, etc is not the answer to the interpretation issues with the PMBs.

The key is the lack of clarity on what the legal provisions actually mean, which leads to application issues. How a particular scheme then gives effect to that meaning, becomes a competitive issue,

IMSA therefore proposes that the *provisions* that are not clear, be clarified, rather than to standardise implementation. This would avoid possible legal- and other problems.

### **3.5 Minimisation of co-payments**

IMSA agrees with the basic legal framework set by regulation 8, which pertains to the management of costs. It also believes that the basic premise, i.e. that the PMBs should be provided for “in full, and without co-payment”, should be retained and not watered down in any way, as it merely shifts the risk, and costs, to the individual, with a substantial risk to the state sector of taking over such unfunded liability.

Clarity may be needed as to what is meant by “payment in full”, so as to not prejudice patients, providers or schemes. If this issue relates to the issue of DSP's (and not to the principle of full payment or full cover for PMB conditions), proper frameworks should be created to enable successful and mutually beneficial contracting between providers and schemes.

One of the most frequent responses when the question on gaps in the PMB framework were put to employees at IMSA member companies, was co-payments (for details, see below). This, by itself, indicates a problem in definitions of what is meant by “covering the PMBs in full”.

IMSA also agrees with the tools provided to schemes to manage this “payment in full”. However IMSA realises the need for clearer definitions of these tools, and the frameworks within which they may be exercised, in order to achieve greater effectiveness of rights, and a clear indication of what factors would ensure that interventions allowed by this framework can be labelled “reasonable”.

### **3.6 Clear, and agreed definitions of cost-effectiveness and affordability as review-criteria**

The law currently does not contain a standardised definition of “cost-effectiveness” and hence the implementation problems being experienced by schemes. “Affordability” is also not defined, and it is not always clear whether “affordability to members” (Annexure A to the Act) and “affordability” (presumably to schemes) (reg 15H and 15I) are interpreted in the same manner. Although, in IMSA and other role-players’ reading of the law, these criteria cannot override that of evidence-based medicine, this principle should perhaps be clarified as part of the review process.

IMSA is of the view that cost-effectiveness should not equate to a cost-minimisation exercise.<sup>1</sup> How to maximise efficiencies and reduce costs/expenditure, should be left to individual schemes. Secondly, IMSA does not agree with the view that all “new technology” per se equates to cost-ineffective interventions.

However, IMSA does propose that a definition of cost-effectiveness should contain the following critical elements:

- Cost-effectiveness should relate to the achievement of health outcomes
- Cost-effectiveness should relate to downstream costs and cost-ballooning in other cost areas
- Cost effectiveness evaluations should take place within a framework which is transparent and principled

IMSA does not believe that a single, standardised cost-effectiveness pronouncement can apply to all schemes and all options at this stage. In the absence of a single risk pool and similar contributions and expenditure levels, appropriately and sufficiently defines cost-effectiveness provides individual schemes with a tool to evaluate various interventions.

However, IMSA does believe that some aspects of cost-effectiveness analyses could be of use in decision-making relating to the possible additions (and changes) to defining the PMB basket, i.e. comparing the costs, and effectiveness, of addressing one condition, versus another.

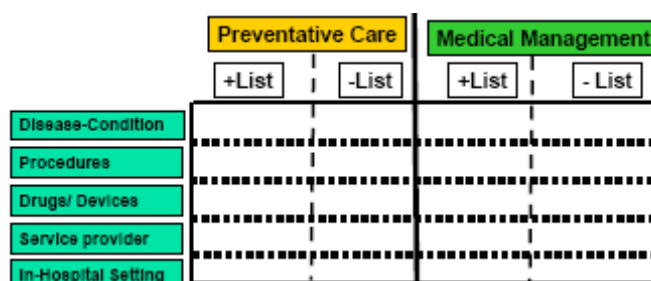
IMSA suggests that this discussion has not yet taken place. IMSA also suggests that and that the focus on creating lists, algorithms and standardisation of the framework, without agreement as to the basis upon which the PMBs will be reviewed, will not result in meaningful results.

## **4. IMSA Proposal to create clarity in the PMBs**

IMSA understands the current framework for the review to have been based on the following premise:

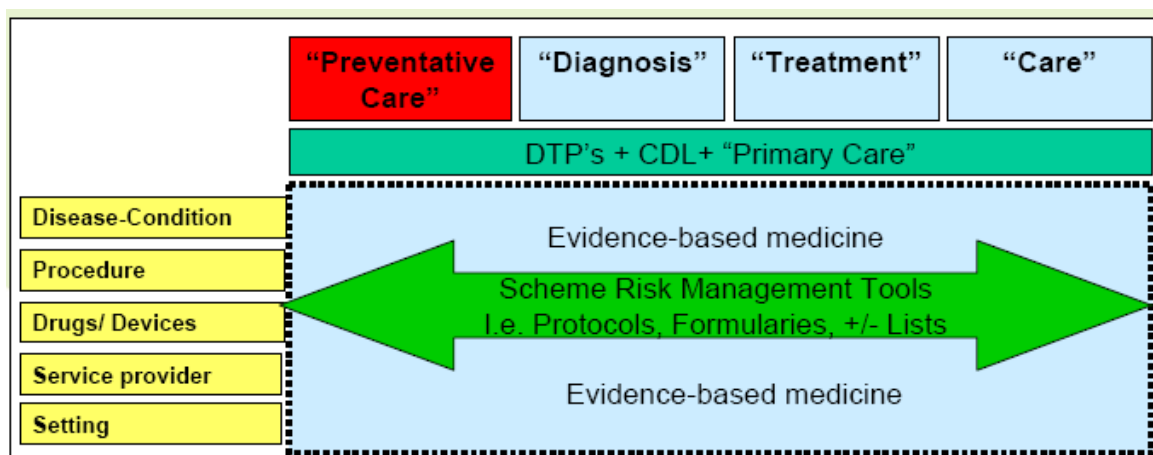
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<sup>1</sup> IMSA has undertaken a survey on how Pharmaco-economics (which could take the form of cost-effectiveness analyses) are perceived to be of value. The results have shown that it is mostly seen as a tool to screen out new technology, and not necessarily as a tool which could also allow access to new technology. Unless cost-effectiveness can be seen as a tool which “cuts both ways”, its application may in some cases be to the benefit of patients and sometimes not.



In evaluating this framework in the light of the principles outlined below, the review seems to be more of a macro-managed care process, than a review of the PMBs.

In order to create the required clarity and certainty, IMSA proposes the following model, which entails greater clarity in what is meant by “medical management”, etc.



In IMSA’s view, the current PMBs definitions should be clarified so that schemes’ obligations should be clear. How schemes should effect that cover, is, once again, a competitive challenge. IMSA proposes the following definitions to guide the provision of cover for a PMB condition, all obviously within the framework of what constitutes evidence-based medicine:

Currently non-specific definitions in law, creating vague entitlements and responsibilities:		Proposed definitions to close gaps / uncertainties in PMBs:
“medical and surgical management” – Annexure A  “Diagnostic, treatment and care costs” regulation 8	As per state protocols	<u>Preventative:</u> Two types: (a) primary; including but not limited to education, screening, vaccination, etc (b) secondary; monitoring, ensuring patient treatment compliance / adherence, for example hypertensive treatment to prevent strokes.
	Not defined at all	<u>Diagnosis:</u> All diagnosing to investigate the existence of a PMB, irrespective of whether the condition is positively diagnosed or not. <u>Treatment:</u> All available options based on evidence-based medicine. <u>Management:</u> This includes all treatment modalities (medical, etc) as per EBM.

## 5. IMSA views on particular issues

## 5.1 Addressing flaws / gaps in the PMBs

The basis on which gaps or flaws will be identified depends on the direction taken with the PMB review. For example, should the basis, as set initially, be to cover the realisation of catastrophic health risks, (as opposed to expanding the existing hospital-basis to also include primary care), this, may be different from the provision of essential care.

IMSA supports the move to include primary care, basic dentistry and basic optometry into the PMBs. It is of the view that access should be provided regardless of setting (these should be up to schemes to determine), and that service delivered must also incorporate the four pillars as defined under the ambit of evidence-based medicine. In order to be meaningful as a basic safety net of cover, these should be paid in full from risk funding.

IMSA does not agree with limitations on cover (par 4.3.3) across funding industry, as this violates the principle of evidence-based medicine.

IMSA members have identified the following gaps in the current PMBs:

- Early treatment is not encouraged, neither is out-of-hospital treatment – consideration of a change here alone could significantly impact costing and a review of the PMBs
- The perception is created that the CDLs should be managed based on cost alone, and that cost is equated with cost-effectiveness. This is inappropriate.
- If an algorithm does not completely cater for all possible eventualities, it becomes difficult for patients to obtain reimbursement for an appropriate level of care.
- Limited provision is made for patients who respond differently on treatments, and such patients (and their providers) have to go through difficult processes to access appropriate care. Evidence-based medicine should allow for sufficient differentiation depending on the particular condition, and the individualisation required in particular conditions. Treatment should continue towards desired outcomes on alternate therapies.
- There should be no co-payment if therapy fails and an alternative therapy is introduced. The perception exists that the PMBs are attracting more and more co-payments and the reasons for this have to be investigated.
- DSPs seem not to be working, and there is no requirement for quality or outcomes monitoring associated with it. Once again, the setting of a proper regulatory framework which enables appropriate quality monitored contracting is required. Until this option is explored, price setting and price capping should not be considered.
- Adherence to other legal provisions around selection of medicines, e.g. those on generic substitution (as opposed to therapeutic substitution which is not allowed) and the adherence to the MCC non-substitutable list is important.
- Therapeutic substitution should not be encouraged through therapeutic reference pricing, without investigations or data on side effect profiles and comparability in therapeutic outcomes.

In terms of the extent to which certain PMB conditions have not kept up with scientific advancements and the principles of evidence-based medicine. The following has been identified as gaps that need to be addressed:

- Glaucoma – visual field tests
- Osteoporosis should be included
- Code 904B – retinal detachment
- Code 155E, 911G, 9011 – vulnerable patients don't get appropriate care, as treatment in relation to transplants covered only to a fixed limit
- Schizophrenia + paranoid disorders – 3 weeks per year may be in order for some patients, but not others
- Treatable cancers
- Associated conditions, brought about or related to DTPs and CDLs are often not included, although they should be a part of appropriate care
- Diabetes algorithm needs to be updated. It should include treatment of an associated disease

that occurs as a result of diabetes. If it is not explicitly stated as such in the algorithm, although medically recognised it may not be appropriately reimbursed

- Depression should be a CDL
- ADHD should be a CDL
- Algorithms, as well as the way in which “medical and surgical management” have been defined have not kept up to date and there is no clear process for review.
- It should be made explicit that “review management” means a review of what would be appropriate, and a serious consideration of alternatives to ensure that appropriate care is received.

IMSA proposes that review **processes** for algorithms and treatment guidelines be standardised, and that reviews should take place on a regular basis, as part of managed care requirements as set by the CMS from time to time. **Professional bodies and experts** should be involved in these processes. This would also allow schemes to cost various treatment options, and to utilise cost-effectiveness criteria in such analyses.

## **5.2 LIMS, REF and the Review**

IMSA is of the view that LIMS discussions should be kept separate from the current PMB Review processes. Clarity may be needed on how this review will impact on advances made in the REF process. However, the entry criteria applied in the REF process should not become the entry criteria in order to access healthcare in terms of the PMBs, as the purposes of these two concepts are very different and it could lead to a reduction in access to care.

IMSA would propose that perhaps a presentation to stakeholders, and members of the REF-subgroup, be undertaken to update the group on where current industry-wide REF data stand, in view of informing decisions taken in, for example, the definition group.

## **5.3 Models of cost-containment other than cost-shifting and standardisation**

Various other, and perhaps more innovative frameworks for cost-effective delivery of healthcare should be considered. Apart from the objections to these mechanisms outlined above, many current proposals relating to cost-containment (e.g. cost-sharing, standardisation in implementation, the adoption of an EDL, etc) may not provide sufficient in-depth analysis of alternatives available locally and internationally. IMSA suggests that these models be collected by the sustainability group, and presented as possible regulation 8 –tools. These are all enablers of greater competition, and does not amount to, or imply agreements on exact treatments and costs associated with those.

IMSA will also investigate this matter further and provide information, as it becomes available.

## **5.4 Timelines**

IMSA proposes that dates and times for meeting be set in advance, in order to allow participants to plan resource, research and input activities.

## **5.5 IMSA experts on subteams**

IMSA is hereby putting forward the following experts from amongst its members to the various subgroups:

Definitions: Gavin Bauer, Ted Shaw, Princess Majola & Alvina Vos

REF: Osborn Mahanjana and Princess Majola

Sustainability: Simon Rakgwale/Wendy Lindeque, Alvina Vos & Gavin Bauer

Due to the unknown dates of meetings etc, team members may substitute each other from time to



time, in order to ensure full participation.

## **6. Conclusion**

IMSA values the opportunity to be involved in this process and endorses the contribution that can be made by all stakeholders in this review process.