INNOVATIVE MEDICINES SA

POSITION STATEMENT ON MEDICAL SCHEME COVER FOR LOW-INCOME HOUSEHOLDS

1. PRINCIPLES TO UNDERPIN LIMS

Access to health funding

IMSA supports efforts to increase access to health care funding mechanisms, including, but not limited to the current low-income medical scheme (LIMS) investigations. However, IMSA firmly believes that low-income should not equate to low-quality.

Flexibility and competition

IMSA does, however, regard such mechanisms as requiring flexibility in design and modes of delivery. There has to be scope for competition, even in this market, both amongst those offering such social health insurance and amongst those participating in its delivery (health services and health products). IMSA believes that one could take a cue from the Mzansi-accounts that offer various types of banking services at various rates in various institutions, with the only overlapping requirement being that relating to the target market. IMSA therefore believes that LIMS should include various types of options tailor-made for various types of constituencies within the broad LIMS target market.

Safety-net

IMSA also supports the notion of a "safety-net" to ensure that all persons have, at least, access to a basic safety-net of access to health services, encompassing primary as well as appropriate secondary care. Such safety-net should, however, not become the maximum level of care offered and should not become the only standard of care. The best mechanism to protect against levels of care from dropping below those awarded as basic benefits, is the institution of mechanisms to ensure attainment of good quality health outcomes through the adoption of appropriate and cost-effective healthcare interventions Social health insurance will be futile if it does not achieve its desired objective, i.e. to ensure that persons are compensated for the loss suffered when falling ill, and are assured that such health interventions lead to good health outcomes. IMSA is of the view that poor people should not receive poor quality healthcare: a low-income person living with hypertension is just as entitled as a well-off person to have his or her hypertension treated to target, in the most clinically appropriate manner.

Health outcomes

Contribution to own social security

IMSA also believes that LIMS should provide a level of care that surpasses that which is currently available at no or limited cost in state facilities, both in terms of alleviating the burden on public facilities and in achieving better health outcomes. Making the LIMS system attractive will also assist in the achievement of the overall social security objective, i.e. to ensure that those who can contribute to their own social security do so.

Demarcated membership

In terms of membership, it is important that LIMS is able to attract and retain members. It is also important, in line with to the principle of substantive equality, that LIMS is ring-fenced in terms of contributions, service and product delivery. IMSA acknowledges that LIMS is, in the overall social security picture, an intermediate measure, that it is a specific response to economic and social inequities in the South African society. The more South Africa moves towards real equality, the lesser the need for differentiating measures in order to meet the needs of all South Africans. It would also be fundamentally unfair, should resources, aimed at the poorest of the poor be used to fund healthcare for those who can afford a measure of contribution, or, vice versa, that people who should contribute more, are contributing less.

IMSA does not believe that the benefits offered in terms of LIMS should be limited to so-called

Access to innovation

"basic" services and products, neither that it should, by definition, exclude ethical and innovative products, specialist or hospital-based care. IMSA does not believe that the basic safety-net package of care for LIMS people should be a PMB "lite" and would support a more scientific, and outcomes-based approach to the basic benefits to be provided to the LIMS market.

Viability

In terms of the costing of services and products for the LIMS market, IMSA believes that benefits should encompass affordable and quality care, and not translate into poor health care for poor people. IMSA also believes that it has to be financially viable for health enterprises to participate in the LIMS market. The viability of the innovative pharmaceutical sector does not only contribute to economic growth, but ensures a supply of innovative products in South Africa and a source for future generic developments. However, the participation in LIMS initiatives may depend on other pressures on prices and exclusions of products in the existing schemes environment.

Access subsidy

IMSA companies are proposing an access subsidy mechanism (see below) which attempts to harmonise the need for viability with the need of people to access innovative products.

All sub-sectors to be scrutinized

IMSA, however, also believe that all other sub-sectors[1] in health must be scrutinized to the same extent in terms of its contribution to the cost of healthcare. All sub-sectors also have to assist in coming up with models that could assist the increase in access to healthcare through LIMS. It should be noted that medicines currently is the only sector facing price regulation and price transparency. Although it has made significant strides in reducing costs at an ex manufacturer-level, it still, in many forums faces the brunt of accusations in terms of the cost of healthcare.

Patient interest & choice

IMSA believes that patient interest must be paramount in any social security- and healthcare access-system. Furthermore, patient choice has to be preserved, and all patients, including LIMS members, have to be treated as informed decision-makers, taking charge of their healthcare destiny. IMSA therefore opposes any system that erodes this right, or aims to disenfranchise members of the LIMS target market.

2. HEALTH OUTCOMES

Change in health outcome

A Health Outcome is a change in the health of an individual, or a group or population of people that is wholly or partially attributable to a health intervention or a series of interventions. Health outcomes include measures of morbidity and mortality; physical, social, and mental functioning; nutritional status; and quality of life.

Better off in terms of health status

IMSA believes that LIMS should, from the start, provide for the measurement of health outcomes, not only to ensure that the LIMS population is indeed "better off" in terms of their health status, but also to better predict and manage health risk. Health outcomes measurement is the countervailing force for a cost reduction aimed at protecting the health rights of patients.

Clinical- and financial aspects

Health outcomes speaks to the effectiveness of health interventions – do our interventions lead to a healthier population or – if we do not fund A, what will long-term impact be on the population? This can, obviously, not only be measured on a year-on-year basis, but requires aspects of healthcare to be linked and measured, both in terms of the clinical- and financial aspects thereof.

Measurement of health outcomes

Measurement

This is simply achieved as outlined below with the measurement of both preventative and

treatment measures:-

Early identification/prevention of disease through proactive screening initiatives

Preventative measures

Defined measurement indicators that include the percentage of patients screened for key primary health conditions. Primary health indicators need to be identified – possible sources for identification include burden of disease statistics, Prescribed Minimum Benefits and Chronic Disease Lists and other relevant health statistics. Examples of indicators include: Cholesterol screening, Blood-glucose screening, Blood pressure monitoring, Cancer screening, TB screening, Immunization levels, HIV-screening & education, etc. – See HEDIS health indicators.

Treatment outcomes (effectiveness of care)

Treatment measures

Measured as percentage of patients meeting current, evidence-based treatment targets or goals. We propose that stakeholders and professional associations involved in the treatment of patients with the specific conditions at stake, debate the relevant treatment targets and/or goals.

Employees and productivity

Health outcomes measurement should be a key component in the manner in which employers evaluate possible participation in LIMS. Employers are entitled to good health outcomes for the money invested into medical scheme cover for their employees. Employers should see this return on investment in increased productivity, reduced absenteeism and longer tenure, even in cases of chronic or debilitating diseases.

Registration requirement

As stated previously, IMSA believes that the current legislative framework provides, at least by implication, for the importance of health outcomes. This could be strengthened in, for example, the registration requirements of LIMS schemes and/or options.

New technologies

Health outcomes measurement relates to quality of healthcare and the adoption and proper cost management of new health technologies. If LIMS is to attract patients that may currently receive their services from the public sector, or limited private sector, health outcomes have to be a priority.

3. MANAGED CARE – NETWORKS & CAPITATION

DSP flexibility

Regulation 8 to the Medical Schemes Act currently provides that, for the provision of PMBs, schemes may limit full reimbursement to beneficiaries who go to so-called Designated Service Providers (DSPs). It does, however, create flexibility for situations beyond the control of the patient.[2] IMSA is of the view that these legislative protections should remain for LIMS patients. Should a LIMS patient be denied (funding for) care, on, for example, due to the unavailability of a DSP and there are no alternative measures to assist such patients, this limitation is likely to constitute an unfair limitation to their health rights.

Communi-cation and contracts

IMSA does, however, believe that improvement is required in terms of the selection and contracting of DSPs, which has to be done in a fair and transparent manner. Cognisance of the remote location of the LIMS target market is imperative in ensuring access to the selected DSPs. It also believes in the full and appropriate communication of the content of DSP requirements and the associated rights and responsibilities to LIMS members.

Co-payments

Although it may be assumed that LIMS members may not have cash for co-payments, IMSA believes that this is not a choice that any health funder or service provider may lawfully make on behalf of LIMS members. Therefore IMSA also believes that the requirements in terms of co-payments,[3] should a LIMS member choose to go outside of network, be upheld. Empowerment in terms of managing health resources, choosing appropriate options and

healthcare interventions is key for all medical scheme members.

Capitation

Sometimes DSP and managed care agreements coincide. Regulation 15F sets three requirements for the utilisation of capitation networks. Capitation networks may allow healthcare practitioners the clinical freedom to manage LIMS patients according to their individual needs (and not in accordance with a narrowly-enforced formulary or protocol) within certain monetary boundaries. IMSA supports the regulation 15F(c) requirement that the capitated payment to be "reasonably commensurate with the extent of the risk transfer" and urge that more work be done in terms of the costing of capitation models.

4. MANAGED CARE – FORMULARIES AND PROTOCOLS

Fairness & transparency

IMSA believes that all formularies, protocols and managed care principles should be used in a fair and transparent way.[4] Checks and balances should be in place to ensure that the utilisation of these is not to the detriment of patient health outcomes.

Evidence-based medicine

Regulation 15ff to the Medical Schemes Act currently provides some checks and balances. These provisions, in IMSA's view, do assist in ensuring competition and choice within the market and should also do so in the LIMS market. Therefore, in IMSA's view, formularies and protocols have to be continued to be set on "evidence-based medicine"[5] as anything less could amount to "poorer healthcare for poorer people". IMSA is also of the view that the two qualifiers "cost-effectiveness" and "affordability" remain in regulation 15H and I for LIMS members, but that it should not be interpreted as overriding factors. Evidence-based medicine also means that all formularies and protocols have to be clinically and morally defensible.

Health outcomes

In terms of health outcomes IMSA wishes to stress that adherence to good clinical outcomes is implied in the definition of evidence-based medicine, i.e. the integration of "individual clinical experience" with the "best available external clinical evidence from systematic research". IMSA also supports the so-called "exceptions" in regulations 15H and 15I, i.e. a patient would be entitled to an alternative treatment should s/he not respond to the formulary / protocol treatment. This, once again, alludes to the fact that good, quality health outcomes are to be achieved.

5. SERVICE / PRODUCT DELIVERY THROUGH THE STATE

The poor should not subsidise the insured

IMSA opposes in the strongest possible terms the utilisation of the state tender system to procure medicines for LIMS patients. IMSA regards the state tender system as a social assistance mechanism (as different from a social insurance system) aimed to alleviate the needs of the most vulnerable in terms of healthcare. Medicines made available to such patients through the tender system should not be used in the insured market, i.e. the poor should not subsidise those can afford some level of insurance.

Requirement for all?

IMSA also believes that, should this be made a requirement for medicines, all other services and products be subjected to the same criterium. IMSA does, however, not regard this as a sustainable option for growth in the whole health sector or as a mechanism to increase in access to healthcare, or access to social health insurance.

Role of the state

IMSA also believes that the role of the state has to be clear. Once the state enters into competition in the private market (and does not act in its ordinary constitutional capacity as "the state" in which it is exempted from, for example, paying tax to itself), the playing fields have to be level, i.e. there has to be fair competition and such state organ has to be subject to the same rules applicable to other players in that market.

Sustainable solutions

Using the state tender system to procure medicines or any other services for the LIMS market is not sustainable. Rather than just focusing on cost, mechanisms have to be found to ensure that all patients can access innovative products and services, where needed. This is already the case in the existing traditionally insured market where risk is pooled in order to ensure access to products and services required by some patients and not by others. IMSA believes that the options through which healthcare can be made more accessible have to be expanded and that price/cost alone will not solve the challenge.

No avoidance of pricing regulations

IMSA realise that legislative changes may be inevitable in some cases, but do not believe that one should make fundamentally different proposals in order to try to force-fit LIMS into the existing market. IMSA views the utilisation of the state tender system in order to avoid the application and operation of the pricing regulations, as legally unsound.

6. ACCESS SUBSIDY MODEL

Medicines critical to disease management

Medicines play a critical role in disease treatment and the overall well being of all South Africans. Medicines and the associated delivery vehicles are only one part of the healthcare, and currently make up 19.2% of the private sector healthcare rand. (CMS report, 2004.) Although Innovative medicines in SA are priced lower than global benchmarks, access for the majority of our citizens is still not adequate. The key challenge in South Africa is the economic reality that the income gap between the rich and poor is so wide that a single price cannot fulfil the needs of the poor in a sustainable manner. In fact, South Africa ranks highest amongst countries in the world in this measure of income distribution. (World Bank Report, 2000.)

Currently, we have a two-tiered pricing system in South Africa. The SEP operates in the private sector while the state uses a tender price system. The logic for this separation is purely economic based on income disparities.

Government' long-term view is for a single price for all South Africans. In theory this is acceptable, but in reality it will come with its own challenges. One way of achieving this single-tier price will require the South African government to spend more in health care to ensure access for the poor, or alternatively for innovative multinational companies to reduce their prices below acceptable global floor prices. The health department already faces budgetary challenges as it is, and therefore chances for an increased spend are unlikely in the foreseeable future. Innovative multinational companies also face a constraint with regards to the extent to which they can lower their prices in a sustainable manner.

Our main role as innovative pharmaceutical companies with respect to access and equity in the health care charter is to ensure that our products are more accessible to all South Africans. In order to achieve this, there will be a need to revisit our current pricing model within the confines of the pricing legislation.

IMSA model

Access Subsidy Proposal

IMSA has developed an access subsidy model that will allow patients access to appropriate medicines without compromising the attending physician's ability to prescribe what he or she believes is the most appropriate therapy for that particular patient. As the progression of disease and response to medical therapies and or surgical interventions is patient specific, this would allow the doctor to tailor appropriate therapy and ensure the patient's condition is controlled according to the latest guidelines for the treatment of that particular disease.

Principles and benefits

This access subsidy model may be adapted and then adopted by other providers of healthcare as the principles are easily transplanted into almost all sectors of the industry.

The access subsidy model is based on the following principles and benefits:

Differential prices to patients and not intermediary

1. The model allows for the separation of income bands into three tiers, with differential pricing for each tier.
2. It allows private sector dispensing of medicines to all patients, whether they are traditional private sector insured market, or LIMS patients.
3. It is based on the principle of differential pricing to patients, and not to intermediaries. This is not an anomaly in the SA market as differential pricing is allowed in the medical schemes environment based on affordability. Amongst others, the GEMS contribution table, the 2005 and 2006 Discovery Health Keycare Plan contribution table as well as the 2005 Retail Medical Aid contribution table serves as points of reference.
4. Implementing an access subsidy pricing model would allow LIMS patients, when appropriate, access, to latest innovative technologies thereby ensuring that the quality of care is not compromised any way whatsoever.

SEP system must not be compromised

5. A multi-tier pricing model could be achieved without compromising the transparent pricing system and single exit pricing system just introduced. Therefore, it preserves the concept of the single exit price whilst ensuring that cost reductions are passed on to the appropriate patient and not to intermediaries as was the case with legacy volume-based discounts and rebates. At the point of sale the SEP from manufacturer to retailer will remain the same for traditionally insured and LIMS patients.

Companies reimburse payors

6. In this model LIMS schemes will, in the end obtain medicines for their LIMS patients at a lower price when compared to current traditional medical aid patients.
7. Multinational Companies may reimburse payors, for these LIMS transactions, the difference between the SEP and the selling price to the patient. This may be accomplished through the REF/central fund based on the agreed tiered price.
8. Payors will reimburse the pharmacies/dispensers with the full SEP plus professional fee. Pharmacists may also introduce a tiered professional fee for fully insured and LIMS, and state patients. A lower professional fee for LIMS should not be viewed negatively as the element of cross-selling over-the-counter and front-shop goods to these patients should not be underestimated.
9. The multi-tier pricing model could also be used across other components of the health care sector to ensure quality access in a sustainable manner.
10. This model integrates pharmaceutical service provision in the country on a single delivery platform.

REF the vehicle

11. The Central Fund of the REF serves as a conduit for any subsidy provided by pharmaceutical companies. This fund will also serve as a validation point for submissions by pharmacies as to the number of prescriptions dispensed to patients from each sector of the market.

The model is predicated on the following:

1. Government approval of the model.
2. A means test to separate patients into the traditionally insured and LIMS sectors.

Ring-fence system

3. A system that ring-fences all income segments in the private sector. This could take the form of a smart-card combined with a central web-based database so that providers are able to identify LIMS patients and prevent fraudulent use of the system. An income based ring-fence is critical to prevent significant buy-down, which could erode the private sector healthcare market drastically. The preservation and sustainability of the major part of the current insured base is critical for the successful implementation of LIMS.

Participation at individual company

4. Individual company participation in the Access subsidy model will be at each company's prerogative and does not imply that all pharmaceutical companies will

participate. However, it creates a framework for participation and contribution to the healthcare needs of all South Africans by all interested parties. **discretion**

5. Legislative changes may be required to allow all elements of the model to function appropriately. However, any legislative changes must ensure the integrity and the transparency of the new SEP system.

7. CONCLUSION

IMSA believes that the LIMS process should provide an improvement in health access to this market which previously it could not attain. We are therefore guided by the following fundamental principles and guidelines towards the LIMS process:

- The development of healthcare packages that will address the need to provide greater access to all low income earners.
- The development of healthcare packages that do not only meet the criteria of affordability but also provides comprehensive equitable benefits.
- Healthcare packages should be developed and managed with healthcare quality outcomes entrenched, measured and reported.
- The healthcare packages should promote market competition (similar to that found in the various Mzansi accounts) between service providers and healthcare suppliers based on quality/health outcomes and not on cost only.
- There should be variation in the LIMS market (provided that a basic safety-net remains intact) that provides for choice.
- LIMS should be seen as providing a better value proposition to patients, i.e. should go beyond what a person could have received for free or at "lower cost" in state facilities.
- LIMS should not necessarily compromise the breadth or depth of PMBs, or a basic package of care – all factors around LIMS that could affect this should be analysed.

And therefore propose:

- That the benefit design of all LIMS healthcare packages allows members access to the widest range of healthcare providers as possible without compromising affordability nor quality of service delivery.
- That healthcare packages are designed for LIMS target the LSM 1-5 market segment on a needs-based basis.
- That the basic benefit package concept be entrenched in the design of a LIMS healthcare package based on the needs of the LSM 1-5 market. Focus on primary care must be enhanced.
- That the basic benefit package at safety-net level be defined in terms of:
    - The level of benefit provided
    - Access to that level of benefit
    - The delivery of that benefit
    - The quality of the delivery of that benefit
    - The measurement of clinical and financial outcomes generated from that benefit.

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[1] Administrators, managed care organizations, hospitals, healthcare professionals, medical device manufacturers and importers, and the various players in medicines supply chain, i.e. manufacturers, dispensers, etc. It may be necessary and fair to subdivide groups these categories, in order to ensure a rational outcome.

[2] Where the service was not available from the designated service provider or would not be provided without unreasonable delay; or where immediate medical or surgical treatment for a prescribed minimum benefit condition was required under circumstances or at locations which reasonably precluded the beneficiary from obtaining such treatment

from a designated service provider; or where there was no designated service provider within reasonable proximity to the beneficiary's ordinary place of business or personal residence.

[3] Including that such co-payments have to be "reasonable", i.e. as close as possible to the real difference in cost between what would have been funded and the freely chosen product or service (CMS Managed Care Policy, 2003).

[4] Regulation 8(4) authorises the use of formularies and protocols, whilst regulations 15H and I provides the parameters within which these are to be exercised.

[5] "Evidence-based medicine" means the conscientious, explicit and judicious use of current best evidence in making decisions about the care of beneficiaries whereby individual clinical experience is integrated with the best available external clinical evidence from systematic research (Reg 15).